Published in final edited form as:

Otolaryngol Head Neck Surg. 2011 April ; 144(4): 623–631. doi:10.1177/0194599810394982.

Studying Life Effects & Effectiveness of Palatopharyngoplasty (SLEEP) Study: Subjective Outcomes of Isolated Uvulopalatopharyngoplasty

Edward M. Weaver, MD, MPH,

Department of Otolaryngology/Head & Neck Surgery, University of Washington, Seattle, WA.

B. Tucker Woodson, MD,

Department of Otolaryngology/Head & Neck Surgery, Medical College of Wisconsin, Milwaukee, WI.

Bevan Yueh, MD, MPH,

Department of Otolaryngology/Head & Neck Surgery, University of Minnesota, Minneapolis, MN.

Timothy Smith, MD, MPH,

Department of Otolaryngology/Head & Neck Surgery, Oregon Health & Sciences University, Portland, OR.

Michael G. Stewart, MD, MPH,

Department of Otolaryngology/Head & Neck Surgery, Weill Cornell Medical College, New York, NY.

Maureen Hannley, PhD,

Tuscon, AZ.

Kristine Schulz, MPH,

American Academy of Otolaryngology-Head & Neck Surgery Foundation, Alexandria, VA.

Milesh M. Patel, MS,

American Academy of Otolaryngology-Head & Neck Surgery Foundation, Alexandria, VA.

David Witsell, MD, MHS, and

Division of Otolaryngology/Head & Neck Surgery, Duke University, Durham, NC.

SLEEP Study Investigators

Abstract

OBJECTIVE—To test the hypothesis that uvulopalatopharyngoplasty (UPPP) improves sleep apnea-related quality of life (measured on the Functional Outcomes of Sleep Questionnaire [FOSQ]) at three-month follow-up. Secondary objectives were to test: 1) the stability of the

Corresponding author: Edward M. Weaver, VA PSHCS 112-OTO, 1660 S. Columbian Way, Seattle, WA 98108. Telephone: 206-764-2424. Fax 206-764-2063. eweaver@uw.edu.

Presented at the Annual Meeting of the American Academy of Otolaryngology—Head and Neck Surgery, Washington, DC, September 16–19, 2007.

outcomes at six months, 2) the effect on global sleep apnea quality of life change, and 3) the effect on sleep apnea symptoms.

STUDY DESIGN—Multicenter, prospective, longitudinal case series.

SETTING—Diverse university- and community-based otolaryngology practices.

SUBJECTS AND METHODS—The cohort included 68 patients from 17 practices, with a mean $\pm$ standard deviation age of 44 ± 12 years and mean apnea-hypopnea index 35 ± 32 events/hour. All patients underwent UPPP, defined as an open procedure modifying the shape and size of the palate, pharynx, and uvula, with or without tonsillectomy. Baseline data were collected on-site before surgery, and outcome data were collected by mail three and six months after surgery, with follow-up rates of 51% and 50%, respectively.

RESULTS—FOSQ scores improved from 14.3 ± 3.4 (scale 5–20, normal 17.9) at baseline to 17.2 ± 2.7 at three months (mean improvement 2.9, 95% confidence interval [1.8, 4.0], $p < 0.001$) and 17.5 ± 2.5 at six months (mean improvement 3.1, 95% confidence interval [2.0, 4.2], $p < 0.001$). All quality of life and symptom measures improved significantly at three and six months (all $p < 0.05$).

CONCLUSION—This prospective, multicenter, university- and community-based study provides evidence that UPPP significantly improves disease-specific quality of life and sleep apnea symptoms in patients with sleep apnea. Validity may be limited by significant loss to follow-up and absence of an unoperated control group.

INTRODUCTION

Uvulopalatopharyngoplasty (UPPP) is the most common surgical treatment for obstructive sleep apnea. UPPP often physiologically improves, but does not eliminate, sleep apnea.^{1, 2} Consequently, the value of UPPP has been questioned in the sleep medicine literature.³ However, basing the value of a treatment modality solely on physiological surrogate outcome measures like polysomnography parameters may not reflect true treatment effects accurately.⁴ Studies do support that UPPP provides benefit for clinically important outcomes like motor vehicle accidents,⁵ incidence of cardiovascular disease,^{6, 7} and mortality.^{8, 9}

Health-related quality of life may be the most important outcome to patients.¹⁰ However, quality of life outcomes have rarely been evaluated for UPPP patients. In their comprehensive review of the literature in 1995, Schechtman et al. found that quality of life outcomes were sorely lacking, yet were necessary, for evaluating surgical treatment for sleep apnea.¹¹ In a follow up review in 2008, Megwalu et al. again found a relative infrequent use of validated quality of life measures.¹² A literature search of UPPP and quality of life revealed a few articles that specifically assessed sleep-related quality of life in UPPP patients, but each article has important limitations.^{13–15}

Our study focuses on patient-based outcomes related to palatal surgery for sleep apnea as a part of a larger, surgical cohort. To this end, our primary objective was to test the hypothesis that UPPP improves sleep-related quality of life measured on the Functional Outcomes of Sleep Questionnaire (FOSQ) at 3 month follow-up. Secondary objectives were to test: 1) the stability of the outcomes at 6 months; 2) the effect on global sleep apnea quality of life

change; and 3) the effect on sleep apnea symptoms including daytime sleepiness measured on the Epworth Sleepiness Scale (ESS), snoring measured on a 100-mm visual analog scale (VAS), and others.

