Efficacy of Upper Airway Stimulation on Collapse Patterns Observed during Drug-Induced Sedation Endoscopy

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To describe upper airway collapse patterns observed on drug-induced sedation endoscopy (DISE) during screening for a clinical trial and to evaluate the impact of collapse patterns found on preoperative DISE on response rates to upper airway stimulation (UAS) therapy.

Study Design. Retrospective review of an ongoing prospective multi-institutional cohort study.

Setting. Twenty-two participating institutions of the STAR trial.

Subjects and Method. In total, 222 subjects were screened with DISE to determine eligibility for an implantable UAS device. Supine laryngoscopy was performed during moderate sedation (propofol and/or midazolam). Airway collapse pattern and severity were graded at 4 levels, including velum, oropharynx, tongue base, and epiglottis (VOTE classification). Patients with complete concentric collapse (CCC) at the velum were excluded from implantation.

Results. The CCC at the velum was observed in 52 (23%) of screened subjects, and these subjects were subsequently excluded from implantation. Of the 170 subjects without CCC at the velum, 126 (74%) underwent implantation: 121 (96%) had multilevel collapse and 5 (4%) had single-level collapse. When comparing preimplantation DISE findings, UAS responders at 12 months had lower baseline VOTE scores compared with therapy nonresponders.

Conclusion. Drug-induced sedation endoscopy is an efficient and safe method for determining UAS eligibility and has the potential to identify UAS nonresponders. Most patients had multilevel airway collapse, illustrating the limitations of single-level upper airway surgery in treating obstructive sleep apnea. Upper airway stimulation is effective therapy for most patients with multilevel airway collapse; however, patients with complete anterior-posterior or lateral soft palate and/or epiglottic collapse may be at increased risk of therapy failure.

Keywords

upper airway stimulation, obstructive sleep apnea, sedation, sleep-disordered breathing, sleep surgery, drug-induced sleep endoscopy, drug-induced sedation endoscopy

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Obstructive sleep apnea (OSA) is a disorder defined by repeated complete (apnea) or partial (hypopnea) closures of the upper airway associated with intermittent hypoxemia and disturbed sleep.¹ This often results in daytime somnolence as well as an increased risk of cardiovascular events, motor vehicle accidents, and death.²⁻⁵ Initial treatment for moderate to severe OSA is continuous positive airway pressure (CPAP), which may decrease cardiovascular mortality and prolong survival.⁶⁻⁷ However, effective use of CPAP is limited due to suboptimal compliance, with almost 50% of patients with insufficient therapy adherence, and many more reporting low therapy satisfaction.⁸⁻¹⁰ Surgical procedures that target specific areas of upper airway obstruction are an option; however, patients may be hesitant to pursue this due to high

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morbidly and a potential for a lower success rate than CPAP. Consequently, there has been an increased interest in developing alternative therapies for moderate to severe OSA and methods to identify sites of obstruction that must be addressed for effective non-CPAP therapy.

Several techniques have been used to characterize patterns of obstruction, including physical examination, awake fiber-optic nasal endoscopy, and cephalometric studies. However, these techniques are performed while awake and may not reveal the patterns of collapse found with reduced upper airway muscular tone during sleep. Drug-induced sedation endoscopy (DISE) was developed for fiber-optic examination of the upper airway in pharmacologically sedated patients in a state that simulates sleep. The major advantage of DISE over other techniques is that it allows direct visualization of dynamic upper airway collapse in a setting shown to be comparable to natural sleep from the standpoint of OSA parameters. Drug-induced sedation endoscopy has been shown to be a safe and reliable diagnostic test, and the structure-based assessment allows identification of upper airway sites that may require treatment.

