The Rise of Upper Airway Stimulation in the Era of Transoral Robotic Surgery for Obstructive Sleep Apnea

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KEYWORDS

• Obstructive sleep apnea • Hypoglossal nerve stimulation • Upper airway stimulation • Inspire • Transoral robotic surgery

KEY POINTS

- Upper airway stimulation (UAS) has shown high success rates in carefully selected patients with moderate to severe sleep apnea.
- UAS has shown equivalent or better outcomes with lower morbidity compared with transoral robotic (TORS) base of tongue surgery.
- Studies comparing UAS and TORS directly have shown clear benefit of UAS over TORS in patients meeting UAS criteria; however, many TORS candidates are not UAS candidates under current candidacy criteria.
- Future studies of UAS will further characterize long-term treatment efficacy, adverse event profile, and effect on medical outcomes.

INTRODUCTION/BACKGROUND

Obstructive sleep apnea (OSA) is a chronic sleep disorder characterized by recurrent episodes of upper airway collapse and associated reduction or cessation of airflow with resulting hypoxia. The adverse health effects on both quality of life and medical comorbidities, including cardiac arrhythmia and stroke, are well described.[1,2] First-line treatment of OSA includes medical measures, with continuous positive airway pressure (CPAP) being the gold standard of treatment.[3] Intolerance of CPAP is common and drives many patients to pursue surgical treatment.[4]

The pathophysiology contributing to OSA is multifactorial and includes mechanical airway obstruction from soft tissue and skeletal elements, as well as dynamic collapse related to decreased tone and inadequate reflex airway dilation.[5] Transoral robotic

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multilevel surgery (TORS) was first approved for removal of benign tongue base tissue in 2009 under the Davinci robotic platform; it became increasingly popular over the last decade as a way to address anatomic obstruction from hypertrophied lingual tonsillar tissue that could not be accessed easily or safely by conventional methods.[6] As the understanding of the pathophysiology of OSA has evolved, recent treatments falling into the category of neurostimulation (upper airway stimulation, UAS) have emerged as a dynamic alternative to traditional static soft tissue and skeletal framework surgery. Currently, hypoglossal nerve stimulation (HGNS) is the only UAS device that is Food and Drug Administration (FDA) approved (Inspire, 2014) for the treatment of OSA.[7,8]

TORS is ideally suited for patients with primarily tongue base obstruction from lingual tonsil hypertrophy, although it may be performed in conjunction with other multilevel surgeries when other sites of mechanical obstruction are present[9] (**Fig. 1**). A major benefit of TORS includes improved surgical access, allowing more complete surgical resection of tongue base tissue, which could not otherwise be addressed by traditional surgical methods.

The UAS procedure effectively works at multiple levels of obstructions simultaneously, as targeted nerve stimulation advances the base of tongue to open the retrolingual airway while simultaneously opening the retropalatal space by palatoglossal coupling[10] (**Fig. 2**). UAS is logically an excellent option for patients with tongue base obstruction primarily due to muscular hypertrophy rather than lymphoid tissue hypertrophy. In contrast to static soft tissue and skeletal framework surgery, UAS

