Washington State Health Care Authority

Obstructive Sleep Apnea: Treatment in Adults

Evidence Update

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Health Technology Assessment Program (HTA)

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This evidence update report is based on research conducted by the Center for Evidence-based Policy (Center) under contract to the Washington State Health Care Authority (HCA). This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the authors, who are responsible for the content. These findings and conclusions do not necessarily represent the views of the Washington HCA and thus, no statement in this report shall be construed as an official position or policy of the HCA.

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Table of Contents

Bottom Line

This evidence review updates studies published since the original evidence review was conducted in 2012. That evidence review informed the coverage policy for obstructive sleep apnea treatments adopted by the Washington State Health Technology Clinical Committee (HTCC) in March 2012. After summarizing the eligible studies in this evidence update, we determined that new studies may likely change the conclusions of the 2012 evidence report for hypoglossal nerve stimulation [HGNS] and other forms of electrical stimulation.

Background

Obstructive sleep apnea (OSA) is characterized by episodes of complete airway collapse or partial collapse with an associated decrease in oxygen saturation or arousal from sleep.[1] Other symptoms include loud, disruptive snoring, witnessed apneas during sleep, and excessive daytime sleepiness.[1] This disturbance results in fragmented, nonrestorative sleep.[1] OSA has significant implications for cardiovascular health, mental illness, quality of life, and driving safety.[1]

Treatment for OSA is often a multi-factorial approach and should be tailored to the individual patient.[1] Options include lifestyle changes (e.g., weight loss), treating underlying medical conditions (e.g., asthma), positional therapy, positive airway pressure (PAP) therapy, oral appliances, and surgery and other devices.[1]

The focus of this evidence update is on the surgical management of OSA and the use of devices for OSA. Coverage for diagnosis of OSA and use of Continuous Positive Airway Pressure (CPAP) are currently covered by the Medicare national coverage determination[2],[3] and are not the focus of this signal search.

Currently, OSA diagnosis and treatment is a covered benefit with conditions consistent with the criteria identified in the reimbursement determination (Table 1).[4] Limitations of coverage are as follows[4]:

- Adults, age 18 years and older
- State approved providers
- Consistent with the Medicare national coverage determination CPAP therapy for OSA and sleep testing for OSA excluding coverage with evidence development (CED)
- Consistent with the Medicare local coverage determination L34526 for surgical treatment of obstructive sleep apnea

Non-covered indications are as indicated in the referenced Medicare national and local coverage determinations.[4]

Table 1. Coverage Status for Devices and Surgery for OSA

OSA Intervention	Washington Medicaid Coverage Status
Devices	
CPAP	Covered as per the Medicare NCD 240.4[2]

OSA Intervention	Washington Medicaid Coverage Status
Oral appliances	Covered 1 mandibular advancement device every 5 years
HGNS	Not covered
Surgery	
UPPP	Covered with conditions Requires prior authorization
Mandibular maxillary osteotomy and advancement or genioglossus advancement with or without hyoid suspension	Covered with conditions Requires prior authorization
Tracheostomy	Covered with conditions For planned or fenestration procedure with skin flaps
Surgeries to correct discrete anatomic abnormalities (e.g., enlarged tonsils, enlarged tongue), including rhinoplasty and septoplasty	Covered with conditions
Laser-assisted uvulopalatoplasty	Covered with conditions Requires prior authorization
Somnoplasty	Not covered
Pillar Procedure	Covered with conditions Requires prior authorization
Submucosal ablation of the tongue base	Covered with conditions Requires prior authorization

Abbreviations. CPAP: continuous positive airway pressure; HGNS: hypoglossal nerve stimulation; NCD: national coverage determination; PAP: positive airway pressure; UPPP: uvulopalatopharyngoplasty.

Policy Context

Due to recent legislative changes in Washington state, topics subject to certain coverage conditions need to be assessed for new evidence (i.e., via a signal search) on an annual basis. Therefore, to meet the new legal requirements, this signal search will focus on the management of OSA though surgery or other devices.

Objectives

The primary aim of this assessment is to determine whether there is new evidence that would likely change the conclusions of the most recent health technology assessment (HTA) report in 2012.[5]

Methods

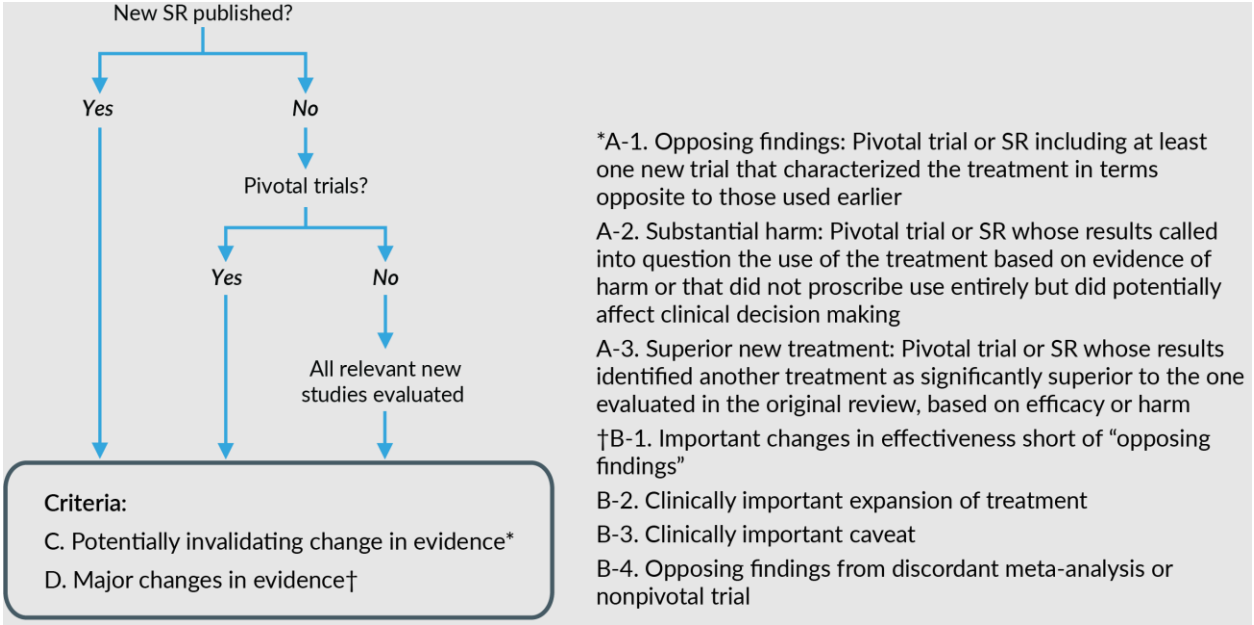
To identify studies published since the 2012 evidence update,[5] we conducted updated searches of Ovid MEDLINE All, Cochrane Database of Systematic Reviews, and the Cochrane Controlled Trials Register database (through May 2024; Appendix A). Further, we searched the reference lists of all identified systematic reviews, meta-analyses, and guidelines for relevant studies.

To determine if a signal exists (i.e., there is new evidence that may change the current coverage determination), we followed a modified Ottawa approach (Figure 1) and examined full texts of new systematic reviews, published in the past 5 years. If a treatment or technology is not currently covered, the signal search centered on efficacy and looked at peer-reviewed abstracts of trials for newly identified randomized controlled trials (RCTs) published since any relevant systematic reviews. Conversely, if a treatment or technology is covered based on a previous HTCC decision, the signal search was on harms as reported in systematic reviews only. For this update, we also agreed not to review any new evidence for CPAP as this is covered by a Medicare national coverage determination (NCD).

To assess whether the conclusions might need updating, we used an algorithm based on a modification of the Ottawa method, Figure 1. Our approach to screening and reviewing eligible studies was as follows:

- We screened the retrieved references and ongoing study records against the inclusion criteria (Appendix B).
- We assessed the likelihood, by indication, of recent evidence triggering an update to the 2012 coverage determination for OSA treatment.

Figure 1. Algorithm of the Modified Ottawa Method of Identifying Signals for Update



We summarized the findings of any eligible published systematic reviews and health technology assessments in the following manner:

- If there were 2 or more comparable reviews identified and 1 is more recent or more comprehensive, then the other review(s) was not summarized, and the rationale for selection was documented.

We did not assess the risk of bias of the eligible reviews or primary studies.

We reported a narrative description of the search results along with key study characteristics of the included reviews and primary studies:

- The number of studies (for systematic reviews) and number of participants (for all study designs)
- The intervention studied
- Comparators to the intervention
- Relevant outcomes reported in the publication

We also highlighted any discrepancies and differences across systematic reviews and individual primary studies.

For each indication, we assessed the evidence of effectiveness and harms, depending on coverage status, and the potential impact on the 2012 coverage decision. The summary assessment aims to give the WA HTA team and the Agency Medical Directors information on whether there is new evidence that may warrant a reconsideration of the existing coverage policy.

PICO

Appendix B lists detailed inclusion and exclusion criteria used to select eligible studies.

Populations

- Adults with OSA

Interventions

- Surgery for OSA
- Hypoglossal nerve stimulation (i.e., stimulation of the 12th cranial nerve)
- Devices (e.g., mandibular advancement devices) for OSA

Comparators

- Another listed intervention
- CPAP
- Sham surgery or treatment
- No treatment

Outcomes

- Measures of sleep and wakefulness, including direct and indirect measures of sleep quality
- Mortality
- Cardiovascular events
- Changes in hypertension or diabetes status
- Depression
- Cost
- Cost-effectiveness
- Safety
- Complications

Key Questions for This Evidence Update

KQ1. What is the comparative effectiveness and harms of OSA treatment (selected surgeries and devices) in adults?

KQ2. What is the evidence of cost implications and cost-effectiveness of OSA treatment (selected surgeries and devices) in adults?

Findings

We identified 1,255 unique publications in our updated searches, with 239 articles screened at the full-text stage. Of these, 27 studies were eligible for inclusion in this report. Tables C1 to C9 summarize the 24 systematic reviews we prioritized, by date, for each intervention. The list of studies excluded at the full-text level, with reasons, is in Appendix D. We also identified pivotal primary studies of covered interventions conducted after the included systematic reviews for noncovered surgeries or devices only; we identified 3 eligible RCTs in total. Table C9 summarizes the included pivotal RCTs.

Devices for OSA in Adults

Oral Appliances

As of the 2012 coverage determination, MADs are currently covered for OSA in adults with conditions (Table 1).[4] We therefore focused on harms only for this evidence update.

Harms

We identified 1 scoping review (using systematic review methods) assessing the association between the use of MAD devices and self-reported oral moistening disorders, and 6 other systematic reviews on the harms associated with MAD use (Appendix C, Table C1).[6-12]

The scoping review by Raoof and colleagues included 48 studies in total, representing a range of nonrandomized study designs; of these, 15 studies reported on the association between MAD use and oral moistening disorders.[6] Overall, xerostomia and drooling were common with MAD device use.[6] The authors observed that oral moistening disorders tended to be mild and transient, often improving with continued use of the MAD device.[6]

A 2023 systematic review assessed long-term occlusal effects with MADs use for OSA.[9] Based on 14 studies including 2 RCTs, the long-term use of MAD therapy, defined as 4 years or more, was associated with upper incisor retroclination, lower incisor proclination, decreased overjet and overbite, and changes in the total occlusal contact area.[9] However, another systematic review also published in 2023 found that overall, the use of MAD therapy was not associated with any consistent increases in temporomandibular disorders (TMDs) or temporomandibular joint (TMJ) symptoms.[8] The study findings (which included 2 RCTs) were mixed with some showing significant reductions in the severity and frequency of TMD symptoms following MAD therapy and other showing no significant changes in TMD symptoms or TMJ-related parameters.[8] Where increases in symptoms did occur, these tended to be temporary and resolved over time.[8] No participants in the studies discontinued MAD therapy because of TMDs.[8] Based on 8 RCTs in a third systematic review from 2019, the most common adverse events related to oral appliance use was pain in the teeth or TMJ.[7]

Another 2023 review evaluated the effect of MAD use on oral and periodontal health.[12] The review had 4 RCTs and 24 nonrandomized studies (NRSs).[12] Overall, the most commonly reported MAD-related side effects were[12]:

- Hypersalivation (33.3%)

- Occlusal changes (30.2%)
- Muscle pain (22.9%)
- Changes in overjet (20.7%)
- Tooth discomfort or pain (20.2%)
- Xerostomia (18.3%)

Other effects were mucosal irritation (11.7%), TMJ pain or TMD (11.7%), TMJ sound (10.1%), and changes in overbite (18.2%).[12] No periodontal effects were reported.[12] While periodontal effects were rarely assessed and reported, 5 studies excluded people with periodontitis.[12] In 1 NRS, people with no periodontal-health issues showed no significant changes in periodontal parameters over 7 years of MAD use.[12]

In 2021, Berger and colleagues found treatment-emergent central sleep apnea (TECSA) can be observed in people after using a range of devices, including MADs.[10] TECSA can be characterized by persistence or emergence of central apneas on exposure to PAP devices without a backup rate, while the obstructive respiratory events noted during the previous diagnostic sleep study have resolved.[10] The review concluded that, due to limited evidence (primarily case studies), an estimated prevalence rate by treatment was not possible.[10]

In 2019, Gao and colleagues published a network meta-analysis comparing all minimally invasive treatments for OSA in adults, including MADs.[11] The network meta-analysis was on effectiveness and included only RCTs; harms associated with MAD therapy were reported narratively only (Appendix C, Table C1).[11] Common adverse effects were dental problems (e.g., teeth pain or sensitivity), excessive salivation, jaw discomfort or pain, and damage to teeth or dental restoration.[11] Overall, the authors concluded side effects and complications would still occur with MAD use, despite its minimally invasive nature when compared with surgery.[11]

Bottom Line

Based on the prior evidence reviews and newly identified evidence, the newly identified review highlighting the harms associated with MADs and the RCTs evaluating the effectiveness and harms of not custom-made MADs is unlikely to change the conclusions of the 2012 evidence review. Adverse events, such as oral moistening disorders and pain, do occur with the use of MADs; however, they tended to be temporary and resolve over time.

Hypoglossal Nerve Stimulation

As of the 2012 coverage determination, HGNS is currently not covered for OSA in adults.[4] For this evidence update, we looked at both effectiveness and harms.

Effectiveness

We identified 2 recent systematic reviews on the use of HGNS for OSA (Appendix C, Table C2). In a systematic review of 10 studies (including 2 RCTs) comparing HGNS with other surgical approaches, CPAP or no treatment, the authors concluded HGNS was an effective option for selected patients with moderate-to-severe OSA and who were intolerant to CPAP.[13] Specifically, the use of HGNS was associated with significantly greater odds of having fewer AHI events per hour than other surgical approaches[13]:

- Odds ratio (OR), 5.33; 95% confidence interval (CI), 1.21 to 23.42 for fewer than 10 events

- OR, 3.48, 95% CI, 1.64 to 7.37 for fewer than 15 events

However, there was no significant difference between HGNS and surgery for fewer than 5 events and no difference between HGNS and CPAP.[13] People who underwent HGNS had a significantly higher odds of surgical success (OR, 3.32; 95% CI, 1.84 to 6.00).[13] Postoperative AHI was significantly lower in the HNS group than in all other airway surgery groups (mean difference [MD], -8.00, 95% CI -12.03 to -3.97 events per hour).[13] However, there were no significant differences in the postoperative Epworth Sleepiness Scale (ESS) score (MD 0.40, 95% CI -1.52 to2.32) between HGNS and surgery.[13] There was also no significant difference when HGNS was compared with CPAP.[13]

The second systematic review looked at the effectiveness of HGNS over the first 12 months after surgery as a minimum.[14] Overall, 44 studies (including 2 RCTs) were reviewed and the authors concluded that while the positive effects gradually decreased over the first 12 months after implantation, effectiveness generally remained consistent between 12 and 36 months.[14]

- The proportion who achieved clinical improvement of an AHI fewer than 5 events was[14]:
  - 60% at 3 months
  - 37% at 12 months
  - 27% at 18 months
  - 27% at 24 months
  - 34% at 36 months
- The proportion who achieved clinical improvement of an AHI fewer than 15 events was[14]:
  - 90% at 3 months
  - 75% at 12 months
  - Not reported at 18 months
  - 73% at 24 months
  - 68% at 36 months
- The proportion who achieved clinical success, defined as a reduction in postoperative AHI by 50% and fewer than 20 events per hour[14]:
  - 85% at 3 months
  - 74% at 12 months
  - 65% at 18 months
  - 75% at 24 months
  - 63% at 36 months

We also identified 1 recently published randomized crossover trial evaluating HGNS and its effect on cardiovascular outcomes.[15] The RCT included 62 adults with moderate-to-severe OSA and found no significant differences in cardiovascular outcomes (e.g., systolic blood pressure) between active and sham HGNS.[15] However, active HGNS was associated with a significantly greater reduction in AHI when compared with sham (a reduction of 4.9 events per hour; 95% CI, 1.0 to 8.8).[15]

Harms

We identified 6 eligible reviews with a range of study designs reporting on the harms associated with HGNS (Appendix C, Table C2).[10,14,16-19]

No deaths were reported related to upper airway stimulation using the Inspire system in a 2022 review.[19] Across the 5 NRSs reporting on post-surgical complications[19]:

- The rate of serious device-related adverse events ranged from 0% to 7%.
- Serious device-related adverse events were surgical repositioning or replacement of the neurostimulator or implanted leads.
- Overall, 0.4% of participants in 1 study experienced a serious intraoperative adverse event, including but not limited to hematoma, infection, extra implant procedure, intraoperative cardiac arrest, and pneumothorax.
- Minor surgery-related complications occurred in around 6% of people and minor device-related adverse events in around 22% of people.

