

## Studies

Indication	Study	Claim	Complications
Snoring, OSAS	Baisch: Combined radiofrequency assisted uvulopalatoplasty in the treatment of snoring, Eur Arch Otorhinolaryngol (2008)	<ul style="list-style-type: none"> <li>- <b>a highly effective treatment of snoring (VAS 8,5 (1,5) -&gt; 2,0 (2,1))</b></li> <li>- Improves daytime sleepiness</li> <li>- Did not cause complications or side effects</li> </ul>	„Complications did not occur. “
	Den Herder: Bipolar radiofrequency induced thermotherapy of the tongue base: its complications, acceptance and effectiveness under local anesthesia, Eur Arch Otorhinolaryngol (2006)	<ul style="list-style-type: none"> <li>- Safe and simple procedure</li> <li>- <b>No postoperative complications</b></li> <li>- compared to monopolar technology reduced morbidity, such as secondary thermal damage</li> <li>- first choice treatment in case of snoring and mild OSAS</li> <li>- For mild pathology it is a less extensive alternative to other procedures</li> </ul>	<p>“No postoperative complications such as infections, abscesses, hematomas, or ulcerations of the tongue base occurred.”</p> <p>„adverse event rate 2/111 = 1.8%“ (“mild and transient tongue deviation directly after the procedure”)</p>
	Kotecha: Radiological airway changes following bipolar radiofrequency volumetric tissue reduction, The Journal of Laryngology & Otology (2010), 124, 1078–1084.	<ul style="list-style-type: none"> <li>- minimal post-operative pain</li> <li>- safe and simple</li> <li>- precise, so tissue damage is avoided</li> <li>- compared to monopolar application: less energy is needed, takes less time</li> </ul>	“None of the five patients in this study experienced intra- or post-operative complications.”
	Kotecha: Histopathological and ultrastructural effects of cutting radiofrequency energy on palatal soft tissues: a prospective study, Eur Arch Otorhinolaryngol (2011) 268:1829–1836	<ul style="list-style-type: none"> <li>- measurable improvement in snoring</li> <li>- compared with CO2 LASER: more accurate and less local trauma</li> <li>- minimal collateral injury</li> </ul>	(no information)
	Tatla: Celon Radiofrequency thermo-ablative alaroplasty for snoring, The Journal of Laryngology & Otology, October 2003, Vol. 117	<ul style="list-style-type: none"> <li>- <b>significant reduction in snoring</b></li> <li>- <b>high patient acceptability</b></li> <li>- only little inconvenience</li> <li>- <b>minimal pain</b></li> <li>- compared to the Somnus unit: less risky because of the bipolar technique, safer</li> </ul>	1/10 patients: “mucosal ulceration”

		<p>because of the auto-stop power control, easier handling because of the unit's simpler design</p>	
	<p>Plzak: Combined bipolar radiofrequency surgery of the tongue base and uvulopalatopharyngoplasty for obstructive sleep apnea</p>	<ul style="list-style-type: none"> <li>- <b>AHI, AI and ODI were improved</b></li> <li>- <b>ESS was significantly improved</b></li> <li>- <b>success rate was 51.7%</b></li> <li>- <b>safe procedure that is easy to perform and well tolerated</b></li> <li>- effective in reducing respiratory parameters and improving subjective symptoms of OSA</li> <li>- <b>advantages of this method are the single session procedure, simple feasibility, bipolar technique and short time of the procedure</b></li> </ul>	<p>-“No severe complications such as infections, abscesses or airway obstruction occurred” -postoperative bleeding -temporary velopharyngeal insufficiency -ulceration of the base of the tongue -temporary taste change</p>
	<p>Balsevicius: Controlled trial of combined radiofrequency-assisted uvulopalatoplasty in the treatment of snoring</p>	<ul style="list-style-type: none"> <li>- <b>Combined RF-UPP showed to be effective in the treatment of snoring and mild to moderate OSAS</b></li> <li>- <b>After combined RF-UPP patients demonstrated improvement in their mean AHI (significantly reduced)</b></li> <li>- <b>The Health Related Quality of Life of the patients improved significantly</b></li> <li>- <b>The mean values of depressive symptoms decreased statistically significantly.</b></li> <li>- <b>mean snoring intensity, measured with the VAS, decreased by more than 50%</b></li> <li>- a safe procedure with low rate of complications and low postoperative morbidity</li> </ul>	<p>“No major complications”</p>
	<p>Civelek S, et al. GlideScope Video Laryngoscope–</p>	<p>/</p>	<p>“None of the patients included</p>