METHODS

Study Design

We performed a multi-center, prospective, university- and community-based, longitudinal case series of isolated UPPP as part of a larger prospective study of sleep apnea surgery. Results are presented only for the UPPP analysis. The multiple centers for this and the parent study included members of the BEST ENT (Building Evidence of Successful Treatments in Ear, Nose, and Throat) network of otolaryngologists who collaborate in prospective studies designed to evaluate the effectiveness and/or changes in disease-specific quality of life interventions on patients with ear, nose, and throat diseases.^{16–19} The network is supported by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) and coordinated through the Duke Clinical Research Institute. Individual sites received no direct financial support for participation or enrollment of participants. This study was approved by the Duke Institutional Review Board (IRB) and each participating site IRB. IRB approval for community physicians who did not have their own IRB was provided by Duke University through an unaffiliated investigator agreement.

Patient Sample

Adults (18 years and older) with palatal obstruction felt to be consistent with the presenting symptoms of obstructive sleep apnea as assessed by the treating surgeon were eligible to participate in this study. Inclusion criteria included: a sleep study demonstrating apnea-hypopnea index ≥ 5 events per hour and symptoms of sleep apnea lasting greater than three months. Qualifying symptoms included excessive daytime sleepiness or two of the following: choking or gasping during sleep, recurrent awakenings from sleep, unrefreshing sleep, daytime fatigue, or impaired concentration.²⁰ Individuals who had prior airway surgery were eligible, but patients who had other upper airway surgeries concomitant with UPPP or between UPPP and 3-month follow up were excluded from this analysis. Other exclusion criteria included: prior palate surgery (tonsillectomy without UPPP was allowed), history of radiation therapy to the head or neck, dysmorphic facies or craniofacial syndrome, American Society of Anesthesiologists Class IV or V, major depression or unstable psychiatric disorder, pregnancy, illiteracy (unable to complete required forms), no phone or mailing address, or plan to change address during the follow up period.

Research participants were recruited directly from the participating otolaryngology practices by the respective surgeons. The enrollment period was November 2004 through October 2006. Most sites enrolled consecutive patients during a part of this enrollment period until they reached their target sample. All enrolled patients gave informed consent.

Sleep Studies

Sleep studies were performed on all patients prior to enrollment and treatment. Sleep studies included types 1–3, full-night or split-night, and attended or unattended. Sleep study data

were used to help define patient eligibility and baseline sleep apnea burden, but sleep study data were not included as an outcome measure. Post-treatment sleep study data were not collected for this study.

Treatment

The operational definition of UPPP was an open procedure modifying the shape and size of the palate, pharynx, and uvula including resection of redundant or obstructive tissue and primary wound closure. UPPP includes tonsillectomy. The specific version of UPPP was left to the discretion of the treating surgeon. All patients underwent UPPP with or without tonsillectomy, and they had no other procedures.

Outcome Measures

The primary outcome variable is change in sleep-specific quality of life measured with the FOSQ at enrollment and at three months post-operatively. This instrument measures sleep-specific quality of life and has been validated in people with and without various sleep disorders.²¹ It produces a score of 5–20, higher is better. Normal is 17.9 or higher. A 5-point change in the FOSQ score corresponds to an average change of one point, or a change of one whole category of answer (ie, “extreme difficulty” to “moderate difficulty,” or “moderate difficulty” to “a little difficulty,” or “a little difficulty” to “no difficulty”), for every item in the 30-item instrument. Outcome was also measured six months post-operatively to test for the stability of the sleep-specific quality of life change.

Secondary outcome measures included global sleep apnea quality of life and symptoms. Global sleep apnea quality of life change is a transition measure that asks “In terms of sleep apnea and your health, has there been any change in your quality of life?” It is scored on a 15-point Likert scale ranging from –7 (a great deal worse) to +7 (a great deal better). It is modeled after a similar global quality of life instrument for asthma.²² Daytime sleepiness was measured with the Epworth Sleepiness Scale. This 24-point scale has been validated in various sleep disorders and has been used extensively in the literature. A normal score is 10 or less, and scores >16 represent severely excessive daytime sleepiness.²³ The frequency of awakening with a headache per week was quantified as <1, 1–2, 3–4, 5–6, or 7. Patients quantified how much of a problem the sleep apnea and snoring is for them, each on a 100-mm visual analog scale, with anchors “not a problem” (0) and “severe problem” (100). Presence or absence of symptoms of choking or gasping during sleep, recurrent awakenings from sleep, unrefreshing sleep, daytime fatigue, or problems concentrating were recorded. No other subjective outcomes were measured. All outcomes were measured three and six months post-operatively.