Most surgical alternatives for OSA focus on the removal and repositioning of tissue thought to be responsible for airway obstruction. Although this strategy may lower the amount of obstructing tissue, it fails to address the underlying pathophysiology of OSA—namely, increased airway collapsibility. Upper airway stimulation (UAS) is a novel implantable device for patients who are intolerant to CPAP, which opens the airway by activating the protractor branches of the hypoglossal nerve and does not require permanent alteration of the upper airway. It is not yet known whether the efficacy of UAS is equivalent in patients with predominantly tongue base obstruction and those with multilevel patterns of obstruction. In the clinical trial that validated the safety and efficacy of UAS (Stimulation Therapy for Apnea Reduction, or STAR), DISE was used to exclude patients with complete concentric collapse (CCC) at the level of the soft palate since this finding was associated with poor treatment response in an earlier phase 1 study. However, even after excluding patients with CCC, up to one-third of patients failed to achieve surgical success with UAS therapy. The purpose of this study, therefore, is to report the levels, patterns, and severity of upper airway collapse as observed during baseline DISE evaluation of the subjects enrolled in the STAR trial and to assess the long-term efficacy of UAS with regard to baseline DISE to determine if additional DISE findings are associated with therapy success or failure.

Methods

Study Design

The STAR trial is a prospective multicenter clinical trial to establish the safety and efficacy of an implantable UAS device (Inspire II, model 3024; Inspire Medical Systems, Maple Grove, Minnesota) for CPAP-intolerant adults with moderate to severe OSA. Significant exclusion criteria included body mass index (BMI) greater than 32 kg/m², neuromuscular disorders including hypoglossal nerve palsy, severe cardiopulmonary disorders, active psychiatric disease, and comorbid nonrespiratory sleep disorders that may confound sleep assessments. Additional screening of subjects included an overnight polysomnography (PSG), surgical consultation visit, and DISE. Subjects were excluded after PSG if the apnea-hypopnea index (AHI) was less than 20 or greater than 50 events per hour, central and/or mixed apnea index was greater than 25% of AHI, or nonsupine AHI was less than 10. In addition, subjects were excluded after DISE if the operator determined the subject had unfavorable anatomical findings that would prevent effective use of UAS, including 3 to 4+ tonsils or CCC of the palate. Further details of subject eligibility and study design have been previously published. This article reports on the use of DISE to determine UAS eligibility and postimplant subject outcomes based on observed baseline patterns of collapse during DISE. All clinical trial sites received investigational review board approval for the study protocol. Authors (R.J.S., B.T.W., O.M.V., N.V., and M.B.G.) are study investigators for the STAR trial.

DISE

Drug-induced sedation endoscopy was performed in the operating room by a participating otolaryngologist, trained using a standardized protocol of DISE sedation. Sedation was performed using propofol and/or midazolam for induction of artificial sleep, which was titrated by either target-controlled infusion (TCI) or to a level of moderate sedation where the patient was unarousable to verbal stimulation. Procedural data, including procedure time, sedation time, and adverse events, were collected per protocol.

Collapse patterns were assessed during inspiration and graded at the level of the velum, oropharynx, tongue base, and epiglottis using the previously validated VOTE classification. Pattern of collapse was characterized as anteroposterior (AP), laterolateral (LL), or concentric. Degree of collapse was characterized as complete, partial, or no collapse. VOTE scores were calculated as the sum of the collapse degree (2 for complete, 1 for partial, and 0 for no collapse) at each site of obstruction for a maximum score of 8. Patients with complete palatal collapse were eligible for implantation if the collapse pattern was AP and not concentric.

UAS Device Implant, Titration, and Follow-up

Patients who met the inclusion and exclusion criteria underwent implantation of the UAS device on a subsequent visit. The UAS device comprises an implantable pulse generator (IPG), respiratory sensing lead, and hypoglossal nerve stimulation lead. The subject was given a handheld remote to activate therapy prior to sleep and to deactivate upon awakening. This also allows for patient-controlled regulation of the stimulation amplitude within a programmed therapeutic range as determined during a sleep laboratory titration.

Each subject underwent a preoperative PSG to determine baseline AHI. Postoperative PSGs were performed initially for titration of therapy, then again at 12 months. All PSGs were scored by a core sleep laboratory using the American Academy of Sleep Medicine criteria.
Oxygen saturation was to 83.5% desaturations were expected. The mean to re-create the upper airway collapse and apneas, oxygen subjects’ previous OSA history, CPAP intolerance, and need was used in both the United States and Europe. Given the respectively, while the midazolam/propofol combination alone were used solely in the United States and Europe, (20%), or midazolam alone (11%) were the sedatives used Propofol alone (68%), midazolam/propofol combination (50%) and the tongue base with AP collapse at the soft palate, and analysis of variance (ANOVA) was used to determine if increasing collapse severity was related to increased AHI. Therapy response was defined as an AHI reduction of >50% and postoperative AHI <20. Independent t test or Wilcoxon signed rank test was used to determine demographic predictors of therapy response, while the \( \chi^2 \) test was used to compare the presence of complete collapse at each site to partial and no collapse in responders and nonresponders. A \( P \) value of <.05 was considered to indicate a statistically significant difference for all statistical tests.

Results
A total of 222 subjects at 22 participating sites (15 in the United States, 3 in Germany, 2 in France, 1 in the Netherlands, and 1 in Belgium) underwent DISE as part of the STAR trial. Patient demographics are shown in Table 1.

DISE Procedure
Propofol alone (68%), midazolam/propofol combination (20%), or midazolam alone (11%) were the sedatives used during the examination. Propofol alone and midazolam alone were used solely in the United States and Europe, respectively, while the midazolam/propofol combination was used in both the United States and Europe. Given the subjects’ previous OSA history, CPAP intolerance, and need to re-create the upper airway collapse and apneas, oxygen desaturations were expected. The mean ± SD minimum oxygen saturation was to 83.5% ± 0.7% (range, 42%-98%). The mean ± SD duration of the DISE examination was 12.9 ± 6.4 minutes (range, 2-40 minutes), and there were no adverse events associated with sedation or examination.

Table 1. Baseline Characteristics of Patients (N = 222).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>54.3 ± 0.7</td>
</tr>
<tr>
<td>Male, No. (%)</td>
<td>188 (85)</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28.6 ± 0.2</td>
</tr>
<tr>
<td>Neck size, cm</td>
<td>41.5 ± 3.3</td>
</tr>
<tr>
<td>Baseline AHI, events/h</td>
<td>32.0 ± 0.8</td>
</tr>
</tbody>
</table>

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index.
*Values are presented as mean ± SD unless otherwise indicated.

Collapse Patterns
The velum and tongue base were the most common collapse locations. The frequency of collapse type by airway level is presented in Table 2. Anteroposterior collapse was the predominant airway collapse direction at all sites, except at the oropharynx. There was a statistically significant association of AP collapse at the velum with AP collapse at the tongue base (\( P = .005 \)). The CCC at the velum was not associated with age, sex, or AHI, although there was a statistically significant association with BMI (\( P = .04 \)) and neck size (\( P = .01 \)), as seen in Table 3.

Table 4 demonstrates the percentage of subjects for each combination of collapse and baseline AHI for each collapse level severity. Most patients had multilevel airway collapse, with 4-level collapse being the most common combination, followed by 3-level collapse at the velum, tongue base, and epiglottis. There was no correlation between airway collapse severity and baseline AHI (\( P = .73 \)).

Effect of UAS on Collapse Severity
A total of 126 subjects were implanted with the UAS. The prevalence of collapse severity in the implanted patients was similar to the total subjects screened with DISE. Patients predominantly had multilevel collapse, with 4-level collapse being the most common at 50% and single-level collapse as least common. Upper airway stimulation therapy resulted in a statistically significant improvement in the AHI regardless of multilevel obstruction, including those with palatal and oropharyngeal wall collapse (Figure 1).

Predictors of UAS Nonresponse
Table 5 presents the outcomes with demographic factors and UAS therapy response. There was no difference in sex, BMI, neck size, and baseline AHI between the responders and nonresponders, although nonresponders were younger (\( P = .04 \)) and had higher baseline VOTE score (\( P = .02 \)). Nonresponders had a higher proportion of complete AP or LL collapse at the velum (\( P = .01 \)) and epiglottis (\( P < .01 \)) compared with therapy responders.

Discussion
The current study illustrates that DISE is a valid procedure to evaluate patient candidacy for UAS. It is a rapid, safe, and reliable examination to observe upper airway collapsibility in...
patients with OSA. Although effective in certain patients, surgical treatments for OSA aimed at reducing obstructing soft tissue in the upper airway fail to address the underlying increase in airway collapsibility caused by reduced neuromuscular tone, which is thought to be the primary pathophysiological basis for OSA. The presence of both factors may limit the effectiveness of surgeries focused on the removal of obstructing tissue, which only addresses the mechanical obstruction but not the blunted neuromuscular response. Upper airway stimulation addresses airway collapsibility, which results in an increased airway diameter that may lessen the contribution of increased tissue mass.