	Assisted Tongue Base Radiofrequency for the Treatment of		in our study demonstrated complications.”
	Van den Broek E, et al. UPPP combined with radiofrequency thermotherapy of the tongue base for the treatment of obstructive sleep apnea syndrome.	<ul style="list-style-type: none"> <li>- overall success rate increased with additional RFITT</li> <li>- RFTB added to UPPP is technically straightforward, easy to perform, safe, and well tolerated</li> </ul>	“No serious adverse events occurred”
	Olszewska: Selected surgical managements in snoring and obstructive sleep apnea patients	/	“No complications were observed in our study.”
<b>Head and neck cancer</b>	Liukko: Radiofrequency induced thermotherapy: an alternative palliative treatment modality in head and neck cancer, Eur Arch Otorhinolaryngol (2006)	<ul style="list-style-type: none"> <li>- efficient, safe, reproducible</li> <li>- minimal damage to adjacent tissue</li> <li>- less side effects than monopolar technique</li> <li>- rapid procedure</li> <li>- destruction of the tumour and pain reduction</li> <li>- precise thermal effects</li> </ul>	“There were no treatment related complications.”
<b>Turbinate Hypertrophy</b>	Ochi: The Clinical Effect of Radiofrequency Thermotherapy in Cases of Allergic Rhinitis , Nippon Jibiinkoka Gakkai Kaiho (Tokyo) 107: 695-701, 2004	<ul style="list-style-type: none"> <li>- <b>more effective than CO2 laser</b></li> <li>- improvement in nasal patency</li> <li>- low risk of complications</li> <li>- improvement of symptoms</li> <li>- <b>high level of patient satisfaction</b></li> <li>- <b>no side effects</b></li> </ul>	(no information)
	O’Connor-Reina: Radiofrequency volumetric tissue reduction for treatment of turbinate hypertrophy in children, Int. J. Pediatr. Otorhinolaryngol. (2007)	<ul style="list-style-type: none"> <li>- <b>less adverse events than other techniques</b></li> <li>- <b>significantly improves nasal breathing (3,5 -&gt; 7 (100%))</b></li> <li>- <b>safe, precise and effective</b></li> <li>- <b>good patient acceptance</b></li> <li>- <b>advantageous over resection or electrocautery</b></li> </ul>	“No adverse effects were encountered. One primary bleed due to tonsillectomy was the only complication in this group.”
	Seeger: Bipolar Radiofrequency-Induced Thermotherapy of Turbinate Hypertrophy: Pilot Study and 20 Month’s Follow-up, Laryngoscope 113: January 2003	<ul style="list-style-type: none"> <li>- improvement of their nasal breathing</li> <li>- no side effects</li> <li>- <b>nasal flow increased significantly (172 -&gt; 32)</b></li> <li>- minimal pain</li> <li>- high patient</li> </ul>	“ <b>Complications that needed to be treated, such as strong bleedings, synechia formation, or rhinitis sicca were not observed. In no case did</b>

		<ul style="list-style-type: none"> <li>- satisfaction efficient, gentle, and function-maintaining alternative</li> </ul>	<b>medication for pain have to be administered."</b>
<b>Tonsils</b>	Stelter: Double-blind, randomised, controlled study of post-operative pain in children undergoing radiofrequency tonsillotomy versus laser tonsillotomy, The Journal of Laryngology & Otology, 1 of 6. 2010	<ul style="list-style-type: none"> <li>- more rapid than treatment with laser</li> <li>- easier to transport and to handle for the surgeon</li> </ul>	(no information)
	Pfaar: Treatment of hypertrophic palatine tonsils using bipolar radiofrequency-induced thermotherapy (RFITT), Acta Oto-Laryngologica, 1 - 6	<ul style="list-style-type: none"> <li>- <b>a gentle and safe treatment alternative to tonsillectomy or tonsillotomy</b></li> <li>- Postoperative pain, swallowing and speaking difficulties, and perioperative blood loss were significantly lower, and the duration of surgery was significantly shorter (all p&lt;0.05) in the RFITT group</li> <li>- <b>significant decrease in the tonsil volume over the total study time (40%)</b></li> </ul>	<b>"no bleeding complications were seen"</b>

## OVERVIEW:

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### Snoring, OSAS:

- **Effective treatment:**
  - o a highly effective treatment of snoring (VAS 8,5 (1,5) -> 2,0 (2,1)) (Baisch)
  - o significant reduction in snoring (Tatla)
  - o AHI, AI and ODI were improved (Plzak)
  - o ESS was significantly improved (Plzak)
  - o success rate was 51.7% (Plzak)
  - o Combined RF-UPP showed to be effective in the treatment of snoring and mild to moderate OSAS (Balsevicius)
  - o After combined RF-UPP patients demonstrated improvement in their mean AHI (significantly reduced) (Balsevicius)
  - o The Health Related Quality of Life of the patients improved significantly (Balsevicius)
  - o The mean values of depressive symptoms decreased statistically significantly. (Balsevicius)
  - o mean snoring intensity, measured with the VAS, decreased by more than 50% (Balsevicius)
- **Patience acceptance:**
  - o high patient acceptability (Tatla)
  - o minimal pain (Tatla)
- **No complications:**

- Complications did not occur (Baisch)
- No postoperative complications (Den Herder)
- **ease of use:**
  - safe procedure that is easy to perform and well tolerated (Plzak)
  - advantages of this method are the single session procedure, simple feasibility, bipolar technique and short time of the procedure (Plzak)

### Turbinates:

- **More effective than other methods:**
  - more effective than CO2 laser (Ochi)
  - advantageous over resection or electrocautery (O'Connor-Reina)
- **Patient acceptance:**
  - high level of patient satisfaction (Ochi)
  - good patient acceptance (O'Connor-Reina)
- **Side effects:**
  - no side effects (Ochi)
  - less adverse events than other techniques, safe, precise and effective (O'Connor-Reina)
  - Complications that needed to be treated, such as strong bleedings, synechia formation, or rhinitis sicca were not observed. (Seeger)
- **No complications:**
  - Complications that needed to be treated, such as strong bleedings, synechia formation, or rhinitis sicca were not observed. In no case did medication for pain have to be administered (Seeger)
- **Effective treatment:**
  - significantly improves nasal breathing (3,5 -> 7 (100%)) (O'Connor-Reina)
  - safe, precise and effective (O'Connor-Reina)
  - nasal flow increased significantly (172 -> 32) (Seeger)

### Tonsils:

- **No complications:**
  - no bleeding complications were seen (Pfaar)
- **Effective treatment:**
  - a gentle and safe treatment alternative to tonsillectomy or tonsillotomy (Pfaar)
  - significant decrease in the tonsil volume over the total study time (40%) (Pfaar)

### **Baisch:**

“Snoring scores were reduced after the first session (...) and showed further improvement after the second session (...). “

“Daytime sleepiness (ESS) improved from baseline to the first follow-up and to the second follow-up (...).”

“All the other parameters (speech, taste, swallowing, pharyngeal irritation) remained unchanged (...).”

„Complications did not occur. “

### **Den Herder:**

„This study demonstrates that bipolar RFTB in patients with obstruction at the tongue base only (...) is a safe and simple procedure under local anesthesia (...).”

“Available tongue base procedures that alleviate obstruction of the lower pharynx include mandibular osteotomy with genioglossus advancement (GA), maxillomandibular advancement (MMA) [3], partial midline tongue resection, and hyoidthyroidpexia (HTP or hyoid suspension) [4, 5]. These invasive approaches, especially MMA, can be very effective in treating severe OSAS. However, these techniques require general anesthesia, longer hospitalization, and appear to result in a higher postoperative morbidity and remain held in reserve for severe OSAS only. **For mild to moderate OSAS, these procedures are too extensive and there is a need for less invasive procedures in case of mild pathology.**”

“Bipolar thermo-technology, as compared to monopolar technology seems to reduce morbidity, such as secondary thermal damage (...).”

„adverse event rate  $2/111 = 1.8\%$ “

„No complications during this study were observed.”

“The RFTB could be considered as first choice treatment in case of snoring and mild OSAS.”

### **Kotecha: Radiological airway changes following bipolar radiofrequency volumetric tissue reduction**

„Post-operative pain is minimal (...). “

“The effect of bipolar energy application on clinical parameters has also been described and has been deemed safe and simple.”

“uses much less energy per treatment session than monopolar application, and thus takes less time to perform.”

“It enables precise placement of energy between two electrodes, with consequent avoidance of secondary thermal damage.”

“Bipolar radiofrequency volumetric tissue reduction offers a safe, quicker, alternative treatment and requires less energy application, compared with monopolar radiofrequency application.”

“None of the five patients in this study experienced intra- or post-operative complications.”

### **Kotecha: Histopathological and ultrastructural effects of cutting radiofrequency energy on palatal soft tissues: a prospective study**

“(…) a safe and effective method for treating patients with snoring and mild obstructive sleep apnoea (OSA).”

“(…) measurable improvement in polysomnography and Epworth sleepiness scores in addition to subjective symptom improvements”

“Our pilot study demonstrated improvements in snoring outcomes in keeping with earlier studies.”

“(… ) increased accuracy and less local trauma when using RF compared to CO2 LASER.”

“Cutting RF surgery causes minimal histological and ultrastructural collateral injury to the soft palate during resection for the treatment of snoring and mild OSA.”

### **Liukko:**

“It has demonstrable efficacy, safety and reproducibility in the management of solid malignancies.”

“(…) minimal damage to adjacent tissue.”

“The automatic power control avoids adhesions of the RFITT probes to the tissue.”

“minimizes the undesirable effects associated with monopolar techniques.”

„An ambulatory application is also possible and the procedure is rapid.”

“The short-term outcome of the treatment (… ) was reduced pain (n=9), decreased secretion and bleeding from the tumour site (n=5), relief of dysphagia (n=2), relief of trismus (n=1), and secured compromised upper airway (n=3).”

“(…) the imaging demonstrated treatment-induced necrosis and destruction of the tumours”

“Nine out of ten patients experienced pain relief. Immediate palliation including relief of trismus, improved breathing through the nose, and improved mouth closure, was seen in several cases.”

“The procedure can be performed safely with precise thermal delivery to the tissue.”

“RFITT seems to be reassuringly effective in palliative treatment”

“There were no treatment related complications.”

### **Ochi:**

“The results of a nasal patency test also demonstrated that a statistically significant improvement in nasal patency was achieved after this treatment (P<0.05).”

“In almost all cases, the general symptoms of allergic rhinitis including nasal obstruction, nasal discharge, olfactory disorder, headache and sleep were improved by RFITT.”

“Radiofrequency electrocoagulation, which carries a lower risk of complications, seems to be an effective therapeutic technique for allergic rhinitis.”

“As demonstrated by these results, this surgical treatment achieved a higher level of patient satisfaction.”

“Another advantage is preservation of the physiological functions of the inferior nasal concha.”

“(…) this surgical treatment entails low risk of forming mucosal lesions or necrosis of the inferior turbinate bone.”

“Kikuchi et al. conducted a questionnaire to evaluate the long-term effect of CO2 laser treatment. According to their results, the effectiveness rate was 44% (...).”

“Seeger et al.7) reported that the effectiveness rate measured 20 months after RFITT was 85%.”

#### **O’Connor-Reina:**

„Eighty-seven children (94%) had significantly improved nasal breathing postoperatively.”

“The results of this study demonstrate that RVTR is a safe, effective method for the treatment of turbinate hypertrophy in children. In addition, our data demonstrates good patient acceptance over a period of 1 year.”

“Laser, diathermy and cold dissection have been the methods of choice for this procedure. Most of these techniques provide satisfactory results, but adverse events are frequently observed (...).”

“RVTR is advantageous over resection or electrocautery and laser surgery because of the applied biophysics of radiofrequency tissue ablation.”

“Because of the lower temperature of RU, we consider it to be more accurate, minimally invasive, and to injure less collateral tissue.”

“The absence of complications is one of the great advantages for treating this pathology by this method.”

“No adverse effects were encountered. One primary bleed due to tonsillectomy was the only complication in this group.”

#### **Tatla:**

“(…) a significant reduction in VAS snoring was noted from initial levels to those scored at six and 16 weeks in nine of 10 patients (...).”

“(…) procedures are well tolerated with minimal analgesia requirements.”

“This study revealed minimal morbidity and high patient acceptability, the patients requiring minimal analgesia and under little inconvenience, returning to work either the same day, or the day thereafter.”

“The authors also found that the simplicity of the Celon unit’s design made for easier handling by the surgeon.”

#### **Stelter:**

“Radiofrequency tonsillotomy took about half the time of laser tonsillotomy (...).”

“Compared with the carbon dioxide laser, the radiofrequency equipment is more easily transportable and does not require a special surgical environment. Furthermore, handling, manoeuvring and adjustment of radiofrequency instruments are easier, compared with the laser probe.”

#### **Seeger:**

“Nearly all patients reported an improvement of their nasal breathing, with 68% of them reporting a full and 29% a partial recovery.”

“Side effects, such as bleeding, synechia, or atrophic changes of the mucosa, which would have to be treated, were not observed.”

“After 20 months, nearly all patients reported an improvement of their nasal breathing, with 68% of the interviewed describing the result to be very good, 17% feeling a considerable relief, 12% stating the effect to be little, and only 3% having no benefit (Fig. 2).”



“At the same time, the nasal flow increased significantly by 30% (...).”

“Ninety-five percent of the patients considered their pain to be low and well tolerable, and 5% felt the pain to be intolerable (Fig. 4).”

“Eighty-five percent of all patients were satisfied with the therapeutic result, 82% reported an improvement in terms of existing accompanying symptoms, and 95% stated that they would be subject to this therapy again if the nasal airway obstruction recurs.”

“We assume that the good results are related to the precise submucosal thermal lesions caused in the turbinate. This is a consequence of the bipolar needle tip into which both electrodes are integrated and the acoustic monitoring of the coagulation procession combination with the automatic power control.”

“(...) treatment of turbinate hypertrophy using bipolar RFITT offer an efficient, gentle, and function-maintaining alternative to other well-established methods. In addition, RFITT can be performed on an outpatient basis using local anesthesia.”

#### **Pfaar:**

“Radiofrequency volume reduction of palatine tonsils is a gentle and safe treatment method in selected patients, which should carefully be considered as an alternative to tonsillectomy or tonsillotomy”

“Postoperative pain, swallowing and speaking difficulties, and perioperative blood loss were significantly lower, and the duration of surgery was significantly shorter (all p<0.05) in the RFITT group.”

“In the patients treated with RFITT, there was a significant decrease in the tonsil volume over the total study time (...).”

“In the inter-group comparisons, there was a significantly higher pain level in the TE group compared with the RFITT group at all visits (...).”

“Difficulty in swallowing and sensation of swelling in the throat: In the inter-group comparisons, there was a significantly higher level in the TE group compared with the RFITT group at visits D4 until D6 (...).”

“In the inter-group comparisons, there was a significantly higher level in difficulty in speaking in the TE group compared with the RFITT group at visits D3 until D6 (...).”

“The blood loss was significantly higher in the TE group compared with the RFITT group (...).”

“no bleeding complications were seen”

#### **Plzak:**

“AHI, AI and ODI were improved, only AHI and AI statistically significantly in both groups.”

“Subjectively, ESS was significantly improved, while snoring VAS was improved but not significantly in both groups.”

“The treatment success rate was 51.7% for the study group and 41.9% for the control group, with a significant difference (p = 0.04).”

“Bipolar RFBT is a minimally invasive and safe procedure that is easy to perform and well tolerated.”

“It is effective in reducing respiratory parameters and improving subjective symptoms of OSA.”

“The advantages of this method are the single session procedure, simple feasibility, bipolar technique and short time of the procedure.”

**Balsevicius:**

“Combined RF-UPP showed to be effective in the treatment of snoring and mild to moderate OSAS overcoming the RFT alone.”

“Combined RF-UPP patients demonstrated improvement in their mean AHI”

“The Health Related Quality of Life of the patients improved significantly after the combined RF-UPP”

“The mean values of depressive symptoms of the patients after the combined RF-UPP treatment decreased statistically significantly.”

“After two sessions of combined RF-UPP, mean snoring intensity, measured with the VAS, decreased from 67.89 points to 33 points ( $p < 0.001$ ) in our series at short follow-up.”

“The RF-UPP showed to be a safe procedure with low rate of complications and low postoperative morbidity.”

“No major complications (paralysis of the soft palate, velopharyngeal insufficiency, palatal fistula, or perforation) were noted after the RFT or RF-UPP treatment”

**Civilek:**

“None of the patients included in our study demonstrated complications.”

**Broek:**

“No serious adverse events occurred.”

“RFTB is well tolerated and safe.”

“In our study the overall success rate increased with 7%, from 42 to 49%, by adding RFTB.”

“We also found that RFTB added to UPPP is technically straightforward, easy to perform, safe, and well tolerated.”

**Olszewska:**

“No complications were observed in our study.”