Data Collection and Management

If a patient met eligibility criteria and agreed to participate, then s/he signed the consent form and completed the baseline questionnaire with demographic and medical information as well as the outcome measures. The treating physician completed a form with information about the baseline sleep study, past and planned procedures, American Society of Anesthesiologists class, and standardized examination findings. Questionnaires and patient contact information were mailed to the Duke Clinical Research Center for data entry, and

patients were contacted by the Center staff to complete the follow up questionnaires three and six months after UPPP. Patients were contacted by mail at least three times and called up to five times for follow up. Data were entered into a secure database (Microsoft Access, Redmond, WA) that met privacy requirements. Patient identifiers were removed from the database and it was sent to the principal investigator (EMW) for analysis.

Analysis

The database was cleaned and prepared for analysis by the principal investigator. This analysis was limited to patients who had UPPP alone. For continuous variables (including variables with a scale range of 15 or more), the paired *t*-test was used to compare baseline and follow-up data. For ordinal data, the Wilcoxon sign rank test was used to compare baseline and follow-up data. Baseline variables were compared between the patients lost to follow up and the followed patients using Student's *t*-test (continuous variables), chi-squared test for linear trend (ordinal variables), and Fisher's exact test (dichotomous variables). All statistical tests were two-sided. A *p*-value less than 0.05 is considered statistically significant.

RESULTS

The parent study of sleep apnea surgery enrolled 243 patients from 19 different states. For this analysis of UPPP alone, patients (*N* = 68) were enrolled from 17 practice locations from 15 different states with nine practices (53%) university-based and eight practices (47%) community-based. The patient sample consisted mainly of middle-aged men who were generally healthy but were obese, on average, with severe sleep apnea by apnea-hypopnea index criteria (Table 1). Overall, the patients were quite symptomatic with clinically important deficits in sleep-related quality of life. Most UPPP operations included tonsillectomy. A minority of patients had prior airway surgery. Follow up data were obtained at three months and six months on 51% and 50%, respectively, of the patient sample.

The primary outcome was measured with the FOSQ, for which a normal score is 17.9. The patient sample had a clinically important baseline deficit in quality of life, which improved significantly and with large effect sizes at three and six months post-operatively (Tables 2–4). The observed 3-point change represents an average change of 0.6 points, or a change of just over half of a category, for every question in the 30-item FOSQ. Among patients who had an abnormal score at baseline and for whom follow up data were available (mean baseline score 13.8 ± 3.2), 42% (13/31) normalized their score at three months.

All other symptom and quality-of-life outcomes were also improved three months and six months after UPPP (all $p < 0.05$) with clinically important effects (Tables 2–4). Among patients who had an abnormal Epworth Sleepiness Scale at baseline (mean 15.9 ± 3.0) and for whom follow up data were available, 75% (18/24) normalized their score at three months. Between three months and six months, there was a minor but statistically significant setback in global sleep apnea-related quality of life ($p = 0.04$) and a statistical trend of a setback measured on the snoring visual analog scale ($p = 0.07$), but each remained much improved compared to baseline (Table 4). Patients lost a mean 8 ± 15 pounds at three months ($p = 0.005$)

and kept it off at six months. In this sample, this weight loss corresponds to a body mass index decrease of $1.1 \pm 2.2 \text{ kg/m}^2$ at three months.

Almost half of the patient sample was lost to follow up. There was no significant difference between the patients followed and the patients lost on most baseline variables, including demographics, general health, sleep apnea severity, symptoms, sleep-related quality of life, past surgical treatment, and current treatment (Table 5). The lost patients did have a significantly lower mean Friedman stage ($p < 0.001$) and a trend toward significantly larger tonsils ($p = 0.054$).

DISCUSSION

UPPP usually does not eliminate obstructive sleep apnea but it appears to have beneficial physiological effect on the disorder.^{1, 2} UPPP may have an even greater effect on clinical outcomes, as has been suggested for mortality,^{8, 9} cardiovascular disease,^{6, 7} motor vehicle accidents,⁵ symptoms, and satisfaction.²⁴ There are few studies examining sleep-related quality of life, which is another clinical outcome important to patients. Given the lack of patient-based data in the literature, we designed this study to focus on important patient-reported outcomes rather than on polysomnography parameters.

This study supports the hypotheses that UPPP improves sleep-related quality of life measured with the validated FOSQ at three and six months after surgery. These data also support the hypotheses that UPPP improves daytime sleepiness, other defining sleep apnea symptoms, and global sleep apnea-related quality of life for at least six months after surgery. Almost half of the patients with abnormal quality of life scores at baseline, and three quarters of those with abnormal sleepiness scores at baseline, were normalized after treatment.

