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Radiofrequency techniques in the treatment of sleep-disordered breathing

Robert J. Troell, MD

Plastic Surgery Institute, 653 North Town Center Drive, Suite 308, Las Vegas, NV 89144, USA

The pathophysiology of sleep-disordered breathing is collapse or obstruction of the upper airway during sleep. This obstruction may occur at any site along the upper airway passages to include the nasal cavity, nasopharynx, oropharynx, hypopharynx, and larynx. Diagnosis requires a nocturnal polysomnogram to document the presence and severity of sleep-disordered breathing. The presurgical evaluation includes a comprehensive head-and-neck physical examination, fiberoptic nasopharyngoscopy, and lateral cephalometric to determine the site or sites of upper airway obstruction. This analysis is essential in directing surgical therapy in a site-specific approach. Numerous surgical procedures have been developed to address each of these sites of obstruction and have offered the surgeon an armamentarium of options, each with its own set of advantages, disadvantages, and success rates.

Radiofrequency (RF) tissue volumetric reduction was developed to reduce tongue-base obstruction by way of an outpatient, minimally invasive procedure using local anesthesia and causing minimal discomfort with a low complication rate. The research to bring this technique to fruition demonstrated the usefulness of temperature-controlled RF for other areas of the upper airway. Radiofrequency may be used to treat nasal obstruction by reducing the size of the inferior turbinate. Soft palatal reduction is an alternative treatment for primary snoring, upper airway resistance syndrome, and mild obstructive sleep apnea syndrome. The current medical information reviewing the use of RF in tissue volumetric reduction in the upper airway for nasal obstruction, primary snoring, and sleep-disordered breathing is reviewed.

E-mail address: rjtroell@aol.com

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Background and biophysics of radiofrequency

The RF energy ablation of soft tissues has been applied successfully, in the past, to humans by specialists in the fields of cardiology, neurology, oncology, and urology [1–4]. Temperature-controlled RF delivers RF at 460 kHz by a high-frequency alternating current flow into the tissue, creating ionic agitation. This ionic agitation heats the tissue and as the temperature rises higher than 47°C, protein coagulation and tissue necrosis ensue. In the first study evaluating RF for sleep-disordered breathing, a porcine study [5] evaluated the relationship of lesion size to total RF energy delivery and subsequent tissue volume reduction. The maximum lesion size is two thirds the diameter of the RF electrode or approximately 7 mm, and the maximum length of the lesion is between 1.5 to 1.75 cm (Fig. 1). Heat is transported by way of conduction to tissue farther away from the electrode and extends the size of the lesion. The computer algorithm controls the power to maximize the lesion size, resulting in tissue coagulation with no charring. The healing process was analyzed through a serial histologic analysis in the porcine model and demonstrated favorable wound healing with a well-defined lesion after 24 hours, with an acute inflammatory response and edematous response. Collagen deposition begins approximately 12 days after injury, and at 3 weeks, chronic inflammation, fibrosis, and tissue volume reduction from scar contracture occur.

The first human clinical study evaluating the use of RF was in the soft palate for snoring and sleep-disordered breathing, and the investigators

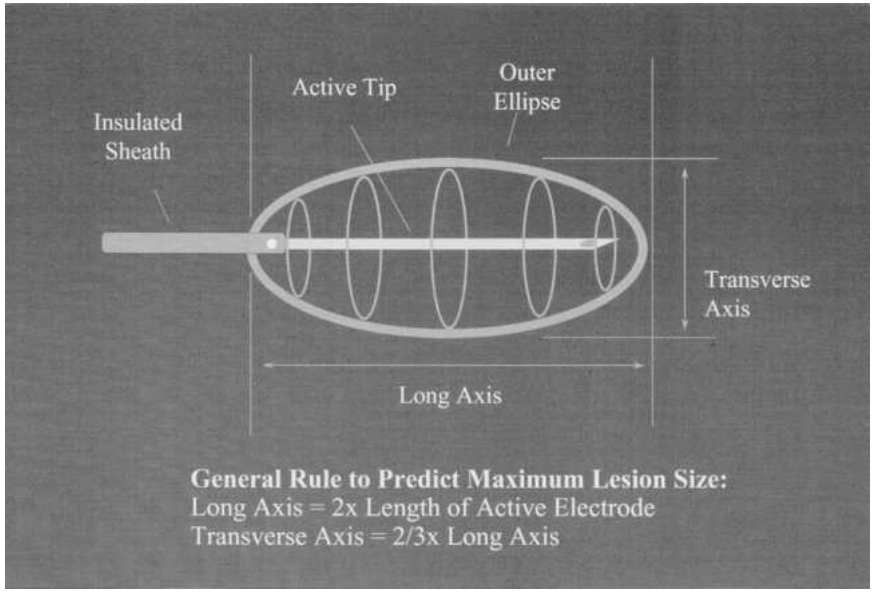

Fig. 1. Biophysical properties of RF.

concluded that the technique was safe with minimal complications. Bleeding, infection, speech disturbances, and swallowing problems were not observed. Results of RF for snoring reduction revealed that the pretreatment snoring level was reduced by an overall mean of 77% [6]. The safety and efficacy reported in the previous animal study were confirmed in the human palate.

Radiofrequency device

The medical RF device (Gyrus ENT LLC, Memphis, TN) is delivered at 460 kHz using an RF generator with custom-fabricated needle electrodes. The essential RF energy parameters of power (watts), temperature limits (Celsius), resistance (Ohms), treatment time (seconds), and total energy delivery in joules (watt × seconds) are controlled by a computer algorithm. The necessary feedback for temperature adjustment is provided by multiple microthermocouples embedded along the electrode. The 22-gauge RF electrodes have a 10-mm active tip. A protective thermal sheath is used on the proximal portion of the electrode to eliminate surface damage. The maximum temperature gradient is regulated to less than 90°C, with a target temperature between 80°C to 85°C. The computer algorithm maximizes the RF lesion size (Fig. 2).

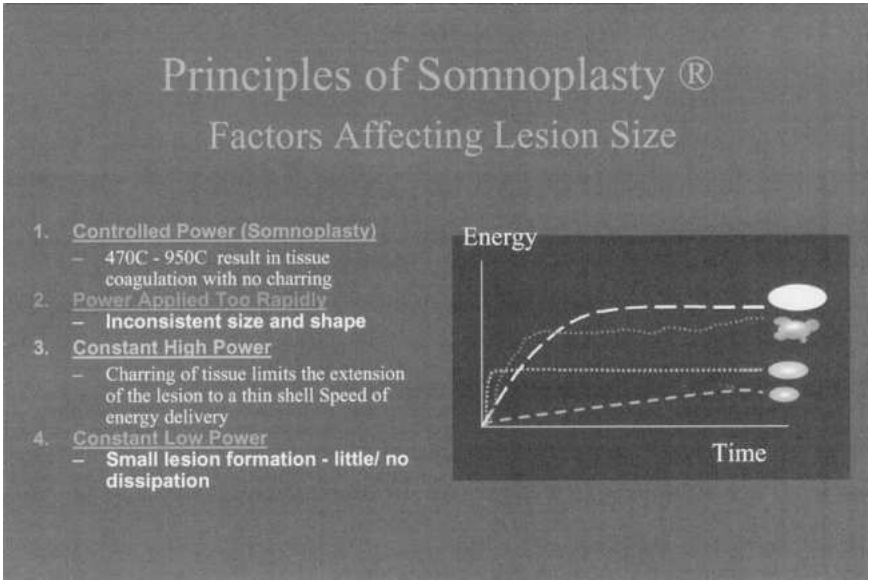

Fig. 2. Radiofrequency factors affecting lesion size.

Treatment philosophy

A full disclosure to the patient describing the available procedures, the success rates, the potential risks and complications, and the possibility of a staged surgical approach or multiple procedures fathers good medicine and a confident patient-physician relationship. The extent of surgery is mediated by the patient's acceptance, severity of symptoms, severity of objective obstruction, level of upper airway collapse, and the severity of the site of obstruction. The philosophy of "treatment to cure" mandates follow-up on all procedures. The systemic presurgical evaluation in sleep-disordered breathing identifies areas of airway collapse or obstruction, logically directing surgical treatment to these site-specific areas.

Presurgical evaluation

Although the etiology of sleep-disordered breathing is still poorly understood, it is clear that there exist specific anatomic abnormalities that obstruct the upper airway during sleep. The three major areas of obstruction are the nose, the palate, and the hypopharynx. Fujita et al [7] described the areas of collapse as retropalatal (type I), retropalatal and retrolingual (type II), or solely retrolingual (type III). An anatomic obstruction at one or all of these levels may create increased airway resistance and varying degrees of sleep-related obstruction.

It is impossible to direct therapy logically without isolating the area of obstruction; unfortunately, it is not always possible preoperatively to define the exact area of obstruction. There are numerous radiologic tests available to aid in determining the suspected sites of obstruction preoperatively. The author's presurgical evaluation includes a nocturnal polysomnography, a comprehensive head-and-neck physical examination, fiberoptic nasopharyngoscopy with the Müller maneuver, and a lateral cephalometric radiograph.

Classification of disease severity

The understanding of the classification of sleep-disordered breathing is important in communicating with other health professionals.

Primary snoring

An apnea-hypopnea index (AHI) of less than five events per hour of sleep with no oxygen saturation (SaO_2) less than 90% during sleep or a peak negative end-inspiratory esophageal pressure or inspiratory nadir (Pes) of less negative than -10 cm H_2O. These patients do not report excessive daytime sleepiness.

Upper airway resistance syndrome

An AHI of less than five events per hour of sleep with an SaO_2 of greater than or equal to 90% during total sleep time and an inspiratory nadir Pes more negative than -10 cm H_2O. Patients without an esophageal pressure monitor displayed frequent arousals associated with snoring or increased diaphragmatic electromyogram activity. Two thirds of these patients snore, and all have an accompanying complaint of excessive daytime sleepiness.

Obstructive sleep apnea syndrome

An AHI of greater than five events per hour of sleep. These patients usually have accompanying oxyhemoglobin desaturations below 90% and neurobehavioral symptoms, most commonly excessive daytime sleepiness.

Review of nasal obstruction

Nasal obstruction may be the primary complaint or it may be a factor in producing primary snoring or sleep-disordered breathing. The pathophysiology of nasal obstruction causing upper airway collapse is an increased nasal resistance, an increased velocity of air flow, an increased negative intraluminal pressure, and resultant partial obstruction and vibration of tissues of the upper airway predisposed to collapse, including the soft palate, tongue, and lateral pharyngeal walls.

Nasal obstruction may be caused by nasal rim or nasal valve collapse, septal deviation, adenoid hypertrophy, nasal polyps or tumors, and inferior turbinate hypertrophy. Patients with mild sleep-disordered breathing with an AHI less than 15 may be treated successfully with nasal surgery alone. Nasal surgery may improve the sleep study parameters in patients with obstructive sleep apnea of moderate or severe disease, but it will not successfully treat these patients. If inferior turbinate hypertrophy is the cause of the nasal obstruction, RF is an excellent treatment modality. The technique can be performed on an outpatient basis with local anesthesia, with a minimal risk of post-treatment complications and minimal discomfort.

Performing nasal surgery simultaneously with other procedures of the upper airway in patients other than those with mild disease may increase the risk of airway compromise. The production of significant postoperative edema or the use of nasal packing prevents the use of nasal continuous positive airway pressure (CPAP), which is used to stent the airway open during sleep-induced upper airway collapse. Nasal septal deviation, turbinate hypertrophy, and nasal ala and valve collapse are corrected by septoplasty, turbinoplasty, and nasal valve cartilage implants, respectively. Adenoid hypertrophy is treated by adenoidectomy.

Nasal obstruction may be addressed in a staged fashion 6 to 8 weeks postoperatively from the first phase of airway reconstruction to allow

adequate healing of the procedures most likely to remedy their disease. It also may be performed initially to provide a patient with the best possibility to tolerate nasal CPAP in those with significant nasal obstruction. In patients with mild severity of sleep-disordered breathing, nasal surgery may be combined with soft palatal surgery, but this approach is not recommended in those patients with moderate or severe disease, because of the risk of the patient not being able to use nasal CPAP in the immediate postoperative period, when the upper airway swelling is at its height.