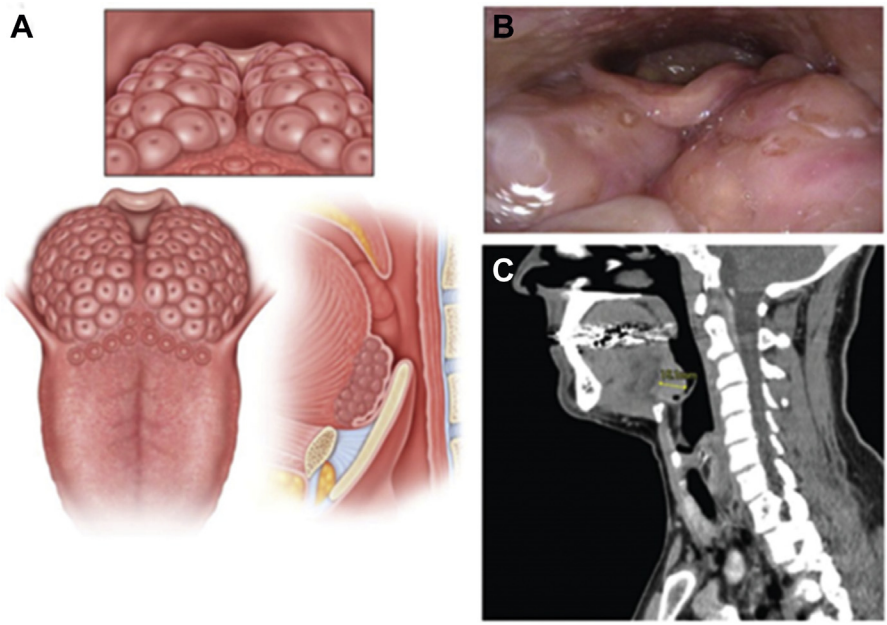

Fig. 1. TORS base of tongue surgery best addresses static obstruction from hypertrophied lingual tonsils. (*A*) Schematic, (*B*) endoscopic, and (*C*) sagittal CT views showing obstruction of the retrolingual space, size 4 lingual tonsils. CT, computed tomography. (*From* Friedman M, Yalamanchali S, Gorelick G, Joseph NJ, Hwang MS. A standardized lingual tonsil grading system: interexaminer agreement. Otolaryngology–head and neck surgery: official journal of American Academy of Otolaryngology-Head and Neck Surgery. 2015;152(4):667-672.)

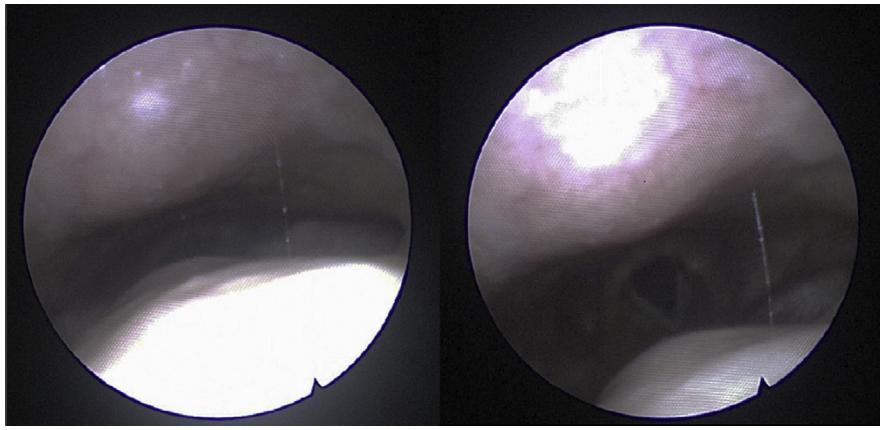

Fig. 2. UAS addresses airway collapse via dynamic airway dilation in phase with respiration. Endoscopic view of hypoglossal nerve stimulation; the base of tongue and palate move together in coordination as a result of palatoglossal coupling.

uniquely addresses the common contributing pathology of low neuromuscular tone by way of dynamic airway dilation during respiration. In its early implementation, highly favorable outcomes in carefully selected patient populations have contributed to the rise of UAS in the current era of sleep medicine.

ASSESSMENT/EVALUATION

Transoral Robotic Surgery

In 2014, TORS was approved for removal of benign base of tongue tissue, rather than specifically for the diagnosis of OSA.[11] Surgical candidates should have significant lymphoid hypertrophy (Friedman lingual tonsil size 3–4), as well as Apnea Hypopnea Index (AHI) less than 60, body mass index (BMI) less than 30, and no evidence of lateral velopharyngeal collapse on drug-induced sleep endoscopy (DISE).[9,11,12] Patients with predominantly muscular tongue hypertrophy should be excluded, as anticipated benefit of muscular resection is low and carries high morbidity. To this point, muscular tongue dissection should be kept to a minimum to prevent dysphagia and foreign body sensation. Swallowing function must be normal and should be routinely assessed preoperatively using a validated questionnaire (eg, MD Anderson Dysphagia Inventory) or formal swallowing evaluation (clinical swallow evaluation or formal swallow study).[13] Feasibility of robotic access must be considered, further excluding patients with retrognathia, or interincisor distance less than 2.5 cm. Patients cannot be on anticoagulation and should have an ASA less than 3.