The most common minor surgery- and device-related complications were incision discomfort and discomfort due to electrical stimulation.

In review from 2021, the European Respiratory Society developed an evidence-based guideline on non-CPAP therapies for OSA.[16] As part of the systematic review based on 3 RCTs underpinning the final recommendations, the authors reported that adverse events were infrequent (around 3% in 1 RCT) and although serious adverse events were observed, very few were device related (2 vs. 33 that were not device related in 1 RCT).[16]

Kim and colleagues evaluated the rate of tongue-abrasion-related adverse effects after HGNS in a systematic review of 44 studies, including 2 RCTs (Appendix C, Table C9).[14] Overall, 9% of patients experienced tongue abrasion related to HGNS; however, the rate of abrasion decreased over time.[14]

Kompelli and colleagues[18] also assessed the safety HGNS in a systematic review of 16 NRSs.[18] In addition to pain (6.2%), tongue abrasion (11.0%), and other adverse effects (7.0%; no further details), the review found 3.0% of people had an internal device malfunction and 5.8% an external device malfunction.[18]

In 2021, Berger and colleagues found that people using a range of devices (such as HGNS) and surgery may have TECSA as an underlying condition; however, due to the limited evidence (primarily case studies), an estimated prevalence rate by treatment was not possible.[10]

Costantino and colleagues conducted a systematic review on the long-term clinical outcomes for HGNS in moderate-to-severe OSA; in total, 12 nonrandomized studies (NRSs) were included.[17] At both 1 and 5 years of follow-up, 6% of participants reported serious device-related events.[17]

Bottom Line

In July 2024, the FDA issued a class 1 recall (the most serious recall type) for the Inspire IV implantable pulse generator, citing a manufacturer defect.[20] The recall includes 32 devices and may require revision surgery to correct.[20] No injuries or death related to this recall were reported by the FDA.[20]

Based on the prior evidence review and newly identified evidence, the newly identified evidence on the benefits and harms associated with HGNS may change the conclusions of the 2012 evidence review; HGNS was not an included intervention at that time.

Surgery for OSA in Adults

Uvulopalatopharyngoplasty

Uvulopalatopharyngoplasty (UPPP) is currently covered by the 2012 HTCC coverage decision (Table 1).[4] For this evidence update, we report on harms only.

Harms

We identified 1 systematic review reporting on the harms associated with UPPP (Appendix C, Table C3).[21] Based on a 2023 systematic review of 14 studies (including 1 RCT) reporting on the complications and side effects of barbed pharyngoplasty (i.e., pharygoplasty using barbed sutures)[21]:

- Intraoperative complications occurred in 7.0% of patients
  - Partial thread extrusion (2.9%)
  - Self-limited bleeding (2.9%)
  - Broken needle (1.0%)
  - Suture rupture (1.0%)
- Short-term complications occurred in 25.2% of patients
  - Thread or knot extrusion (12.4%)
  - Dysphagia (5.6%)
  - Bleeding (1.5%)
  - Velopharyngeal insufficiency (1.5%)
  - Anterior pharyngoplasty dehiscence (1.2%)
  - Tonsillar hemorrhage (1.0%)
  - Excessive postnasal discharge (1.0%)
  - Barbed suture failure (0.5%)
  - Acute infection (0.2%)
  - Mucosal granulomas (0.2%)
  - Chipped tooth caused by mouth gag displacement (0.2%)
  - Fibrous scarring (0.2%)
- Long-term complications occurred in 23.3% of patients
  - Foreign body sensation (7.8%)
  - Sticky mucus in throat (5.9%)
  - Dysphagia (3.6%)
  - Rhinolalia (3.1%)
  - Throat phlegm (1.1%)
  - Nose regurgitation (0.8%)
  - Dry throat (0.6%)
  - Throat lump (0.3%)

Bottom Line

Based on the prior evidence review and newly identified evidence, the newly identified review highlighting the harms associated with UPPP (specifically, barbed pharyngoplasty) is unlikely to change the conclusions of the 2012 evidence review.

Mandibular Maxillary Osteotomy and Advancement or Genioglossus Advancement With or Without Hyoid Suspension

Mandibular maxillary osteotomy and advancement or genioglossus advancement (with or without hyoid suspension) is currently covered by the 2012 HTCC coverage decision (Table 1).[4] We focused only on harms for this evidence update.

Harms

We identified 4 eligible reviews on the harms associated with mandibular maxillary osteotomy and advancement or genioglossus advancement (Appendix C, Table C4).[16,19,22,23]

A 2024 scoping review using a range of nonrandomized study designs, found that modified maxillomandibular advancement (an alternative to the classic maxillomandibular advancement in people with bimaxillary protrusion) is safe; few surgical complications, which were mostly minor, were reported in the included studies.[22] The review examined populations from East Asia and Southeast Asia.[22]

Based on a review of 46 NRSs, around 6% of people who underwent maxillomandibular advancement surgery were dissatisfied with their facial appearance after surgery; 3% of physicians and 15% of lay people reported a decline in attractiveness after surgery.[23]

In a 2022 review of maxillomandibular advancement surgery, no deaths were reported related to surgery.[19] Across the 10 NRSs reporting on post-surgical complications[19]:

- Major complications ranged from 0% to 18% and included reoperations for removal of osteosynthesis screws and plates, reoperations for maxillary nonunion, and acute dyspnea.
- The most commonly reported minor complication was paresthesia caused by the impairment of inferior alveolar nerve; rates varied across studies (for transient paresthesia, from 32% to 100%; for persistent paresthesia, from 0% to 60%).
- Other minor complications were developed malocclusion, TMDs, local infection, and minor postoperative wound pain.
- Based on 2 small studies, around 13% to 15% of people reported worsening of their facial appearance after surgery.

A 2021 review from the same research team found an overall rate of major complications of 3.2% and 10.1% for minor complications.[24]

In a review from 2021, the European Respiratory Society developed an evidence-based guideline on non-CPAP therapies for OSA.[16] As part of the systematic review underpinning the final recommendations and based on 1 RCT, the authors concluded that maxillomandibular osteotomy was associated with moderate adverse effects (no further details), including the risk of additional orthodontic work.[16]

Bottom Line

Based on the prior evidence review and newly identified evidence, the newly identified reviews highlighting the harms associated with maxillomandibular advancement surgery are unlikely to change the conclusions of the 2012 evidence review.

Tracheostomy

Tracheostomy is currently covered by the 2012 HTCC coverage decision (Table 1).[4] For this evidence update, we looked only at harms.

Harms

We identified 1 eligible review on the harms associated with tracheostomy; the review primarily studied case reports (Appendix C, Table C5).[10]

In 2021, Berger and colleagues found people using a range of devices and surgery (including tracheostomy) may have TECSA as an underlying condition; however, due to the limited evidence, an estimated prevalence rate by treatment was not possible.[10]

Bottom Line

Based on the prior evidence review and newly identified evidence, the newly identified review highlighting the harms associated with tracheostomy is unlikely to change the conclusions of the 2012 evidence review.

Surgeries to Correct Discrete Anatomic Abnormalities

Surgeries to correct discrete anatomic abnormalities are currently covered by the 2012 HTCC coverage decision (Table 1).[4] For this evidence update, we focused on harms only.

Harms

We did not identify any systematic review reporting on the harms associated with surgery to correct discrete anatomic abnormalities, including rhinoplasty and septoplasty.

Bottom Line

Based on the prior evidence review and the lack of newly identified evidence, the conclusions of the 2012 evidence review are unlikely to change.

Laser-Assisted Uvulopalatoplasty

As of the 2012 coverage determination, laser-assisted uvulopalatoplasty (LAUP) is currently covered for OSA in adults (Table 1).[4] For this evidence update, we focused on harms only.

Harms

We identified 1 systematic review on the complications associated with LAUP (Appendix C, Table C6).[25] Based on a systematic review of 42 studies with study designs including 3 RCTs and a mean follow-up of 16.1 months, 3,093 patients who underwent LAUP had a complication.[25] Of complications reported across all of the 42 studies, LAUP was associated with an overall complication rate of 25.6%, comprising[25]:

- Bleeding (2.6%)
- Candidiasis (0.3%)
- Dryness (7.2%)
- Dysgeusia (0.3%)
- Dysosmia (0.2%)
- Globus (8.2%)
- Surgical site infection (1.3%)

- Velopharyngeal insufficiency (3.9%)
- Velopharyngeal stenosis (1.6%)

When compared with the incidence of these complications in the general surgical population or the post-oropharyngeal surgery population, the risks of globus and velopharyngeal insufficiency were significantly higher (relative risk [RR] for globus, 1.48; 95% CI [confidence interval], 1.07 to 2.06; RR for velopharyngeal insufficiency, 1.29; 95% CI, 1.29 to 3.94).[25]

Bottom Line

Based on the prior evidence review and newly identified evidence, the new review highlighting the harms associated with LAUP (specifically, complications related to the surgery) is unlikely to change the conclusions of the 2012 evidence review.

Somnoplasty

As of the 2012 coverage determination, Somnoplasty, a specific, branded surgical procedure also called radiofrequency tissue reduction or radiofrequency tissue ablation, is currently not covered for OSA in adults (Table 1).[4] For this evidence update, we looked at both effectiveness and harms.

Effectiveness

We did not identify any eligible systematic reviews or pivotal RCTs on the effectiveness of Somnoplasty for OSA in adults.

Harms

We did not identify any eligible systematic reviews or pivotal RCTs on the harms of Somnoplasty for OSA in adults.

Bottom Line

Based on the prior evidence review and the lack of newly identified evidence, the conclusions of the 2012 evidence review are unlikely to change.

Pillar Procedure

As of the 2012 coverage determination, the Pillar Procedure is currently covered for OSA in adults (Table 1).[4] For this evidence update, we focused on harms only.

Harms

We did not identify any eligible systematic reviews on the harms of Pillar Procedure for OSA in adults.

Bottom Line

Based on the prior evidence review and the lack of newly identified evidence, the conclusions of the 2012 evidence review for the Pillar Procedure are unlikely to change.

Submucosal Ablation of the Tongue Base and Other Tongue Surgeries

As of the 2012 coverage determination, submucosal ablation of the tongue base and other tongue surgeries are currently covered for OSA in adults (Table 1).[4] For this evidence update, we focused on harms only.

Harms

We identified 2 systematic reviews on the harms associated with tongue ablation (Appendix C, Table C7).[26,27]

In a 2022 systematic review, Calvo-Henriquez and colleagues[26] studied the complications associated with a range of minimally invasive base of tongue procedures for OSA in adults.[26] The surgeries of interest were submucosal minimally invasive lingual excision (SMILE), tongue base ablation (TBA), tongue base radiofrequency (TBRF), lingual suspension (LS) and transoral robotic surgery (TORS).[26] Across the 20 NRSs with a range of study designs, the rates were as follows[26]:

- Mean overall complication rate of 12.8%, ranging from 4.2% with TBRF to 42.4% with TBA
- Mean minor complication rate of 4.7%, ranging from 1.8% with TBRF to 11.9% with TORS; 6.1% in TBA
- Mean moderate complication rate of 6.4%, ranging from 1.0% with TBRF to 22.0% with TORS; 21.2% in TBA
- Mean severe complication rate of 1.77%, ranging from 0.6% with LS to 15.1% with TBA

The most reported complication overall was infection (1.9%), followed by transient swallowing disorder (1.3%).[26] For TBA, the most common minor complication was bleeding (6.1%), the most common moderate complication was mild edema (12.1%), and the most common severe complication was permanent taste disorder (15.1%).[26]

Lechien and colleagues[27] also concluded that TORS was a safe procedure. The most frequent complications were minor and major hemorrhages, dehydration, dysgeusia, dysphagia, pain, and pharyngeal scarring; however, prevalence varied by study.[27]

Bottom Line

Based on the prior evidence review and newly identified evidence, the conclusions of the 2012 evidence review for tongue surgeries are unlikely to change.

Other Surgical Techniques and Devices

Limited Palatal Muscle Resection

We identified 1 systematic review on limited palatal muscle resection.[10,28] The review included 4 studies; none were RCTs and only 1 compared limited palatal muscle resection with another intervention (specifically, uvulopalatal flap surgery).[28] People had a significant improvement in AHI (a decrease of 2.6) and in the lowest pulse oximetry values (an increase of 1.2) after limited palatal muscle resection.[28] No information on AEs was reported.[28]

Electrical Stimulation (Other Than Hypoglossal Nerve Stimulation)

We identified 1 systematic review on the use of transcutaneous electrical stimulation (TENS) for OSA.[29] The review included 10 studies; of which, 2 were RCTs.[29] Although the use of TENS was associated with a significant improvement in AHI, it was not associated with other improvements in measures of oxygen saturation or arousal.[29] Overall, 8% of people discontinued use, primarily citing TENS was too restricting.[29]

Another systematic review of 4 studies found that non-invasive electrical stimulation devices may reduce snoring in people with snoring and mild to moderate OSA; however, there was no significant impact on measures of sleep apnea, including AHI.[30]

We also identified 2 new RCTs (Appendix C, Table C9) evaluating the use of daytime neuromuscular electrical stimulation (NMES) and domiciliary transcutaneous electrical stimulation (TESLA).[31,32]

In people with newly diagnosed mild OSA, there was no statistically significant difference in adherence to active daytime NMES compared with sham NMES.[32] No other outcomes of interest were reported.[32]

In people with OSA and limited adherence to usual care (specifically, CPAP), participants in the TESLA group experienced significantly greater improvements in OSA-related outcomes than participants in the usual care group.[31] In addition, significantly more people used TESLA compared with people in the CPAP group.[31] Harms associated with TESLA were mild headaches, patches peeling in hot weather, and skin irritation.[31]

Both RCTs were small, with sample sizes of 40 and 56, and only reported short-term follow-ups of 6 weeks and 3 months.[31,32]

Bottom Line

Based on the prior evidence review and newly identified evidence, the conclusions of the 2012 evidence review for forms of electrical stimulation other than HGNS may change; these interventions were not reviewed in the original evidence review.

Costs and Cost-Effectiveness of Surgery and Devices for Obstructive Sleep Apnea

We did not identify any eligible studies for this evidence update.

Bottom Line

Based on the prior evidence review and the lack of newly identified evidence, the conclusions of the 2012 evidence review are unlikely to change.

Summary

OSA is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life.

The first-line treatment for OSA is CPAP, but there are several options for those who have difficulty tolerating CPAP, such as oral appliances and surgical interventions. New studies, although numerous, include few pivotal RCTs. After summarizing the eligible studies in this evidence update, we determined the new studies may likely change the conclusions of the 2012 evidence report for HGNS and other forms of electrical stimulation.