The rationale for nasal surgery is to improve nasal patency, which establishes physiologic breathing and minimizes oral breathing during sleep. Oral breathing during sleep causes the tongue to be positioned posteriorly, increasing the risk of upper airway obstruction. Also, resolving nasal obstruction reduces nasal resistance and improves the negative intraluminal pressure, which generates upper airway collapse.

Inferior turbinate radiofrequency indications

Nasal obstruction is caused by inferior turbinate enlargement. There are numerous other methods of turbinate reduction that are available alternatives, including the following:

Inferior turbinate reduction techniques
1. Traditional total turbinectomy
2. Traditional partial turbinectomy
3. Submucous resection
4. Submucous diathermy
5. Cryotherapy
6. Laser vaporization
7. Coblation
8. RF

Radiofrequency can be used along the entire length of the inferior turbinate, depending on the location and magnitude of the turbinate hypertrophy. This technique has been attempted by the author for the middle turbinate, but because the thickness of the submucosa is much thinner than the inferior turbinate, direct surgical excision is the preferred technique for a concha bollosum or middle turbinate hypertrophy.

Surgical technique of inferior turbinate radiofrequency

Radiofrequency of the inferior turbinate can be performed on an outpatient basis or in the operating room associated with other operative procedures, such as a nasal septoplasty. In an outpatient setting, the patient is placed in the sitting position. The anterior nasal cavity is anesthetized with a topical local anesthetic without epinephrine and then cotton pledgets with the same solution are placed along the anterior and middle aspects of the

inferior turbinate. After approximately 5 minutes, the anterior aspect of the inferior turbinate is injected with between 3 to 5 mL of 1% or 2% lidocaine without epinephrine. The injection provides anesthesia and enlarges the diameter of the turbinate to prevent mucosal injury while the RF energy is being delivered. Between 350 to 550 J of energy are delivered to the anterior and, if required, middle aspects of the inferior turbinate. After the probe is removed, a cotton pledget with oxymetazoline (HC 0.05%) is placed along the inferior turbinate for hemostasis.

Inferior turbinate radiofrequency results

The initial human study [8] evaluating the efficacy of RF for the treatment of nasal obstruction caused by inferior turbinate hypertrophy was a prospective nonrandomized study of 22 adult volunteers (18 men). The mean age was 41.1 years $\pm$ 10.7. The subjects were diagnosed with nasal obstruction solely from inferior turbinate hypertrophy that had failed to respond to conservative medical management. A mean RF energy delivery per treatment was 382 J $\pm$ 102, with a mean temperature of 77°C $\pm$ 8.4 and mean duration of RF energy of 102.9 minutes $\pm$ 57. A subjective visual analog score (VAS) of nasal obstruction was completed 8 weeks after treatment, with 21 of 22 patients (95%) having improved nasal symptoms. The patients experienced mild edema for 24 to 48 hours after treatment, and 20 of 22 (91%) reported post-treatment discomfort, with a visual analog pain score of 1 $\pm$ 1.8. Three subjects (14%) used analgesics, with a total of six 500-mg acetaminophen tablets administered. No bleeding, crusting, dryness, adhesions, or infections were noted.

Additional outcome studies have revealed similar improvement in nasal patency. Utley et al [9] evaluated 10 patients using a 15-mm RF probe (no longer available), with two lesions per turbinate. A mean RF energy delivery on the left turbinate of 492 J $\pm$ 72 and 429 J $\pm$ 104 and on the right of 412 J $\pm$ 103 and 465 J $\pm$ 13 revealed a subjective improvement of 75% on the left and 68% on the right. Eight of nine patients no longer required allergic medications, and no narcotics were required postoperatively. Smith et al [10] evaluated 11 patients using a 10-mm RF probe, with one lesion per turbinate. The mean RF energy delivery on the left of 423 J $\pm$ 17 and on the right of 428 J $\pm$ 13 revealed an improvement in subjective nasal obstruction VAS from 7.5 to 3.3. Six of 11 patients reported mild pain during the treatment, but only one acetaminophen tablet was administered.

Powell et al [11] evaluated the use of inferior turbinate reduction to improve compliance with nasal CPAP in patients with nasal obstruction. The double-blinded, prospective study evaluated 22 patients (12 women) with a mean age of 54.3 years, body mass index of 29.3 kg/m^2, and a mean AHI of 33.5. A mean of 413 J of RF energy was delivered to each inferior turbinate. The investigators discovered an overall reduction in size of the inferior turbinate by 27% on a four-point scale (n = 17) compared with the

VAS subjective patient improvement of nasal patency of 48%. Tolerance to nasal CPAP improved by 28.9% (VAS, 4.9–6.3) compared with the placebo group (n = 5) who decreased CPAP use by 10.4% (VAS, 4.4–3.3).

Inferior turbinate radiofrequency side effects

The post-treatment findings after inferior turbinate RF include nasal swelling for 24 to 72 hours. No wound care or limitation of daily activities is necessary. Narcotic analgesics are not required, and few patients administer acetaminophen. Bleeding, crusting, dryness, adhesions, and infection are rare complications. Final reduction is complete in 3 to 4 weeks, and re-treatment can be performed if nasal obstruction persists.

Rhee et al [12] evaluated nasal function after RF treatment to the inferior turbinate. No ciliary dysfunction was appreciated using the saccharin transit time and ciliary beat frequency tests. Butanol threshold testing revealed improved olfaction, probably from improved nasal patency. Mucous rheologic properties were unchanged. Improved nasal obstruction was compared with laser vaporization and revealed an improvement of 81.3% in the RF group and 87.5% in the laser group.

Inferior turbinate radiofrequency: conclusions

Inferior turbinate RF is a technically simple, minimally invasive procedure that can be performed as an outpatient procedure under local anesthesia with improved nasal obstruction, minimal side effects, and unchanged ciliary and mucous properties.

Review of soft palatal obstruction

Primary snoring, upper airway resistance syndrome, obstructive sleep apnea syndrome, and obesity-hypoventilation syndrome encompass a spectrum of sleep-related upper airway obstruction. Patients with primary snoring seek treatment because of the social annoyance and disruption of sleep of a bed partner. The etiology of primary snoring in approximately 85% of patients is partial airway obstruction from soft palatal redundancy causing tissue vibration, with resultant sound production [13].

The initial procedure devised to address primary snoring was the uvulopalatopharyngoplasty designed by Ikematsu [13] and modified by Fujita et al [7,14] and Simmons et al [15]. Unfortunately, the procedure usually is performed under general anesthesia, produces significant postoperative pain, and has short- and long-term failures for both snoring resolution and persistent obstructive sleep apnea. There have been numerous other soft palatal reduction procedures that have been discovered (see following list); unfortunately, each procedure has its limitations and disadvantages.

Soft palatal reduction procedures
1. Uvulopalatopharyngoplasty
2. Laser-assisted uvulopalatoplasty
3. Uvulopalatal flap
4. Cautery-assisted palatal-stiffening operation
5. Transpalatal advancement
6. Coblation
7. Injection snoreplasty
8. RF

Alternatively, since the early 1980s, there have been numerous nonprescription, noninvasive medical management options, including nasal CPAP, oral appliances, nasal appliances, and medications. There are more than 300 patented appliances for snoring and sleep-disordered breathing. These devices have yielded either limited success or are fraught with low compliance rates. Minimally invasive procedures, including RF volumetric tissue reduction of the soft palate, injection snoreplasty, and coblation, have gained favor with both patients and surgeons because of the ability to perform them as an outpatient procedure under local anesthesia with minimal posttreatment discomfort, a limited complication rate, and good surgical results.

Soft palatal radiofrequency indications

Most patients with primary snoring and sleep-disordered breathing are candidates for surgical intervention. Patients must be medically and psychologically stable and wish to undergo a surgical procedure. Patients should be informed of the treatment philosophy.

Surgical indications for soft palatal RF include the following: (1) socially disruptive snoring; (2) neurobehavioral derangements and excessive daytime sleepiness caused by sleep fragmentation as a result of soft palatal collapse in upper airway resistance syndrome and mild obstructive sleep apnea syndrome—this neurocognitive dysfunction may be confirmed to be due to upper airway collapse with resolution of these symptoms by a nasal CPAP trial; (3) mild sleep-disordered breathing with an AHI or respiratory disturbance index less than 20, with mild soft palatal redundancy or tonsillar hypertrophy; and (4) patients with persistent snoring after other soft palatal reduction procedures have been unsuccessful, such as laser assisted uvulopalatoplasty (LAUP), uvulopalatopharyngoplasty, and uvulopalatal flap (UPF).

Soft palatal radiofrequency limitations

Patients with a long, thick uvula most likely will require sharp amputation of part or all of the uvula to treat a redundant soft palate successfully. Patients with a thin, soft palate, especially the banding between the posterior tonsillar pillar and the uvula, are poor candidates for RF because the mean ablative

lesion diameter is 7 mm. The technique will result in a perforation of the soft palate or lateral scarring and contraction of this band of tissue, narrowing the oropharyngeal introitus. Patients with other than mild sleep-disordered breathing most likely will require other surgical procedures, especially those addressing the hypopharynx, to treat their disease severity effectively.

Soft palatal radiofrequency surgical technique

The soft palate is sprayed with 20% benzocaine as a topical anesthetic. A local anesthetic as a gel (2% lidocaine) is placed on a cotton-tipped applicator at the initial soft palatal injection site. A 27- or 30-gauge needle is used to inject 2.0 mL of 0.25% bupivacaine (Marcaine) 1:100,000 with epinephrine at this superior palatal midline site. The local anesthetic diffuses over approximately 5 to 7 minutes caudally, making additional inferior and lateral injections nearly painless. The soft palate from the uvular base to the posterior nasal spine and the paramedian area extending approximately 2 cm laterally from the midline is selected for treatment.

The temperature-controlled RF energy delivery maximizes the size of the lesion compared with non-temperature-controlled RF delivery systems (Fig. 3). A 22-gauge RF needle electrode (10-mm active length with a 10-mm protective sheath) in a custom-fabricated device allows placement of the electrode under the palatal mucosa in the area selected for treatment. This electrode is bent with a crimping tool on an individual patient basis to contour to the curvature of the soft palate. Radiofrequency energy then is

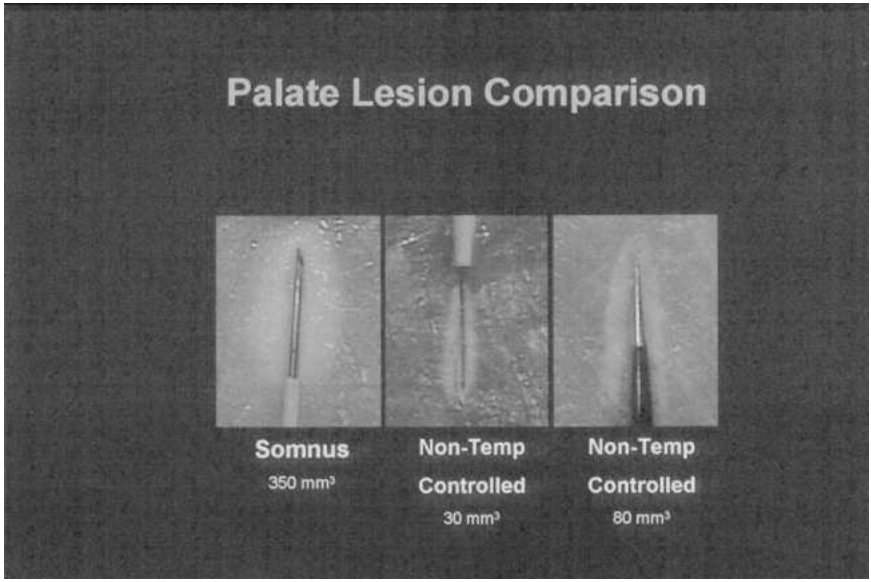

Fig. 3. Soft palatal lesion size comparison: temperature- and non–temperature-controlled RF.

delivered for 60 to 170 seconds. Four potential sites of treatment during each treatment are selected, dependent on the size of the soft palate. The recommended maximum amount of energy delivered to the superior midline soft palate is 750 J; the recommended maximum amount to the uvular base and the paramedian areas is 350 J. Patients who previously have undergone other palatal procedures can tolerate higher energy levels laterally, up to 550 J, with limited risk of mucosal erosion or perforation. An assessment of the thickness of the soft palate should be performed before treatment to determine the maximal safe dose of RF energy and to limit the risk of soft palatal perforation.

In patients with a long uvula, sharp amputation of the uvular tissue up to the muscle reflection may improve the success rate without any additional post-treatment discomfort. If the muscle is cut, then the patient experiences heightened pain and may require narcotic analgesic administration. Non-steroidal anti-inflammatory medications are an excellent choice for post-operative pain, especially the new generation of Cox-II inhibitors. These medications have the same pain relief as hydrocodone combined with acetaminophen, with the anti-inflammatory properties to relieve swelling.

Patients who have a prominent gag reflex may benefit from a pretreatment 10- to 20-mg oral dose of oral diazepam. Although they are not necessary, oral antibiotics or corticosteroids may be used postoperatively. The author does not use antibiotics after soft palatal RF and has not identified any patients with soft palatal cellulitis. A short course of oral methylprednisolone (Medrol), for 3 to 5 days, may be used to limit soft palatal edema, especially in those patients with a long uvula or thick soft palate.

Soft palatal radiofrequency results

The initial human soft palatal RF study [6] revealed a reduction of snoring by 77%, in 22 subjects with a pretreatment subjective snoring VAS mean score of 8.3 ± 1.8 and a post-treatment mean score of 1.9 ± 1.2. The mean number of treatment sessions per patient was 3.6 ± 1.2, with a total mean of 5 ± 2 sites and mean RF energy delivered per treatment session of 688 ± 106 J. A follow-up study [16] 12 to 18 months (mean, 14 months) later reported that subjective snoring scores relapsed by 29% overall. Thirteen patients (59%) reported continual success without relapse of snoring or daytime sleepiness. Nine patients (41%) noted relapse of snoring from 2.1 ± 1.1 to 5.7 ± 2.7. Eight of these patients underwent further RF sessions with a reduction of snoring from 5.8 ± 2.9 to 3.3 ± 3.1. Six patients received one treatment session, and two patients received two treatment sessions. The mean RF energy delivered per treatment session was 786 ± 114 J, and each patient received a minimum of one and a maximum of three separate RF ablations per treatment session. Overall, 21 of the 22 patients (95%) were satisfied with the procedure and would repeat it if necessary.

A prospective, nonrandomized multicenter study [17] of 113 patients validated the use of RF applied to the soft palate for snoring reduction. The snoring VAS scores went from a mean of 7.8 ± 2.1 pretreatment to 3.2 ± 2.3 after treatment by delivering a mean of 1977.6 ± 887 J with a mean of 2.4 ± 1.2 treatment sessions per patient. The average follow-up period after treatment was 8 weeks.

Another prospective, nonrandomized study [18] evaluated 43 patients undergoing soft palatal RF and revealed a 71% reduction of subjective snoring. Nineteen patients had a single midline lesion created, with RF delivering a mean of 698 ± 52 J per treatment, a total mean of 2165 ± 1057 J per patient with a mean of 3.3 ± 1.6 treatment sessions per patient. Reduction in subjective snoring occurred from 7.8 ± 1.8 to 2.3 ± 2.1 (70.5%). Twenty-four patients had three separate lesions, one midline and left and right lateral sites, per treatment session, with RF delivering a mean of 1254 ± 191 J per treatment, a total mean of 2196 ± 1158 J per patient with a mean of 1.8 ± 0.9 treatment sessions per patient. Reduction in subjective snoring occurred from 8.9 ± 1.7 to 2.5 ± 0.8 (71.9%).

Another study comparing single-lesion versus multilesion soft palatal RF in 47 patients [19] revealed a more-than-twice-as-likely cure rate for snoring after two RF treatment sessions, with 61% of multilesion patients and 25% of single-lesion patients being treated successfully. The authors concluded that multilesion RF, using higher energy levels per treatment, is safe and increased the efficacy without increasing complications relative to single-lesion therapy.

A study of 12 patients [20] undergoing midline RF to the soft palate revealed an improvement of subjective snoring from 8.3 ± 2.1 to a post-treatment snoring level of 2.1 ± 1.4 or a 75% reduction of snoring. These patients required an average of 2.3 treatment sessions per patient, with between 495 and 693 J per treatment session. The mean follow-up period was 5.1 weeks after the final RF procedure. The available soft palatal RF studies reveal a 70% to 77% subjective snoring reduction, with minimal pain and complications.

The author prefers to deliver enough energy per treatment session as possible without producing mucosal erosions, significant uvular and soft palatal swelling, and post-treatment pain to require narcotic analgesics. One or two lesions are created at the initial treatment session, and the amount of soft tissue swelling and post-treatment subjective pain is assessed. If the patient experiences minimal swelling and pain, then high midline palatal, uvular base, and paramedian lesions are created at the second treatment session as dictated by the palatal anatomy.

Soft palatal radiofrequency complications

The advantage of the RF technique of the soft palate, which is used principally for primary snoring, is the minimally invasive nature of the

procedure. Most subjects experience restless sleep on the first post-treatment night in response to palatal swelling and mild discomfort.

The post-treatment discomfort of RF of the soft palate was compared with laser-assisted uvulopalatoplasty and uvulopalatopharyngoplasty [21]. The mean number of days with pain after RF, LAUP, and uvulopalatopharyngoplasty was 2.6, 13.8, and 14.3, respectively. The mean number of days requiring narcotic pain medication for RF, LAUP, and uvulopalatopharyngoplasty was 0.2, 11.8, and 12.4, respectively, whereas the total narcotic equivalent was 0.3, 7.4, and 29.6 days, respectively. Soft palatal RF produced significantly less post-treatment pain than either LAUP or uvulopalatopharyngoplasty, making this procedure well tolerated by patients.

The discomfort experienced with this procedure is related to the number of lesions, the amount of energy delivered, and the presence of a mucosal injury. Powell et al's initial study [6] revealed a mucosal injury rate of 7.6%, with other studies revealing mucosal injury rates as high as 45% [18]. Except for superficial mucosal injuries, when the mucosa is disturbed, patients experience increased discomfort. Palatal fistulas or perforations also may occur. This complication can be avoided by decreasing the amount of energy delivered in thin soft palates and by refraining from placing the RF probe lateral to the uvular and levator veli palatini muscles (Fig. 4).

Uvular slough also may occur, which can lead to increased post-treatment pain. Because the goal of RF therapy is to shrink and tighten the soft tissue of the soft palate, this incident is not a complication unless significant pain is created. Decreasing the amount of energy delivered to the uvular base and the distance away from the uvular base may aid in diminishing this occurrence.

Most studies evaluating soft palatal RF did not note bleeding, infection, speech disturbances, or swallowing problems. Soft palatal swelling may produce a globus sensation, but it usual resolves in 2 to 4 days. Dysphagia, velopalatal insufficiency, and nasopharyngeal stenosis have not been reported. Except for some post-treatment mild discomfort, swelling, and a low incidence of mucosal erosions, complications are minimal.

Overview of hypopharyngeal obstruction

The pathophysiology of sleep-disordered breathing is collapse or obstruction of the upper airway during sleep. This obstruction may be partly or entirely due to the hypopharynx, and there are preoperative factors that may suggest the hypopharyngeal area as a site of collapse (see following list) [22].

Factors influencing hypopharyngeal obstruction

1. Morbid obesity (body mass index >31 kg/m^2)
2. Mandibular skeletal deficiency (sella-nasion-supramentale (SNB) $<76^\circ$)

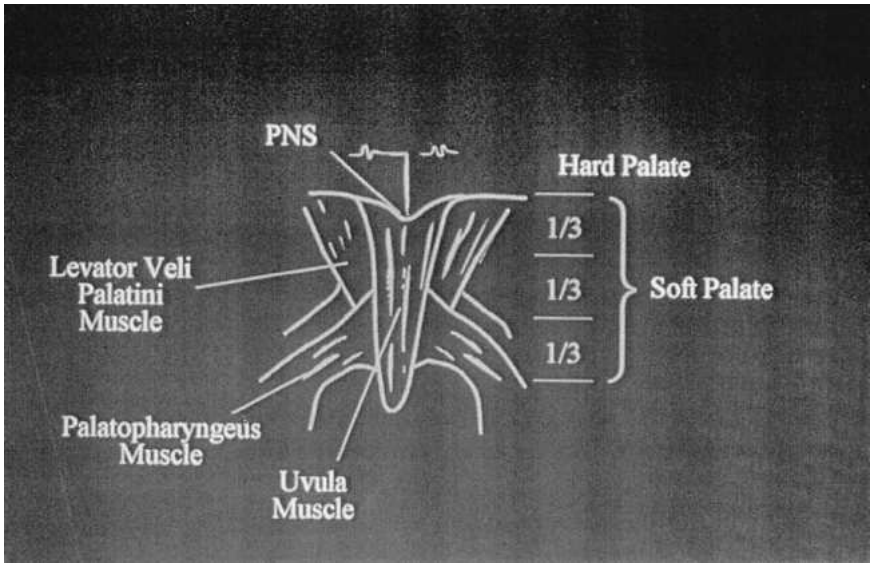

Fig. 4. Soft palatal musculature anatomy. PNS – Posterior Nasal Spine.

3. Severe sleep-disordered breathing (AHI >40)
4. Minimal soft palatal redundancy
5. Retrodisplaced tongue or lateral wall collapse on nasopharyngoscopy
6. Narrowed posterior airway space on lateral cephalometric radiograph (posterior airway space <11 mm)

Once the hypopharynx is suggested to be a site of collapse of the upper airway in sleep-disordered breathing, determining reconstructive procedure is the next step (see following list). Tongue-base RF is an alternative treatment to decrease the volume of the tongue and to improve the posterior airway space.

Hypopharyngeal surgical procedures
1. Genioglossus advancement
2. Hyoid myotomy and suspension
3. Partial glossectomy or lingualplasty
4. Repose tongue suspension
5. Maxillomandibular advancement
6. Tongue-base RF

Tongue-base radiofrequency indications

Patients diagnosed with obstructive sleep apnea for whom the preoperative evaluation suggests tongue-base collapse as the cause of the hypopharyngeal obstruction are candidates for RF. Patients need to be in

stable medical condition, understand that the procedure is a multiple-stage process, and appreciate the potential complications. Post-treatment airway concerns and requirements for monitoring need to be addressed by the surgeon.

Patients with complaints of dysphagia or dysarthria preoperatively may undergo a modified barium-swallow or speech-therapy evaluation before considering these therapeutic options. Those patients with underlying diabetes mellitus should be counseled regarding the increased risk of tongue abscess formation. Two treatment approaches exist: (1) performing RF alone and (2) performing RF with other base-of-tongue procedures, such as the genioglossus advancement or hyoid suspension procedures.

Tongue-base radiofrequency technique

The technique can be performed as an outpatient or an inpatient procedure in a monitored setting. Depending on the severity of the patient's sleep-disordered breathing, post-treatment airway protection with nasal CPAP or a tracheotomy should be considered. The oral cavity is prepared with 0.12% oral chlohexidene (Peridex), and either oral or parenteral cephalexin is administered before placing the electrode. If under local anesthesia, the tongue is sprayed with 20% benzocaine as a topical anesthetic. A local anesthetic as a gel (2% lidocaine) is placed on a sterile, cotton-tipped applicator at the tongue-injection sites. A 25- or 27-gauge needle is used to inject 5.0 mL of 0.25% bupivacaine (Marcaine) with 1:100,000 epinephrine into each site. A different sterile needle is used at each site of injection. Treatment sites should be spaced a minimum of 1.5 cm apart. Lingual nerve blocks may be used but are not necessary. The author does not inject saline into the treatment area because there is no study to date verifying the increased tissue destruction with this method. There is an increased risk of infection with each additional injection at the lesion site by bringing potential superficial tongue debris and bacteria into the area to be ablated.