The surgeon must determine whether lingual tonsil hypertrophy is the entire cause of obstruction or whether there is multilevel collapse of the airway. Thus, patients being considered for TORS should have preoperative DISE. If multilevel obstruction is determined, the surgeon can elect to perform single stage surgery including palate, palatine tonsils, and lingual tonsils. The option to stage the procedure with an interval polysomnogram is also reasonable, with the disadvantage of subjecting the patient to multiple procedures with attendant risk.

To better assess candidacy in patients with OSA, Lin and colleagues[12] developed a scoring system to predict surgical response based on combined measures of BMI, AHI, and DISE findings (**Table 1**). Several measures of success have been reported;

Table 1
Algorithm for transoral robotic surgery candidacy proposed by Lin and colleagues

Clinical	Stratif.	Score
BMI	<30	0
	>30 but <40	1
	>40	2
AHI	<60	0
	>60	1
Lat. VP Collapse	No	0
	Yes	1

Combined Assigned Score	Surgical Response Rate
0	86.7% (13/15)
1	71.4% (5/7)
2	25% (2/8)
3	16.7% (1/6)
4	0.0% (0/3)

Scoring system includes combined measures of BMI, AHI, and DISE pattern of collapse. Surgical response rates highly depend on preoperative score.

Data from Lin HS, Rowley JA, Folbe AJ, Yoo GH, Badr MS, Chen W. Transoral robotic surgery for treatment of obstructive sleep apnea: factors predicting surgical response. *The Laryngoscope.* 2015;125(4):1013-1020.

here, surgical response was defined by greater than 50% reduction in AHI and final AHI less than 15 (mild OSA) with resolution of daytime somnolence (symptomatic improvement).[12,14]

Upper Airway Stimulation

The *Inspire* device was FDA approved in 2014 and is currently the only FDA-approved UAS device available for treatment of OSA. Hypoglossal nerve stimulation is currently approved for adults (age >18 years) with BMI less than 35 and moderate to severe OSA (AHI 15–65, <25% central/mixed apneas)[8] (**Table 2**). Patients must have failed

Table 2
Candidacy criteria for upper airway stimulation

Age	>18
Body mass index	≤35
Polysomnography	AHI 15–65 events per hour <25% central or mixed apneas
DISE	Excludes pattern of concentric collapse at the palate
Contraindications	• Anticipated need for MRI[a] • Some neurologic or psychiatric conditions • Pregnancy

[a] New *Inspire* model is compatible with head and extremity MRI under most conditions.

conservative treatment including CPAP. Patients meeting these criteria and pursuing UAS treatment must have a recent polysomnogram and must undergo DISE to determine the pattern (anteroposterior, lateral, concentric), level (velum, oropharynx, tongue base, epiglottis), and severity of airway collapse.[15] UAS will best address anteroposterior collapse at the tongue base (retroglossal space) and velum (retropalatal space). A pattern of complete circumferential collapse (CCC) is a contraindication to UAS, as patients with this pattern of obstruction on DISE are felt to be poor surgical candidates[16] (Fig. 3). Potential candidates for surgery should be evaluated by both the surgeon and sleep medicine physician before undergoing hypoglossal nerve stimulator implantation. Although currently only approved for adults, UAS has been performed in children with hypotonia related to trisomy 21 on a clinical trial basis with encouraging results.[17,18]

SURGICAL TECHNIQUE AND POSTOPERATIVE CARE

Transoral Robotic Surgery

The DaVinci Si robot is the standard platform for the procedure (Xi and SP models are not required). To prepare for robotic access, patients are intubated transnasally, the bed is rotated 180°, and plastic eye shields are placed. The tongue is retracted with a stitch to better expose the lingual tonsils. A tonsil mouth gag with a short tongue blade and integrated suction is used to expose the lingual tonsils. The robot cart is brought into the field and docked. The robotic instruments include a 30-degree camera, monopolar cautery, and Maryland grasper, typically arranged in a tripod configuration (Fig. 4). The bedside assistant aids with suction cautery, surgical clips as needed for hemostasis, and retraction.