Other studies have examined the effect of UPPP on quality of life, with each finding improvement with UPPP.^{13–15} Each of these high-level studies had many important strengths, but none used a validated sleep-specific quality of life instrument and each was limited to one or two sites of practice. One trial did not screen UPPP patients for the site of obstruction, so isolated UPPP may not have been appropriate for each patient.¹⁴ In one of the studies, the majority of patients underwent tongue surgery in addition to UPPP, so the study reflects the effect of multi-level surgery rather than isolated UPPP.¹⁵ Our study complements these studies by demonstrating a significant improvement in quality of life using a validated sleep-specific quality of life instrument in a multi-site study.

The major strength of this study is the enrollment from multiple practices, both university-based and community-based, with many different surgeons, from wide geographic distributions across the United States. The heterogeneity of site types and locations minimizes selection bias, and the heterogeneity of surgical techniques maximizes generalizability (external validity). This degree of heterogeneity and generalizability has not been achieved in an UPPP quality of life study before.

Other strengths of this study are its prospective design, use of validated instruments, patient-oriented outcomes assessment, the consistency of the outcomes, and physicians not involved

in collecting outcomes data (which would risk reporting bias by patients or physicians). All of these features strengthen the validity of the findings by reducing biases that might exaggerate the treatment effects.

This study has important limitations. The follow up rate was relatively low. Follow up is a particular challenge for multi-site studies where the follow up is obtained by mail from research staff not familiar to the research participants. These methods were necessary for this AAO-HNSF sponsored BEST ENT study. Furthermore, community-based studies include patients who may not be familiar with the importance for the research follow up. These challenges for follow up may be a tradeoff for the major strength of generalizability described above. It is worth noting that the follow up rate was similar to other published multi-center, community-based studies in the otolaryngology literature.^{19, 25}

One of the main concerns with a low follow up rate is that the followed patients may have experienced better outcomes that are captured in the outcomes analysis, which would exaggerate the reported treatment effectiveness. It is reassuring that the only baseline differences between patients followed and lost from this cohort were that the followed patients had smaller tonsils and a higher Friedman stage, both of which predict that the *followed patients* would have a *worse* outcome,² opposite to the feared bias. That is, to the best of our ability to compare the followed to the lost patients, the followed patients appear more likely to have experienced worse outcomes, which would blunt the reported treatment effectiveness (a conservative bias toward the null hypothesis of no treatment effect). Nevertheless, it is impossible to know how the lost patients actually did, so the low follow up rate still poses an important risk of bias.

This study was a case series with no control group, which risks regression to the mean, placebo effect, or other natural variation being ascribed to a treatment effect. The risk of placebo effect is possible because the outcomes are self-reported. Placebo-control is not feasible for UPPP because of the visible anatomic effects and the significant post-operative pain. However, the consistency of the benefits across outcome measures suggests there is a real beneficial effect. Furthermore, some of the outcome variables reflect specific events (e.g., choking or gasping during sleep, recurrent awakenings from sleep, the number of awakenings with headache per week, and the FOSQ), which are less prone to placebo effect. Also, the rating of the snoring problem often reflects the concern of a bed partner, which may also be less prone to placebo effect.

The lack of polysomnography outcomes is a study limitation. However, the purpose of this study was to quantify the effect of UPPP on quality of life and symptoms in a heterogeneous surgical and clinical population. Polysomnography parameters do not correlate well with these outcome measures either at baseline or at outcome.⁴ The polysomnographic variability between laboratories and scoring technologists²⁶ would make it difficult or impossible to compare polysomnography results across multiple different centers in a valid way without a standardized central polysomnography core.²⁷ The study burden and prohibitive expense of polysomnography would have made the current study and its primary outcome impossible. This study highlights the need for a more accessible and accurate objective surrogate measure of sleep apnea disease burden and outcome.

Surgical complication is another important clinical outcome, and it was not included in this study. Some have suggested that UPPP complications are frequent enough to justify not ever doing UPPP, even in clinical trials.³ However, it is important to note that the studies that show frequent UPPP complications also found that the complications were usually minor, they often decreased with time, and few patients regretted UPPP.^{24, 28} Surgical complications produce an adverse effect on quality of life, so the improvement we observed in quality of life suggests the patients experienced a net benefit.

Some of the directions for future research include assessment of cardiovascular outcomes of UPPP, assessment of subjective and objective patient-oriented outcomes of multi-level surgery, prognostication of beneficial outcomes, and the effects of surgery in subgroups. The Studying Life Effects and Effectiveness of Palatopharyngoplasty parent study has data to begin to address these directions and will be analyzed separately.

CONCLUSIONS

This prospective, multicenter, university- and community-based study provides evidence that UPPP significantly improves disease-specific quality of life and sleep apnea symptoms in patients with sleep apnea. Validity may be limited by significant loss to follow-up and absence of an unoperated control group.

