

## Non-Pressure Therapies for Obstructive Sleep Apnea: Surgery and Oral Appliances

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**The first-line treatment of obstructive sleep apnea (OSA) is positive airway pressure (PAP). If PAP fails to adequately treat the OSA, oral appliances that enlarge the airway (mandibular advancement devices primarily, or the tongue retaining device if the patient has no dentition) are the next line of therapy. The third-line treatment of OSA is surgery. Surgeries that have been used to treat OSA include septoplasty, tonsillectomy adenoidectomy, uvulopalatopharyngoplasty, mandibular advancement procedures, tongue reduction surgery, hyoid bone suspension, maxillofacial surgery, and bariatric procedures. There are scant data to support or compare the various procedures. Key words: obstructive sleep apnea; OSA; mandibular advancement device; tongue retaining device; septoplasty; tonsillectomy adenoidectomy; uvulopalatopharyngoplasty; mandibular advancement procedures; tongue reduction surgery; hyoid bone suspension; maxillofacial surgery; bariatric surgery. [Respir Care 2010;55(10):1314–1320. © 2010 Daedalus Enterprises]**

### Introduction

Sleep-disordered breathing affects a vast population of individuals. For obstructive sleep apnea (OSA), positive

airway pressure (PAP) therapies are often first-line treatment. Success of PAP therapies, however, is not universal, and alternative or ancillary treatments are often of benefit. Additionally, although PAP therapies have demonstrated

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success for more severe sleep-disordered breathing, their role in non-OSA sleep-disordered breathing has not been shown. Sleep-disordered breathing encompasses a wide spectrum of disease that includes not only OSA but disorders of upper-airway resistance, nasal obstruction, and snoring. Although a major focus is appropriately directed at defined OSA, less appreciated is the role that these “non-apneic” breathing disorders contribute to sleep disease. Abnormal non-apneic ventilation may also impact conditions as diverse as nasal obstruction, pregnancy, dental health, chronic lung disease, obesity, and gastroesophageal reflux. Both apneic and non-apneic ventilatory disorders have major if not primary contributions from a structurally vulnerable upper airway that then interacts with sleep-related physiology. For many sleep-related breathing disorders, reducing the structural burden of the disorder results in improved outcomes and treatment.

Treatment of OSA is best approached using a treatment ladder. Progressive steps may include treating predisposing conditions, treating medical causes, medications, devices, and surgery. Not all patients require all those steps, but often the best disease-management outcomes are obtained with several of the steps. Often patient outcomes are limited by a focus on a narrow number of treatment steps. In this review I assess the use of non-PAP therapies, including surgery and oral appliances, both as primary and ancillary treatment.

### Role of Non-PAP Therapies

Non-PAP therapies may have 3 general intents. These intents markedly affect treatment types and decisions. Treatment intent may be “curative,” “salvage,” or ancillary. Curative intent is probably a poor term in that, for a chronic disease such as sleep apnea, many may question whether a cure exists. Rather than eliminating disease, this intent is directed at a form of definitive treatment to reduce disease burden of symptoms and disease morbidity for an extended period of time. Salvage therapy is directed at treating patients following failure of first-line therapies (eg, PAP devices). As a salvage treatment, the ideal outcome is definitive treatment, such as with curative intent; however, successful treatment may be achieved by significantly reducing disease severity to lessen disease morbidity and mortality. Finally (and probably of most benefit), treatment intent may be ancillary. This intent is to combine the ancillary therapy with the primary or more conservative therapies to add additional therapeutic benefit.