The lingual tonsil resection is performed sequentially from right to left, and resections of the right and left tonsils are performed separately (Fig. 5). Care is taken not to enter the muscular tongue, which avoids postoperative pain, risk to the dorsal branch of the lingual artery, as well as persistent dysphagia and globus sensation. Care should be taken not to demucosalize the lingual surface of epiglottis, and resection of the upper third of epiglottis should be avoided unless there is clear evidence of collapse at this level. If single-stage surgery is performed, it is imperative to leave a bridge of mucosa in the glossotonsillar sulcus between the lingual and palatine

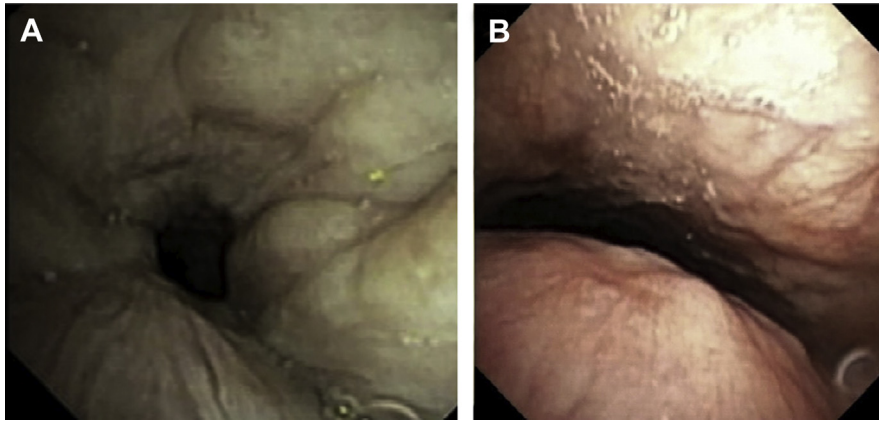

Fig. 3. DISE examination showing (*A*) complete circumferential collapse versus (*B*) anteroposterior collapse at the velum.

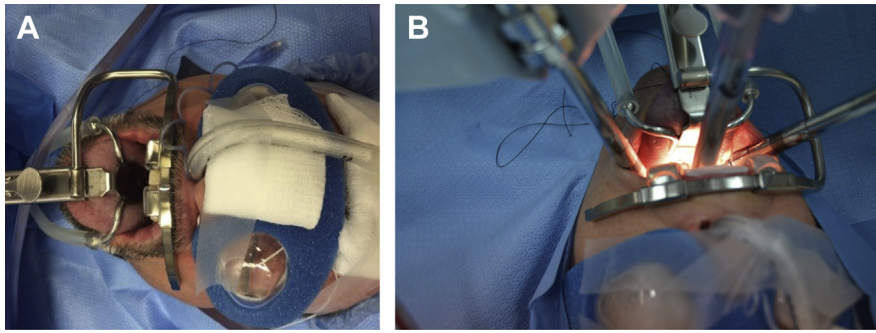

Fig. 4. TORS surgical set up showing (*A*) positioning with mouth gag in place, nasal intubation, and eye shields. (*B*) Robotic arms in tripod configuration including the Maryland retractor and monopolar spatula tip cautery (lateral placement), as well as 30-degree endoscope placed centrally.

tonsillectomy sites in order to prevent circumferential scarring. The volume of resected tissue should be measured and sent to pathology. Measured volume of lymphoid tissue should be greater than 7 to 10 cc; resected volume between 10 and 20 cc has been correlated with improved outcomes as measured by decrease in AHI.[19]

Hypoglossal nerve stimulator

The anatomy and physiology of the hypoglossal nerve allows easy surgical access in the submandibular triangle. Integral to the UAS procedure, the distal branching pattern of the nerve can be leveraged to preferentially stimulate the muscles that protrude and stiffen the tongue. Lateral branches of the hypoglossal nerve innervate the styloglossus and hyoglossus muscles, whereas more medial branches innervate the genioglossus muscle, the geniohyoid muscle (C1 contribution), and intrinsic tongue muscles of the tongue (**Fig. 6**).