### Table 2. Frequency of Collapse Type by Site of Obstruction.

<table>
<thead>
<tr>
<th>Collapse</th>
<th>Velum</th>
<th>Oropharynx</th>
<th>Tongue Base</th>
<th>Epiglottis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete, %</td>
<td>23</td>
<td>0</td>
<td>52</td>
<td>17</td>
</tr>
<tr>
<td>Partial, %</td>
<td>6</td>
<td>31</td>
<td>19</td>
<td>6</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>30</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>% with Any Collapse</td>
<td>94</td>
<td>69</td>
<td>73</td>
<td>73</td>
</tr>
</tbody>
</table>

Abbreviations: AP, anteroposterior; C, concentric; DISE, drug-induced sedation endoscopy; E, epiglottis; L, lateral; O, oropharynx; T, tongue base; V, velum.

### Table 3. Demographic Predictors of Palatal CCC.

<table>
<thead>
<tr>
<th>Variable</th>
<th>CCC Present</th>
<th>CCC Absent</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>54.4 ± 9.7</td>
<td>54.3 ± 9.8</td>
<td>.91</td>
</tr>
<tr>
<td>Male</td>
<td>142</td>
<td>.17</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>29.3 ± 2.5</td>
<td>28.4 ± 2.6</td>
<td>.04</td>
</tr>
<tr>
<td>Neck size, cm</td>
<td>42.5 ± 3.3</td>
<td>41.2 ± 3.2</td>
<td>.01</td>
</tr>
<tr>
<td>Baseline AHI, events/h</td>
<td>33.2 ± 10.8</td>
<td>31.6 ± 12.3</td>
<td>.41</td>
</tr>
</tbody>
</table>

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index; CCC, complete concentric collapse at velum.

### Table 4. Distribution of Screened and Implanted Patients by Collapse Severity.

<table>
<thead>
<tr>
<th>Collapse</th>
<th>Velum</th>
<th>Oropharynx</th>
<th>Tongue Base</th>
<th>Epiglottis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution in Screened Patient Characteristics (N = 222), %</td>
<td>33.6 ± 4.1</td>
<td>1.6</td>
<td>29.7 ± 3.5</td>
<td></td>
</tr>
<tr>
<td>Screened Patient AHI, Mean ± SD</td>
<td>31.6 ± 1.5</td>
<td>10.3</td>
<td>33.5 ± 1.9</td>
<td></td>
</tr>
<tr>
<td>Distribution in Implanted Patients (n = 126), %</td>
<td>32.8 ± 1.5</td>
<td>50.0</td>
<td>32.1 ± 1.5</td>
<td></td>
</tr>
<tr>
<td>Implanted Patient Baseline AHI, Mean ± SD</td>
<td>31.6 ± 1.5</td>
<td>50.0</td>
<td>32.1 ± 1.5</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: AHI, apnea-hypopnea index.
The finding that DISE can be performed safely in the CPAP-intolerant population is consistent with other literature showing few, if any, adverse events during DISE.\textsuperscript{18,27} Drug-induced sedation endoscopy is typically performed in the operating room by an otolaryngologist and anesthesiology staff, and patients are continuously monitored with electrocardiogram and pulse oximetry during induced apneas and hypopneas. In the present study, there were no adverse events requiring intervention related to the anesthesia or the procedure itself. Given the short procedure duration and safety profile, DISE has been recommended as a patient selection tool for UAS, due to its ability to select patients with an increased probability of therapeutic success.\textsuperscript{20} The US Food and Drug Administration (FDA) agreed on the importance of DISE as the minimum screening tool to determine eligibility for UAS implantation; however, otolaryngologists must undergo the appropriate training for DISE prior to performing UAS implantation. Notably, UAS is the first therapy for OSA to require DISE as a prerequisite to surgical implantation.

Figure 1. Improvements in apnea-hypopnea index (AHI) after device implantation, categorized by collapse severity. The reductions in AHI were statistically significant vs baseline (\(P < .0001\)) in all groups and all visits.