Acknowledgments

We acknowledge the study coordination by Tasha Carmon and preliminary statistical analyses by Robert Clare, PhD, both at the Duke Clinical Research Institute. This study was supported by the American Academy of Otolaryngology-Head & Neck Surgery Foundation. Dr. Weaver was supported by a career development award (HL068849) from the National Heart, Lung, and Blood Institute.

SLEEP Study Investigators enrolling patients for this analysis: David C. Brodner, Boca Raton, FL; Karen Calhoun, Columbia, MO; John S. Donovan, Salem, OR; Mark Gibbons, Fort Sill, OK; Philip T. Ho, New Milford, CT; James Jarrett, Missoula, MT; Jonas Johnson, Pittsburgh, PA; F.P.J. Langford, Concord, NC; Jonathan D. McGinn, Hershey, PA; Mary Mitskavich, Wall, NJ; Steven Y. Park, New York, NY; Regina Walker, Maywood, IL; Edward M. Weaver, Seattle, WA; Samuel Welch, Little Rock, AR; David Witsell, Durham, NC; B. Tucker Woodson, Milwaukee, WI; and Kathleen Yaremchuk, Detroit, MI.

Additional SLEEP Study Investigators enrolling in the parent study: David I. Astrachan, Hamden, CT; David R. Bruce, Sterling, IL; Gary A. Buxa, Redding, CA; Cecelia C. Damask, Fayetteville, NC; Dwight Ellerbe, Anchorage, AK; Joseph Giebfried, Bangor, ME; Bruce R. Gordon, Hyannis, MA; Andrew Gould, Louisville, KY; Robert E. Harley, Charlotte, NC; Wayne Harsha, Tacoma, WA; Kenneth Hodge, Louisville, KY; John Houck, Oklahoma City, OK; Sean Houston, Wall, NJ; Ofer Jacobowitz, Middletown, NY; James E. Kallman, Anchorage, AK; Eric J. Kezirian, San Francisco, CA; Alan Kominsky, Cleveland, OH; Richard Lenz, Bangor, ME; Jennifer Lynch, Greenbay, WI; Nicole Maronian, Seattle, WA; John Morris, Louisville, KY; Lionel M. Nelson, San Jose, CA; Michael Y. Parker, Wilmington, NC; Mark Reinke, Greenbay, WI; Richard Scher, Durham, NC; Frederic Schmidt, Greenbay, WI; Douglas Sorensen, Tacoma, WA; Jordan Stern, New York, NY; David L. Steward, Cincinnati, OH; Michael G. Stewart, Houston, TX; Richard Waguespack, Birmingham, AL; David Wexler, Worcester, MA; Stefan Zechow, Santa Rosa, CA; and Larry Zieske, Minneapolis, MN.

This study was supported by the American Academy of Otolaryngology-Head & Neck Surgery Foundation. Dr. Weaver was supported by a career development award (HL068849) from the National Heart, Lung, and Blood Institute.

References

1. Sher AE, Schechtman KB, Piccirillo JF. The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep*. 1996; 19:156–77. [PubMed: 8855039]