The current *Inspire* device has 3 components: a stimulation lead, an implantable pulse generator (IPG), and a breath sensing lead (**Fig. 7**). The stimulating electrode sits around the hypoglossal nerve to deliver mild electrical stimulation in phase with inspiration to maintain multilevel airway patency. The IPG sits in a subcutaneous

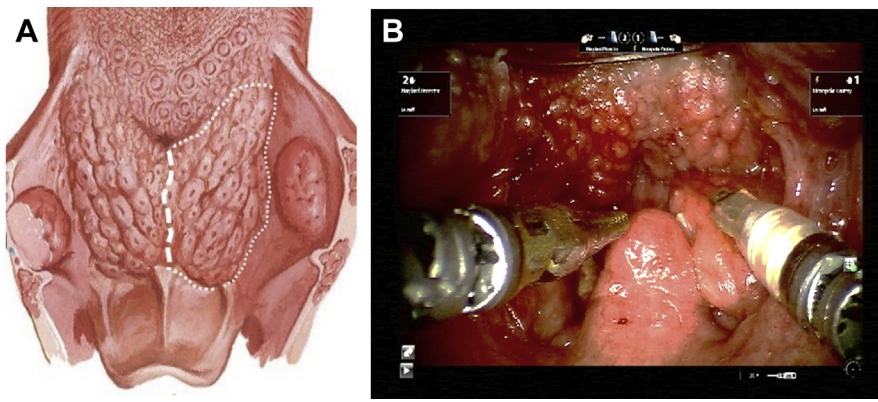

Fig. 5. (*A*) Ideal resection of lingual tonsil tissue (right lingual tonsil outlined) and (*B*) intraoperative view. Resection of the right and left lingual tonsils are performed separately.

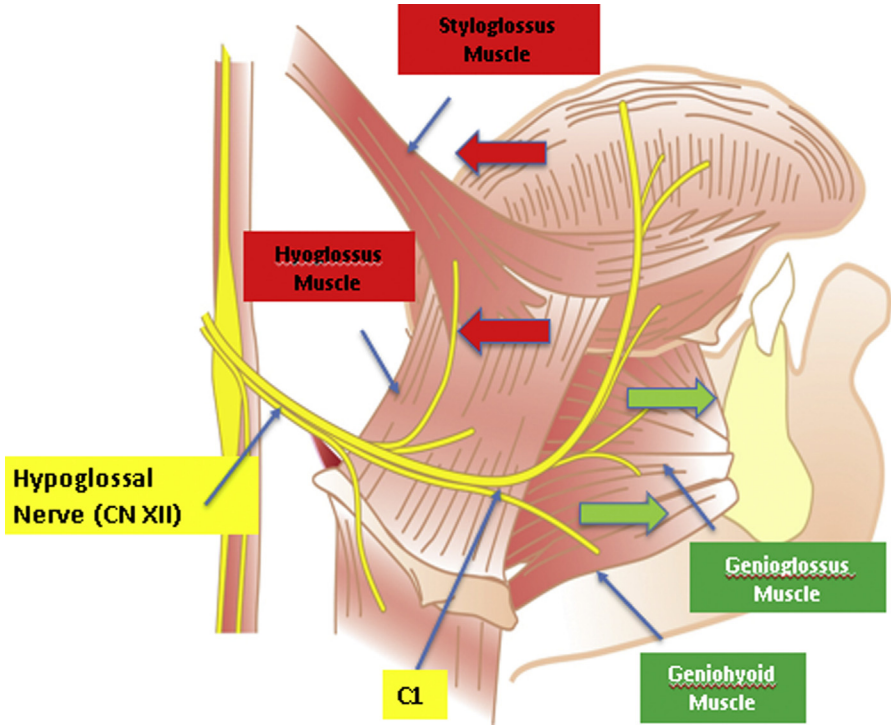

Fig. 6. Distal branching pattern of the hypoglossal nerve. Retractors of the tongue include the styloglossus and hyoglossus. Protrusion muscles of the tongue include the genioglossus and geniohyoid (C1 contribution). The intrinsic muscles of the tongue stiffen the tongue.