The major advantage of DISE is identification of the sites (velum, oropharynx, tongue, epiglottis), severity (none, partial, complete), and patterns of airway collapse (AP, LL, concentric) under simulated sleep conditions. Collapse was primarily in the complete AP direction, with the velum and tongue base being the most commonly involved areas, in line with previous studies.\textsuperscript{20,28} Early feasibility studies demonstrated that CCC at the velum predicted therapy failure in patients with OSA treated with UAS.\textsuperscript{20,29} This finding influenced the selection criteria for the pivotal large cohort study, which confirmed that most patients without CCC at the velum had therapeutically significant AHI reduction with UAS.

In the current study, 52 subjects (23\%) had CCC at the velum, which could not be predicted by age, sex, or AHI. A small but statistically significant association of CCC at the velum and elevated BMI and neck size was seen. The latter findings are associated with increased amounts of parapharyngeal adipose tissue, which may not be adequately treated by UAS.\textsuperscript{28,30-33} Because velum CCC cannot be accurately predicted by other demographic factors, DISE remains an important screening tool for identifying patients with this type of collapse. Conversely, approximately 80\% of subjects with BMI \(\leq 32\) kg/m\(^2\) undergoing DISE did not have CCC at the velum, and most of these patients can be expected to meet the UAS DISE selection criteria.

The high prevalence of multilevel collapse seen in this cohort illustrates the difficulty of resolving OSA with single-level surgery and necessitates tailoring of multiple surgical procedures to address each level of obstruction. Long-term follow-up of at least 3 years of patients with OSA treated by various types of soft tissue surgery has shown variable decreases in AHI of 44\% to 74\%.\textsuperscript{34-36} In comparison, upper airway stimulation in this large cohort study with predominant multilevel airway collapse demonstrated significant mean reductions in AHI of nearly 70\%, which was maintained 36 months postimplantation.\textsuperscript{37}

<table>
<thead>
<tr>
<th>Variable</th>
<th>Response (n = 84)</th>
<th>Nonresponse (n = 40)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>55.6 ± 10.3</td>
<td>51.6 ± 9.4</td>
<td>.04</td>
</tr>
<tr>
<td>Male, No.</td>
<td>69</td>
<td>35</td>
<td>.45</td>
</tr>
<tr>
<td>BMI, kg/m(^2)</td>
<td>28.3 ± 2.7</td>
<td>28.7 ± 2.4</td>
<td>.42</td>
</tr>
<tr>
<td>Neck size, cm</td>
<td>41.1 ± 3.4</td>
<td>41.6 ± 2.9</td>
<td>.47</td>
</tr>
<tr>
<td>Baseline AHI, events/h</td>
<td>30.7 ± 10.8</td>
<td>33.7 ± 13.0</td>
<td>.21</td>
</tr>
<tr>
<td>VOTE score</td>
<td>5.0 ± 1.4</td>
<td>5.7 ± 1.2</td>
<td>.02</td>
</tr>
<tr>
<td>Complete collapse, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Velum</td>
<td>49 (58)</td>
<td>33 (83)</td>
<td>.01</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>17 (20)</td>
<td>7 (17)</td>
<td>.91</td>
</tr>
<tr>
<td>Tongue base</td>
<td>53 (63)</td>
<td>28 (70)</td>
<td>.58</td>
</tr>
<tr>
<td>Epiglottis</td>
<td>26 (31)</td>
<td>24 (60)</td>
<td>&lt;.01</td>
</tr>
</tbody>
</table>

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index.

\(^a\)Values are presented as mean ± SD unless otherwise indicated.
data suggest that UAS simultaneously addresses multiple levels of airway collapsibility, despite the primary mechanism of action of tongue base protrusion. Improvement in upper airway collapse using UAS is supported by previous case studies where imaging was used to confirm multilevel airway opening during acute stimulation. Although UAS primarily activates the protrusor muscles of the tongue, such as the genioglossus, it is important to note that the palatal airway is directly coupled to the tongue base via the palatoglossus muscle. In addition, forward motion of the tongue dorsum reduces contact with the soft palate and allows the velum to drop away from the posterior pharyngeal wall in a mechanism similar to the use of an oral appliance. The ability of UAS to reduce the AHI in patients with multilevel airway collapse may be due to this coupling effect. The current results suggest that a single procedure, UAS implantation, has the potential to resolve multilevel upper airway obstruction in a group of well-selected patients with OSA.

