

Radiofrequency volumetric reduction of the palate: An extended follow-up study

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OBJECTIVE: The goal was to evaluate the effect of radiofrequency (RF) of the palate on speech, swallowing, taste, sleep, and snoring 12 to 18 months after treatment.

METHODS: Twenty-two patients were evaluated by clinical examination, questionnaires, and visual analog scales. The patients with relapse of snoring were offered further RF treatment.

RESULTS: After a mean follow-up of 14 months, no adverse effect was reported. Subjective snoring scores relapsed by 29% overall. Nine patients (41%) noted relapse of snoring from 2.1 ± 1.1 to 5.7 ± 2.7 ($P < 0.001$). Eight of the patients underwent further RF treatment with a reduction of snoring from 5.8 ± 2.9 to 3.3 ± 3.1 ($P = 0.01$).

CONCLUSION: The success of RF volumetric reduction of the palate diminishes with time, as with other surgical procedures of the palate. However, the minimal invasiveness of the RF provided a high patient acceptance for retreatment, and relapse of snoring can be improved. (*Otolaryngol Head Neck Surg* 2000;122:410-4.)

Powell et al¹ introduced radiofrequency volumetric reduction (RFVR) of the soft palate for the treatment of sleep-disordered breathing and snoring in 1997. The initial investigation of this novel treatment approach demonstrated objective polysomnographic improvement in esophageal pressure measurements, as well as the sleep efficiency index. Subjective improvement was also achieved, with a mean reduction of 77% in snoring scores accompanied by improvement of the mean Epworth Sleepiness Score (ESS) score. More importantly, the safety parameters for radiofrequency (RF) in the soft palate were established in that postoperative pain was minimal and of short duration and neither speech

nor swallowing was adversely affected. However, despite these encouraging initial results, the long-term treatment outcomes, as well as the effects of this new technology on the delicate soft palate, are entirely unknown.

The primary study objectives of this investigation were to evaluate the effect of RFVR of the palate on speech, swallowing, taste, sleep, and snoring 12 to 18 months after treatment. The secondary objectives of the study were to evaluate the effect of additional RF treatments to the soft palate of patients whose snoring had relapsed.

METHODS AND MATERIAL

Study Design

This was a follow-up study of the first 22 patients (18 men) with sleep-disordered breathing treated 12 to 18 months previously with RF to the palate. The study was conducted prospectively. Clinical examination was performed in all patients, and questionnaires and visual analog scales (VASs) were used to subjectively assess speech, swallowing, taste, sleep, and snoring. Patients with relapse of snoring were offered further RF treatments. After the completion of retreatment in those patients with snoring relapse, the above variables were reassessed.

Population

All 22 patients were enrolled in this study. All were seeking treatment for symptomatic chronic (habitual) snoring and reported symptoms of daytime sleepiness at the time of the prior study. The mean age was 45.3 ± 9.1 year, with a mean pretreatment body mass index of 27.4 ± 3.72 kg/m². The diagnosis was obstructive sleep apnea syndrome in 7 patients (31.8%) and upper airway resistance syndrome in 14 patients (63.6%). The diagnosis of the remaining patient was either simple snoring or upper airway resistance syndrome.

Summary of Initial RF Treatment and Results

The mean number of treatment sessions was 3.6 ± 1.2 per patient. The mean total energy administered per patient was 2377 ± 869 J, with 688 ± 106 J per treatment session. The mean ESS improved from 8.5 ± 4.5 to 5.2 ± 3.3 , a change of -3.3 ± 3.2 ($P < 0.00001$). The mean snoring scores by VAS (0-10) improved from 8.3 ± 1.8 to 1.9 ± 1.2 , a change of -6.4 ± 1.7 ($P \leq 0.0001$). There were no major complications, includ-

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ing bleeding, infection, tissue slough, or speech, taste, or swallowing problems. Soft palate edema occurred in all patients at 1 to 3 days after treatment, but all cases resolved without problems.

Questionnaires

Questionnaires were completed to assess the following variables.

Follow-up study (n = 22).

1. ESS: An ESS was completed to reflect the chance of dozing in specific situations.
2. Snoring: Whether snoring has relapsed since the completion of RF treatment.
3. Taste: Whether alteration in taste exists since the completion of RF treatment.
4. Speech: Whether alteration in speech exists since the completion of RF treatment.
5. Swallowing: Whether alteration in swallowing exists since the completion of RF treatment.
6. Satisfaction: Whether the patient would repeat the RF treatment.
7. Additional RF treatment: Whether additional RF treatment is desired in cases where relapse of snoring occurred.

Retreatment study (n = 8).

1. ESS: An ESS was completed to reflect the chance of dozing in specific situations.
2. Pain: Type and amount of analgesic medication taken.
3. Taste: Whether taste is affected 8 to 12 weeks after retreatment.
4. Speech: Whether speech is affected 8 to 12 weeks after retreatment.
5. Swallowing: Whether swallowing is affected 8 to 12 weeks after retreatment.

VASs

Standard 10-cm VASs with anchors such as "no pain" and "excruciating or intense pain" were used to evaluate each subject's symptoms and assessments of study variables, which included the following.

1. Pain: A VAS scale of 0 (no pain) to 10 (excruciating or intense pain) was used to document the existence of pain.
2. Snoring: A VAS scale (amount of snoring noise during sleep) was used that required the subject, along with his or her bed partner, to assess snoring levels. The scale was from 0 (no snoring noise) to 10 (extreme noise—bed partner leaves the room).

Determination of Factors Leading to Relapse

To identify whether anatomic factors or the amount of energy administered might have affected the relapse rate, we compared the baseline palate length, palate width, and poste-

Table 1. Snoring data

Patient No.	Relapse	Baseline	Project end	1-y follow-up	Final
1	No	10	4	1.8	—
2	Yes	10	2	10	9.4
3	Yes	9	4	6.7	1.8
4	No	4	0	2	—
5	No	9	2	3.1	—
6	No	10	1	1	—
7	Yes	6	1	1.9	1
8	No	10	2	3.5	—
9	Yes	7	2	3.9	1.6
10	Yes	9	3	3.4	2.3
11	Yes	10	2	9.8	6.8
12	No	9	2	3.7	—
13	No	5	0	2.2	—
14	No	8	3	1.5	—
15*	Yes	7	1	5.3	—
16	No	8	0	1.6	—
17	No	6	2	1.6	—
18	No	7	3	3.7	—
19	No	10	1	1	—
20	Yes	10	1	5.5	2.4
21	Yes	8	3	5.2	1
22	No	10	3	4.8	—
TOTAL		182	42	83.2	26.3
MEAN		8.27	1.91	3.78	3.29
SD		1.83	1.19	2.54	3.09

Baseline, Snoring level before RF treatment; Project end, snoring level at the completion of the first study; 1-y follow-up, snoring level 12 to 18 months after RF treatment; Final, snoring level after the completion of retreatment.

*Patient did not undergo retreatment.

rior airway space obtained from cephalometric radiographs, as well as the total energy delivered in the initial study between patients with snoring relapse and patients with continual success.

RF Procedure

Patients with relapse of snoring were offered additional RF treatments. Informed consent was obtained before treatment. The same investigator performed all treatments and subsequent follow-up. The soft palate was sprayed with 20% benzocaine as a topical anesthetic. The midpoint of the soft palate from the base of the uvula to the posterior nasal spine was anesthetized with 5 mL of 0.5% bupivacaine hydrochloride (Marcaine) with a 30-gauge needle. RF energy was delivered to the soft palate with a 22-gauge RF needle electrode (Somnus Medical Technologies Inc, Sunnyvale, CA). The patients were observed for 3 to 5 minutes after the completion of treatment. Antibiotics, corticosteroids, or prescriptive analgesics were not given.

Clinical Follow-up After Retreatment

Each patient was scheduled for follow-up on the first and second or third postoperative days and then at 1 and 4 weeks.

Table 2. ESS data

Patient No.	Relapse	Baseline	Project end	1-y follow-up	Final
1	No	2	1	1	—
2	Yes	15	7	14	12
3	Yes	13	7	13	6
4	No	6	7	6	—
5	No	14	3	5	—
6	No	8	1	3	—
7	Yes	5	2	2	2
8	No	12	8	9	—
9	Yes	11	4	7	6
10	Yes	15	12	15	14
11	Yes	5	5	7	5
12	No	5	5	6	—
13	No	14	12	2	—
14	No	4	3	3	—
15*	Yes	14	6	9	—
16	No	2	2	2	—
17	No	7	3	2	—
18	No	12	11	13	—
19	No	8	5	4	—
20	Yes	5	4	3	4
21	Yes	2	1	1	1
22	No	7	5	6	—
TOTAL		186	114	133	50
MEAN		8.45	5.2	6.05	6.25
SD		4.54	3.3	4.41	4.56

Baseline, Snoring level before RF treatment; Project end, snoring level at the completion of the first study; 1-y follow-up, snoring level 12 to 18 months after RF treatment; Final, snoring level after the completion of retreatment.