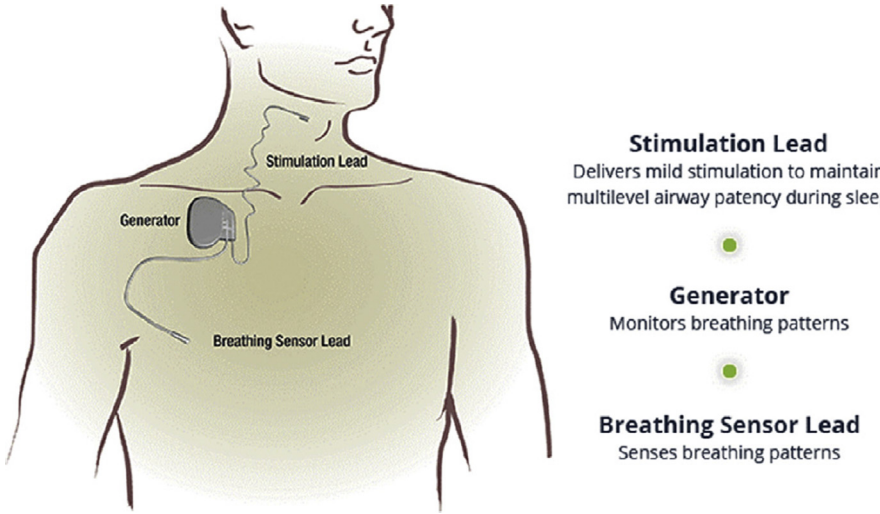

Fig. 7. Inspire UAS device with 3 components: (1) stimulation lead, (2) pulse generator, and (3) breath sensing lead.

pocket overlying the pectoralis fascia and generates the impulses based on input from the sensing lead. The breath sensing lead is placed between the external and internal intercostal muscles at the fourth to sixth rib space and senses breathing patterns, which are relayed to the pulse generator.

For surgical positioning, the bed is turned 180° and a bump is placed under the right chest to allow better access to the chest wall for the breath sensing lead placement. A bite block or other oral retractor is placed to allow placement of the neuromonitoring electrodes: an exclusion lead is placed in the superficial lateral tongue to monitor stimulation of the hyoglossus and styloglossus, and an inclusion lead is placed in the anterior floor of mouth lateral to the frenulum to monitor stimulation of the genioglossus and geniohyoid muscles. The patient is then prepped and draped, including a clear plastic drape over the face to maintain a sterile field while allowing visualization of the tongue. Long-acting paralytics are avoided due to need for neuromonitoring and nerve stimulation during the case.

The procedure includes 3 surgical sites. The first incision is placed 1 to 2 cm below the border of the mandible to the right of midline: dissection to expose the distal hypoglossal nerve includes raising subplatysmal flaps, retraction of the submandibular gland superiorly, retraction of the digastric tendon inferiorly, and retraction of the mylohyoid anteriorly. A ranine vein is often encountered in the vicinity of the hypoglossal nerve and can be ligated or, preferentially, freed and retracted using blunt dissection to avoid bleeding in the surgical field. Meticulous dissection of the hypoglossal nerve is carried out under loupe or microscope magnification, and the nerve is stimulated along its course to identify inclusion and exclusion branches (Fig. 8). The stimulation electrode cuff is placed around a 1 cm segment of the hypoglossal nerve, which ideally excludes proximal branches innervating the retractors of the tongue and includes the C1 contribution branch and distal hypoglossal branches that

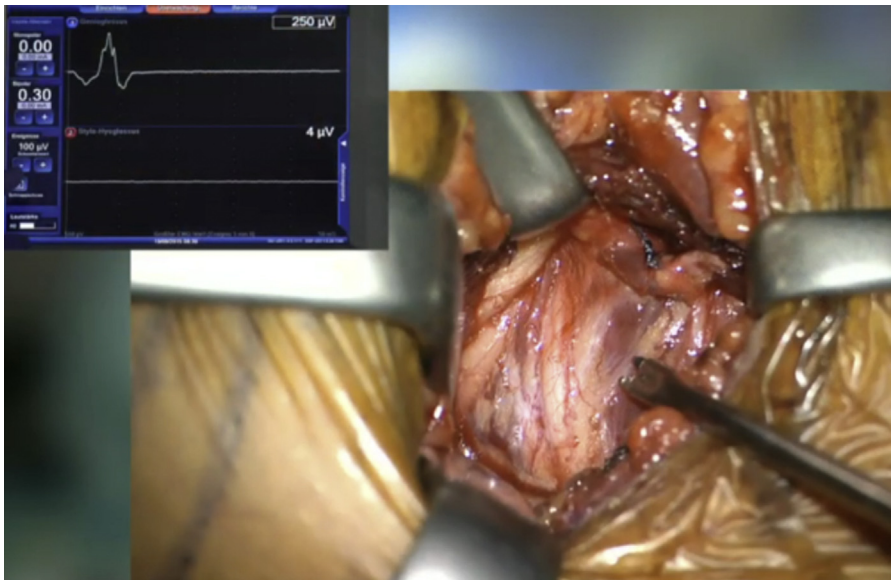

Fig. 8. Intraoperative stimulation of the hypoglossal nerve to determine location of the functional breakpoint. Inset: NIMS monitor output showing inclusion versus exclusion branches.

innervate protrusion and stiffening muscles of the tongue. This location is referred to as the functional breakpoint.