### Oral Appliances

Oral appliances are devices that are directed at opening or enlarging the pharyngeal airway by mechanical action.<sup>1</sup> These devices increase airway size or stiffness through

direct tissue advancement of the tongue or jaw. Oral appliances are of 2 general types: mandibular advancement devices, and the tongue retaining device. The predominant and most common oral appliance is the mandibular advancement device, which protrudes the lower jaw and increases vertical opening during sleep to reduce airway obstruction, hypopneas, apneas, and snoring. Teeth are required on both the mandibular and the maxillary arches to anchor the device. Similar to PAP devices, a mandibular advancement device requires nightly use for effect. A large number of proprietary mandibular advancement devices are available and differ in design, materials, and cost. They may be custom made for the patient or non-custom off-the-shelf. Custom appliances require construction of dental impressions, from which the custom device is made. The custom devices as a group have historically resulted in better patient comfort and fit. In contrast, the off-the-shelf devices are often constructed of thermoplastic material that is molded directly to the patient’s dentition. These devices generally have not been as comfortable or had the retention of the custom devices. As new materials develop, however, the distinction between custom and off-the-shelf devices may disappear.

Both custom and off-the-shelf mandibular advancement devices may be designed to have either a fixed amount of mandibular protrusion or adjustable protrusion. It is the opinion of many that best results are achieved with adjustable devices.<sup>2</sup> Few studies have actually compared the outcomes with the 2 types. No adequately powered studies have been performed with the 2 designs. Even if performed, the results probably would be affected by the practitioner’s skill and the nature of the device.

When no dentition is present, the tongue retaining device may be used. A tongue retaining device does not use dentition to advance tissues, but, instead, a suction bulb to hold the soft tissue tongue in a more advanced position. Tongue retaining devices are less commonly and less successfully used, but may offer success in a subset of patients.

### Mechanism

Oral appliances enlarge the pharynx. Increases in airway size are recorded at both the level of the tongue base and the palate. Studies using magnetic resonance imaging and sedated sleep found that during sleep major collapse occurs at the soft palate and the level of the epiglottis. Maximum protrusion with a mandibular advancement device restores airway area to its awake level, but does so by increasing the lateral wall dimensions, not the anterior-posterior dimensions, compared to awake. Successful use requires adequate enlargement of the airway. No studies have demonstrated a consistent method of predicting the amount of advancement required for any given patient. Often  $\geq 6$  mm advancement is needed to treat both snor-

ing and apnea. This uncertainty is one of the reasons that adjustable devices are favored for many patients.

### Clinical Outcomes

Outcomes with mandibular advancement devices have been studied in multiple controlled trials. The apnea-hypopnea index (AHI) outcome has been variable.<sup>3-6</sup> The average success rate of reducing the AHI to less than 10 events per hour is 52%. Understandably, effectiveness varies by population treated and specific device used. In general, those with mild and moderate disease have a greater likelihood of reducing the AHI to low levels (81%). Success is generally less in those with more severe disease. Alternatively, clinical success is dependent on technical success in improving airway size and stability. Limited evidence suggests that individuals who are less obese, have greater protrusion range, and those who have positional apnea respond better to mandibular advancement devices.

Mild adverse effects, such as sore teeth and gums and excessive salivation, are common, affecting up to 50% of patients. More severe adverse effects such as occlusal changes and myofascial pain are less common. Major adverse effects are probably determined by aggressiveness of protrusion and duration of use. To date, most studies have been of short duration, and ultimate complication rates with long-term use have yet to be determined.

### Surgery

Reconstructive surgery has the goal to modify tissue to improve form and function. Upper-airway reconstructive surgery for sleep disorders encompasses a wide variety of procedures that may be directed at multiple upper-airway anatomical structures. This is in contrast to the misperception of many practitioners who conceive of upper-airway surgery as primarily uvulopalatopharyngoplasty. The specific goal of surgery in sleep-disordered breathing is to normalize ventilation or to decrease ventilator abnormalities below a threshold of disease. Unfortunately, the threshold defining physiologic abnormality from disease is poorly defined. In lieu of this, physiologic measures such as the AHI often define the disease. Polysomnographic measurements are often poorly correlated to actual disease. Treatment of one does not necessarily imply treatment of the other, and failure to affect the measurement does not necessarily mean that the treatment had no effect on clinical disease. This concept is critical in evaluating therapies that do not eliminate all physiologic obstruction in sleep-disordered breathing, such as surgery and oral appliances. The concept also applies to positional therapy, expiratory pressure devices, treatment of obesity, and even nasal continuous PAP (CPAP). Although when correctly applied and used, nasal CPAP may eliminate apnea, the device is

often incorrectly applied and inadequately used. Furthermore, non-apneic obstruction may persist in many patients.

The biggest problem in assessing non-PAP and surgical outcomes in sleep-disordered breathing is a lack of adequate data. Data from mandibular advancement devices are strengthening for polysomnography metrics but are weaker for clinical metrics. Good data on most metrics for most surgical procedures are absent or limited. Historically, obtaining surgical data has been difficult. Few areas of surgery other than those with enormous financial resources have adequate data, and few would argue that advances in evidence-based medicine for most areas of surgery lag behind their medical counterparts. Surgery for sleep-disordered breathing is an extreme example of an area with scant data. There is a wide divergence between the advocates and opponents of surgery. The result affects patients with inconsistent, sometimes arbitrary, treatment (or no treatment). Patients who would benefit (or not) from non-PAP therapies are inadequately treated.

Treatment of OSA may involve the use of multiple therapies. It is a chronic condition lasting years or decades. There is no solitary cause, although it is widely accepted that sleep apnea results from a structurally vulnerable airway combined with loss of muscle compensation during sleep. The resulting obstruction increases arousals, work of breathing, and desaturations, and initiates pathophysiologic process that cause disease. OSA treatment may involve treating predisposing conditions or using conservative therapies, medications, devices, and/or surgery. Most agree that few if any of these treatments actually cure any disease. Rather, all to one degree or another, manage disease. Ultimately, then, the use of a treatment is determined by its effectiveness, morbidity, and cost.

### Definition

Surgery for OSA includes a range of reconstructive procedures<sup>7</sup> that may bypass or modify the supraglottic, hypopharyngeal, oropharyngeal, nasopharyngeal, or nasal airways. The reconstruction methods may involve modification of skeletal or soft tissues or both. It is widely accepted that surgery is technically ultimately effective by modifying the shape, size, volume, and compliance of upper-airway structures. Surgical procedures may be conceived as attempt tools. As with tools, uses may overlap, although for some tools uses are unique. Not all tools and surgical techniques have curative intent. Surgical techniques are generally named by the anatomical structure they modify, and the techniques to modify a structure may radically differ. Open cholecystectomy is a radically different and more morbid procedure than endoscopic cholecystectomy. Unfortunately, in procedures for treating sleep-disordered breathing there are very few data comparing how well different surgical procedures mediate these

technical changes. There are also very few surgical data measuring direct clinical outcomes. Virtually all surgical data relate to polysomnographic outcomes. Making clinical decisions on these data is imprecise at best.<sup>8-10</sup>

A useful way to approach surgery is to assess the surgical intent, which can be classified into 3 general surgical approaches for OSA. First is the ancillary use of surgery to assist other therapies. An often-used example is nasal surgery to improve PAP use and outcomes. Second, surgery may attempt to be curative. In adults, isolated pathologies causing OSA are infrequent, but they do occur, and correcting these may eliminate the OSA. Third, surgery can be for “salvage,” following failure of medical or other treatment options.

### Nasal Surgery

The nasal airway is the primary route of ventilation in humans, both during sleep and awake. The impact of the nasal airway quality on sleep, sleep-disordered breathing, OSA syndrome, and OSA is incompletely understood. Multiple studies have demonstrated that nasal obstruction is a risk factor for sleep apnea and snoring. Treatment of nasal abnormalities probably have significant effects on sleep and sleep-disordered breathing. Like other surgeries, however, the high-level evidence on such treatment effects is limited.<sup>11-16</sup>

Anatomically, the nose has 3 segments: the nasal valve, the nasal cavum, and the nasopharynx. Structural combinations to each are complex and beyond the scope of this paper. Common nasal procedures include septoplasty, nasal turbid surgery, nasal valve surgery, adenoidectomy, and obstructive lesions such as nasal polyps.

The vast majority of surgical data on the nose and sleep-disordered breathing relate to septoplasty. Since septal pathology is only a small spectrum of nasal pathology, these studies probably underestimate the potential effect of reconstructive nasal surgery. Although there are few data about the prevalence of nasal surgery, there is a consensus that most surgeons use nasal surgery in an ancillary role for sleep-disordered breathing. Multiple large case series and secondary outcomes from randomized trials support the idea that nasal surgery has significant favorable impact on sleep. This is in contrast to data from multiple case series and randomized trials suggesting that nasal surgery as an isolated intervention fails to improve OSA. Those studies, however, focused only on the apnea-hypopnea index as a metric of sleep and breathing disease. That focus is incorrect. Pharyngeal and control-of-breathing characteristics drive the AHI. This measure has significant limitations and should not be used as the only metric of sleep-related breathing disease. The effect of nasal treatment on snoring is controversial, and related data are few. As an isolated treatment it is sometimes highly effective, but

selecting the patients likely to benefit is yet to be determined. For most patients, nasal surgery’s effect on snoring is probably partial effectiveness.

### The Nose and Nasal CPAP

Increased nasal resistance is a major predictor of acceptance of, adherence to, and successful use of nasal CPAP. Increased nasal resistance is associated with failure of oral appliances for OSA. Several small surgical studies support the position that nasal or selected pharyngeal surgeries may lessen CPAP pressure and may improve CPAP adherence.

Most nasal surgery is associated with low morbidity. Although nasal surgery historically often involved nasal packing, that is now used less frequently. Especially in sleep apnea patients, nasal packing is associated with more perioperative morbidity and complications. A vast majority of nasal procedures can be performed under local anesthesia and sedation, which reduces risks. However, many OSA patients still have nasal surgery under general anesthesia, and in these cases the increased anesthesia risks in the sleep apnea patient must be weighed against the benefits of treatment.

### Tonsillectomy

Tonsillectomy and adenoidectomy are common procedures in children with sleep-disordered breathing.<sup>17-21</sup> In pediatric patients, the effect of tonsillectomy and adenoidectomy can be dramatic on AHI, quality-of-life, and cognitive abilities. The procedure, however, should not be considered curative. Most of the data to date are from case series with control groups. The data suggest that outcomes differed by population treated, airway and facial structure, obesity, and the presence of other pathologies. In non-complicated patients, AHI after tonsillectomy was predicted.

### Uvulopalatopharyngoplasty

Uvulopalatopharyngoplasty modifies the upper pharynx and palate.<sup>22-31</sup> Many technical variations have been described, and many differ considerably from the commonly performed excision of distal soft palate, tonsils, uvula, and redundant mucosa. These modifications promise lower morbidity in many cases, preserve anatomy, and have been more effective in randomized clinical trials. Initially, uvulopalatopharyngoplasty was developed as a treatment for snoring. It was subsequently modified by Fujita to treat sleep apnea.<sup>26</sup> Although initially revolutionary, it was soon replaced by PAP therapies in many patients. Although high-level controlled trials with surgery are exceedingly difficult, a small number of studies of uvulopalatopharyngoplasty and related procedures have been performed and indicate that it is effective in treating physiologic measures

of sleep, respiration, and quality of life. Additionally, population-based studies show that uvulopalatopharyngoplasty reduces the risk of motor-vehicle accidents and probably reduces cardiovascular risk, and large-population studies support that it reduces mortality and adult OSA. Although severe complications with uvulopalatopharyngoplasty are infrequent, adverse effects are common and include minor difficulties with swallowing, dry throat, sensation of foreign body, and increased sensation of phlegm.

A common application of uvulopalatopharyngoplasty is the treatment of snoring.<sup>32-40</sup> Various procedures, including laser uvulopalatoplasty, injection snoreplasty, placement of Pillar implants, and other palate-stiffening procedures have been described, and the outcomes of these procedures have differed in short-term studies but probably not in long-term studies. The procedures probably differ significantly in adverse effects. More invasive procedures may have higher short-term effectiveness but do so at the price of greater adverse effects. Fortunately, the trend of recent procedures is lower adverse effect rates.

The effectiveness of uvulopalatopharyngoplasty varies. Its use is controversial. The variability in effectiveness is only partially understood. Failure is probably due to inadequate airway diagnostics, failure of technique, and failure of application. Although much of the uvulopalatopharyngoplasty literature has focused on failure resulting from poor patient selection and obstruction at non-palatal sites, more recent analysis and data suggest that much of uvulopalatopharyngoplasty failure is technical, and failure often occurs at palatal sites following surgery. Newer more physiologic and reconstructive techniques have been advocated and developed, but to date are not in widespread use.

Diagnostic prediction of uvulopalatopharyngoplasty has been improved by the Friedman staging system for the oral cavity and oropharyngeal portions of the upper airway, which defines 4 stages, based on: tonsil size (1 to 4+); a modification of the Mallampati classification (1 to 4+); presence or absence of severe obesity (body mass index  $40 \text{ kg/m}^2$ ); and major craniofacial abnormalities.<sup>25</sup> The Friedman staging system identifies patients at risk of apnea who present with symptoms of snoring. It also demonstrates both positive and negative uvulopalatopharyngoplasty predictive values.

Friedman staging stratifies groups into favorable and unfavorable characteristics. Large tonsils (tonsil grades 3 and 4) are a favorable surgical characteristic. Small tonsils (tonsil grades 1 and 2) are unfavorable. The Mallampati classification is favorable when the tongue size is small for the mouth (grades 1 and 2, visualizing the free margin of the soft palate), and unfavorable when the tongue is large and fills the oral cavity (grades 3 and 4, free margin of palate not visible). Severe obesity (body mass index  $> 40 \text{ kg/m}^2$ ) is unfavorable. With the Friedman staging system, outcomes can be better stratified (Friedman stage

1 = 70% success, stage 2 = 40% success, and stage 3 = 10% success).

Conceptually, one of the major causes of failure of palate surgery is obstruction at other non-palatal sites. Hypopharyngeal airway narrowing has been implicated as a cause of surgical failure. A number of techniques have been directed at treating the hypopharyngeal airway,<sup>41,42</sup> including manipulation of skeletal structure and soft tissue. Procedures include partial glossectomy, ablational glossectomy, mandibular advancement, limited mandibular advancement, tongue and hyoid suspension procedures, lingual tonsillectomy, and limited laryngeal procedures. Only few data are available on any of these procedures. Few of the procedures have been compared, and procedure selection is often based on surgeon preference. Some procedures are selected on specific anatomical abnormalities (such as lingual tonsillectomy for lingual tonsil hypertrophy). Hypopharyngeal procedures are rarely definitive treatment when used alone. Mandibular advancement alone may successfully treat apnea, but this procedure treats both the hypopharyngeal and upper pharyngeal airway.

The most widely described methods of treating the hypopharynx have been the limited mandibular advancement procedures, which were developed and popularized at Stanford University. The procedures focus on moving the ligament insertion of the tongue anteriorly by moving the attachments to the bone. Numerous case series have reported success rates better than 60% with this treatment alone, but few prospective studies have been done. As alternatives to skeletal advancement to advance the soft tissues, a number of less invasive therapies using soft tissue anchors to advance the tongue have been proposed. These procedures are conceptually appealing because they have less morbidity and have demonstrated some surgical success, but their effectiveness is still to be determined. They do offer the potential to open the airway and decrease collapsibility during sleep following a minor surgical procedure.

An alternative to expanding the bony framework of the face is reducing the soft tissues surrounding the airway. A common technique to achieve this is tongue reduction surgery.<sup>43-46</sup> Both excision and ablation techniques have been described. Level I evidence demonstrates ablation glossectomy is effective in treating many measures of sleep apnea severity. The effects on physiologic measures such as AHI are only partial, however, so these techniques remain controversial and have not been widely adopted. Excision glossectomy techniques differ widely in their degree of surgical aggressiveness. In general, the more aggressive procedures reduce AHI more, but at the cost of greater adverse effects. Increasingly, the focus has been on development of glossectomy techniques with greater effectiveness but less morbidity and adverse effects. Newer techniques have also been developed to address hypertrophic lingual

tonsils, a historically difficult problem. Lingual tonsil enlargement has been a frequently overlooked treatable cause of OSA. Using plasma surgical techniques, these can be removed endoscopically, with much less morbidity than in the past.

Various hyoid bone suspension procedures have been described,<sup>47-49</sup> which may support lower pharyngeal and supraglottic tissues without the need of major skeletal reconstruction. As with other surgical procedures, success has been variable. In general, most studies support the view that these procedures can be performed with relatively low surgical morbidity. They are rarely performed alone and are usually used in combination with another procedure, such as uvulopalatopharyngoplasty.

### Maxillofacial Surgery

Maxillofacial surgery includes various skeletal procedures that advance the entire mandible or both the mandible and the lower maxilla. In moving the skeletal in closure, soft tissues are moved and the airway is enlarged. Success rates with maxillofacial surgery are high. Studies quote success rates greater than 90% and reducing AHI to low levels. However, although highly successful in improving polysomnographic outcomes, the clinical role of maxillofacial surgery remains unclear. For many patients with mild or moderate disease, such a major and costly intervention is poorly accepted. In patients with severe disease, especially those at high risk of complications or with craniofacial abnormalities, the use of maxillofacial surgery is more certain. Although maxillofacial surgery for sleep apnea has certain technical similarities to maxillofacial surgery done for dental and cosmetic reasons, it differs significantly from those procedures. The focus of treatment is airway, not dental or skeletal, metrics.

### Bariatric Surgery

Obesity is a major risk factor for sleep apnea. Obesity combines with abnormalities of craniofacial structure to create the structural variability that is a fundamental predisposing cause of OSA. In some patients, obesity is the primary cause of sleep apnea. In other patients, obesity is the primary factor contributing to the severity of disease. As would be expected, weight reduction may have a significant impact on the presence and severity of OSA. Unfortunately, behavioral weight loss programs are often disappointing. The highest success rate in achieving major weight loss is with bariatric surgery. Multiple techniques are available, and not all are equivalent. Relatively short-term studies in selected groups of patients found that bariatric surgery significantly affects AHI. The effect of weight loss may be life-saving. Such health improvements may be independent of sleep apnea, however. The sleep apnea

associated with morbid obesity may be a different physiologic process than traditional sleep apnea. Hypoventilation and rapid-eye-movement-associated apneas are much more common in this group. For patients with traditional sleep apnea, especially those with craniofacial abnormalities, bariatric surgery as a stand-alone treatment has not been advocated. Nonetheless, the need for effective weight reduction strategies in the sleep apnea population is an extraordinarily important goal.

### Summary

Non-PAP OSA therapies encompass a broad range of devices and surgical techniques. Mandibular advancement devices are used for both first and second-line therapy. Surgical therapies are less commonly used as first-line therapy. Both therapies are used as ancillary and salvage treatments following PAP failure. Effective treatment of sleep-disordered breathing and sleep apnea requires the use of multiple treatments to address the currently wide spectrum of disease. The future challenge is that of better defining which populations to treat with specific therapies. Additional challenges include maintaining effective treatment over a lifetime and minimizing adverse effects and complications.

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## Discussion

**Kapur:** Where do palate implants fit into the scheme of things?

**Woodson:** We did a randomized study<sup>1</sup> with 100 patients, and palate implants reduced snoring in some of those patients, but it had only a small impact on AHI. The nice thing about palate implants is that morbidity is extremely low, but the cost is very high, so I do them infrequently because the cost/benefit ratio isn't acceptable for my population in Milwaukee. Palate implants' ability to change the compliance of the airways is exciting, and if I could somehow integrate the tools that help me change compliance so I had to do fewer other interventions, that would be a huge advance. I find them conceptually favorable, but clinically their success rate in reducing bed partners' complaints about snoring is only about 50%, and I can't predict it very well. So I get very few people willing to roll the dice, given that the cost is usually between \$1,000 and \$2,000.

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**Kapur:** You mentioned how the combination of nasal procedures and oral appliances improved CPAP results. Is there any evidence that you can improve outcomes with oral appliances by relieving nasal obstruction? What is your opinion and practice on that?

**Woodson:** I think combining oral appliances with surgery is very promising. It's been proposed that this would be a good subject for a prospective controlled study. Some of the more reconstructive palate procedures we do are well tolerated and a lot less pain-

ful, and it's addressing an area that the oral appliances do poorly in. The oral appliances, on the other hand, do very well with the lower pharynx and the tongue base, and they fail when they're advanced too far. If we could get more oral appliances to work in that 50–70% of maximum protrusive range, I think the dental complications would be a lot less. It's certainly a promising area that warrants further assessment.

There's always the question with oral appliances and surgery: if you had just used oral appliances alone, would that have worked just as well? And that would have been my thought 3 or 4 years ago, before I did a lot of oral appliances, but now that I'm doing them more I'm seeing a lot more relapse and failure with oral appliances. And it's not in 6 months; it's more like 3 to 5 years. So I think there's a role for combining oral appliances and surgery.

**Carlin:** Could you expand on how reimbursement and coverage drive the use of oral appliances and/or surgery?

**Woodson:** In Wisconsin, currently, most major carriers will cover oral appliances after failure of CPAP. For many of the doctors and surgeons the hurdles required to get surgeries approved dissuade them from doing it. The reimbursement rates for some surgical procedures are not that high, compared to other things. So I think that's moved some surgeons away from doing surgery in adults. Reimbursement is a big issue. It's difficult to get it approved; insurance companies often specifically exclude it. Many of the newer devices and techniques—from tongue suspension devices to radio-frequency devices—aren't available to many patients because of exclusions. We need a lot more cost-effectiveness evaluations as we get more surgery data.

**Quan:** What about tracheostomies, somnoplasty, and lasers?

**Woodson:** Lasers I've never liked; they create scars, and a laser is nothing more than a medical blowtorch. In an area that is a highly delicate and with a sophisticated physiologic system, going in there and creating scars gets rid of snoring for a while, but I don't see a lot of use for lasers. Current radio-frequency technique has low morbidity, but in the ways we currently use it, it has relatively low effectiveness. It does have an effect, but for most people it's a relatively small effect. But it offers something for some people and it's an avenue for further research. It could do a lot more for patients than it's currently doing.

The morbidity of tracheostomy makes it something that's not performed very often. Traditional tracheostomy was associated with a lot of morbidity and complications, which makes it both socially and medically unacceptable to many patients. I'm not sure that it needs to be revisited. However, we had a patient who was too sick to be on the heart/lung transplant list who was using bi-level PAP all the time and he was still deteriorating, but we did a tracheostomy and within a few weeks he lost about 70 pounds and his medical condition improved enough that he no longer needed a heart/lung transplant and subsequently got the tracheostomy decannulated. A tracheostomy does things for some patients that isn't done by bi-level PAP, which raises the question of small fenestrated tracheostomies. Patients can wear a tracheostomy button and go swimming, as long as they put a catheter in it at night. I don't see a lot of patients who need traditional tracheostomy, but I wonder if there is any use for developing some method to bypass the upper airways.