*Patient did not undergo retreatment.

At each visit, a clinical examination was performed, and questionnaires and VASs were completed. Additional RF treatment was offered at the 4-week follow-up if necessary. The final evaluation was conducted 8 to 12 weeks after the completion of treatment.

Statistical Analysis

Statistical significance was determined with the Wilcoxon nonparametric analog of paired *t* tests and the Mann-Whitney *U* test for analog of *t* tests for independent samples. Results are expressed as mean \pm SD and were generated with an SAS computerized statistical package.

RESULTS

All 22 patients underwent follow-up evaluation. There was a mean weight increase of 3.1 ± 7.9 kg. The mean follow-up period was 14 months (range 12-18 months). No adverse effect on speech, swallowing, or taste was reported by any of the patients. Snoring scores relapsed from 1.9 ± 1.2 to 3.8 ± 2.5 ($P < 0.001$), a change of 29% (Table 1). This was accompanied by an increase of ESS from 5.2 ± 3.3 to 6.1 ± 4.4 ($P < 0.05$) (Table 2). Thirteen patients (59%) reported continual

success without relapse of snoring or daytime sleepiness. Nine patients (41%) reported relapse of snoring (VAS 0-10) from 2.1 ± 1.1 to 5.7 ± 2.7 ($P < 0.001$). This was accompanied by worsening of ESS from 5.7 ± 3.2 to 7.9 ± 5.3 ($P < 0.05$). The palate length ($P = \text{NS}$), palate width ($P = \text{NS}$), posterior airway space ($P = \text{NS}$), and the amount of total energy delivered ($P = \text{NS}$) did not affect the relapse rate.

Twenty-one patients (95%) were satisfied with the procedure and would repeat it if necessary. One patient thought that there was insufficient response to the treatment and therefore would not have the procedure again.

Eight of the 9 patients with relapses consented to retreatment for further control of snoring, and they underwent a total of 10 RF treatments, with 6 patients receiving 1 treatment and 2 patients receiving 2 treatments. The mean RF energy delivered per treatment session was 786 ± 114 J. Each patient received a minimum of 1 and a maximum of 3 separate RF ablations per treatment session, with each ablation given at a different site of the palate.

Mild edema was seen in the first 3 days, which usually resulted in restless sleep on the first postoperative day. There was no report of alteration in daily activities, and normalization of sleep occurred after 3 days. No mucosal erosion was encountered in any patient, and no adverse effect on speech, taste, or swallowing was reported. The pain score was the highest at 2.7 ± 1.9 on posttreatment day 1 and decreased to 0.7 ± 1.1 at 1 week. Oral analgesic was used by 3 patients and was limited to 1 tablet of codeine (30 mg) and either acetaminophen or ibuprofen in low doses. The snoring score fell from 5.8 ± 2.9 to 3.3 ± 3.1 ($P = 0.01$), with an improving trend in ESS from 7.8 ± 5.6 to 6.3 ± 4.6 ($P = 0.07$).

DISCUSSION

This investigation demonstrated that 12 to 18 months after the completion of RF treatment, subjective snoring score relapsed by a mean of 29% overall. In the 9 patients (41%) who reported relapse of snoring, the VAS changed from 2.1 ± 1.1 to 5.7 ± 2.8 . These findings are not surprising because a decline of success rate over time has been reported in other forms of surgical palatal modification for snoring, including uvulopalatopharyngoplasty (UPPP),^{2,3} laser-assisted uvulopalatoplasty (LAUP),⁴ and laser palatal mucosal ablation.⁵

Levin and Becker² reported a declining success rate with UPPP in controlling snoring from 87% to 46% after 13 months. Interestingly, although the mean follow-up was 44 months, most of the failures occurred between 6 and 12 months, with the success rate remain-

ing stable after this time period. In another long-term follow-up study after UPPP, Macnab et al³ also reported a diminishing success rate in snoring control.

Since its introduction by Kamami⁶ in 1990, LAUP has been highly effective in controlling snoring.^{6,7} However, a recent study by Wareing et al⁴ demonstrated that 22% of patients with successful results 6 months after treatment reported failure of snoring control after 18 months, reducing the overall success rate to 55%. A less invasive laser-assisted palatal modification technique advocated by Ellis⁵ has also been shown to have a declining success rate with increasing length of follow-up.

It has been demonstrated that UPPP stiffens the pharynx, thus reducing the pharyngeal collapsibility and improving snoring.⁸ It is likely that LAUP achieves similar effects on the pharynx and, in turn, reduces snoring. It can be speculated that the maturing of scar tissue results in the recurrence of pharyngeal collapse and snoring. RF creates tissue coagulation necrosis, leading to fibrosis and contraction.⁹ It is likely that after RF treatment of the soft palate, the resulting fibrosis and scarring of the palatal musculature stiffens the soft palate, leading to the reduction of snoring. Therefore, it can be postulated that, as with any other surgical scars, the gradual maturation and softening of scar tissue lead to the relapse of snoring over time. Furthermore, the relapse is independent of palate length, palate width, posterior airway space, or the amount of total RF energy delivered.

The biophysics of RF tissue ablation results in a predictable tissue injury pattern and minimizes potential complications. RF generates frictional heating of the tissues around the electrode because of ionic agitation; thus the electrode itself does not become hot, and the heat actually emanates from the tissue. Because the RF energy disbursement is proportional to $1/\text{radius}$,⁴ heat dissipation is limited, and excessive tissue injury is minimized. Furthermore, when the temperature reaches 90°C to 100°C, char formation on the electrode leads to an increase in the impedance and results in disruption of current flow, thus serving as a second layer of protection. The low incidence of surface injury after treatment is reflected in the absence of long-term adverse effects on speech, swallowing, or taste after a mean follow-up period of 14 months. This finding compares favorably with those of other surgical modalities in that 29% of the patients had persisting dysphagia after UPPP¹⁰ and 40% of the patients reported minor pharyngeal symptoms after LAUP in long-term follow-up.⁴

Postoperative pain appears to be a major factor in patient satisfaction after UPPP or LAUP in that only 70% to 75% of the patients stated that in retrospect they

would have the procedure again.^{3,4} Postoperative pain also influences the initial treatment success of LAUP because some patients refuse additional treatments because of pain intolerance. Cheng et al¹¹ reported that only 15.6% of their patients underwent more than 1 treatment session partly because of severe postoperative pain and sore throat. Astor et al¹² found that 18% of the LAUP failures were due to premature discontinuation of treatment because of pain. In contrast, because only mild postoperative pain was encountered after RF treatment,¹³ patient satisfaction was high in that 91% of the patients would undergo the treatment again. In addition, 8 of the 9 patients underwent retreatment with improvement of snoring from 5.8 ± 2.9 to 3.3 ± 3.1 while encountering only mild postoperative pain, which further demonstrates the safety, effectiveness, and high patient tolerance of RF palate treatment.

The ESS¹⁴⁻¹⁶ was used to subjectively evaluate daytime sleepiness in our investigation. Our results demonstrated that ESS correlated with the level of snoring in that snoring relapsed from 2.1 ± 1.1 to 5.7 ± 2.8 accompanied by worsening of ESS from 5.4 ± 3.2 to 7.8 ± 5.3 . After retreatment, the level of snoring decreased from 5.8 ± 2.9 to 3.3 ± 3.1 , accompanied by an improving trend of ESS from 7.8 ± 5.6 to 6.3 ± 4.6 . The attenuation of snoring by RF treatment of the soft palate would suggest an improvement in sleep-disordered breathing, as reflected in the ESS scores.

It must be emphasized that the findings of this investigation result from the application of an established treatment technique and RF parameters from our previous study. The administration of excessive RF energy to limit the number of total treatments, or the altering of treatment location and technique, may lead to excessive tissue injury and, in turn, may result in increased complications and adverse effects.

CONCLUSION

The primary and secondary study objectives were evaluated. The results suggest that the success of RFVR of the palate diminishes with time, as with other surgical procedures of the palate. The 12- to 18-month outcome variables are, at a minimum, comparable with those of LAUP or UPPP. However, the minimal invasiveness of the RF treatment provided a high patient acceptance for retreatment, and relapse of snoring can be improved after retreatment.

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