The second incision is made several centimeters below the clavicle centered on the midclavicular line. A subcutaneous pocket superficial to the pectoralis fascia is bluntly dissected to create a pocket for the pulse generator.

The final incision is made at the fourth to sixth rib space, 5 cm lateral to the nipple line. The serratus muscles are retracted to expose the external intercostal muscles, and a window is made in the external intercostal muscles to create a pocket between the internal and external intercostal muscles for placement of the breath sensing lead along a malleable retractor. It is critical that the breath sensing lead be placed in the correct layer and with the correct orientation with the sensing side facing the pleura. Wires from the breath sensing lead and the stimulation lead are then tunneled in a subcutaneous plane to the chest pocket and are connected to the IPG, which is then secured with suture to the pectoralis fascia. Finally, breath sensing and stimulation of the tongue are tested before closing the incisions. A successful test will show gross excursion of the tongue favoring protrusion.

DISCUSSION

Clinical Outcomes

Comparisons of both TORS and UAS with conventional surgery (eg, uvulopalatopharyngoplasty, UPPP) have been made, with each showing benefits over traditional surgical approaches.[11,20] The usage of TORS for management of OSA began with a pilot study by Vicini and colleagues[21] evaluating the utility and feasibility of robotic management of tongue base hypertrophy. Following this innovation, several studies have evaluated and demonstrated the efficacy of TORS tongue base reduction, with a meta-analysis demonstrating impressive success (68%) and cure rates (24%) for patients.[22] Prospective comparison studies to previously established techniques such as radiofrequency tongue base reduction and/or palatoplasty procedures demonstrate potential for improvement in clinical outcomes in those who undergo TORS.[23] In terms of newer technology, TORS is most readily comparable to coblation lingual tonsillectomy, where outcomes are roughly equivalent, and the anticipated TORS benefits including more complete and easier removal for large lingual tonsils are tempered by higher cost, longer hospital stay, and higher morbidity than coblation.[24]

There exists great clinical promise for UAS as well. A landmark study from the Stimulation Therapy for Apnea Reduction (STAR) trial group was published in 2014 evaluating the safety and efficacy of UAS at 12 months. In the original study of 126 patients meeting selection criteria (AHI 15–65, BMI <32, failed CPAP, DISE without CCC), significant improvements were seen in all primary (AHI and oxygen desaturation index [ODI]) and secondary (Epworth sleepiness scale [ESS], functional outcomes of sleep questionnaire [FOSQ], and percentage of sleep with O2 saturation <90%) outcomes.[8] Two-thirds of patients had a successful response, defined as 50% reduction in AHI and AHI score less than 20. Further, responders of this study were randomized to treatment continuation and treatment withdrawal groups, showing significant worsening of AHI and ODI when therapy was withdrawn at 12 months. A 5-year follow-up study was recently published showing that outcomes including AHI, ODI, ESS, FOSQ, and patient-reported snoring, all showed durable responses at 60 months following implantation.[25]

Similar efficacy was demonstrated by early reports from the Adherence and Outcomes of Upper Airway Stimulation for OSA (ADHERE) International Registry, which was designed to study UAS outcomes as the procedure transitioned from trail to

clinical practice.[26] The ADHERE registry collects data including demographics, surgical outcomes, complications, quality of life, and other patient-reported outcomes for patients undergoing treatment in the United States and Europe and will prove a powerful tool to study outcomes. Recent results of a cohort of 508 patients from the AHDERE registry notably show significant reductions in AHI (36.3 baseline to 10.2 posttitration, events per hour) and ESS (11.8 baseline to 7.7 posttitration) following implantation, as well as uniformly high percentages of patient satisfaction (94%–96%). Steffen and colleagues[27] observed similarly excellent outcomes for AHI reduction, ESS improvement, and FOSQ improvement in a postmarket study of 60 patients where a BMI cutoff of less than 35 was used.[28] A study by Hofsauer and colleagues also found that in addition to the improved metrics discussed earlier, UAS had significant effects on sleep architecture, with PSG REM time increasing from 9.5% pretreatment to 15.7% posttreatment.

Predictors of success based on AHDERE data included increased age (OR 1.04 for each additional year) and lower BMI (OR 0.91 for each 1 unit BMI increase).[26] Among the STAR trial population, UAS responders had lower VOTE scores on DISE than did UAS nonresponders.[29] Prior studies have shown CCC at the velum to predict poor response to UAS and thus use of this finding as a contraindication to surgery.[16] With regard to other multilevel surgery, UAS has shown higher cure rates (AHI <5) compared with traditional UPPP in patients with moderate to severe OSA intolerant of CPAP.[20] Further, having prior soft tissue or skeletal framework surgery has not been shown to negatively impact UAS outcomes.[26]

These favorable outcomes have prompted consideration of UAS as an alternative to TORS base of tongue reduction.[23,30] As TORS has been used for treatment of OSA since 2009, and UAS was approved for treatment of OSA in 2014, the 2 modalities constitute separate but overlapping eras of treatment. Retrospective cohort comparisons of TORS to UAS have shown consistently superior reduction in AHI and cure rates with UAS when groups are matched to include only the subset of patients who would be potential candidates for both procedures.[30] As we move toward an era of precision medicine and surgery, although, candidacy criteria become increasingly important; when TORS cohorts are evaluated retrospectively for UAS candidacy by the current criteria, dual candidacy has been observed in as low as just 20% of patients.[30] Thus, there is still clearly a role for TORS in a large proportion of patients with tongue base hypertrophy who do not qualify for UAS. When considering a treatment algorithm that includes DISE-directed therapy, this direct comparison of TORS with UAS is a potential area of future study, particularly in the likely event that UAS inclusion criteria broaden.

Serious adverse events following UAS are reported around 2%, most commonly device discomfort requiring surgical revision.[8,26] More commonly, transient changes to tongue sensation, temporary weakness, minor discomfort related to the implanted device, and discomfort during the initial titration period are noted (up to 40% of patients).[7,8] This adverse event profile is distinct from that of TORS, which has longer hospital stay, higher readmission rates, and higher bleeding rates compared with UAS.[11,23]

Considerations/Future Directions

Studies of UAS since FDA approval have reported treatment success rates upward of 80%. Under the current paradigm, criteria for candidacy continue to be highly selective. In light of this, it is unclear why some patients continue to fail treatment, and further studies to determine predictors of treatment success and failure are warranted. This rise of UAS will allow optimization patient outcomes as surgical volume increases

and long-term follow up data become available. Treatment effect on medical comorbidities, including cardiovascular outcomes and mortality, will be additional critical areas of future study.

As existing UAS devices continue to evolve and new devices enter the market, the field will likely benefit from increased access, lower cost, and liberalized criteria for candidacy. There are opportunities to improve and optimize multidisciplinary care, training during and after residency, and delivery of care in various practice settings.

SUMMARY

OSA remains a challenging disease process to treat. Given the complexity and unique anatomic profile of each individual patient, the addition of the HGNS to the sleep surgeon's armamentarium has had promising early results. This period is the golden age of sleep surgery, where medical management with CPAP is complemented by cutting edge surgical technology including UAS and TORS to provide sleep physicians with the personalized options that this complex patient population demands.

CLINICS CARE POINTS

1. Candidacy criteria for TORS multilevel surgery include AHI less than 60, BMI less than 30, and DISE finding showing no evidence of lateral velopharyngeal collapse.
2. Candidacy criteria for UAS are selective and include adults (age >18 years) with BMI less than 35, moderate to severe OSA (AHI 15–65), and DISE examination demonstrating absence of complete circumferential collapse.
3. In patients qualifying for both UAS and TORS, studies have shown superior outcomes and lower morbidity in those undergoing UAS.
4. UAS with the HGNS is predominantly being performed in high-volume centers in conjunction with device technicians and sleep medicine physicians to allow for optimal postimplant titration and calibration.

DISCLOSURE

The authors have nothing to disclose.

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