2. Friedman M, Ibrahim H, Bass L. Clinical staging for sleep-disordered breathing. *Otolaryngol Head Neck Surg.* 2002; 127:13–21. [PubMed: 12161725]
3. Franklin KA, Anttila H, Axelsson S, et al. Effects and side-effects of surgery for snoring and obstructive sleep apnea—a systematic review. *Sleep.* 2009; 32:27–36. [PubMed: 19189776]
4. Weaver EM, Woodson BT, Steward DL. Polysomnography indexes are discordant with quality of life, symptoms, and reaction times in sleep apnea patients. *Otolaryngol Head Neck Surg.* 2005; 132:255–62. [PubMed: 15692538]
5. Haraldsson PO, Carenfelt C, Lysdahl M, et al. Does uvulopalatopharyngoplasty inhibit automobile accidents? *Laryngoscope.* 1995; 105:657–61. [PubMed: 7769954]
6. Peker Y, Hedner J, Norum J, et al. Increased incidence of cardiovascular disease in middle-aged men with obstructive sleep apnea: a 7-year follow-up. *Am J Respir Crit Care Med.* 2002; 166:159–65. [PubMed: 12119227]
7. Peker Y, Carlson J, Hedner J. Increased incidence of coronary artery disease in sleep apnoea: a long-term follow-up. *Eur Respir J.* 2006; 28:596–602. [PubMed: 16641120]
8. Weaver EM, Maynard C, Yueh B. Survival of veterans with sleep apnea: continuous positive airway pressure versus surgery. *Otolaryngol Head Neck Surg.* 2004; 130:659–65. [PubMed: 15195049]
9. Marti S, Sampol G, Munoz X, et al. Mortality in severe sleep apnoea/hypopnoea syndrome patients: impact of treatment. *Eur Respir J.* 2002; 20:1511–8. [PubMed: 12503712]
10. Piccirillo JF, Gates GA, White DL, et al. Obstructive sleep apnea treatment outcomes pilot study. *Otolaryngol Head Neck Surg.* 1998; 118:833–44. [PubMed: 9627245]
11. Schechtman KB, Sher AE, Piccirillo JF. Methodological and statistical problems in sleep apnea research: the literature on uvulopalatopharyngoplasty. *Sleep.* 1995; 18:659–66. [PubMed: 8560132]
12. Megwalu UC, Piccirillo JF. Methodological and statistical problems in uvulopalatopharyngoplasty research: a follow-up study. *Arch Otolaryngol Head Neck Surg.* 2008; 134:805–9. [PubMed: 18711052]
13. Cahali MB. Lateral pharyngoplasty: a new treatment for obstructive sleep apnea hypopnea syndrome. *Laryngoscope.* 2003; 113:1961–8. [PubMed: 14603056]
14. Walker-Engstrom ML, Wilhelmsson B, Tegelberg A, et al. Quality of life assessment of treatment with dental appliance or UPPP in patients with mild to moderate obstructive sleep apnoea. A prospective randomized 1-year follow-up study. *J Sleep Res.* 2000; 9:303–8. [PubMed: 11012871]
15. Robinson S, Chia M, Carney AS, et al. Upper airway reconstructive surgery long-term quality-of-life outcomes compared with CPAP for adult obstructive sleep apnea. *Otolaryngol Head Neck Surg.* 2009; 141:257–63. [PubMed: 19643262]
16. Stewart MG, Witsell DL, Smith TL, et al. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) Scale. *Otolaryngol Head Neck Surg.* 2004; 130:157–63. [PubMed: 14990910]
17. Stewart MG, Smith TL, Weaver EM, et al. Outcomes after nasal septoplasty: Results from the Nasal Obstruction Septoplasty Effectiveness (NOSE) study. *Otolaryngol Head Neck Surg.* 2004; 130:283–90. [PubMed: 15054368]
18. Goldstein NA, Stewart MG, Witsell DL, et al. Quality of life after tonsillectomy in children with recurrent tonsillitis. *Otolaryngol Head Neck Surg.* 2008; 138:S9–S16. [PubMed: 18164376]
19. Witsell DL, Orvidas LJ, Stewart MG, et al. Quality of life after tonsillectomy in adults with recurrent or chronic tonsillitis. *Otolaryngol Head Neck Surg.* 2008; 138:S1–8. [PubMed: 18164373]
20. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep.* 1999; 22:667–89. [PubMed: 10450601]
21. Weaver TE, Laizner AM, Evans LK, et al. An instrument to measure functional status outcomes for disorders of excessive sleepiness. *Sleep.* 1997; 20:835–43. [PubMed: 9415942]
22. Juniper EF, Guyatt GH, Willan A, et al. Determining a minimal important change in a disease-specific quality of life questionnaire. *J Clin Epidemiol.* 1994; 47:81–7. [PubMed: 8283197]
23. Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep.* 1991; 14:540–5. [PubMed: 1798888]

24. Grontved AM, Karup P. Complaints and satisfaction after uvulopalatopharyngoplasty. *Acta Otolaryngol Suppl.* 2000; 543:190–2. [PubMed: 10909017]
25. Witsell DL, Stewart MG, Monsell EM, et al. The Cooperative Outcomes Group for ENT: a multicenter prospective cohort study on the effectiveness of medical and surgical treatment for patients with chronic rhinosinusitis. *Otolaryngol Head Neck Surg.* 2005; 132:171–9. [PubMed: 15692523]
26. Michaelson PG, Allan P, Chaney J, et al. Validations of a portable home sleep study with twelve-lead polysomnography: comparisons and insights into a variable gold standard. *Ann Otol Rhinol Laryngol.* 2006; 115:802–9. [PubMed: 17165661]
27. Stepnowsky CJ Jr, Berry C, Dimsdale JE. The effect of measurement unreliability on sleep and respiratory variables. *Sleep.* 2004; 27:990–5. [PubMed: 15453560]
28. Jaghagen EL, Berggren D, Dahlqvist A, et al. Prediction and risk of dysphagia after uvulopalatopharyngoplasty and uvulopalatoplasty. *Acta Otolaryngol.* 2004; 124:1197–203. [PubMed: 15768818]
29. Kazis LE, Anderson JJ, Meenan RF. Effect sizes for interpreting changes in health status. *Med Care.* 1989; 27:S178–89. [PubMed: 2646488]

Table 1

Cohort Baseline Description (N=68).