A 22-gauge RF needle electrode (10 mm of active length with a 10-mm protective sheath) in a custom-fabricated device allows placement of the electrode under the superficial tongue musculature in the area selected for treatment. This electrode may be additionally bent on an individual patient basis to contour to the curvature of the tongue. Continual pressure on the electrode and visualization that the insulation sheath is not retracting out of the tongue tissue reduce the risk of superficial tissue injury. A single- or dual-channel tongue probe may be selected to deliver the RF energy. If the dual-channel probe is selected, the author prefers to bend the probe proximal to the retractable sheath to separate the two RF lesions farther apart. Potential sites of treatment include the midline, paramedian, and ventral tongue areas. As an inpatient procedure, up to 750 J in four sites, with 3000 J total delivery, can be administered safely without significant

tongue swelling, dysphagia, or postoperative pain. Documenting the specific tongue sites of treatment is prudent so that future RF tongue sessions do not place the RF electrode in previously ablated tongue tissue.

In an outpatient setting, it is prudent to deliver only two sites of RF energy secondary to the risk of postoperative swelling and airway compromise in an unmonitored setting at home. Also, too much RF energy can result in dysphagia to the point at which oral intake of fluid is impaired, necessitating a hospital admission for hydration. The recommended maximum amount of energy delivered per site is between 750 to 1000 J. The amount of swelling and postoperative discomfort significantly increases with RF energy delivered at more than 750 J per treatment site. If tongue-base RF is being performed simultaneously with other base-of-tongue procedures such as the genioglossus advancement, decreasing the amount of RF energy may be warranted to prevent severe floor-of-mouth and tongue swelling, which may encroach on the airway. Nonsteroidal anti-inflammatory medications are an excellent choice for postoperative pain, especially the new generation of Cox- II inhibitors. These medications have the same pain relief as hydrocodone combined with acetaminophen, with the anti-inflammatory properties to relieve swelling. Occasionally, narcotic analgesia is necessary.

Patients with a prominent gag reflex who are undergoing the procedure under local anesthesia may benefit from a pretreatment 10- to 20-mg dose of diazepam. Although they are not necessary, corticosteroids may be used postoperatively. The author does not use methylprednisolone because of the concern of tongue abscess formation. If postoperative swelling and airway compromise are of concern, using nasal CPAP, monitoring the patient on an inpatient basis with pulse oximetry, or intensive care monitoring is preferred.

Tongue-base radiofrequency results

In the first report evaluating RF for sleep-disordered breathing, a porcine study [5] evaluated the relationship of lesion size to total RF energy delivery and subsequent tissue volume reduction. The study showed that tongue musculature volume could be reduced safely using RF energy in a precise and controlled manner with minimal risk of mucosal injury or infection.

The first human tongue pilot study [23] investigated the feasibility, safety, and possible efficacy of RF in the treatment of sleep-disordered breathing. Eighteen patients who were treated incompletely for sleep-disordered breathing with other upper airway reconstruction procedures enrolled in the study, and all of them underwent at least a uvulopalatopharyngoplasty. The mean preoperative AHI of 39.6 improved to a mean of 17.8 (55%) after treatment, the mean apnea index of 22.1 improved to a mean of 4.1 (80%), and the mean preoperative SaO_2 nadir of 81.9% improved to 88.3% (12%) after treatment. The mean energy delivery per treatment session was 1543 J,

for a mean total energy delivery of 8490 J. Tongue volume, as assessed with magnetic resonance imaging, was reduced by 17%, with an improvement of the posterior airway space by 15%. Speech and swallowing, as evaluated by VAS scores, were unchanged. Pain was controlled by oral hydrocodone for up to 4 days. The only complication in 181 treatment sessions was one tongue abscess, which resolved after incision and drainage.

A long-term follow-up study [24] of these same patients revealed that 16 patients completed the follow-up at a mean of 28 months after the initial treatment. Sleep studies were performed using a new nasal cannula by Sleep Solutions (Redwood City, CA) that can quantitate airflow. This technique is believed to be more accurate in identifying hypopneas. The follow-up data revealed that the apnea index remained the same at 5.4, but the overall AHI relapsed to 28.7 and the SaO_2 nadir relapsed to 85.8%. There were no changes in the quality-of-life scale (SF-36), Epworth sleepiness scale, or speech or swallowing VAS scores. The conclusion was that the success of tongue-base RF may reduce with time with the primary relapse in the hypopnea index. The limitation of the study was the use of different monitoring devices to document hypopneas.

A prospective, nonrandomized study [25] evaluated 10 sleep apneic patients who underwent uvulopalatopharyngoplasty and nasal surgery (when indicated), along with tongue-base RF under general anesthesia. Two additional RF sessions were performed postoperatively in an outpatient setting. Nine of the 10 patients received a cumulative dose of approximately 12,000 J. The final patient received only the initial 4000 J of RF energy. Five of these patients were treated successfully, defined as an AHI less than 20 with at least a 50% reduction in AHI. The mean preoperative AHI of 29.5 ± 14.8 improved to a mean AHI of 18.8 ± 14.6, and the mean apnea index of 8.7 ± 6.4 improved to a mean apnea index of 3.7 ± 4.9.

A multi-institutional study [26] evaluated 73 patients with underlying obstructive sleep apnea; 56 (76.7%) of these patients completed tongue-base RF and follow-up polysomnography. Sixty-five (92.9%) had prior pharyngeal surgery. A mean of 5.4 ± 1.8 treatment sessions were performed, with a mean of 3.1 ± 0.9 lesions per treatment session and an overall energy delivery of $13{,}394 \pm 5459$ J. The mean AHI of 40.5 ± 21.5 decreased to a mean of 32.8 ± 22.6 after treatment. The investigators concluded that RF tongue reduction diminishes the severity of obstructive sleep apnea with subjective outcomes comparable to nasal CPAP.

Tongue-base radiofrequency complications

Tongue-base RF is a treatment of tongue-base collapse in patients with sleep-disordered breathing. These patients have inherent postoperative airway concerns with upper airway reconstructive surgery. To avoid postoperative airway obstruction after tongue-base RF, the surgeon should consider in-patient monitoring, nasal CPAP use, and limiting the amount of

RF energy delivery, especially when performed with other upper airway reconstructive procedures. The potential complications are listed below.

Tongue-base radiofrequency complications
1. Superficial ulcer formation
2. Infection or cellulitis
3. Tongue abscess
4. Hypoglossal nerve injury
5. Tongue or floor-of-mouth swelling
6. Upper airway obstruction

Infection is an uncommon complication, with progression to a tongue abscess in less than 1% of treatment lesions. Some of these suppurative infections drain spontaneously, some may be treated by needle aspiration, but definitive treatment usually requires incision and drainage. The symptoms are a rapid onset of severe tongue pain, usually only mild or moderate swelling, and occasional cervical adenopathy or swelling. Diagnosis requires a high index of suspicion, because the initial physical examination findings may reveal a normal-appearing tongue or only mild swelling. Needle aspiration, ultrasound scanning, or computer tomography scanning may be required to confirm the diagnosis.

To diminish the risk of infection, the following precautions can be taken: (1) pretreatment with oral antibiotics, usually cephalexin, and a 3-day prophylactic antibiotic course; (2) instructing the patient to gargle with 0.12% oral chlorhexidene (Peridex) for at least 1 minute immediately before treatment; (3) use of sterile technique as much as possible; (4) use of a new sterile needle with each injection site; (5) avoidance of steroids, which may lower the immune response; (6) ensuring that the electrode is seated completely into the tongue musculature to prevent a superficial ulceration; (7) checking the curvature of the tongue base to prevent the electrode tip from being placed close to the superficial aspect of the tongue; (8) wiping the electrode tip using sterile technique between treatment lesion sites to remove debris; (9) not delivering greater than 1000 J of energy per treatment site; and (10) considering other treatment alternatives in patients with diabetic mellitus. Following these recommendations limits the incidence of tongue superficial ulcerations and infection.

To avoid hypoglossal nerve injury, the surgeon should limit the ablation sites to no more than 2 cm lateral to midline. The neurovascular bundle is approximately 2 to 3 cm from the surface epithelium and approximately 3 cm lateral from midline in a normal-sized tongue (Fig. 5). With decreased tongue volumes, the RF lesions should not extend beyond 1.5 to 2.0 cm from midline to prevent hypoglossal nerve injury. Four studies revealed no hypoglossal nerve injuries, whereas one study had only mild and transient tongue deviations, which resolved completely postoperatively.

Tongue discomfort, odynophagia, and dysphagia may occur for 3 to 5 days after treatment. To lower the incidence of significant post-treatment

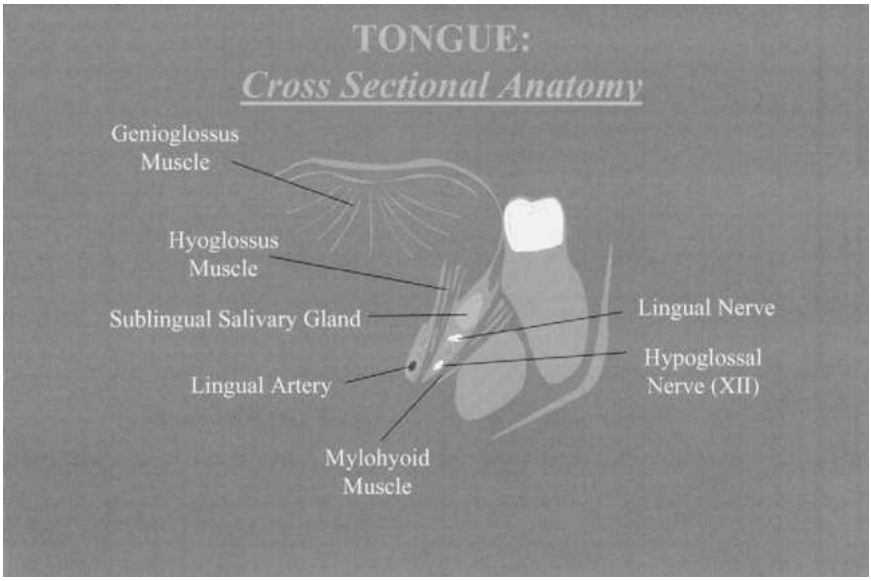

Fig. 5. Tongue cross-sectional anatomy.

discomfort, the physician should (1) limit the energy per treatment site to 750 J, (2) limit the treatment sites to four per treatment session, (3) use crushed ice by mouth as much as possible for the first two post-treatment days, and (4) follow the treatment techniques to limit the risk of infection. In the author's experience with more than 200 base-of-tongue RF treatments following these recommendations, no patient has had a tongue ulcer, infection, abscess, lingual neuralgia, or hypoglossal nerve injury. The incidence of these complications is largely technique-dependent.

Tongue-base radiofrequency limitations

The specific role of tongue-base RF in sleep-disordered breathing has not been established. The efficacy of this procedure when performed simultaneously with other hypopharyngeal reconstructive procedures has not been studied. The effect of saline infiltration into the area to be ablated in altering the lesion size has not been delineated. Finally, there are only limited results on the long-term efficacy and side effects of tongue-base RF.

Tongue-base radiofrequency: conclusions

Tongue-base RF seems to offer promising results in upper airway reconstruction in patients with sleep-disordered breathing. The technique can be performed as an outpatient or inpatient procedure, under local or general

anesthesia, with minimal risks of complications and minimal quality-of-life changes.

Upper airway reconstruction surgery follow-up

Three to 4 months after completing upper airway reconstruction, patients undergo a polysomnogram to determine surgical outcome. Surgical success is defined as an AHI of less than 20 with at least a 50% reduction compared with the preoperative study and the lowest oxyhemoglobin saturation levels equivalent to those seen with nasal CPAP or greater than 90%. In addition to objective polysomnographic data, patients should experience improvement in their snoring and sleep hygiene. Elimination of the daytime hypersomnolence corresponds to reports of better-quality sleep, improved ability to concentrate, elimination of the necessity of naps, and improved work performance. The surgeon should use the procedures that are the most effective, with the lowest morbidity, and technically reproducible for him or her.

Radiofrequency in upper airway reconstruction: conclusions

Radiofrequency for upper airway reconstructive surgery in sleep-disordered breathing for the nasal inferior turbinate, the soft palate, and the tongue base offers additional therapeutic options in the surgical armamentarium in an area in which there were once limited options. The procedures are technically simple and minimally invasive; they are associated with reduced postoperative pain compared with traditional surgical approaches; and they can be performed in an outpatient setting under local anesthesia with a low complication rate and generally good therapeutic results. Future studies will aid in delineating the specific role of RF in nasal obstruction and sleep-disordered breathing.

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