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Appendix A. Search Strategies

Ovid MEDLINE All

Ovid MEDLINE(R) ALL <1946 to May 24, 2024>

1 exp sleep apnea, obstructive/ 28514

2 ((nocturnal or sleep*) adj3 (apn?e* or apn?ea-hypopne* or apn?eic-hypopne* or hypopn?e* or hypo-apn?e*)).ti,ab,kf. 50252

3 ((Pickwickian or Obesity-Hypoventilation or Obesity Hypoventilation) adj2 Syndrome*).ti,ab,kf. 972

4 osa.ti,ab,kf. 21060

5 osahs.ti,ab,kf. 1762

6 sahs.ti,ab,kf. 628

7 or/1-6 56437

8 hypoglossal nerve/ 3507

9 electric stimulation/ 117238

10 electric stimulation therapy/ 22285

11 implantable neurostimulators/ 841

12 ((electric* or neuro* or nerve* or upper airway or hypoglossal) adj3 stimulat*).ti,ab,kf. 118884

13 electrotherap*.ti,ab,kf.2594

14 (neurostimulat* or neuro-stimulat*).ti,ab,kf. 5138

15 hgns.ti,ab,kf. 159

16 or/8-15 209561

17 7 and 16 1031

18 exp pharynx/su 6773

19 exp palate/su 4590

20 tongue/su 1715

21 exp laryngeal cartilages/su 2731

22 hyoid bone/su 421

23 adenoidectomy/ 5167

24 pharyngectomy/ 1424

25 tonsillectomy/ 11036

26 glossectomy/ 1186

27 laryngoplasty/ 819

28 mandibular advancement/ 2258

29 adenoidectom*.ti,ab,kf. 3739

30 adenotonsil?ectom*.ti,ab,kf. 2991

31 adenotonsil?otom*.ti,ab,kf. 22

32 palatoplast*.ti,ab,kf. 1497

33 pharyngectom*.ti,ab,kf. 386

34 pharyngoplast*.ti,ab,kf. 810

35 uvulopalatal flap*.ti,ab,kf. 42

36 uvulopalatoplast*.ti,ab,kf. 234

37 uvulopalatopharyngoplast*.ti,ab,kf. 1093

38 uppp.ti,ab,kf. 721

39 tonsil?ectom*.ti,ab,kf. 10482

40 tonsil?otom*.ti,ab,kf. 315

41 ((adenoid* or palat* or pharyn* or tonsil* or uvula or uvulopalat* or uvulo-palat*) adj3 (ablat* or coblat* or dissect* or excis* or implant* or laser* or operat* or reduc* or remov* or resect* or surg*)).ti,ab,kf. 11204

42 glossectom*.ti,ab,kf. 1064

43 lingualplast*.ti,ab,kf. 10

44 ((geniogloss* or gloss* or lingual* or tongue*) adj3 (ablat* or advance* or coblat* or operat* or reduc* or remov* or resect* or stabiliz* or surg* or suspen*)).ti,ab,kf. 3307

45 epiglottidectom*.ti,ab,kf. 15

46 epiglottopex*.ti,ab,kf. 61

47 epiglottoplast*.ti,ab,kf. 69

48 laryngoplast*.ti,ab,kf. 985

49 ((epiglott* or laryn*) adj3 (ablat* or coblat* or dissect* or excis* or laser* or operat* or reduc* or remov* or resect* or surg*)).ti,ab,kf. 8610

50 ((mandib* or maxillomandib* or maxillo-mandib*) adj3 (advance* or osteotom* or operat* or setback or surg*)).ti,ab,kf. 8419

51 (hyoid adj3 suspen*).ti,ab,kf. 146

52 (multilevel adj surg*).ti,ab,kf. 468

53 or/18-52 57988

54 clinical decision rules/ 961

55 exp clinical protocols/ 193975

56 consensus/ 22860

57 exp consensus development conferences as topic/ 3009

58 critical pathways/ 8031

59 decision making, shared/ 2204

60 exp guidelines as topic/ 173680

61 health planning guidelines/ 4165

62 consensus development conference.pt. 12410

63 consensus development conference, NIH.pt. 801

64 guideline.pt. 16382

65 practice guideline.pt. 31451

66 guideline?.ti,kf. 113494

67 ((committee or executive) adj2 (recommend* or statement or summary)).ti,kw. 2302

68 ((consensus or joint or position) adj2 (recommend* or statement)).ti,kw. 10585

69 ((clinical or critical or practice) adj2 (path* or pathway or standard? or statement)).ti,kw. 23919

70 or/54-69 519911

71 exp meta-analysis as topic/ 29851

72 systematic reviews as topic/ 13224

73 technology assessment, biomedical/ 11235

74 meta-analysis.pt. 201170

75 systematic review.pt. 261631

76 (metaanaly* or meta-analy* or meta analy*).ti,ab,kf. 308277

77 (systematic adj2 (overview? or review?)).ti,ab,kw. 344759

78 (technology adj assessment?).ti,ab,kw. 8825

79 cinahl.ab. 50211

80 cochrane.ab. 150286

81 embase.ab. 173836

82 medline.ab. 178673

83 (psychinfo or psycinfo).ab. 65241

84 pubmed.ab. 238160

85 scopus.ab. 68442

86 web of science.ab. 92235

87 or/71-86 686685

88 7 and (16 or 53) 7574

89 (exp Animals/ not Humans/) or (baboon$1 or bovine$1 or canine$1 or cat$1 or chimpanzee$1 or cow$1 or dog$1 or feline$1 or fish or goat$1 or hens or macque$1 or mice or monkey$1 or mouse or murine$1 or ovine or pig$1 or porcine or primate$1 or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent$1 or zebrafish).ti. 5705529

90 88 not 89 7405

91 90 and 87 448

92 90 and 70 142

93 limit 91 to (english language and yr="2019 -Current") 213

94 limit 92 to (english language and yr="2019 -Current") 44

95 94 not 93 32

Appendix B. Detailed Inclusion and Exclusion Criteria

Table B1. Detailed Inclusion and Exclusion Criteria for This Evidence Review

Study Component	Inclusion	Exclusion
Populations	• Adults with OSA	• Studies in children with OSA • Studies in adults without OSA
Interventions	• Surgery for OSA • Hypoglossal nerve stimulation (i.e., stimulation of the 12th cranial nerve) • Devices (e.g., mandibular advancement devices) for OSA	• Interventions other than those listed
Comparators	• Another listed intervention • CPAP • Sham surgery or treatment • No treatment	• Comparators other than those listed
Outcomes	• Measures of sleep and wakefulness, direct and indirect measures of sleep quality • Mortality • Cardiovascular events • Changes in hypertension or diabetes status • Depression • Cost • Cost-effectiveness • Safety • Complications	• Studies that do not report outcomes of interest • Economic outcomes from studies performed in non-US countries • Economic outcomes from studies performed in the US that were published more than 5 years ago
Timing	• Any point in the care pathway	• None listed
Setting	• Any outpatient or inpatient clinical setting in countries categorized as very high on the UN Human Development Index	• Emergency settings • Nonclinical settings (e.g., studies in healthy volunteers, animal models of disease) • Countries categorized other than very high on the UN Human Development Index
Study Design	• Systematic reviews and meta-analyses published within the past 5 years • Comparative primary studies published since the date of the systematic review, for newer devices and procedures only	• Abstracts, conference proceedings, posters, editorials, letters • Studies without a comparator • Proof-of-principle studies (e.g., device development or surgical technique modification)
Sample Size	• None specified	• None specified

Study Component	Inclusion	Exclusion
Publication	• Published, peer-reviewed, English-language articles	• Studies with abstracts that do not allow study characteristics to be determined • Studies that cannot be located • Duplicate publications of the same study that do not report different outcomes or follow-up times, or single-site reports from published multicenter studies • Studies in languages other than English

Abbreviations. CPAP: continuous positive airway pressure; OSA: obstructive sleep apnea; UN: United Nations.

Appendix C. Summary Characteristics of Included Studies

Systematic Reviews

Table C1. Summary Characteristics of Included Systematic Reviews of Oral Appliances for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Berger et al.[10] 2021	N = 18 studies • Years 2006 to 2020 • 284 patients	AEs with MAD use reported in 1 of the 18 included studies: • 5 patients developed treatment-emergent central sleep apnea ○ 4 of these had arterial hypertension or a structural cardiac disease	• Treatment-emergent central sleep apnea was reported in 31 of 284 patients using different treatments • Difficult to determine a clear prevalence of treatment-emergent central sleep apnea • This review suggests a < 4% rate of treatment-emergent central sleep apnea
Gao et al.[11] 2019	N = 89 studies • Years 1997 to 2015 • 6346 patients	AEs with MAD use reported in 12 of the 89 included studies: • Initial jaw discomfort early in the morning, and some degree of discomfort in the TMJ, facial musculature, or teeth on waking • Sore teeth, sore jaw muscles, excessive salivation, and difficulty chewing in the morning In most patients the side effects were mild and improved with time • 1 patient withdrew because of nausea and 2 because of appliance displacement; also excessive salivation • Sensitive teeth upon awakening (N = 9), tenderness in the masseter muscle region upon awakening (N = 13), discomfort in wearing (N = 10), hypersalivation (N = 9), dry mouth (N = 4), feeling of a changed occlusion upon awakening (N = 9), and difficulty in swallowing with the MAD in situ (N = 3) • Excessive salivation (56%), temporomandibular joint discomfort (38%), dryness of the throat (33%), and tooth discomfort (33%); all side effects considered mild and acceptable	• Despite the minimally invasive nature of MAD use, side-effects and complications are inevitable

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• Sensation of pressure on the face (N = 2), pressure in the mouth (N = 2), early morning, nonpersistent discomfort in the mouth and TMJ (N = 8) • Pain in teeth, gum, or jaw (69%), appliance removed or coming off during sleep (40%), sleep disturbance (25%), excessive salivation (19%), and damaged dental crown (6%) • 2 patients could not tolerate the appliance, 1 patient suffered loosening of the teeth, and 1 suffered pain of the temporomandibular joint • Excess salivation while wearing the appliance, occlusal and TMJ symptom • Adverse effects more common with MAD than with sham, with more complaints of jaw pain, tooth pain, hypersalivation, and bite changes • Hypersalivation, dry mouth (xerostomia), tenderness in the masseter muscle region upon awakening (N = 12), sensitive teeth upon awakening (N = 9), uncomfortable wearing (N = 9), feeling of changes in occlusion upon awakening (N = 7), and difficulty swallowing with the MAD in situ (N = 4) • Hypersalivation, mouth dryness, gingival pain, dental pain, lingual pain, TMJ pain, temporal bite change, unspecific splint intolerance (0 in sham group), damage to dental restoration, and splint fracture	
Langaliya et al.[8] 2023	N = 13 studies • Years 2000 to 2020 • 754 patients	• MAD treatment had no effect on TMD-related outcomes compared with baseline • Reduction in TMD symptoms was transient • Long-term occurrence of TMDs was steady • Some studies reported a temporary increase in TMJ-related pain or symptoms ○ Symptoms and pain later subsided • 4 studies reported significant reduction in severity and frequency of TMD symptoms at the end of follow-up • In 1 study, MAD treatment was not influenced by TMD	• Different outcomes associated with TMD are affected differently by MAD treatment for OSA • According to a few studies, MAD therapy significantly reduced the severity and frequency of TMD symptoms • Other research, however, found no appreciable modifications in TMD symptoms or TMJ-related indicators

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• In 8 studies, TMJ symptoms were more severe at the beginning of treatment and later subsided • In 1 study, MAD treatment did not affect TMD symptoms, severity, or frequency • In 3 studies, TMD symptoms remained unchanged • In 2 studies, TMD symptoms were not noted at baseline or follow-up • Effects varied based on type of MAD, TMD assessment used, and follow-up duration	• Although the overall results point to no significant effect of MAD treatment on TMD symptoms, the disparity in results between studies highlights the need for additional studies using standardized approaches

Mansour et al.[12] 2023	N = 28 studies
	• Years 2001 to 2022
	• NR
		• The most frequently reported MAA-related effects were as follows:
		  ○ Hypersalivation (33.3%)
		  ○ Occlusal changes (30.2%)
		  ○ Muscle pain (22.9%)
		• 1 study by evaluated periodontal status in 21 patients
		  ○ Periodontal variables assessed were and remained within the normal limits over time, although a significantly increased inclination of the mandibular incisors was observed, authors concluded
			• Despite MAA-related occlusal changes, there was no evidence for periodontal changes

Rana et al.[9] 2023	N = 14 studies
	• Years 2003 to 2020
	• 746 participants
		• 10 studies showed MADs decreased overjet and overbite compared with baseline
		• 4 studies showed retroclination of maxillary incisors and proclination of mandibular incisors after long-term MAD use
		• 1 study showed no conclusions for overjet and overbite but found significant change in total occlusal contact area with long-term MAD use
		• Long-term MAD use effects occlusion
		  ○ Upper incisor retroclination
		  ○ Lower incisor proclination
		  ○ Decreased overjet and overbite
		• Change in total occlusal contact area
			• The review concludes that long-term MAD therapy has statistically and clinically significant effects on occlusion

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Raoof et al.[6] 2024	N = 48 studies • Years 2005 to 2022 • 4,018 patients	15 articles addressed the association between MAD and oral moistening disorders: • 14 studies reported drooling and dry mouth as side effects of MADs ○ 3 studies reported these side effects are mild and improve as patients use their MAD ○ 1 study showed 19.4% of patients had persistent dry mouth and 10.3% had persistent drooling with MADs ○ 1 study reported drooling and dry mouth did not improve over time in 30% and 34% of patients, respectively	• Dry mouth is a common side effect of OSA • Dry mouth is a common side effect of MAD use • MAD therapy is associated with oral moistening disorders • Oral moistening disorders may be mitigated with long-term therapy
Zhang et al.[7] 2019	N = 14 studies • Years 1996 to 2014 • NR	• TMJ discomfort was mentioned in 3 studies • 21 of 46 patients ○ 1 study did not give numbers • Muscle tenderness was mentioned in 3 studies • 3 of 20 patients ○ 2 studies did not give numbers • Pain, discomfort, or damage in teeth, gums, or jaw was mentioned in 5 studies • 56 of 102 patients ○ 2 studies did not give numbers • Occlusal change was mentioned in 2 studies • 9 of 20 patients ○ 1 study did not give numbers • Excessive salivation was mentioned in 4 studies • 37 of 102 patients ○ 1 study did not give numbers • Airway dryness was mentioned in 3 studies • 15 of 54 patients ○ 1 study did not give numbers • Swallowing problem was mentioned in 2 studies • 3 of 20 patients ○ 1 study did not give numbers • Pressure on face or in mouth was mentioned in 1 study	• The most common AEs for CPAP were discomfort, airway dryness, and inconvenience • The most common AE for MAD was pain in the teeth or TMJ

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• 2 of 20 patients • Discomfort in wearing was mentioned in 2 studies • 29 of 68 patients • Sleep disruption or problem with expiration was mentioned in 1 study • 12 of 48 patients	

Abbreviations. AE: adverse event; MAD: mandibular advancement device; NR: not reported; OSA: obstructive sleep apnea; TMD: temporomandibular disorder; TMJ: temporomandibular joint.