Variable	Mean	Range
<i>Demographics</i>		
Age (years)	44±12	18 – 69
Sex: Male	78%	
Race: White	79%	
Marital Status: Married/partner	66%	
Employment Status: Full-time	76%	
<i>General Health</i>		
American Society of Anesthesiologists Class	1.7±0.7	1 – 3
Current Smoker	12%	
Alcohol Use (drinks/week)	2.9±4.5	0 – 20
Systolic Blood Pressure (mmHg), in clinic at enrollment	129±10	106–150
Diastolic Blood Pressure (mmHg), in clinic at enrollment	82±6	69–100
<i>Anatomy</i>		
Body Mass Index (kg/m ²)	31±5	20 – 41
Tonsil Size (0–4)	2±1	0 – 4
Friedman Stage (1–3) ²	2.2±0.6	1 – 3
<i>Sleep Apnea Severity</i>		
Apnea-Hypopnea Index (events/h)	35±32	5 – 164
Apnea Index (events/h)	19±24	0 – 96
Lowest Saturation (%)	84±7	64 – 98
<i>Symptoms & Quality of Life</i>		
Sleep Apnea Symptoms (0–5)	4±1	0 – 5
Awakening With Headache (days/week)	2±2	0 – 7
Sleep Apnea Problem Visual Analog Scale (0–100)	72±27	0 – 100
Snoring Visual Analog Scale (0–100)	55±34	0 – 100
Epworth Sleepiness Scale (0–24)	13±6	0 – 22
Functional Outcomes of Sleep Questionnaire (5–20)	14±3	7 – 20
<i>Sleep Apnea Treatment</i>		
Uvulopalatopharyngoplasty Included Tonsillectomy	63%	
Using CPAP Therapy at Baseline	44%	
Prior Airway Surgery: Any	25%	
Prior Airway Surgery: Nasal	18%	
Prior Airway Surgery: Tonsillectomy or adenoidectomy	9%	
Prior Airway Surgery: Tongue	6%	
<i>Follow Up</i>		
Total Sample (N)	68	

Variable	Mean	Range
Follow Up Data Available: 3-Month (N)	51% (35/68)	
3-Month Follow Up (median days)	125	77 – 170
Follow Up Data Available: 6-Month (N)	50% (34/68)	
6-Month Follow Up (median days)	273	167 – 849

CPAP = Continuous Positive Airway Pressure.

Table 2

Outcomes Between Baseline, Three Months, and Six Months.

Outcome	Baseline	3-Month	6-Month	P-Value* (0–3 mos)	P-value* (0–6 mos)	P-Value* (3–6 mos)
Primary						
Functional Outcomes of Sleep Questionnaire (5–20)	14.3±3.4	17.2±2.7	17.5±2.5	<0.001	<0.001	0.77
Secondary						
Epworth Sleepiness Scale (0–24)	12.9±5.5	7.0±4.7	6.9±4.2	<0.001	<0.001	0.54
Sleep Apnea Symptoms (0–5)	3.7±1.1	1.1±1.5	1.5±1.7	<0.001	<0.001	0.32
Awakening With Headache (days/week)	1.7±2.3	1.0±2.1	1.0±1.9	0.048	0.008	0.66
Sleep Apnea Problem VAS (0–100)	68±30	24±28	24±27	<0.001	<0.001	0.88
Snoring VAS (0–100)	53±32	8±12	18±22	<0.001	<0.001	0.07
Global Sleep Apnea QOL Change (–7 – +7)	N/A	3.5±2.6	2.5±2.7	<0.001	<0.001	0.04
Body Mass Index Self Report (kg/m ²)	30±4	29±4	29±5	0.006	<0.001	0.41

VAS = Visual Analog Scale (0–100).

* P-value based on the one-sample paired *t-test* (two-sided) for comparison of means for continuous variables or Wilcoxon sign rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance ($p < 0.05$).

Table 3

Three-Month Outcomes.

Outcome	N	Difference [*]	95% CL	P-value [†]	Effect Size [‡]
Primary					
Functional Outcomes of Sleep Questionnaire (5–20)	35	2.9±3.3	(1.8, 4.0)	<0.001	0.85
Secondary					
Epworth Sleepiness Scale (0–24)	35	–5.946.0	(–8.0, –3.8)	<0.001	1.07
Sleep Apnea Symptoms (0–5)	35	–2.7±1.5	(–3.2, –2.1)	<0.001	2.45
Awakening With Headache (days/week)	31	–0.742.0	(–1.4, 0.0)	0.048	0.30
Sleep Apnea Problem VAS (0–100)	34	–44±36	(–57, –31)	<0.001	1.47
Snoring VAS (0–100)	33	–45±32	(–57, –34)	<0.001	1.41
Global Sleep Apnea QOL Change (–7 – +7) [§]	35	3.5±2.6	(2.6, 4.4)	<0.001	1.35

CL = Confidence Limits, VAS = Visual Analog Scale, QOL = Quality of Life.