Despite alleviating multilevel obstruction of the upper airway, UAS does have its limitations, with approximately one-third of subjects failing to achieve surgical success 12 months postoperatively. Currently, to be eligible for UAS implantation, patients must have moderate to severe OSA (AHI >20), have a BMI <32 kg/m², and have no evidence of CCC on DISE. This study suggests that more stringent criteria may have even better results if implantation is limited to nonobese (BMI <30 kg/m²) patients with a thin neck (circumference <42 cm) who do not have complete collapse of the soft palate or epiglottis on DISE. Subjects who did not respond were younger and had increased upper airway collapsibility (eg, higher VOTE scores) on baseline DISE examination. A higher proportion of nonresponders also had complete collapse at the level of the velum and epiglottis. In the STAR trial, the 17% of subjects who had undergone uvulopalatopharyngoplasty (UPPP) prior to UAS therapy showed a slightly better therapy response (71% vs 66%) compared with the entire cohort. Therefore, there may be select subjects (eg, younger, VOTE >5, complete AP or LL soft palate collapse) who may benefit from a phased surgical approach with UPPP followed by UAS therapy. Given the expense of UAS therapy, it is critical to continue to improve patient selection to increase therapy response rates. Further studies are warranted to determine if there are DISE findings in addition to CCC that should be addressed by traditional surgical approaches or used to exclude patients altogether from UAS therapy.

There are some limitations in the present study. Although DISE has been validated as a reliable tool, each test is scored in a subjective manner, and grading may differ from operator to operator. In this case, all operators were trained in performing DISE per clinical trial protocol, and operators were permitted to request secondary review to ensure accurate grading of each subject. Finally, although UAS implantation significantly improved AHI in subjects with single-level collapse, further study with a larger population must be done to verify the efficacy of UAS in this population.

Conclusion
The current study confirms that DISE is a quick and safe method in determining UAS eligibility. Upper airway stimulation is an effective OSA therapy for most patients with multilevel airway collapse; however, patients with complete soft palate and/or epiglottic collapse may be at increased risk of therapy failure. Further study is needed to identify criteria in addition to CCC on DISE to better select patients for UAS to improve response rates to therapy.

Acknowledgment
Teri Yurk (Namsa, Inc) performed the statistical analysis presented in this study.

Author Contributions
Adrian A. Ong, acquired/analyzed/interpreted data, drafted and edited article, approved version to be published; Alexander W. Murphy, developed study concept and design, acquired/analyzed/interpreted data, drafted and edited article, approved version to be published; Shaun A. Nguyen, acquired/analyzed/interpreted data, drafted and edited article, approved version to be published; Ryan J. Soose, developed study concept and design, acquired data, drafted and edited article, approved version to be published; B. Tucker Woodson, developed study concept and design acquired data, drafted and edited article, approved version to be published; Olivier M. Vanderveken, developed study concept and design, acquired data, drafted and edited article, approved version to be published; Nico de Vries, developed study concept and design, acquired data, drafted and edited article, approved version to be published; M. Boyd Gillespie, developed study concept and design acquired data, drafted and edited article, approved version to be published.

Disclosures
Competing interests: Ryan J. Soose received research support and is a consultant with Inspire Medical Systems. B. Tucker Woodson is a study investigator and/or consultant for the following: Inspire Medical Systems, Medtronic, Siesta Medical, Linguaflex, Cryosa, and Zelegant. Olivier M. Vanderveken received research support from Inspire Medical Systems and Nyxoah; is a consultant for Inspire Medical Systems, Nyxoach, and Philips Electronics; is a promoter of a research grant at Antwerp University; has received support for free devices for an RCT with a sleep position trainer in 20 patients from Nightbalance NV (Delft, the Netherlands); and received research support and lecture fees from SomnoMed. Nico de Vries received research support from Inspire Medical Systems, is a consultant for Philips Electronics and Olympus, is a medical adviser for and has shares in NightBalance, and has stock options and is a medical adviser for ReVent. M. Boyd Gillespie received research support from Inspire Medical Systems and Olympus and is a consultant for Medtronic and Olympus.

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