Table C2. Summary Characteristics of Included Systematic Reviews of HGNS for Effectiveness and Harms

Author Year	Evidence Base Used	Outcomes	Effectiveness	Harms	Authors' Conclusions
Berger et al.[10] 2021	N = 18 studies • Years 2006 to 2020 • 284 patients	• Harms	• NR	• 5 of 141 patients in a cohort study plus 3 patients in case reports developed treatment-emergent central sleep apnea ○ All 5 were male • All 3 of the case study patients were male ○ 2 had comorbidities including chronic kidney disease, cardiac disease, and atrial fibrillation ○ 1 of 40 with central apneas before surgery saw an increase after surgery ○ No correlation with demographics	• Treatment-emergent central sleep apnea was reported in 31 of 284 patients using different treatments • Difficult to determine a clear prevalence of treatment-emergent central sleep apnea • This review suggests a < 4% rate of treatment-emergent central sleep apnea
Constantino et al.[17] 2020	N = 12 studies (9 included in meta-analysis, 3	• AHI • ESS • Harms	• See Kim et al., 2024 and Kim et al, 2024 for	STAR Trial: • After 5 years, 6% (8 of 126) had serious device-related	• HGNS has a high success rate

	included in the STAR trial)
	• Years 2011 to 2018
	• 350 patients
			newer reviews on effectiveness[13,14]	AEs requiring surgical repositioning or replacement of the neurostimulator or leads
				• Most common unserious device-related AE was discomfort due to electrical stimulation (N = 76; 60.3%)
				  ○ 81 occurrences in year 1
				  ○ 5 occurrences in year 5
				• Second most common unserious device-related AE was tongue abrasion (N = 34; 27%)
				  ○ 28 occurrences in year 1
				  ○ 2 occurrences in year 5
				• Most common procedure-related AE was discomfort
				  ○ Related to incision (N = 52; 30.2%)
				  ○ Independent of incision (N = 42; 27%)
				• Second most common procedure-related AE was discomfort (N = 23; 18.3%)
				Other studies:
				• 14 SAEs in 12 patients (6.1%) at 6 and 12 months
				• 81 patients (41.5%) reported AEs related to implantation procedure
				• 56 patients (28.7%) reported AEs related to device
					• HGNS has a good long-term complication rate
					• HGNS is a good option for those who have difficulty accepting or adhering to CPAP

Kim et al.[14] 2024	N = 44 studies • Years 2013 to 2023	• AHI • Success rate • Quality of life • Harms	Results up to 12 months • AHI: MD, 22.9006; 95% CI, 20.6626 to 25.1387	About 9% of patients had device-related tongue abrasion: • 0.0703 (95% CI, 0.0356 to 0.1341)	• HGNS can improve quality of life scores and polysomnography

	• 8,670 patients		• ODI: MD, 15.7599; 95% CI, 14.9799 to 16.5399 • T90: MD, 2.8204; 95% CI, 1.4856 to 4.1552 • LSAT: MD, -7.6914; 95% CI, -10.4528 to –4.9300 Results up to 36 months • AHI: MD, 20.6068; 95% CI, 18.8567 to 22.3570 • ODI: MD 14.7627; 95% CI, 13.2778 to 16.2476 • T90: MD, 2.4467; 95% CI, 1.2740 to 3.6193 • ESS: MD, 5.0532; 95% CI, 4.6540 to 5.4524 • FOSQ: MD, -3.1762; 95% CI, -3.3777 to –2.9748 Subgroup analysis based on follow-up timing – postoperative 3 months to 12 months • AHI at 3 months, 25.9473; 95% CI, 22.8469 to 29.0477 • AHI at 12 months, 20.8690; 95% CI, 18.5959 to 23.1421 • AHI, P = .01 • ESS at 3 months, 4.2682; 95% CI, 3.9371 to 4.5992 • ESS at 12 months, 4.7307; 95% CI, 4.5230 to 4.9384	Tongue abrasion decreased over time: • 12 months, 0.0779 (95% CI, 0.030 to 0.1829) • 24 months, 0.1263 (95% CI, 0.0732 to 0.2094) • 36 months, 0.0379 (95% CI, 0.0191 to 0.0740) • *P* = .02	• Positive effects gradually decreased up to month 12, but remained consistent from month 12 to month 36

			• ESS: P = .02 • FOSQ at 3 months, -2.3342; 95% CI, -3.2606 to −1.4079 • FOSQ at 12 months, -3.2789; 95% CI, -3.5166 to −3.0411 • FOSQ: P = .05 • LSAT at 3 months, -7.9102; 95% CI, -11.4382 to −4.3822 • LSAT at 12 months, -6.8430; 95% CI, -9.3303 to −4.3558 • LSAT: P = .63 • ODI at 3 months, 16.5768; 95% CI, 15.3210 to 17.8326 • ODI at 12 months, 15.0130; 95% CI 14.0328 to 15.9932 • ODI: P = .05 • T90 at 3 months, 4.4738; 95% CI 1.4585 to 7.4891 • T90 at 12 months, 2.4174; 95% CI, 0.9289 to 3.9060 • T90: P = .23 Subgroup analysis based on follow-up timing – postoperative 12 months to 36 months • AHI at 12 months, 21.1334; 95% CI, 18.7904 to 23.4763		

			• AHI at 18 months, 17.3955; 95% CI, 12.3197 to 22.4713 • AHI at 24 months, 19.7118; 95% CI, 15.8633 to 23.5602 • AHI at 36 months, 20.6802; 95% CI, 16.7487 to 24.6117 • AHI: P = .60 • ESS at 12 months, 5.0262; 95% CI, 4.6254 to 5.4270 • ESS at 18 months, 4.5606; 95% CI, 3.5840 to 5.5373 • ESS at 24 months, 6.0358; 95% CI, 3.9806 to 8.0909 • ESS at 36 months, 4.6326; 95% CI, 3.3950 to 5.8702 • ESS: P = .56 • FOSQ at 12 months, -3.2789; 95% CI, -3.5166 to −3.0411 • FOSQ at 18 months, -2.9835’ 95% CI, -3.6875 to −2.2796 • FOSQ at 24 months, -2.9000; 95% CI, -3.4903 to −2.3097 • FOSQ at 36 months, -2.8491; 95% CI, -3.4373 to −2.2610 • FOSQ: P = .39		

			• ODI at 12 months, -13.9326; 95% CI, 12.0113 to 15.8540
			• ODI at 18 months, 16.5274; 95% CI, 13.6386 to 19.4161
			• ODI at 24 months, 12.3483; 95% CI 4.7051 to 19.9916
			• ODI at 36 months, 17.5769; 95% CI 14.7777 to 20.3760
			• ODI: P = .12
			• T90 at 12 months, 2.4174; 95% CI, 0.9289 to 3.9060
			• T90 at 18 months, 2.7520; 95% CI, 0.1455 to 5.3585
			• T90 at 36 months, 2.2000; 95% CI, -0.5868 to 4.9868
			• T90: P = .96
			Rates of clinical improvement at 12 months
			• AHI
			  ○ <5, 47% (0.4703; 95% CI, 0.3817 to 0.5608)
			  ○ <10, 72% (0.7229; 95%CI, 0.6510 to 0.7849)
			  ○ <15, 82% (0.8218; 95% CI, 0.7499 to 0.8764)
			  ○ Success rate according to Sher criteria was 80%		

			(0.8030; 95% CI, 0.7495 to 0.8474) Rates of clinical improvement at 36 months • AHI ○ <5, 34% (0.3387; 95% CI, 0.2882 to 0.3931) ○ <15, 74% (0.7463; 95% CI, 0.7195 to 0.7714) ○ Success rate according to Sher criteria was 73% (0.7323; 95% CI, 0.0717 to 0.7609) Subgroup analysis based on follow-up timing – postoperative 3 months to 12 months • AHI <5 at 3 months, 0.5969; 95% CI, 0.4965 to 0.6898 • AHI <10 at 3 months, 0.7627; 95% CI, 0.6946 to 0.8195 • AHI <15 at 3 months, 0.89548; 95% CI, 0.7672 to 0.9132 • Success rate according to Sher criteria, 0.8548; 95% CI, 0.7672 to 0.9132 • AHI <5 at 12 months, 0.3442; 95% CI, 0.2884 to 0.4048; P < .001		

			• AHI <10 at 12 months, 0.6325; 95% CI, 0.5748 to 0.6867; P = .003 • AHI < 15 at 12 months, 0..7493; 95% CI, 0.7215 to 0.7751; P < .001 • Success rate according to Sher criteria, 0.7414; 95% CI, 0.7092 to 0.7712; P = .02 Outcomes were evaluated according to postoperative timing • Rate of AHI <5 ○ 12 months, 0.3677' 95% CI, 0.3021 to 0.4386 ○ 18 months, 0.2727; 95% CI, 0.1977 to 0.3633 ○ 24 months, 0.2683; 95% CI, 0.1552 to 0.4225 ○ 36 months, 0.3421; 95% CI, 0.2101 to 0.5041 ○ P = .31 • Rate of AHI <15 ○ 12 months, 0.3677; 95% CI, 0.3021 to 0.4386 ○ 18 months, 0.2727; 95% CI, 0.1977 to 0.3633 ○ 24 months, 0.2683; 95% CI, 0.1552 to 0.4225		

			○ 36 months, 0.3421; 95% CI, 0.2101 to 0.5041 ○ P = .31 • Success rate according to Sher criteria ○ 12 months, 0.7362; 95% CI, 0.7034 to 0.7665 ○ 18 months, 0.6429; 95% CI, 0.5556 to 0.7216 ○ 24 months, 0.7561; 95% CI, 0.6032 to 0.8634 ○ 36 months, 0.6316' 95% CI, 0.4700 to 0.7682 ○ P = .10		
Kim et al.,[13]	N = 10 studies • Years 2014 to 2022 • 2,209 patients	• AHI • ODI • ESS • Percentages of AHI <5, <10, and <15 events per hour • Success rate	Comparison of HNS and all other airway surgeries • AHI <10 lower in the HNS group than in other airway surgery groups ○ OR, 5.3275; 95% CI, 1.2117 to 23.4228 • AHI <15 lower in the HNS group than in other airway surgery groups ○ OR, 3.4806; 95% CI, 1.6434 to 7.3718 • Success rate based on Sher criteria higher in	NR	• Compared to other airway surgeries, the rates of post-treatment AHI <10 and <15 were significantly lower in the HNS group • Postoperative AHI was significantly lower in the HNS group than in other surgery groups • There were no significant differences in the rate of post-treatment AHI <5 or ESS scores between groups • HNS is effective for selected patients with

			the HNS group than other airway surgery groups ○ OR, 2.9546; 95% CI, 1.9634 to 4.4462 • Postoperative AHI lower in the HNS group than other airway surgery groups ○ MD, -8.0000; 95% CI, -12.0344 to –3.9656 • No significant difference in the rate of post-treatment AHI <5 ○ OR, 1.9286; 95% CI, 0.7352 to 5.0597 • No significant difference in the rate of postoperative ESS ○ MD, 0.3968; 95% CI, 1.5231 to 2.3167 Comparison of HNS and control • AHI was lower after HNS than the control group ○ MD, -12.8394; 95% CI, -16.1475 to –9.5312 • ESS was lower after HNS than the control group		moderate-to-severe OSA who cannot tolerate CPAP

			○ MD, -5.3929; 95% CI, -6.6078 to –4.1781 • ODI was lower after HNS than the control group ○ MD, -11.8384; 95% CI, -17.4476 to –6.2292 Comparison of Comparison of HNS and CPAP • No significant differences in rate of post-treatment AHI <5 ○ OR, 0.7254; 95% CI, 0.3588 to 1.4665 • No significant differences in rate of post-treatment AHI <10 ○ OR 0.6912; 95% CI, 0.2963 to 1.6121 • No significant differences in rate of post-treatment AHI <15 ○ OR, 0.7709; 95% CI, 0.2827 to 2.1025 • No significant differences in postoperative AHI ○ MD, 1.5000; 95% CI, -1.0145 to 4.0145 • No significant differences in postoperative ESS		

			○ MD, -1.8236; 95% CI, -4.5634 to 0.9163 Comparison of effectiveness among HNS, all other surgeries, CPAP, and control • ORs for post-treatment AHI <10 and 15 were lower for HNS versus CPAP • OR, 0.6912 versus 5.3275; P = .02 • ORs for post-treatment AHI <10 and 15 were lower for HNS versus other surgeries • OR, 0.7719 versus 3.4806; P = .02 • The MD in postoperative AHI of HNS versus CPAP was significantly different from those in HNS versus all other airway surgeries and control • 1.5000 versus 8.0000 and 12.8394; P < .001 • 1.8236 versus 0.3968 and 5.3929; P < .001		
Kompelli et al.[18] 2019	N = 16 studies (12 included in meta-analysis) • Years 2001 to 2018 • 381 patients	• AHI • ESS • Quality of life • Harms	• See Kim et al., 2024 and Kim et al, 2024 for newer reviews on effectiveness[13,14]	• Pain: 6.2% (95% CI, 0.7% to 16.6%; *P* < .001) • Tongue abrasion: 11.0% (1.2% to 28.7%; *P* < .001) • Internal device malfunction: 3.0% (0.3% to 8.4%; *P* < .001)	• HGNS is safe and effective for OSA • HGNS is associated with high compliance • HGNS significantly improves subjective

				• External device malfunction: 5.8% (0.3% to 17.4%; *P* < .001) • Other: 7.0% (0.6% to 19.2%; *P* < .001)	and objective sleep outcomes • Complications are generally minor and uncommon
Randerath et al.[16] 2021	N = 41 studies • Years 1988 to 2020 • NR	• AHI • ODI • Sleep efficiency • Sleepiness • Quality of life • Harms	• See Kim et al., 2024 and Kim et al, 2024 for newer reviews on effectiveness[13,14]	2 studies reported AEs narratively: • The STAR trial ○ 2 serious adverse device-related events ○ 33 serious adverse events that were not device-related ○ Most unserious adverse events were implantation-related • The TESLA trial ○ 1 complained about claustrophobia at night; this was during both nights (intervention and sham-control) ○ Mild side-effects occurred in 2.8% of the studied cohort	• Conditional recommendation against the intervention as first line • Conditional recommendation for use as a salvage therapy
Zhou et al.[19] 2022	N = 9 studies • Years 2012 to 2021 • 1,029 patients	• AHI • ODI • ESS • Success rate • Cure • Harms	• See Kim et al., 2024 and Kim et al, 2024 for newer reviews on effectiveness[13,14]	• No deaths reported • Serious device-related adverse events range from 0% to 7% • 50 serious device-related adverse events requiring surgical repositioning or replacement of the neurostimulator or implanted leads • In 1 study, 0.4% of the patients reported serious	• The most common postoperative complication was discomfort due to electrical stimulation • HGNS is effective and generally safe for OSA

				intraoperative adverse events, including but not limited to hematoma (N = 8), infection (N = 2), extra implant procedure (N = 1), intraoperative arrest (N = 1), and pneumothorax (N = 1). • Minor surgery-related complications occurred in around 6% of people and minor device-related adverse events in around 22% of people • Most common minor surgery- and device-related complications were incision discomfort and discomfort due to electrical stimulation	

Abbreviations. AE: adverse event; AHI: apnea–hypopnea index; CI: confidence interval; CPAP: continuous positive airway pressure; ESS: Epworth sleepiness scale; HGNS: hypoglossal nerve stimulation; NR: not reported; NRS: nonrandomized study; ODI: oxygen desaturation index; OSA: obstructive sleep apnea; SAE: serious adverse event.

Table C3. Summary Characteristics of Included Systematic Reviews of UPPP for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Moffa et al.[21] 2023	N = 14 • Years 2014 to 2020 • 769 patients • 14 prospective cohort studies	Intraoperative complications: • Partial thread extrusion (2.9%) • Self-limited bleeding (2.9%) • Broken needle (1.0%) • Suture rupture (1.0%) Short-term complications: • Thread/knot extrusion (12.4%) • Dysphagia (5.6%) • Bleeding (1.5%) • Velopharyngeal insufficiency (1.5%)	• Barbed pharyngoplasty is generally safe for OSA • Studies were heterogeneous so further study is needed

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• Anterior pharyngoplasty dehiscence (1.2%) • Tonsillar hemorrhage (1.0%) • Excessive postnasal discharge (1.0%) • Barbed suture failure (0.5%) • Acute infection (0.2%) • Mucosal granulomas (0.2%) • Chipped tooth caused by mouth gag displacement (0.2%) • Fibrous scar (0.2%) Long-term complications: • Foreign body sensation (7.8%) • Sticky mucus in throat (5.9%) • Dysphagia (3.6%) • Rhinolalia (3.1%) • Throat phlegm (1.1%) • Nose regurgitation (0.8%) • Dry throat (0.6%) • Throat lump (0.3%)	
Pang et al.[33] 2023	N = 16 • Years 2017 to 2020 • 747 patients	No significant AEs reported with expansion sphincter pharyngoplasty	• Expansion sphincter pharyngoplasty is effective in managing OSA and has minimal morbidity and complications compared with other palatoplasty technique

Table C4. Summary Characteristics of Included Systematic Reviews of MMA for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Jamal and Ibrahim[23] 2023	N = 46 • Years 1999 to 2020	• Approximately 6% of people were dissatisfied with their facial appearance after surgery • 3% of physicians and 15% of lay people reported a decline in attractiveness post surgery	• MMA is a generally safe procedure that substantially contributes to enhancement of perceived facial aesthetic appeal

Author Year	Evidence Base Used	Harms	Authors' Conclusions
	• 1,268 patients		
Randerath et al. [16] 2021	N = 41 studies • Years 1988 to 2020 • NR	• Maxillo-mandibular osteotomy (compared with CPAP) • Moderate AEs and could require additional orthodontic work	• Conditional recommendation for use
Yong et al.[22] 2024	N = 10 studies • Years 2003 to 2023 • 166 patients	4 studies included AEs: • 1 study of 82 participants • 3.7% (N = 3) of participants had maxillary division of the trigeminal nerve • 96.3% (N = 79) of participants had mandibular division of the trigeminal nerve • 1.2% (N = 1) of participants had wound healing issues • 1.2% (N = 1) of participants had eustachian tube dysfunction • 1 study of 12 participants • 75% (N = 9) of participants had mandibular division of the trigeminal nerve • 33.3% (N = 4) of participants had wound dehiscence • 8.3% (N = 1) of participants had infection • 8.3% (N = 1) of participants had joint pain • 1 study of 11 participants • 27.3% (N = 3) of participants had mandibular division of the trigeminal nerve • 18.2% (N = 2) of participants had postoperative pain requiring hardware removal • 1 study of 12 participants • 8.3% (N = 2) of (N = 24) sides had mandibular division of the trigeminal nerve	• Surgical complications are uncommon and mostly minor in nature

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Zhou et al.[19] 2022	N = 21 studies • Years 1997 to 2020 • 581 patients	• Across the 10 NRSs reporting on post-surgical complications[19]: ○ Major complications ranged from 0% to 18% and included reoperations for removal of osteosynthesis screws and plates, reoperations for maxillary nonunion, and acute dyspnea ○ Most commonly reported minor complication was paresthesia caused by the impairment of inferior alveolar nerve; rates varied across studies (for transient paresthesia, from 32% to 100%; for persistent paresthesia, from 0% to 60%) ○ Other minor complications included developed malocclusion, TMDs, local infection, and minor postoperative wound pain ○ Based on 2 small studies, around 13% to 15% of people reported worsening of their facial appearance after surgery	• The most common postoperative complications were facial paresthesia in the mandibular area • MMA is effective and generally safe for OSA
Zhou et al.[24] 2021	N = 20 • Years 1997 to 2020 • 568 patients	• No deaths reported • Major complication rate, 3.2% ○ 10 reoperations for removal of osteosynthesis screws and plates (n = 8) and maxillary nonunion (n = 2) ○ 1 sudden dyspnea • Most frequent complication was facial paresthesia caused by the impairment of inferior alveolar nerve or maxillary nerve ○ 18.5% reported persistent symptoms, with a mean follow-up of 6.0 years • Minor complication rate, 10.1% ○ Malocclusion ○ TMDs ○ Minor wound pain ○ Unfavorable split ○ Loss of an interdental gingiva ○ Perforation of the palate ○ Transient unilateral angulus oris deviation • 9 of 206 patients perceived worsening of their facial appearance after surgery	• MMA is an effective treatment option; however, the complication rate of MMA is higher than multi-level surgery

Abbreviations. AE: adverse event; CPAP: continuous positive airway pressure; MMA: maxillomandibular advancement; TMD: temporomandibular disorder.