^{*} Difference = 3-Month Score – Baseline Score.[†] P-value based on paired *t*-test (two-sided) for comparison of means for continuous variables or Wilcoxon sign rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance (*p* < 0.05).[‡] Effect Size = (3-Month Score – Baseline Score)/(Baseline Standard Deviation). Positive indicates UPPP improved the outcome, negative indicates UPPP worsened the outcome. Effect Size 0.20 is clinically important, 0.80 indicates large effect size.²⁹[§] Global Sleep Apnea QOL Change is a transition measure, which is measured only at outcome.

Table 4

Six-Month Outcomes.

Outcome	N	Difference [*]	95% CL	P-value [†]	Effect Size [‡]
Primary					
Functional Outcomes of Sleep Questionnaire (5–20)	32	3.1±3.1	(2.0, 4.2)	<0.001	0.91
Secondary					
Epworth Sleepiness Scale (0–24)	34	–5.8±5.6	(–7.7, –3.8)	<0.001	0.98
Sleep Apnea Symptoms (0–5)	34	–2.1±1.6	(–2.7, –1.6)	<0.001	1.75
Awakening With Headache (days/week)	30	–0.9±1.8	(–1.6, –0.2)	0.008	0.39
Sleep Apnea Problem VAS (0–100)	32	–46±31	(–57, –35)	<0.001	1.64
Snoring VAS (0–100)	31	–37±33	(–49, –25)	<0.001	1.12
Global Sleep Apnea QOL Change (–7 – +7) [§]	33	2.5±2.7	(1.5, 3.4)	<0.001	0.93

CL = Confidence Limits, VAS = Visual Analog Scale, QOL = Quality of Life.

^{*} Difference = 6-Month Score – Baseline Score.[†] P-value based on paired *t*-test (two-sided) for comparison of means for continuous variables or Wilcoxon sign rank test for comparison of ordinal variables (sleep apnea symptoms, awakening with headache). Bold indicates statistical significance (*p* < 0.05).[‡] Effect Size = (6-Month Score – Baseline Score)/(Baseline Standard Deviation). Positive indicates UPPP improved the outcome, negative indicates UPPP worsened the outcome. Effect Size 0.20 is clinically important, 0.80 indicates large effect size.²⁹[§] Global Sleep Apnea QOL Change is a transition measure, which is measured only at outcome.

Table 5

Baseline Comparison of Patients Followed and Lost at Three Months.

Variable	Followed	Lost	P-Value*
Demographics			
N	51% (35/68)	49% (33/68)	
Age (years)	46±12	44±11	0.46
Sex: Male	77%	79%	1.00
Race: White	83%	76%	0.70
Marital Status: Married/partner	63%	70%	0.61
Employment Status: Full-time	77%	84%	0.19
General Health			
American Society of Anesthesiologists Class	1.7±0.7	1.8±0.8	0.83
Current Smoker	11%	12%	1.00
Alcohol Use (drinks/week)	3.1±5.3	2.6±3.5	0.64
SBP (mmHg), in clinic at enrollment	127±10	131±10	0.24
DBP (mmHg), in clinic at enrollment	81±7	84±5	0.13
Anatomy			
Body Mass Index (kg/m ²)	30±5	31±6	0.49
Tonsil Size (0–4)	1.5±0.9	2.0±1.0	0.054
Friedman Stage (1–3)	2.4±0.5	1.9±0.6	<0.001
Sleep Apnea Severity			
Apnea-Hypopnea Index (events/h)	31±32	39±32	0.31
Apnea Index (events/h)	16±19	25±30	0.26
Lowest Saturation (%)	85±7	82±7	0.23
Symptoms & Quality of Life			
Sleep Apnea Symptoms (0–5)	3.7±1.1	3.4±1.3	0.20
Awakening With Headache (days/week)	1.6±2.2	2.0±2.1	0.46
Sleep Apnea Problem VAS (0–100)	68±30	75±22	0.28
Snoring VAS (0–100)	53±31	58±37	0.58
Epworth Sleepiness Scale (0–24)	12.9±5.5	12.2±5.8	0.59
Functional Outcomes of Sleep Questionnaire (5–20)	14.3±3.4	14.4±3.1	0.90
Sleep Apnea Treatment			
UPPP Included Tonsillectomy (%)	60%	67%	0.62
Current CPAP Therapy at Baseline	35%	55%	0.13
Prior Airway Surgery: Any	29%	21%	0.58
Prior Airway Surgery: Nasal	20%	15%	0.75
Prior Airway Surgery: Pharyngeal	9%	9%	1.00
Prior Airway Surgery: Tongue	3%	9%	0.35

SBP = Systolic Blood Pressure. DBP = Diastolic Blood Pressure. VAS = Visual Analog Scale. UPPP = Uvulopalatopharyngoplasty. CPAP = Continuous Positive Airway Pressure.

* P-value based on Student's *t*-test (two-sided) for comparison of means for continuous variables, chi-squared test for linear trend for ordinal variables, and Fisher's exact test for dichotomous variables. Bold indicates statistical significance ($p < 0.05$).

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript