Temperature-Controlled Radiofrequency Treatment of Tonsillar Hypertrophy for Reduction of Upper Airway Obstruction in Pediatric Patients

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Objectives: To determine if temperature-controlled radiofrequency (TCRF) tonsil reduction and adenoidectomy (TCRF&A) and conventional tonsillectomy and adenoidectomy (T&A) are statistically similar in outcome and to compare morbidity between TCRF&A and conventional T&A.

Design: Randomized control trial.

Setting: Tertiary care children’s hospital.

Participants: The study population comprised 23 patients aged 2.6 to 12.5 years with symptoms of obstructive sleep apnea, hypertrophic tonsils with no other areas of upper airway obstruction with the exception of hypertrophic adenoids, and a body mass index (calculated as weight in kilograms divided by the square of height in meters) of less than 30.

Intervention: Temperature-controlled radiofrequency tonsil reduction (mean ± SD, 12.6±1.5 ablations per patient and 994.68±91.88 J per insertion) and adenoidectomy or traditional bovie T&A.

Main Outcome Measures: Primary outcomes were respiratory distress index and total volume reduction. Secondary outcomes include postoperative pain, daytime sleepiness, speech and swallowing problems, weight and diet, narcotic use, and analogue snoring scale.

Results: The respiratory distress index difference for TCRF&A was 5.63 vs 6.56 for standard T&A. On postoperative day 1 for the 13 patients who underwent TCRF&A, 0 reported severe pain, 11 (85%) had mild to moderate pain, and 2 (15%) had no pain. In the 10 patients who underwent standard T&A, 1 (10%) had severe pain and 9 (90%) had mild to moderate pain. By postoperative week 1, all TCRF&A patients experienced mild or no pain, whereas 1 (10%) of the standard T&A patients still had moderate pain. Mean visual analogue snore scores (0-10) 4 weeks after surgery were less than 1 for both groups. The mean±SD weight loss at postoperative week 1 for TCRF tonsil reduction patients was 1.0±3.5 lb (0.45±1.58 kg) vs 4.6±3.9 lb (2.07±1.76 kg) for standard T&A patients. Return to normal diet at postoperative week 1 occurred in 11 TCRF&A patients (85%) and 0 standard T&A patients.

Conclusions: The respiratory distress indexes were similar for TCRF&A patients and standard T&A patients. In addition, there were similar analog snoring scales, decreased pain, and weight loss.


Obstructive Sleep Apnea syndrome (OSAS) or upper airway obstruction is a relatively common problem in children. It is estimated that 1.6% to 3.4% of children carry this diagnosis. There are numerous physiological and developmental consequences of undiagnosed OSAS. Some of these issues may relate to the variability of the diagnosis in that the degree of upper airway obstruction may range from complete obstruction (obstructive sleep apnea [OSA]) to partial obstruction (obstruction hypopnea) of the airway in both children and adults. The most common cause of upper airway obstruction in children at present is thought to be due to adenotonsilar hypertrophy. The most common treatment for this is surgery, and the most common surgical procedure performed is a tonsillectomy or complete removal of the palatine tonsils. A variety of instruments are used for this procedure including knives and scissors (so-called cold steel), an electrocautery device, or laser. Some nonsurgical treatment options are also available and include nasal continuous positive airway pressure, weight loss, and/or corticosteroids. Because of poor patient compliance, continuous positive airway pressure is often not a viable treatment option. Although weight loss is often recommended, it is rare to achieve a large enough change in weight for complete resolution of OSAS symptoms. Corticosteroids also have a demonstrated lack of effectiveness.

Currently, the American Academy of Otolaryngology–Head and Neck Surgery...
recommends tonsillectomy for tonsillar hypertrophy causing upper airway obstruction or sleep disorders. The efficacy of adenotonsillectomy for the treatment of upper airway obstruction has been well documented. Snoring, episodes of oxygen desaturation, and periodic breathing are reduced or eliminated. The average nadir arterial oxygen percentage of saturation increases while end-tidal carbon dioxide decreases. Other studies have shown improvements in obstructive respiratory events, malocclusions, behavior, and learning. However, current tonsillectomy techniques are not free of disadvantages or complications. Some are hypersalivation, hemorrhage, pain, velopharyngeal insufficiency, and odynophagia with associated dysphagia, causing dehydration, local edema, and comorbid conditions associated with the need for narcotic analgesics. The complication rates range from less than 1% to 8%. Other studies have shown improvements in obstructive respiratory events, malocclusions, behavior, and learning.

The Somnoplasty (Gyrus ENT, LLC, Bartlett, Tenn) temperature-controlled radiofrequency (TCRF) procedure has been used successfully to treat obstruction at the level of the soft palate, turbinates, and base of tongue in adults. Radiofrequency tissue volume reduction (RFTVR) uses radiofrequency energy to ablate tissue in a minimally invasive fashion. A pilot study by Nelson examined the use of RFTVR for tonsil reduction in adults. The study demonstrated that RFTVR was successful in reducing the tonsil size by 70% and increased the size of the oropharyngeal airway by 12 mm. Daytime sleepiness, snoring, voice clarity, swallowing, and throat irritation were also substantially improved. The RFTVR was performed and well tolerated in an in-office setting using local anesthesia. The postoperative morbidities and discomfort were minimal compared with standard tonsillectomy procedures performed using general anesthesia in the operating room.

With the Somnoplasty TCRF procedure, the target temperature is held constant (85°C for tonsils), forming consistent lesions inside the tonsil. The instrument possesses a safety shutoff in the event that the target temperature increases to more than 105°C or decreases to less than 65°C on the surface of the tonsil. These features minimize damage to both the surrounding tissues and mucosa, allowing the Somnoplasty TCRF tonsil reduction to be accurate, minimally invasive, and less morbid without compromising treatment efficacy compared with complete tonsillectomy.

For the treatment of tonsillar hypertrophy giving rise to upper airway obstruction, TCRF reduction of the palatine tonsils may be an alternative surgical approach; it has the potential advantages of less pain and hemorrhage compared with conventional surgery because injury to surrounding tissues are avoided or minimized and might also have a significant positive impact on the postoperative care, loss of work or school time, and other associated complications that result from complete tonsillectomy. This study was a randomized, prospective trial to compare TCRF tonsil reduction and adenoidectomy (TCFR&A) to complete tonsillectomy and adenoidectomy (T&A) for the treatment of polysomnographic-documented OSAS in pediatric patients.

### METHODS

This study was reviewed and approved by the institution review board at all 4 participating institutions: Good Samaritan Hospital, San Jose, Calif (L.N.); University Hospitals of Cleveland and Case Western Reserve University, Cleveland, Ohio (J.M.C. and R.D.Y.); and Childrens Hospital Los Angeles, Los Angeles, Calif (J.K.). The project was funded by Somnus Medical Technologies, Inc (Sunnyvale, Calif).

### PATIENT POPULATION

Children aged 4 to 15 years with signs and symptoms of OSA and hypertrophic tonsils with no other areas of upper airway obstruction with the exception of hypertrophic adenoids were screened with a detailed history review and physical examination for inclusion in the study. Inclusion criteria included a body weight of less than 150% of the ideal weight (body mass index [calculated as weight in kilograms divided by the square of height in meters] <30). Persons were excluded if they had a history of surgery for upper airway obstruction; active respiratory infection or chronic lung disease; Down syndrome; speech, swallowing, or neurological disorders; craniofacial abnormalities; and other comorbid conditions (such as cor pulmonale). A total of 27 patients (11 female and 16 male) were selected from all 4 centers seeking treatment for upper airway obstruction (Table 1). The sample size was limited because this investigation was a preliminary study.

Informed consent and assent were provided by the patient and parent or guardian. All patients were assessed by the principal investigator for eligibility. The patients then underwent overnight polysomnography. All sleep studies were performed using the Somnoplasty system (Respironics, Pittsburgh, Pa). The protocol for the preoperative and postoperative sleep studies were designed by a board-certified pediatric sleep physician. All raw data from the polysomnography were evaluated by the same sleep physician who was blinded to the treatment arms assigned to the patients. We believe that this was the best way to standardize collection of the polysomnography data.

### Table 1. Demographics and Baseline Characteristics for Patients Undergoing TCRF&A and T&A

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TCRF&amp;A (n = 13)</th>
<th>T&amp;A (n = 10)</th>
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<tbody>
<tr>
<td>Age, y</td>
<td>6.07 ± 2.63</td>
<td>6.77 ± 2.31</td>
</tr>
<tr>
<td>BMI</td>
<td>17.63 ± 4.76</td>
<td>19.17 ± 3.58</td>
</tr>
<tr>
<td>Height, in</td>
<td>46.87 ± 7.76</td>
<td>48.69 ± 5.98</td>
</tr>
<tr>
<td>Weight percentile</td>
<td>61.37 ± 43.02</td>
<td>62.09 ± 23.37</td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>RDI (baseline)</td>
<td>7.6</td>
<td>7.7</td>
</tr>
<tr>
<td>Daytime sleepiness†</td>
<td>4.1 ± 2.5</td>
<td>3.5 ± 3.7</td>
</tr>
<tr>
<td>Snoring†</td>
<td>7.4 ± 2.4</td>
<td>6.8 ± 3.4</td>
</tr>
<tr>
<td>Speech†</td>
<td>3.7 ± 2.6</td>
<td>2.1 ± 3.1</td>
</tr>
<tr>
<td>Swallowing†</td>
<td>2.4 ± 2.8</td>
<td>1.2 ± 1.7</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); RDI, respiratory distress index; T&A, tonsillectomy and adenoidectomy; TCFR&A, temperature-controlled radiofrequency tonsil reduction and adenoidectomy.

*Data are given as mean ± SD unless otherwise specified. †Visual analogue scale score (1-10).
The respiratory distress index (RDI) was the principle measure evaluated by the polysomnographic examinations to determine inclusion in the investigation. Only patients with mild to moderate OSA were included in the study. Patients with severe OSA (RDI ≥30) were excluded owing to the potential high risk associated with anesthesia. Because of the lack of prior evidence regarding the efficacy of TCRF tonsil reduction, we did not deem it ethical to treat patients with severe OSA (RDI ≥30) to avoid placing them at possibly higher risk. Subsequently, patients with mild to moderate OSA were randomized to a treatment number. In addition, patients who were not diagnosed as having OSA by polysomnography were excluded from the study. The patients were assigned a study number and randomized to a treatment protocol of either Somnoplasty TCRF&A or standard T&A. Both the patient and parent/guardian were notified of the specific treatment parameter (TCRF&A or standard T&A), which was randomized to them 1 week prior to the surgery date. Of the 27 patients enrolled, 23 underwent surgery (13 underwent Somnoplasty TCRF&A and 10 underwent standard T&A) (Table 1). All 23 patients received the allotted treatment protocol initially assigned to them, and thus no crossover occurred. Four patients were not treated, as they did not return and were excluded from the study because no further information could be obtained regarding their whereabouts. In all patients, the adenoids were removed if determined to be hypertrophic by the surgeon using standard surgical procedures such as curette, Thompson–St Clair forceps, or suction cautery unless contraindicated.

The tonsils were graded according to a tonsil grading scale (0, tonsils are in fossa; +1, <25% occupation of oropharynx; +2, 25%-50%; +3, 50%-75%; and +4, >75%), and photographs were taken. A quality-of-life assessment and patient questionnaires were completed. Prior to either procedure, all patients received a 3-day course of amoxicillin (40 mg/kg 3 times daily) orally. In those cases of an allergy to penicillin, clindamycin (25 mg/kg 4 times daily) was given instead of amoxicillin. All procedures were performed using general anesthesia.

TCRF TONSIL REDUCTION AND ADENOIDECECTOMY

The tonsillar pillars on each side were infiltrated with 5.0 mL of 0.25% bupivacaine hydrochloride without epinephrine. The tonsil parenchyma was infiltrated with 5.0 mL of isotonic sodium chloride solution on each side (Figure 1). The TCRF reduction of the palatine tonsils was performed using a hand-piece with 2 electrodes. Depending on the size of the tonsil, 5 to 7 insertions were made in each tonsil (Figure 2). This resulted in a mean±SD of 12.6±1.50 ablations per patient and 994.68±91.88 J per insertion. Dexamethasone sodium phosphate (Decadron; Merck & Co Inc, Whitehouse Station, NJ) was given intravenously (0.5 mg/kg, up to a maximum dose of 20 mg) at 0, 6, and 12 hours postoperatively. All patients were admitted to the hospital for 24 hours of observation. Most were admitted to the intensive care unit as a safety precaution following the procedure owing to the anticipated tonsillar edema postoperatively. As experience was gained with this procedure and when the patients were older (age ≥6 years), some patients were admitted to a regular hospital bed (Table 2).

COMPLETE TONSILLECTOMY AND ADENOIDECECTOMY

Complete tonsillectomies were performed via a dissection method using a monopolar electrocautery device. The settings for the cutting or coagulation modes were not standardized as part of the study’s protocol. The tonsillar pillars on each side were infiltrated with 5.0 mL of 0.25% bupivacaine hydrochloride without epinephrine. Decadron was given intravenously (0.5 mg/kg up to a maximum dose of 20 mg) at time 0, 6, and 12 hours postoperatively. All patients were admitted and observed overnight in a regular hospital bed. Hemostasis was obtained in both the nasopharynx and tonsillar fossae using a combination of packing and suction cautery.

At discharge from the hospital, all patients received a 7-day course of either amoxicillin or clindamycin orally at the same dose as before surgery. They also received a 7-day course of acetaminophen (Tylenol; McNeil PPC Inc, Fort Washington, Pa) with codeine elixir (0.5-1.0 mg/kg codeine every 4 hours as needed orally). All patients completed questionnaires daily for the first 7 days, then once at weeks 4, 8, 12, 24, and 52 postoperatively. The information collected included pain, type of diet consumed, type and amount of
medication consumed, level of activity, and severity of obstructive symptoms. All patients were examined at these intervals, and postoperative overnight polysomnography was performed 3 months after treatment.

RESULTS

No significant complications were observed. There were no postoperative admissions for dehydration or primary or secondary hemorrhage.

RDI AND TONSIL GRADE ASSESSMENT

Median pretreatment and 3-month posttreatment RDI for the 2 study groups were compared. To be able to compare polysomnography results, all sleep studies were completed using a standard protocol with identical equipment. All raw data were interpreted by 1 pediatric pulmonologist who was blinded to the treatment performed. Using the RDI scale, a difference of 5.6 was reported in the TCRF&A patients, while a difference in 6.5 was observed in the T&A patients (Table 3). Before TCRF treatment, the mean ± SD tonsil grade was 3.0 ± 0.6 (range, 2.0-4.0). At 1 month after treatment, the mean ± SD tonsil grade was 1.3 ± 0.6 (range, 0.3-2.5) (change, 1.7 ± 0.8; percentage, % change, 57%).

PAIN ON POSTOPERATIVE DAY 1

A subjective pain assessment visual analogue scale was used to record pain level (no pain, mild pain, moderate pain, and severe pain) among the Somnoplasty TCRF&A and T&A patients. Degrees of pain were defined as mild (an awareness of signs or symptoms but easily tolerated, causing no loss of time from normal activities or requiring medication); moderate (discomfort severe enough to cause interference with usual activities); and severe (incapacitating pain with inability to do work or usual activities or signs and symptoms that may be of systemic nature or requiring medical evaluation or treatment).

On postoperative day 1, decreased pain was observed among the TCRF&A patients (Figure 3) compared with the T&A patients. Within the TCRF&A subgroup, severe pain was not reported. Of the 13 TCRF&A patients, 10 (77%) had mild pain, 2 (15%) had no pain, and 1 (8%) had moderate pain. In contrast, of the 10 standard T&A patients, 1 (10%) reported severe pain at postoperative day 1. Most T&A patients had mild (n = 5 [50%]) and moderate (n = 4 [40%]) pain. By postoperative week 1, all patients who underwent Somnoplasty TCRF&A...
were at a mild pain level (n=6 [46%]) or had no pain (n=7 [54%]) in contrast to the 1 standard T&A patient (10%) who still was at a moderate level of pain. (Figure 4)

**VISUAL ANALOGUE SCORE AT 1 MONTH AFTER TREATMENT**

The visual analogue scores (0-10) for the TCRF&A and standard T&A patients for daytime sleepiness, snoring, speech, and swallowing at pretreatment and 1 month after are given in Table 4.

**WEIGHT AND DIET AT 1 WEEK AFTER TREATMENT**

Weight loss at postoperative week 1 was compared between the 2 treatment groups. All patients were instructed to eat a regular diet when able. The TCRF&A patients only lost an average of 1.0±3.5 lb (0.45±1.58 kg), whereas the T&A patients lost an average of 4.6±3.9 lb (2.07±1.76 kg) (Table 5). By postoperative day 7, of the 13 TCRF&A patients, 11 (85%) resumed a normal diet, 2 (16%) were on a soft diet, and 1 (5%) was on a liquid diet. Note that the percentages for each day do not necessarily add up to 100% as patients could select more than 1 diet choice for each day. In contrast, none of the T&A patients at day 7 were on a normal diet. Most of these patients still remained on a liquid (n=3 [25%]) or soft (n=10 [100%]) diet (Table 6).

**COMMENT**

The postoperative course following tonsillectomy may include considerable pain, weight loss, dehydration due to difficulty in swallowing, and in some cases, hospitalization due to respiratory problems or bleeding. Tonsillectomy by laser or electrocautery has not been shown to decrease postoperative pain or hemorrhage rates. In fact, laser surgery of mucosal tissue has been demonstrated to cause pathologic changes beyond the point of application, which may contribute to the pharyngeal dryness and sleep apnea shown after treatment in some patients.
It seems reasonable to conclude that preserving the overlying mucosa may be an important factor in controlling the complications often associated with traditional tonsillectomies. In fact, an animal study using mucosal intact laser tonsillar ablation, which preserves the overlying mucosa, was shown to exhibit significant benefits in parameters such as onset of eating solid food, amount of food ingested per day, onset of normal activity, and degree of weight loss.\textsuperscript{30} In addition, a recent case report cited preservation of normal histologic architecture in the tonsils after radiofrequency treatment.\textsuperscript{30} Over the last 10 years, other tonsil surgeons have recognized the advantages of avoiding or minimizing injury to the tissues surrounding the tonsillar fossa and have described procedures to remove a portion of the tonsil to avoid or lessen the problems associated with complete tonsillectomy. Some include a Bochon loop, carbon dioxide laser, ionized field ablation or coblation, and the use of a microdebrider.\textsuperscript{31–34}

Temperature-controlled radiofrequency tonsil reduction provides a minimally invasive alternative method for the surgical treatment of upper airway obstruction due to tonsillar hypertrophy compared with complete tonsillectomy by electrocautery. Statistically similar results in pretreatment and posttreatment RDI were seen in both the TCRF&A and T&A groups, in which most of these patients were diagnosed by RDI with mild OSA. Following TCRF&A or T&A, these patients demonstrated comparable changes in RDI of 5.63 (TCRF&A) and 6.45 (T&A). Using an RDI of 5 as a cutoff for pediatric OSA, most of the patients in both arms of the study did not appear to have OSA at 3 months after treatment (TCRF&A median RDI, 0.30; T&A median RDI, 1.55). Because all polysomnographic examinations were performed by 1 pediatric pulmonologist blinded to the study, we are confident in the conclusion that these treatment modalities demonstrated no statistical difference. Therefore, from our data we conclude that TCRF&A elicits no significant difference in treatment outcomes compared with standard T&A for mild to moderate OSA.

In addition, several morbidity factors were compared between the 2 treatment modalities. Temperature-controlled radiofrequency tonsil reduction ablates tissue inside the tonsil and optimizes volume reduction with the help of isotonic sodium chloride solution injected into the tonsil prior to inserting the probe. This technique results in a gradual reduction of the tonsil size, while leaving the tonsil’s surface and surrounding tissues with minimal or no injury. Compared with the standard T&A method, the benefits observed of TCRF&A include preservation of overlying mucosa, decreased pain from the first postoperative day, decreased dependence on analgesics, decreased weight loss, more rapid return to normal diet, and comparable differences in obstructive symptoms such as snoring, daytime sleepiness, speech difficulties, and swallowing difficulties. One might also anticipate a decrease in emotional distress compared with the complete tonsillectomy procedure. In fact, of the 13 TCRF&A patients, 12 (95%) had no pain by day 7, 11 (85%) returned to a normal diet by day 7, and 0 were using analgesics by 1 week after treatment.

Clinically, no demonstrable difference in treatment outcomes appears between Somnoplasty TCRF&A and standard T&A. The possible clinical advantage to this approach over tonsillectomy may be the reduced postoperative morbidities and decreased level of patient discomfort. Our data compare favorably to a recent non-randomized case series using TCRF tonsil reduction in children by Nelson.\textsuperscript{35} In our investigation, substantial improvement was seen in symptoms such as daytime sleepiness, snoring, and speech and swallowing difficulties as well as a more rapid return of normal diet than that seen with traditional tonsillectomy procedures. However, variability was observed in the amount of tonsil tissue remaining 6 weeks after treatment when comparing one patient with another. In addition, the cost of TCRF instrumentation is higher compared with cold-steel and electrocautery devices that are currently in use. Indeed, future studies will be directed at investigating the variability of tonsil tissue remaining posttreatment. In addition, larger sample sizes will be required to assess whether these 2 procedures have equal efficacies. Although this investigation was a preliminary study, valuable data regarding treatment outcomes were obtained and suggest that additional studies may help promote further development and use of TCRF tonsil reduction.

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Table 6. Patient Diet During the First Week Following TCFR&A and T&A*

<table>
<thead>
<tr>
<th>Diet</th>
<th>Day 1</th>
<th>Day 3</th>
<th>Day 5</th>
<th>Day 7</th>
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<tbody>
<tr>
<td>Normal diet, %</td>
<td>23</td>
<td>46</td>
<td>65</td>
<td>84</td>
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<tr>
<td>T&amp;A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Soft diet, %</td>
<td>46</td>
<td>36</td>
<td>30</td>
<td>16</td>
</tr>
<tr>
<td>TCRF&amp;A</td>
<td>75</td>
<td>50</td>
<td>67</td>
<td>100</td>
</tr>
<tr>
<td>T&amp;A</td>
<td>55</td>
<td>26</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Liquid diet, %</td>
<td>50</td>
<td>50</td>
<td>100</td>
<td>25</td>
</tr>
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</table>

Abbreviations: T&A, tonsillectomy and adenoidectomy; TCRF&A, temperature-controlled radiofrequency tonsil reduction and adenoidectomy.

*Percentages for each day do not necessarily add up to 100% because patients could select more than 1 diet choice for each day.
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REFERENCES


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