Table C5. Summary Characteristics of Included Systematic Reviews of Tracheostomy for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Berger et al.[10] 2021	N = 18 studies • Years 2006 to 2020 • 284 patients	• 5 of 141 patients in a cohort study plus 3 patients in case reports developed treatment-emergent central sleep apnea ○ All 5 were male • All 3 of the case study patients were male ○ 2 had comorbidities including chronic kidney disease, cardiac disease, and atrial fibrillation ○ 1 of 40 with central apneas before surgery saw an increase after surgery ○ No correlation with demographics	• Treatment-emergent central sleep apnea was reported in 31 of 284 patients using different treatments • Difficult to determine a clear prevalence of treatment-emergent central sleep apnea • This review suggests a < 4% rate of treatment-emergent central sleep apnea

Table C6. Summary Characteristics of Included Systematic Reviews of Laser-Assisted Uvulopalatoplasty for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Wischhusen et al.[25] 2019	N = 42 studies • Years 1990 to 2014 • 3,093 patients	15 studies (975 patients) reported about pain: • Mean duration 11.65 days • 1 study (21 patients) reported that 2 patients refused further procedures due to pain from this primary surgery • 2 studies (25 patients) reported on mean duration of narcotic use (5.56 days) Other complications: • Overall: 25.6% • Bleeding: 2.6% (relative risk, 0.43; 95% CI, 0.27 to 0.67) • Candidiasis: 0.3% (relative risk, 2.36; 95% CI, 0.25 to 22.37)	• Laser-assisted uvulopalatoplasty is associated with a statistically significant rate of velopharyngeal insufficiency and globus • Overall complication rate was 26%

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• Dryness: 7.2% (relative risk, 0.46; 95% CI, 0.35 to 0.59) • Dysgeusia: 0.3% (relative risk, 0.05; 95% CI, 0.02 to 0.15) • Dysosmia: 0.2% (relative risk, 0.02; 95% CI, 0.00 to 0.10) • Globus: 8.2% (relative risk 1.48; 95% CI, 1.07 to 2.06) • Surgical site infection: 1.3% (relative risk, 0.94; 95% CI, 0.45 to 1.98) • Velopharyngeal insufficiency: 3.9% (relative risk, 2.25; 95% CI, 1.29 to 3.94 • Velopharyngeal stenosis: 1.6% (Relative risk, 1.61; 95% CI, 0.73 to 3.53) Incidence of globus and velopharyngeal insufficiency were statistically significant compared with the general population or the post-oropharyngeal surgery population	

Abbreviations. CI: confidence interval; NR: not reported.

Table C7. Summary Characteristics of Included Systematic Reviews of Tongue Ablation for Harms Only

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Calvo-Henriquez et al.[26] 2022	N = 20 studies • Years 1999 to 2019 • 542 patients	Total complication rate was 12.83%: • TBRF: 4.16% (95% CI, 2.70 to 5.62) • TORS: 36.7% (95% CI, 27.65 to 45.75) • LS: 29.07% (95% CI, 22.28 to 35.86) • SMILE: 10% (95% CI, 0.70 to 19.30) • TBA: 42.42% (95% CI, 25.56 to 59.29) • Total: 12.83% (95% CI, 10.84 to 14.83) Minor bleeding:	• Tongue base procedures are associated with a variety of complications • Included studies were heterogeneous

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• TBRF: 0 • TORS: 7.34% (95% CI, 2.44 to 12.24) • LS: 0.58% (95% CI, -0.5 to 1.72) • SMILE: 2.50% (95% CI, -2.34 to 7.34) • TBA: 6.06% (95% CI, -2.08 to 14.20) • Total: 1.12% (95% CI, 0.49 to 1.74) Pain: • TBRF: 0 • TORS: 3.67% (95% CI, 0.14 to 7.20) • LS: 2.91% (95% CI, 0.40 to 5.42) • SMILE: 0 • TBA: 0 • Total: 0.84% (95% CI, 0.29 to 1.38) Infection: • TBRF: 1.00% (95% CI, 0.26 to 1.73) • TORS: 0.92% (95% CI, -0.87 to 2.71) • LS: 6.98% (95% CI, 3.17 to 10.78) • SMILE: 2.50% (95% CI, -2.34 to 7.34) • TBA: 0 • Total: 1.95% (95% CI, 1.13 to 2.78) Odynophagia: • TBRF: 0.14% (95% CI, -0.14 to 0.42) • TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0.19% (95% CI, -0.07 to 0.44) Foreign body feeling: • TBRF: 0 • TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• Total: 0.09% (95% CI, -0.09 to 0.28) Mucosal erosion or ulceration: • TBRF: 0.71% (95% CI, 0.09 to 1.34) • TORS: 0 • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.47% (95% CI, 0.06 to 0.87) Total minor complications: • TBRF: 1.80% (95% CI, 0.83 to 2.77) • TORS: 11.93% (95% CI, 5.84 to 18.01) • LS: 11.63% (95% CI, 6.84 to 16.42) • SMILE: 5% (95% CI, -1.75 to 11.75) • TBA: 6.06% (95% CI, -2.08 to 14.20) • Total: 4.65% (95% CI, 3.39 to 5.91) Floor cyst: • TBRF: 0 • TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Granulated tissue: • TBRF: 0 • TORS: 0 • LS: 1.74% (95% CI, -0.21 to 3.70) • SMILE: 0 • TBA: 0 • Total: 0.28% (95% CI, -0.04 to 0.59) Transient speech disorder: • TBRF: 0 • TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Transient hypoglossal palsy: • TBRF: 0.43% (95% CI, -0.06 to 0.91) • TORS: 0 • LS: 0 • SMILE: 2.50% (95% CI, -2.34 to 7.34) • TBA: 0 • Total: 0.28% (95% CI, -0.04 to 0.59) Transient neuralgia: • TBRF: 0.14% (95% CI, -0.14 to 0.42) • TORS: 0 • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Transient hypoesthesia: • TBRF: 0 • TORS: 0 • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.19% (95% CI, -0.07 to 0.44) Hematoma: • TBRF: 0 • TORS: 0 • LS: 1.16% (95% CI, -0.44 to 2.76) • SMILE: 2.50% (95% CI, -2.34 to 7.34) • TBA: 0 • Total: 0.28% (95% CI, -0.04 to 0.59) Transient taste nerve disorder: • TBRF: 0 • TORS: 0.92% (95% CI, -0.87 to 2.71)	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0.74% (95% CI, 0.23 to 1.26) Subcutaneous emphysema: • TBRF: 0 • TORS: 0.92% (95% CI, -0.87 to 2.71) • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Transient swallowing disorder: • TBRF: 0.14% (95% CI, -0.14 to 0.42) • TORS: 8.26% (95% CI, 3.09 to 13.42) • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 9.09% (95% CI, -0.72 to 18.90) • Total: 1.30% (95% CI, 0.62 to 1.98) Suture extrusion or fracture: • TBRF: NA • TORS: NA • LS: 9.30% (95% CI, 4.96 to 13.64) • SMILE: NA • TBA: NA • Total: NA Transient tongue atrophy: • TBRF: 0 • TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Mild edema: • TBRF: 0.29% (95% CI, -0.11 to 0.68) • TORS: 4.59% (95% CI, 0.66 to 8.51)	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• LS: 1.16% (95% CI, -0.44 to 2.76) • SMILE: 0 • TBA: 12.12% (95% CI, 0.99 to 23.26) • Total: 1.30% (95% CI, 0.62 to 1.98) Total moderate complications: • TBRF: 0.97% (95% CI, 0.26 to 1.69) • TORS: 22.02% (95% CI, 14.24 to 29.80) • LS: 16.86% (95% CI, 11.27 to 22.46) • SMILE: 5% (95% CI, -1.75 to 11.75) • TBA: 21.21% (95% CI, 7.26 to 35.16) • Total: 6.42% (95% CI, 4.95 to 7.88) Tongue abscess or severe infection: • TBRF: 0.43% (95% CI, -0.06 to 0.91) • TORS: 0 • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.28% (95% CI, -0.04 to 0.59) Major bleeding: • TBRF: 0 • TORS: 0.92% (95% CI, -0.87 to 2.71) • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Severe mouth floor edema: • TBRF: 0.86% (95% CI, 0.17 to 1.54) • TORS: 0.92% (95% CI, -0.87 to 2.71) • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0.84% (95% CI, 0.29 to 1.38) Permanent speech disorder: • TBRF: 0	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
		• TORS: 0 • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: 0 • TBA: 0 • Total: 0 Permanent taste disorder: • TBRF: 0 • TORS: 6.42% (95% CI, 1.82 to 11.02) • LS: 0 • SMILE: 0 • TBA: 15.15% (95% CI, 2.92 to 27.38) • Total: 0.47% (95% CI, 0.06 to 0.87) Oropharyngeal stenosis: • TBRF: 0 • TORS: 0.92% (95% CI, -0.87 to 2.71) • LS: 1.74% (95% CI, -0.21 to 3.70) • SMILE: 0 • TBA: 0 • Total: 0.09% (95% CI, -0.09 to 0.28) Permanent hypoglossal nerve palsy: • TBRF: 0 • TORS: 0 • LS: 0 • SMILE: 0 • TBA: 0 • Total: 0 Total severe complications: • TBRF: 1.39% (95% CI, 0.53 to 2.24) • TORS: 2.75% (95% CI, -0.32 to 5.82) • LS: 0.58% (95% CI, -0.55 to 1.72) • SMILE: NA • TBA: 15.15% (95% CI, 2.92 to 27.38) • Total: 1.77% (95% CI, 0.98 to 2.55)	

Author Year	Evidence Base Used	Harms	Authors' Conclusions
Lechien et al.[27] 2021	N = 31 • Years 2012 to 2019 • 1,693 patients	Complications were reported in 24 studies: • Airway edema: 2 of 75 (rate = 2.67) • Aspiration: 23 of 98 (rate = 23.47) • Dehydration: 42 of 599 (rate = 7.01) • Dental injury: 1 of 64 (rate = 1.56) • Dysgeusia: 66 of 447 (rate = 14.77) • Dysphagia: 54 of 459 (rate = 14.77) • Globus: 22 of 282 (rate = 7.0) • Hypoxemia: 6 of 289 (rate = 2.08) • Lip burning: 1 of 166 (rate = 0.60) • Major hemorrhage: 20 of 605 (rate = 3.31) • Minor hemorrhage: 60 of 973 (rate = 6.17) • Pain: 22 of 325 (rate = 6.77) • Pharyngeal scarring: 5 of 307 (rate = 1.63) • Pharyngeal synechia: 1 of 6 (rate = 16.67) • Pharyngeal edema: 1 of 243 (rate = 0.41) • Pneumonia: 6 of 289 (rate = 2.08) • Tongue edema: 93 of 151 (rate = 61.59) • Tongue or pharyngeal paresthesia: 21 of 28 (rate = 75.0) • Xerostomia: 2 of 16 (rate = 12.50)	• TORS BOT reduction may be effective and safe • TORS BOT is associated with short and mid-term improvements of AHI, ESS and LSAT

Abbreviations. AHI: apnea-hypopnea index; BOT: robotic surgery; CI: confidence interval; ESS: Epworth sleepiness scale; LS: lingual suspension; LSAT: lowest oxygen saturation; NA: not applicable; NR: not reported; SMILE: submucosal minimally invasive lingual excision; TBA: tongue base ablation; TBRF: tongue base radiofrequency; TORS: transoral robotic surgery.

Table C8. Summary Characteristics of Included Systematic Reviews of Other Surgery or Device Types for Effectiveness and Harms

Author Year	Evidence Base Used	Outcomes	Results	Harms	Authors' Conclusions
Surgery – Limited Palatal Muscle Resection					
Park et al.[28] 2023	N = 6 • Years 2008 to 2018 • 119 patients	• AHI • RDI • SpO2	• AHI or RDI decreased after surgery • 1 study did not show a significant decrease • Minimum SpO2 increased after surgery ○ 1 study showed a significant decrease	• Possible AEs include dry throat and foreign body sensation ○ Resolved after 83 months	Limited palatal muscle resection is an effective and safe alternative to UPPP
Devices – Transcutaneous Electrical Stimulation					
Byun et al.[29] 2020	N = 10 • Years 1989 to 2016 • 198 patients	• AHI • SpO2 • AEs	• Significant reduction in AHI after treatment • No difference in O2 saturation, lowest O2, or arousal index	• No permanent AEs observed • 8% of people discontinued	Transcutaneous electrical stimulation resulted in reduction of AHI in patients with OSA; however, other effects were equivocal
Devices – Noninvasive Electrical Stimulation Devices					
Moffa et al.[30] 2023	N = 4 • Years 2004 to 2018 • 265 patients	• Snoring • AHI	• Significant reduction in snoring • No significant reduction in AHI	• Not reported	Intraoral non-invasive electrical stimulation devices can be considered a valid option to current therapies for snoring. Further studies are needed to support these devices for treatment of OSA.

Abbreviations. AE: adverse event; AHI: apnea-hypopnea index; RDI: Respiratory Disturbance Index; SpO2: lowest pulse oximetry value; UPPP: uvulopalatopharyngoplasty.

Pivotal Randomized Controlled Trials

Table C9. Summary Characteristics of Included RCTs of Effectiveness

Author Year NCT Identifier Location	Population Study Duration	Intervention	Comparison	Relevant Outcomes and Findings
Hypoglossal Nerve Stimulation				
Dedhia et al.,[15] 2024 NCT03359096 CARDIOSA-12 Single center in the US	• 62 adults with moderate-to-severe OSA with an implanted HGNS • 4 weeks	• HGNS	• Sham	Primary outcome: • No difference between groups for measures of blood pressure Secondary outcome: • Significantly greater reduction in AHI with active HGNS compared with sham (a reduction of 4.9 events per hour; 95% CI, 1.0 to 8.8)
Electrical Stimulation (other than hypoglossal nerve stimulation)				
Abreu et al.[32] 2023 NCT04974515 Single center in the US	• 40 adults with newly diagnosed mild OSA • 6 weeks	• Daytime NMES (eXciteOSA)	• Sham	Primary outcome: • No significant difference in adherence between groups Secondary outcomes: • No direct comparisons between groups reported Safety: • NR

Rateneswaran et al.[31] 2023 NCT03160456 Single center in the UK	• 56 adults with OSA and limited adherence to CPAP • 3 months	• Domiciliary transcutaneous electrical stimulation (TESLA)	• Usual care (CPAP)	Primary outcome: • Significantly greater improvement in AHI with TESLA when compared with usual care (between group difference, -11.5; 95% CI, -20.7 to -2.3); however, this difference became nonsignificant when adjusted for baseline values Secondary outcomes: • Significantly greater improvement in ODI with TESLA when compared with usual care (between group difference, -11.3; 95% CI, -19.3 to -3.2); this difference remained significant when adjusted for baseline values • Significantly greater improvement in ESS with TESLA when compared with usual care (between group difference, -3.0; 95% CI, -5.4 to -0.5); this difference remained significant when adjusted for baseline values • No significant differences between

				groups in terms of quality of life • Fewer participants in the TESLA group did not use the intervention compared with the CPAP group (10.3% vs. 59.3%; *P* < .001) • No significant differences in response between groups Safety: • 1 participant in the TESLA group reported mild headaches which resolved on stopping treatment • 1 participant in the TESLA group reported a beneficial effect on headaches and migraine • Other AEs included patches peeling off in hot weather and skin irritation

Abbreviations. AE: adverse event; AHI: Apnea-Hypopnea Index; CI: confidence interval; CPAP: continuous positive airway pressure; ESS: Epworth Sleepiness Scale; FOSQ: Functional Outcome of Sleep Questionnaire; HGNS: hypoglossal nerve stimulation; MAD: mandibular advancement device; NCT: National Clinical Trials identifier; NMES: neuromuscular electrical stimulation; NR: not reported; ODI: oxygen desaturation index; OSA: obstructive sleep apnea; TORS: transoral robotic surgery; UPPP: uvulopalatopharyngoplasty.

Appendix D. Excluded Studies With Reasons

Citation	Reason for Exclusion
Anonymous. Errors in Table 2. *JAMA Otolaryngol Head Neck Surg*. 2024;150(6):530. doi: 10.1001/jamaoto.2024.0412.	Publication Type
Abd-Ellah ME, Mohamed FS, Khamis MM, Abdel Wahab NH. Modified biblock versus monoblock mandibular advancement appliances for treatment of obstructive sleep apnea: A randomized controlled trial. *J Prosthet Dent*. 2024;131(4):633-642. doi: 10.1016/j.prosdent.2022.02.019.	Setting
Ahn SH, Jeong Y, Shin GC, Yoon JH, Kim CH, Cho HJ. Outcomes of multilevel upper airway surgery, including tongue base resection, in patients with torus mandibularis. *J Craniomaxillofac Surg*. 2021;49(8):682-687. doi: 10.1016/j.jcms.2021.02.008.	Study Design
Al-Sherif M, He B, Schwarz EI, et al. Ultrasound assessment of upper airway dilator muscle contraction during transcutaneous electrical stimulation in patients with obstructive sleep apnoea. *J*. 2020;12(Suppl 2):S139-S152. doi: 10.21037/jtd-cus-2020-001.	Outcomes
Alessandri-Bonetti A, Bortolotti F, Moreno-Hay I, et al. Effects of mandibular advancement device for obstructive sleep apnea on temporomandibular disorders: A systematic review and meta-analysis. *Sleep Med Rev*. 2019;48:101211. doi: 10.1016/j.smrv.2019.101211.	Newer Systematic Review Available
Almutairi N, Alshareef W, Almakoshi L, Zakzouk A, Aljasser A, Alammar A. Is adenotonsillectomy effective in improving central apnea events in patients with obstructive sleep apnea? A systematic review and meta-analysis. *Eur Arch Otorhinolaryngol*. 2023;280(12):5205-5217. doi: 10.1007/s00405-023-08202-7.	Population
Alshhrani WM, Hamoda MM, Okuno K, et al. The efficacy of a titrated tongue-stabilizing device on obstructive sleep apnea: a quasi-experimental study. *J Clin Sleep Med*. 2021;17(8):1607-1618. doi: 10.5664/jcsm.9260.	Study Design
Amali A, Motiee-Langroudi M, Saedi B, Rahavi-Ezabadi S, Karimian A, Amirzargar B. A Comparison of Uvulopalatopharyngoplasty and Modified Radiofrequency Tissue Ablation in Mild to Moderate Obstructive Sleep Apnea: A Randomized Clinical Trial. *J Clin Sleep Med*. 2017;13(9):1089-1096. doi: 10.5664/jcsm.6730.	Setting
Arens P, Hansel T, Wang Y. Hypoglossal Nerve Stimulation Therapy. *Adv Exp Med Biol*. 2022;1384:351-372. doi: 10.1007/978-3-031-06413-5_21.	Publication Type
Asadian A, Soheilipour S, Taleban R, Feizi A. A comparative study on the effects of surgery alone and along with radiofrequency in improvement of patients with nocturnal snoring in Isfahan, Iran. *Journal of research in medical sciences*. 2012;17(1 SPL.1):S42-S48.	Setting
Askar S, Awad A, Oraby T, Khazbak A. Trans-hyoid hyoidthyroidpexy: A modified technique for selected cases of obstructive sleep apnea. *Am J Otolaryngol*. 2021;42(6):103159. doi: 10.1016/j.amjoto.2021.103159.	Study Design
Askar SM, Khazbak AO, Mobasher MA, Abd Al Badea AM, Abu Sharkh AA, Awad AM. Role of DISE in the surgical outcome for patients with obstructive sleep apnea. *Am J Otolaryngol*. 2023;44(4):103869. doi: 10.1016/j.amjoto.2023.103869.	Aim
Babademez MA, Gul F, Sancak M, Kale H. Prospective randomized comparison of tongue base resection techniques: robotic vs coblation. *Clin Otolaryngol*. 2019;44(6):989-996. doi: 10.1111/coa.13424.	Comparator

Citation	Reason for Exclusion
Babademez MA, Yorubulut M, Yurekli MF, et al. Comparison of minimally invasive techniques in tongue base surgery in patients with obstructive sleep apnea. *Otolaryngol Head Neck Surg.* 2011;145(5):858-864. doi: 10.1177/0194599811414793.	Comparator
Bahgat A, Bahgat Y, Alzahrani R, Montevecchi F, Cammaroto G, Vicini C. Transoral Endoscopic Coblation Tongue Base Surgery in Obstructive Sleep Apnea: Resection versus Ablation. *ORL J Otorhinolaryngol Relat Spec.* 2020;82(4):201-208. doi: 10.1159/000506994.	Setting
Balsevicius T, Uloza V, Vaitkus S, Sakalauskas R, Miliauskas S. Controlled trial of combined radiofrequency-assisted uvulopalatoplasty in the treatment of snoring and mild to moderate OSAS (pilot study). *Sleep Breath.* 2013;17(2):695-703. doi: 10.1007/s11325-012-0744-9.	Population
Barewal RM. Obstructive Sleep Apnea: The Role of Gender in Prevalence, Symptoms, and Treatment Success. *Dent Clin North Am.* 2019;63(2):297-308. doi: 10.1016/j.cden.2018.11.009.	Aim
Bartolucci ML, Bortolotti F, Corazza G, Incerti Parenti S, Paganelli C, Alessandri Bonetti G. Effectiveness of different mandibular advancement device designs in obstructive sleep apnoea therapy: A systematic review of randomised controlled trials with meta-analysis. *J Oral Rehabil.* 2021;48(4):469-486. doi: 10.1111/joor.13077.	Aim
Bartolucci ML, Bortolotti F, Martina S, Corazza G, Michelotti A, Alessandri-Bonetti G. Dental and skeletal long-term side effects of mandibular advancement devices in obstructive sleep apnea patients: a systematic review with meta-regression analysis. *Eur J Orthod.* 2019;41(1):89-100. doi: 10.1093/ejo/cjy036.	Newer Systematic Review Available
Bartolucci ML, Incerti Parenti S, Bortolotti F, et al. The Effect of Bite Raise on AHI Values in Adult Patients Affected by OSA: A Systematic Review with Meta-Regression. *J.* 2023;12(11):23. doi: 10.3390/jcm12113619.	Aim
Baslas V, Chand P, Jurel SK, et al. A Pilot Study to Determine the Effect of Three Months of Oral Appliance Therapy using a Mandibular Advancement Device on HbA1c in Subjects with Type 2 Diabetes Mellitus and Obstructive Sleep Apnea. *J Prosthodont.* 2019;28(3):271-275. doi: 10.1111/jopr.12973.	Setting
Bastier PL, Gallet de Santerre O, Bartier S, et al. Guidelines of the French Society of ENT (SFORL): Drug-induced sleep endoscopy in adult obstructive sleep apnea syndrome. *Eur Ann Otorhinolaryngol Head Neck Dis.* 2022;139(4):216-225. doi: 10.1016/j.anorl.2022.05.003.	Publication Type
Baudouin R, Alali A, Hans S, Blumen M, Chabolle F. OSAS and upper pharynx surgery: Does basilingual collapsus always rhyme with failure? *Eur Ann Otorhinolaryngol Head Neck Dis.* 2021;138(3):135-139. doi: 10.1016/j.anorl.2020.07.004.	Study Design
Belanche Monterde A, Zubizarreta-Macho A, Lobo Galindo AB, Albaladejo Martinez A, Montiel-Company JM. Mandibular advancement devices decrease systolic pressure during the day and night in patients with obstructive sleep apnea: A systematic review and meta-analysis. *Sleep Breath.* 2024;05:05. doi: 10.1007/s11325-023-02984-0.	Outcomes
Belkhode V, Godbole S, Nimonkar S, Pisulkar S, Nimonkar P. Comparative evaluation of the efficacy of customized maxillary oral appliance with mandibular advancement appliance as a treatment modality for moderate obstructive sleep apnea patients-a randomized controlled trial. *Trials.* 2023;24(1):73. doi: 10.1186/s13063-022-07054-6.	Setting
Beltran JF, Ramirez OE, Carrillo A, et al. Multidisciplinary Treatment in Patients with Craniofacial, Neurocognitive, and Neuromuscular Disorders with Obstructive Sleep Apnea: A Systematic Review of the Literature. *Pediatr Ann.* 2024;53(2):e62-e69. doi: 10.3928/19382359-20231205-04.	Population

Citation	Reason for Exclusion
Benedek P, Balakrishnan K, Cunningham MJ, et al. International Pediatric Otolaryngology group (IPOG) consensus on the diagnosis and management of pediatric obstructive sleep apnea (OSA). *Int J Pediatr Otorhinolaryngol.* 2020;138:110276. doi: 10.1016/j.ijporl.2020.110276.	Population
Bergeron M, Lee DR, DeMarcantonio MA, et al. Safety and cost of drug-induced sleep endoscopy outside the operating room. *Laryngoscope.* 2020;130(8):2076-2080. doi: 10.1002/lary.28397.	Publication Type
Beri A, Pisulkar SG, Dubey SA, Sathe S, Bansod A, Shrivastava A. Appliances Therapy in Obstructive Sleep Apnoea: A Systematic Review and Meta-Analysis. *Cureus.* 2023;15(11):e48280. doi: 10.7759/cureus.48280.	Outcomes
Bernhardt O, Giannakopoulos NN, Heise M, et al. Mandibular advancement device: prescription in adult dental sleep medicine - guideline of the German Society of Dental Sleep Medicine. *Sleep Breath.* 2023;27(1):389-397. doi: 10.1007/s11325-022-02601-6.	Publication Type
Bortolotti F, Corazza G, Bartolucci ML, Incerti Parenti S, Paganelli C, Alessandri-Bonetti G. Dropout and adherence of obstructive sleep apnoea patients to mandibular advancement device therapy: A systematic review of randomised controlled trials with meta-analysis and meta-regression. *J Oral Rehabil.* 2022;49(5):553-572. doi: 10.1111/joor.13290.	Aim
Bosschieter PFN, Uniken Venema JAM, Vonk PE, et al. Equal effect of a noncustom vs a custom mandibular advancement device in treatment of obstructive sleep apnea. *J Clin Sleep Med.* 2022;18(9):2155-2165. doi: 10.5664/jcsm.10058.	Comparator
Braun M, Stoerzel M, Wollny M, Schoebel C, Ulrich Sommer J, Heiser C. Patient-reported outcomes with hypoglossal nerve stimulation for treatment of obstructive sleep apnea: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol.* 2023;280(10):4627-4639. doi: 10.1007/s00405-023-08062-1.	Outcomes
Brunetto DP, Moschik CE, Dominguez-Mompell R, Jaria E, Sant'Anna EF, Moon W. Mini-implant assisted rapid palatal expansion (MARPE) effects on adult obstructive sleep apnea (OSA) and quality of life: a multi-center prospective controlled trial. *Prog Orthod.* 2022;23(1):3. doi: 10.1186/s40510-021-00397-x.	Setting
Buller M, Jodeh DS, Rottgers SA. Maxillomandibular Advancement for the Treatment of Obstructive Sleep Apnea in Patients With Normal or Class I Malocclusion. *J Craniofac Surg.* 2020;31(3):716-719. doi: 10.1097/SCS.0000000000006239.	Aim
Calvo-Henriquez C, Chiesa-Estomba C, Lechien JR, et al. The Recumbent Position Affects Nasal Resistance: A Systematic Review and Meta-Analysis. *Laryngoscope.* 2022;132(1):6-16. doi: 10.1002/lary.29509.	Population
Camacho M, Noller MW, Del Do M, et al. Long-term Results for Maxillomandibular Advancement to Treat Obstructive Sleep Apnea: A Meta-analysis. *Otolaryngol Head Neck Surg.* 2019;160(4):580-593. doi: 10.1177/0194599818815158.	Newer Systematic Review Available
Camanes-Gonzalvo S, Bellot-Arcis C, Marco-Pitarch R, et al. Comparison of the phenotypic characteristics between responders and non-responders to obstructive sleep apnea treatment using mandibular advancement devices in adult patients: Systematic review and meta-analysis. *Sleep Med Rev.* 2022;64:101644. doi: 10.1016/j.smrv.2022.101644.	Aim
Cammaroto G, Stringa LM, Iannella G, et al. Manipulation of Lateral Pharyngeal Wall Muscles in Sleep Surgery: A Review of the Literature. *Int J Environ Res Public Health.* 2020;17(15):23. doi: 10.3390/ijerph17155315.	Aim
Carney AS, Antic NA, Catcheside PG, et al. Sleep Apnea Multilevel Surgery (SAMS) trial protocol: a multicenter randomized clinical trial of upper airway surgery for patients with obstructive sleep apnea who have failed continuous positive airway pressure. *Sleep.* 2019;42(6):11. doi: 10.1093/sleep/zsz056.	Publication Type

Citation	Reason for Exclusion
Cerritelli L, Hatzopoulos S, Catalano A, et al. Rapid Maxillary Expansion (RME): An Otolaryngologic Perspective. *J.* 2022;11(17):05. doi: 10.3390/jcm11175243.	Population
Chaiard J, Weaver TE. Update on Research and Practices in Major Sleep Disorders: Part I. Obstructive Sleep Apnea Syndrome. *J Nurs Scholarsh.* 2019;51(5):500-508. doi: 10.1111/jnu.12489.	Publication Type
Chang CC, Wu JL, Hsiao JR, Lin CY. Real-Time, Intraoperative, Ultrasound-Assisted Transoral Robotic Surgery for Obstructive Sleep Apnea. *Laryngoscope.* 2021;131(4):E1383-E1390. doi: 10.1002/lary.29135.	Study Design
Chang ET, Kwon YD, Jung J, et al. Genial tubercle position and genioglossus advancement in obstructive sleep apnea (OSA) treatment: a systematic review. *Maxillofac Plast Reconstr Surg.* 2019;41(1):34. doi: 10.1186/s40902-019-0217-1.	Aim
Chang JL, Goldberg AN, Alt JA, et al. International Consensus Statement on Obstructive Sleep Apnea. *Int Forum Allergy Rhinol.* 2023;13(7):1061-1482. doi: 10.1002/alr.23079.	Publication Type
Chekkoury Idrissi Y, Lechien JR, Besnainou G, Hans S. Is tracheotomy necessary for transoral robotic surgery base of tongue reduction in obstructive sleep apnoea syndrome? Our experience in 20 patients. *Clin Otolaryngol.* 2021;46(3):654-658. doi: 10.1111/coa.13701.	Intervention
Chen H, Eckert DJ, van der Stelt PF, et al. Phenotypes of responders to mandibular advancement device therapy in obstructive sleep apnea patients: A systematic review and meta-analysis. *Sleep Med Rev.* 2020;49:101229. doi: 10.1016/j.smrv.2019.101229.	Aim
Chen H, Wang J, Huang X, Huang Y, Lu J, Li X. Z-palatopharyngoplasty combined with 70-degree endoscopy-assisted coblator partial medial glossectomy on severe obstructive sleep apnea. *Acta Otolaryngol.* 2019;139(10):902-907. doi: 10.1080/00016489.2019.1635711.	Study Design
Chwiesko-Minarowska S, Minarowski L, Szewczak WA, Chyczewska E, Kuryliszyn-Moskal A. Efficacy of daytime transcutaneous electrical stimulation of the genioglossus muscle in patients with obstructive sleep apnea syndrome: short report. *Eur Arch Otorhinolaryngol.* 2016;273(11):3891-3895. doi: 10.1007/s00405-016-4047-9.	Study Design
Ciger E, Islek A. Anterior Palatoplasty With Expansion Sphincter Pharyngoplasty for All Type of Pharyngeal Collapse. *Laryngoscope.* 2022;132(6):1313-1319. doi: 10.1002/lary.29999.	Intervention
Clements AC, Dai X, Walsh JM, et al. Outcomes of Adenotonsillectomy for Obstructive Sleep Apnea in Prader-Willi Syndrome: Systematic Review and Meta-analysis. *Laryngoscope.* 2021;131(4):898-906. doi: 10.1002/lary.28922.	Population
Correa EJ, O'Connor-Reina C, Rodriguez-Alcala L, et al. Does Frenotomy Modify Upper Airway Collapse in OSA Adult Patients? Case Report and Systematic Review. *J.* 2022;12(1):27. doi: 10.3390/jcm12010201.	Population
Costanzo MR, Ponikowski P, Javaheri S, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *Lancet.* 2016;388(10048):974-982. doi: 10.1016/S0140-6736(16)30961-8.	Population
Dahy KG, Takahashi K, Saito K, et al. The Relationship Between Cephalogram Analysis and Oxygen Desaturation Index During Sleep in Patients Submitted for Mandibular Setback Surgery. *J Craniofac Surg.* 2018;29(4):e375-e380. doi: 10.1097/SCS.0000000000004386.	Study Design

Citation	Reason for Exclusion
Daskalakis D, Tsetsos N, Karagergou S, Goudakos J, Markou K, Karkos P. Intracapsular coblation tonsillectomy versus extracapsular coblation tonsillectomy: a systematic review and a meta-analysis. *Eur Arch Otorhinolaryngol.* 2021;278(3):637-644. doi: 10.1007/s00405-020-06178-2.	Population
De Meyer MMD, Vanderveken OM, De Weerdt S, et al. Use of mandibular advancement devices for the treatment of primary snoring with or without obstructive sleep apnea (OSA): A systematic review. *Sleep Med Rev.* 2021;56:101407. doi: 10.1016/j.smrv.2020.101407.	Population
de Vries GE, Hoekema A, Vermeulen KM, et al. Clinical- and Cost-Effectiveness of a Mandibular Advancement Device Versus Continuous Positive Airway Pressure in Moderate Obstructive Sleep Apnea. *J Clin Sleep Med.* 2019;15(10):1477-1485. doi: 10.5664/jcsm.7980.	Study Design
Di Bari M, Colombo G, Giombi F, et al. The effect of drug-induced sleep endoscopy on surgical outcomes for obstructive sleep apnea: a systematic review. *Sleep Breath.* 2023;18:18. doi: 10.1007/s11325-023-02931-z.	Aim
Dontsos VK, Chatzigianni A, Papadopoulos MA, Nena E, Steiropoulos P. Upper airway volumetric changes of obstructive sleep apnoea patients treated with oral appliances: a systematic review and meta-analysis. *Eur J Orthod.* 2021;43(4):399-407. doi: 10.1093/ejo/cjaa035.	Aim
Eesa M, Hendawy E, El-Anwar MW. Modified Z-Palatoplasty for Correction of Acquired Nasopharyngeal Stenosis Following Palatal Surgery: A Case Series. *Cleft Palate Craniofac J.* 2022;59(6):774-778. doi: 10.1177/10556656211021702.	Publication Type
El Youssef N, Marchi A, Bartolomei F, Bonini F, Lambert I. Sleep and epilepsy: A clinical and pathophysiological overview. *Rev Neurol (Paris).* 2023;179(7):687-702. doi: 10.1016/j.neurol.2023.07.006.	Publication Type
El-Anwar MW, Askar S, El-Sinbawy AH, Salem AMH. Single versus double suspension sutures for selected cases of obstructive sleep apnea. *Auris Nasus Larynx.* 2019;46(5):754-757. doi: 10.1016/j.anl.2018.12.014.	Setting
Emara TA, Elmonem M, Khaled AM, Genedy HAH, Youssef RS. Anterolateral advancement pharyngoplasty versus barbed reposition pharyngoplasty in patients with obstructive sleep apnea. *Eur Arch Otorhinolaryngol.* 2024;281(4):1991-2000. doi: 10.1007/s00405-023-08402-1.	Setting
Emara TA, Ibrahim HA, Elmalt AE, Dahy KG, Rashwan MS. Upper airway multilevel radiofrequency under local anesthesia can improve CPAP adherence for severe OSA patients. *Am J Otolaryngol.* 2023;44(1):103671. doi: 10.1016/j.amjoto.2022.103671.	Setting
Eun YG, Shin SY, Kim SW. Effects of uvulopalatopharyngoplasty with or without radiofrequency tongue base reduction on voice in patients with obstructive sleep apnea. *Laryngoscope.* 2013;123(7):1806-1810. doi: 10.1002/lary.23456.	Study Design
Farhood Z, Isley JW, Ong AA, et al. Adenotonsillectomy outcomes in patients with Down syndrome and obstructive sleep apnea. *Laryngoscope.* 2017;127(6):1465-1470. doi: 10.1002/lary.26398.	Population
Feltner C, Wallace IF, Aymes S, et al. Screening for Obstructive Sleep Apnea in Adults: An Evidence Review for the U.S. Preventive Services Task Force. *Agency for Healthcare Research and Quality (US).* 2022:11.	Aim
Francis CE, Quinnell T. Mandibular Advancement Devices for OSA: An Alternative to CPAP? *Pulm Ther.* 2021;7(1):25-36. doi: 10.1007/s41030-020-00137-2.	Publication Type

Citation	Reason for Exclusion
Francisco I, Nunes C, Baptista Paula A, et al. Patient-Reported Outcomes of Maxillomandibular Surgery for Obstructive Sleep Apnea Treatment: A Scoping Review. *J.* 2024;13(5):21. doi: 10.3390/jcm13051232.	Intervention
Friedman M, Hamilton C, Samuelson CG, et al. Transoral robotic glossectomy for the treatment of obstructive sleep apnea-hypopnea syndrome. *Otolaryngol Head Neck Surg.* 2012;146(5):854-862. doi: 10.1177/0194599811434262.	Study Design
Fu W, Li L, Zhang S, Liu S, Liu W. Effects of CPAP and Mandibular Advancement Devices on depressive symptoms in patients with obstructive sleep apnea: a meta-analysis of randomized controlled trials. *Sleep Breath.* 2023;27(6):2123-2137. doi: 10.1007/s11325-023-02829-w.	Intervention
Gafar HA-L, Abdulla AE-DA, Ghanem YY, Bahgat AY. Comparative study between single-stage multilevel surgery and staged surgery for management of snoring and/or obstructive sleep apnea. *The Egyptian Journal of Otolaryngology*. 2022;38(1). doi: 10.1186/s43163-022-00268-0.	Setting
Garcia NM, Blaya F, Urquijo EL, Heras ES, D'Amato R. Oral appliance for Obstructive Sleep Apnea: Prototyping and Optimization of the Mandibular Protrusion Device. *J Med Syst.* 2019;43(5):107. doi: 10.1007/s10916-019-1235-3.	Publication Type
Gillespie MB, Wylie PE, Lee-Chiong T, Rapoport DM. Effect of palatal implants on continuous positive airway pressure and compliance. *Otolaryngol Head Neck Surg.* 2011;144(2):230-236. doi: 10.1177/0194599810392173.	Not Pivotal Trial
Giralt-Hernando M, Valls-Ontanon A, Guijarro-Martinez R, Masia-Gridilla J, Hernandez-Alfaro F. Impact of surgical maxillomandibular advancement upon pharyngeal airway volume and the apnoea-hypopnoea index in the treatment of obstructive sleep apnoea: systematic review and meta-analysis. *BMJ Open Respir Res.* 2019;6(1):e000402. doi: 10.1136/bmjresp-2019-000402.	Newer Systematic Review Available
Guo MY, Li PJ, Xiao Y, Cao Y, Liang ZA. Effectiveness of mandibular advancement devices in the treatment of obstructive sleep apnea and the impact of different body positions on treatment： A systematic review and meta-analysis. *Sleep Med.* 2024;113:275-283. doi: 10.1016/j.sleep.2023.11.1134.	Outcomes
Haskell BS, Voor MJ, Roberts AM. A consideration of factors affecting palliative oral appliance effectiveness for obstructive sleep apnea: a scoping review. *J Clin Sleep Med.* 2021;17(4):833-848. doi: 10.5664/jcsm.9018.	Aim
He M, Yin G, Zhan S, et al. Long-term Efficacy of Uvulopalatopharyngoplasty among Adult Patients with Obstructive Sleep Apnea: A Systematic Review and Meta-analysis. *Otolaryngol Head Neck Surg.* 2019;161(3):401-411. doi: 10.1177/0194599819840356.	Newer Systematic Review Available
Hendricks R, Davids M, Khalfey H, et al. Sleepiness Score-Specific Outcomes of a Novel Tongue Repositioning Procedure for the Treatment of Continuous Positive Airway Pressure-Resistant Obstructive Sleep Apnea. *Ann Maxillofac Surg.* 2019;9(1):28-36. doi: 10.4103/ams.ams_151_18.	Study Design
Hoff PT, D'Agostino MA, Thaler ER. Transoral robotic surgery in benign diseases including obstructive sleep apnea: Safety and feasibility. *Laryngoscope.* 2015;125(5):1249-1253. doi: 10.1002/lary.25026.	Study Design
Holmlund T, Franklin KA, Levring Jaghagen E, et al. Tonsillectomy in adults with obstructive sleep apnea. *Laryngoscope.* 2016;126(12):2859-2862. doi: 10.1002/lary.26038.	Study Design
Holmlund T, Levring-Jaghagen E, Franklin KA, Lindkvist M, Berggren D. Effects of Radiofrequency versus sham surgery of the soft palate on daytime sleepiness. *Laryngoscope.* 2014;124(10):2422-2426. doi: 10.1002/lary.24580.	Not Pivotal Trial

Citation	Reason for Exclusion
Honglertnapakul Y, Peanchitlertkajorn S, Likitkulthanaporn A, Saengfai NN, Chaweewannakorn C, Boonpratham S. Impacts of mandibular setback with or without maxillary advancement for class III skeletal correction on sleep-related respiratory parameters: A systematic review and meta-analysis. *Orthod Craniofac Res*. 2024;25:25. doi: 10.1111/ocr.12798.	Population
Hou T, Hu S, Jiang X. Tongue coblation via the ventral approach for obstructive sleep apnea-hypopnea syndrome surgery. *Laryngoscope*. 2012;122(11):2582-2586. doi: 10.1002/lary.23556.	Study Design
Hsu HJ, Wu JL, Hsiao JR, Lin CY. Quantification of the Impact of Intraoperative Ultrasound in Transoral Robotic Tongue Base Reduction. *Laryngoscope*. 2022;132(5):1125-1131. doi: 10.1002/lary.29931.	Study Design
Huai D, Dai J, Xu M, et al. Combination of CO2 laser-assisted uvulopalatopharyngoplasty and nasal cavity expansion enhances treatment of obstructive sleep apnea-hypopnea syndrome. *Int J Clin Exp Med*. 2015;8(10):19764-19774.	Setting
Huai D, Ju L, Wang S, Wu H, Xu M, Cao Y. Effect Evaluation of Modified Uvulopalatopharyngoplasty With Low-Temperature Plasma and Selective Nasal Cavity Vasodilatation With Tongue Volume Reduction in Patients With Obstructive Sleep Apnea Hypopnea Syndrome. *J Craniofac Surg*. 2018;29(2):437-439. doi: 10.1097/SCS.0000000000004129.	Study Design
Huang F, Wang M, Chen H, et al. Analgesia and patient comfort after enhanced recovery after surgery in uvulopalatopharyngoplasty: a randomised controlled pilot study. *BMC anesthesiol*. 2021;21(1):237. doi: 10.1186/s12871-021-01458-8.	Aim
Huntley C, Boon M, Tschopp S, et al. Comparison of Traditional Upper Airway Surgery and Upper Airway Stimulation for Obstructive Sleep Apnea. *Ann Otol Rhinol Laryngol*. 2021;130(4):370-376. doi: 10.1177/0003489420953178.	Study Design
Hwang CS, Kim JW, Kim JW, et al. Comparison of robotic and coblation tongue base resection for obstructive sleep apnoea. *Clin Otolaryngol*. 2018;43(1):249-255. doi: 10.1111/coa.12951.	Study Design
Iannella G, Magliulo G, Cammaroto G, et al. Effectiveness of drug-induced sleep endoscopy in improving outcomes of barbed pharyngoplasty for obstructive sleep apnea surgery: a prospective randomized trial. *Sleep Breath*. 2022;26(4):1621-1632. doi: 10.1007/s11325-021-02528-4.	Intervention
Iannella G, Lechien JR, Perrone T, et al. Barbed reposition pharyngoplasty (BRP) in obstructive sleep apnea treatment: State of the art. *Am J Otolaryngol*. 2022;43(1):103197. doi: 10.1016/j.amjoto.2021.103197.	Not Pivotal Trial
Iftikhar IH, Cistulli PA, Jahrami H, et al. Comparative efficacy of mandibular advancement devices in obstructive sleep apnea: a network meta-analysis. *Sleep Breath*. 2023;27(4):1365-1381. doi: 10.1007/s11325-022-02744-6.	Outcomes
Ilea A, Timus D, Hopken J, et al. Oral appliance therapy in obstructive sleep apnea and snoring - systematic review and new directions of development. *Cranio*. 2021;39(6):472-483. doi: 10.1080/08869634.2019.1673285.	Outcomes
Johal A, Haria P, Manek S, Joury E, Riha R. Ready-made versus custom-made mandibular repositioning devices in sleep apnea: a randomized clinical trial. *J Clin Sleep Med*. 2017;13(2):175-182. doi: 10.5664/jcsm.6440.	Comparator
Kakkar M, Malik S, Gupta B, Vaid N, George R, Singh S. Use of Laser in Sleep Disorders: A Review on Low Laser Uvulopalatoplasty. *sleep disord*. 2021;2021:8821073. doi: 10.1155/2021/8821073.	Quality Concern

Citation	Reason for Exclusion
Kamel AA, Tabbakh HAE, Dewidar HR, Fouly MSE. Evaluating the effectiveness of barbed reposition palatopharyngoplasty compared to uvulopalatopharyngoplasty for treatment of obstructive sleep apnea. *The Egyptian Journal of Otolaryngology*. 2023;39(1). doi: 10.1186/s43163-023-00454-8.	Setting
Kang KT, Yeh TH, Hsu YS, et al. Effect of Sleep Surgery on C-Reactive Protein Levels in Adults With Obstructive Sleep Apnea: A Meta-Analysis. *Laryngoscope*. 2021;131(5):1180-1187. doi: 10.1002/lary.29212.	Outcomes
Kang KT, Yeh TH, Ko JY, Lee CH, Lin MT, Hsu WC. Effect of sleep surgery on blood pressure in adults with obstructive sleep apnea: A Systematic Review and meta-analysis. *Sleep Med Rev*. 2022;62:101590. doi: 10.1016/j.smrv.2022.101590.	Outcomes
Karaman M, Gun T, Temelkuran B, Aynaci E, Kaya C, Tekin AM. Comparison of fiber delivered CO(2) laser and electrocautery in transoral robot assisted tongue base surgery. *Eur Arch Otorhinolaryngol*. 2017;274(5):2273-2279. doi: 10.1007/s00405-017-4449-3.	Study Design
Kent D, Huyett P, Yu P, et al. Comparison of clinical pathways for hypoglossal nerve stimulation management: in-laboratory titration polysomnography vs home-based efficacy sleep testing. *J Clin Sleep Med*. 2023;19(11):1905-1912. doi: 10.5664/jcsm.10712.	Aim
Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(12):2499-2505. doi: 10.5664/jcsm.9592.	Aim
Kim MK, Park SW, Lee JW. Randomized comparison of the Pentax AirWay Scope and Macintosh laryngoscope for tracheal intubation in patients with obstructive sleep apnoea. *Br J Anaesth*. 2013;111(4):662-666. doi: 10.1093/bja/aet201.	Intervention
Kiss B, Neagos CM, Jimborean G, Sarkozi HK, Szathmary M, Neagos A. Comorbidities and Laryngeal Cancer in Patients with Obstructive Sleep Apnea: A Review. *Medicina (Kaunas)*. 2023;59(11):06. doi: 10.3390/medicina59111959.	Aim
Knowles S, Dekow M, Williamson ML. Oral Appliances for OSA Treatment: Meeting the Quadruple Aim. *Mil Med*. 2023;188(3-4):e718-e724. doi: 10.1093/milmed/usab316.	Study Design
Kou C, Zhao X, Lin X, Fan X, Wang Q, Yu J. Effect of different treatments for obstructive sleep apnoea on blood pressure. *J Hypertens*. 2022;40(6):1071-1084. doi: 10.1097/HJH.0000000000003131.	Outcomes
Krishnamurthy P, Banu F, Kumar VA. Impact of Complete Denture and Mandibular Advancement Device in the Management of Completely Edentulous Obstructive Sleep Apneic Individuals: A Systematic Review with Meta-Analysis. *J Dent (Shiraz)*. 2023;24(1 Suppl):84-94. doi: 10.30476/dentjods.2022.93891.1743.	Outcomes
Kwak KH, Lee YJ, Lee JY, Cho JH, Choi JH. The Effect of Pharyngeal Surgery on Positive Airway Pressure Therapy in Obstructive Sleep Apnea: A Meta-Analysis. *J*. 2022;11(21):30. doi: 10.3390/jcm11216443.	Aim
Lagravere MO, Zecca PA, Caprioglio A, Fastuca R. Metabolic effects of treatment in patients with obstructive sleep apnea: a systematic review. *Minerva Pediatr*. 2019;71(4):380-389. doi: 10.23736/S0026-4946.18.05223-4.	Population
Lai YJ, Su PL, Li CY, Lin CY, Hung CH, Lin CY. Oropharyngeal Rehabilitation for Patients With Moderate to Severe Obstructive Sleep Apnea After Transoral Robotic Surgery. *Otolaryngol Head Neck Surg*. 2022;167(6):971-978. doi: 10.1177/01945998221088752.	Study Design
Lan WC, Chang WD, Tsai MH, Tsou YA. Trans-oral robotic surgery versus coblation tongue base reduction for obstructive sleep apnea syndrome. *Peerj*. 2019;7:e7812. doi: 10.7717/peerj.7812.	Study Design

Citation	Reason for Exclusion
Law M, Villar S, Oscroft N, et al. Continuous Positive Airway Pressure plus Mandibular Advancement Therapy (PAPMAT): study protocol for an adaptive randomised crossover trial comparing the benefits and costs of combining two established treatments for obstructive sleep apnoea. *Trials*. 2023;24(1):474. doi: 10.1186/s13063-023-07484-w.	Publication Type
Lee CC, Gandotra S, Lahey ET, Peacock ZS. Is Intensive Care Unit Monitoring Necessary After Maxillomandibular Advancement for Management of Obstructive Sleep Apnea? *J Oral Maxillofac Surg*. 2022;80(3):456-464. doi: 10.1016/j.joms.2021.11.010.	Study Design
Lee JM, Weinstein GS, O'Malley BW, Jr., Thaler ER. Transoral robot-assisted lingual tonsillectomy and uvulopalatopharyngoplasty for obstructive sleep apnea. *Ann Otol Rhinol Laryngol*. 2012;121(10):635-639. doi: 10.1177/000348941212101002.	Study Design
Lee CH, Hsu WC, Yeh TH, Ko JY, Lin MT, Kang KT. Effect of sleep surgery on lipid profiles in adults with obstructive sleep apnea: a meta-analysis. *Eur Arch Otorhinolaryngol*. 2022;279(8):3811-3820. doi: 10.1007/s00405-022-07382-y.	Outcomes
Lee CH, Hsu WC, Yeh TH, Ko JY, Lin MT, Kang KT. Effect of Sleep Surgery on Inflammatory Cytokines in Adult Obstructive Sleep Apnea: A Systematic Review and Meta-Analysis. *Laryngoscope*. 2022;132(11):2275-2284. doi: 10.1002/lary.30176.	Outcomes
Lee JA, Byun YJ, Nguyen SA, Lentsch EJ, Gillespie MB. Transoral Robotic Surgery versus Plasma Ablation for Tongue Base Reduction in Obstructive Sleep Apnea: Meta-analysis. *Otolaryngol Head Neck Surg*. 2020;162(6):839-852. doi: 10.1177/0194599820913533.	Comparator
Lembacher S, Gantner S, Uhl B, Holzer M, Patscheider M, Hempel JM. The RonchAP(R) palatinal device: A conservative approach in treating obstructive sleep apnea syndrome-a randomized, controlled study. *Eur Arch Otorhinolaryngol*. 2023;280(5):2373-2385. doi: 10.1007/s00405-022-07738-4.	Not Pivotal Trial
Li HY, Lee LA, Kezirian EJ. Efficacy of Coblation Endoscopic Lingual Lightening in Multilevel Surgery for Obstructive Sleep Apnea. *JAMA Otolaryngol Head Neck Surg*. 2016;142(5):438-443. doi: 10.1001/jamaoto.2015.3859.	Study Design
Li P, Ning XH, Lin H, Zhang N, Gao YF, Ping F. Continuous positive airway pressure versus mandibular advancement device in the treatment of obstructive sleep apnea: a systematic review and meta-analysis. *Sleep Med*. 2020;72:5-11. doi: 10.1016/j.sleep.2020.03.015.	Intervention
Li S, Wu D, Shi H. Treatment of obstructive sleep apnea hypopnea syndrome caused by glossoptosis with tongue-base suspension. *Eur Arch Otorhinolaryngol*. 2013;270(11):2915-2920. doi: 10.1007/s00405-013-2536-7.	Study Design
Liao J, Shi Y, Gao X, et al. Efficacy of oral appliance for mild, moderate, and severe obstructive sleep apnea: a meta-analysis. *Otolaryngol Head Neck Surg*. 2024;170(5):1270-1279. doi: 10.1002/ohn.676.	Outcomes
Liu C, Qin J, Xing D, et al. Ultrasonic Measurement of Lingual Artery and Its Application for Midline Glossectomy. *Ann Otol Rhinol Laryngol*. 2020;129(9):856-862. doi: 10.1177/0003489420913581.	Study Design
Liu J, Xu J, Guan S, Wang W. Effects of different treatments on metabolic syndrome in patients with obstructive sleep apnea: a meta-analysis. *Front Med (Lausanne)*. 2024;11:1354489. doi: 10.3389/fmed.2024.1354489.	Outcomes
Llewellyn CM, Noller MW, Camacho M. Cautery-assisted palatal stiffening operation for obstructive sleep apnea: a systematic review and meta-analysis. *World J Otorhinolaryngol Head Neck Surg*. 2019;5(1):49-56. doi: 10.1016/j.wjorl.2018.05.007.	Quality Concerns

Citation	Reason for Exclusion
Lou BX, Greenberg H, Korotun M. Advances in Treatment of Sleep-Disordered Breathing. *Am J Ther.* 2021;28(2):e196-e203. doi: 10.1097/MJT.0000000000001345.	Study Design
Luca C, Pasquale C, Caterina T, et al. Barbed palatal surgery: single stage or multilevel setting-a systematic review by the Young Otolaryngologists of the Italian Society of Otolaryngology. *Eur Arch Otorhinolaryngol.* 2023;280(9):3905-3913. doi: 10.1007/s00405-023-08018-5.	Outcomes
MacKay S, Carney AS, Catcheside PG, et al. Effect of Multilevel Upper Airway Surgery vs Medical Management on the Apnea-Hypopnea Index and Patient-Reported Daytime Sleepiness Among Patients With Moderate or Severe Obstructive Sleep Apnea: The SAMS Randomized Clinical Trial. *Jama.* 2020;324(12):1168-1179. doi: 10.1001/jama.2020.14265.	Intervention
Maghsoudipour M, Nokes B, Bosompra NO, et al. A Pilot Randomized Controlled Trial of Effect of Genioglossus Muscle Strengthening on Obstructive Sleep Apnea Outcomes. *J.* 2021;10(19). doi: 10.3390/jcm10194554.	Intervention
Mandavia R, Mehta N, Veer V. Guidelines on the surgical management of sleep disorders: A systematic review. *Laryngoscope.* 2020;130(4):1070-1084. doi: 10.1002/lary.28028.	Study Design
Maniaci A, Di Luca M, Lechien JR, et al. Lateral pharyngoplasty vs. traditional uvulopalatopharyngoplasty for patients with OSA: systematic review and meta-analysis. *Sleep Breath.* 2022;26(4):1539-1550. doi: 10.1007/s11325-021-02520-y.	Outcomes
Marzetti A, Tedaldi M, Passali FM. Preliminary findings from our experience in anterior palatoplasty for the treatment of obstructive sleep apnea. *Clin.* 2013;6(1):18-22. doi: 10.3342/ceo.2013.6.1.18.	Intervention
Mashaqi S, Patel SI, Combs D, et al. The Hypoglossal Nerve Stimulation as a Novel Therapy for Treating Obstructive Sleep Apnea-A Literature Review. *Int J Environ Res Public Health.* 2021;18(4):09. doi: 10.3390/ijerph18041642.	Study Design
Maurer JT, Sommer JU, Hein G, Hormann K, Heiser C, Stuck BA. Palatal implants in the treatment of obstructive sleep apnea: a randomised, placebo-controlled single-centre trial. *Eur Arch Otorhinolaryngol.* 2012;269(7):1851-1856. doi: 10.1007/s00405-011-1920-4.	Not Pivotal Trial
Mecenas P, Miranda GHN, Fagundes NCF, Normando D, Ribeiro KCF. Effects of oral appliances on serum cytokines in adults with obstructive sleep apnea: a systematic review. *Sleep Breath.* 2022;26(3):1447-1458. doi: 10.1007/s11325-021-02485-y.	Outcomes
Moffa A, Giorgi L, Carnuccio L, et al. Barbed Pharyngoplasty for Snoring: Does It Meet the Expectations? A Systematic Review. *Healthcare (Basel).* 2023;11(3):03. doi: 10.3390/healthcare11030435.	Population
Moffa A, Rinaldi V, Mantovani M, et al. Different barbed pharyngoplasty techniques for retropalatal collapse in obstructive sleep apnea patients: a systematic review. *Sleep Breath.* 2020;24(3):1115-1127. doi: 10.1007/s11325-020-02088-z.	Newer Systematic Review Available
Mulholland GB, Jeffery CC, Ziai H, et al. Multilevel Palate and Tongue Base Surgical Treatment of Obstructive Sleep Apnea: A Systematic Review and Meta-analysis. *Laryngoscope.* 2019;129(7):1712-1721. doi: 10.1002/lary.27597.	Newer Systematic Review Available
Neruntarat C, Khuancharee K, Saengthong P. Barbed Reposition Pharyngoplasty versus Expansion Sphincter Pharyngoplasty: A Meta-Analysis. *Laryngoscope.* 2021;131(6):1420-1428. doi: 10.1002/lary.29357.	Outcomes
Neruntarat C, Wanichakorntrakul P, Khuancharee K, Saengthong P, Tangngekkee M. Upper airway stimulation vs other upper airway surgical procedures for OSA: a meta-analysis. *Sleep Breath.* 2022;26(1):407-418. doi: 10.1007/s11325-021-02402-3.	Outcomes

Citation	Reason for Exclusion
O'Toole S, Moazzez R, Wojewodka G, et al. Single-centre, single-blinded, randomised, parallel group, feasibility study protocol investigating if mandibular advancement device treatment for obstructive sleep apnoea can reduce nocturnal gastro-oesophageal reflux (MAD-Reflux trial). *BMJ Open*. 2023;13(8):e076661. doi: 10.1136/bmjopen-2023-076661.	Publication Type
Omrani M, Barati B, Omidifar N, Okhovvat AR, Hashemi SA. Coblation versus traditional tonsillectomy: A double blind randomized controlled trial. *J Res Med Sci*. 2012;17(1):45-50.	Setting
Panah ZE, Sharifi A, Zoafa S, et al. Uvulopalatopharyngoplasty with and without modified thyrohyoid suspension for obstructive sleep apnea treatment: a randomized clinical trial. *Eur Arch Otorhinolaryngol*. 2023;280(10):4677-4685. doi: 10.1007/s00405-023-08068-9.	Setting
Pang KA, Pang KP, Lim JW, et al. Clinical outcomes of expansion sphincter pharyngoplasty-a 17-year systematic review. *Eur Arch Otorhinolaryngol*. 2024;281(5):2691-2698. doi: 10.1007/s00405-024-08469-4.	Outcomes
Pang KP, Pang EB, Win MT, Pang KA, Woodson BT. Expansion sphincter pharyngoplasty for the treatment of OSA: a systemic review and meta-analysis. *Eur Arch Otorhinolaryngol*. 2016;273(9):2329-2333. doi: 10.1007/s00405-015-3831-2.	Outcomes
Patel S, Rinchuse D, Zullo T, Wadhwa R. Long-term dental and skeletal effects of mandibular advancement devices in adults with obstructive sleep apnoea: A systematic review. *Int Orthod*. 2019;17(1):3-11. doi: 10.1016/j.ortho.2019.01.004.	Newer Systematic Review Available
Pattipati M, Gudavalli G, Zin M, et al. Continuous Positive Airway Pressure vs Mandibular Advancement Devices in the Treatment of Obstructive Sleep Apnea: An Updated Systematic Review and Meta-Analysis. *Cureus*. 2022;14(1):e21759. doi: 10.7759/cureus.21759.	Outcomes
Pengo M, Sichang X, Ratneswaran C, Shah N, Chen T, Douiri A. Randomised, sham-controlled, double-blind cross-over trial of transcutaneous electrical stimulation of the pharyngeal dilator muscles in obstructive sleep apnoea. *Eur Respir J*. 2016;48(Suppl 60):PA3432.	Publication Type
Pengo MF, Soranna D, Giontella A, et al. Obstructive sleep apnoea treatment and blood pressure: which phenotypes predict a response? A systematic review and meta-analysis. *Eur Respir J*. 2020;55(5):05. doi: 10.1183/13993003.01945-2019.	Aim
Pengo MF, Xiao S, Ratneswaran C, et al. Randomised sham-controlled trial of transcutaneous electrical stimulation in obstructive sleep apnoea. *Thorax*. 2016;71(10):923-931. doi: 10.1136/thoraxjnl-2016-208691.	Follow-up
Pietzsch JB, Richter AK, Randerath W, et al. Clinical and Economic Benefits of Upper Airway Stimulation for Obstructive Sleep Apnea in a European Setting. *Respiration*. 2019;98(1):38-47. doi: 10.1159/000497101.	Publication Type
Plzak J, Zabrodsky M, Kastner J, Betka J, Klozar J. Combined bipolar radiofrequency surgery of the tongue base and uvulopalatopharyngoplasty for obstructive sleep apnea. *Arch Med Sci*. 2013;9(6):1097-1101. doi: 10.5114/aoms.2013.39226.	Study Design
Rahavi-Ezabadi S, Su YY, Wang YH, et al. Minimally invasive, single-stage, multilevel surgery for obstructive sleep apnoea: A systematic review and meta-analysis. *Clin Otolaryngol*. 2023;48(6):828-840. doi: 10.1111/coa.14098.	Intervention
Rangarajan H, Padmanabhan S, Ranganathan S, Kailasam V. Impact of oral appliance therapy on quality of life (QoL) in patients with obstructive sleep apnea - a systematic review and meta-analysis. *Sleep Breath*. 2022;26(3):983-996. doi: 10.1007/s11325-021-02483-0.	Outcomes

Citation	Reason for Exclusion
Ratneswaran D, Guni A, Pengo MF, et al. Electrical stimulation as a therapeutic approach in obstructive sleep apnea - a meta-analysis. *Sleep Breath.* 2021;25(1):207-218. doi: 10.1007/s11325-020-02069-2.	Newer Systematic Review Available
Rinaldi V, Costantino A, Moffa A, Baptista P, Sabatino L, Casale M. "Barbed snore surgery" simulator: a low-cost surgical model. *Eur Arch Otorhinolaryngol.* 2019;276(8):2345-2348. doi: 10.1007/s00405-019-05497-3.	Aim
Rocha NS, de Franca AJB, Nino-Sandoval TC, do Egito Vasconcelos BC, Filho JRL. Efficiency of maxillomandibular advancement for the treatment of obstructive apnea syndrome: a comprehensive overview of systematic reviews. *Clin Oral Investig.* 2022;26(6):4291-4305. doi: 10.1007/s00784-022-04489-8.	Study Design
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