

Intraindividual Comparison of 1,470 nm Diode Laser versus Carbon Dioxide Laser for Tonsillotomy: A Prospective, Randomized, Double Blind, Controlled Feasibility Trial

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Introduction: The need for reduction of post-tonsillectomy hemorrhage has led to promotion of tonsillotomy techniques for tonsil tissue reduction in obstructive tonsillar hypertrophy. This trial compares ablative tissue effects using 1,470 nm diode laser and carbon dioxide laser for tonsillotomy in an intraindividual design.

Methods: 21 children aged 3–13 years (mean age 6.3 years) underwent laser tonsillotomy for obstructive tonsillar hypertrophy in this double blind, prospective, randomized, clinical feasibility trial. In each of the blinded patients, tonsillotomy was performed using fiber guided 1,470 nm diode laser (contact mode, 15 W power) on the one side and carbon dioxide laser (12 W power) on the other side. An independent, blinded physician documented clinical presentation and patients' symptoms preoperatively and on Days 1, 3, 7, 14, and 21 post-operatively using standardized questionnaire including VAS for each side separately.

Results: The mean duration of operative treatment was 2.7 min using 1,470 nm laser and 4.9 min using carbon dioxide laser respectively. Intraoperative bleeding and the frequency of bipolar forceps use for intraoperative bleeding control was significantly less using 1,470 nm diode laser system. There was no difference in post-operative pain scores between the carbon dioxide laser treated and the 1,470 nm fiber guided diode laser treated side. No infections, hemorrhages or other complications occurred in the course of the 3 weeks post-operative period.

Conclusions: A fiber-guided 1,470 nm diode laser system offers an efficient and safe method for tonsillotomy as treatment of obstructive tonsillar hypertrophy. Compared to our standard practice (carbon dioxide laser), 1,470 nm laser application provides comparable tissue ablation effects with less intraoperative bleeding and shorter operation time. *Lasers Surg. Med.* 44:558–563, 2012.

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Key words: carbon dioxide laser; diode laser; intraindividual design; tonsillar hypertrophy; tonsillotomy; tonsillectomy

INTRODUCTION

Tonsil removal is one of the most commonly performed surgical interventions in otolaryngology. Otolaryngologists throughout history have explored a wide number of different techniques for tonsil reduction and/or removal to identify the most effective surgical method that reduces intra-operative blood-loss, operative time, post-operative pain, and post-operative haemorrhage [1]. Recurrent and in part life-threatening hemorrhages have recently led to an even more strict indication for tonsillectomy especially in children [2]. Consequently, tonsillotomy techniques are nowadays even more promoted to hit these requirements. Besides the reported reduced risk for post-operative haemorrhage when compared to tonsillectomy [3], tonsillotomy also may reduce the period and severity of post-operative pain and allows a faster return to normal activity and diet [4,5]. In tonsillectomised patients pain can last for up to 3 weeks [6] and requires strict analgesia regimes for pain control [7]. In addition to the conventional "cold"/blunt dissection, numerous techniques for total tonsil removal and/or volume reduction have been developed in order to reduce pain and post-operative bleeding, for example, bipolar radiofrequency-induced thermotherapy [8], coblation [9], monopolar electrical knife [10], ultrasound scalpel [11], bipolar electrosurgical scissors [12], argon supported monopolar needle [13], microdebrider [14]. Since the introduction of laser-assisted surgery in the ENT-field in the early 1980s, carbon dioxide laser

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Miriam Havel and Ronald Sroka contributed equally to this study.

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represents the most frequently employed laser system in tonsillotomy [15] as it provides excellent tissue ablation and haemorrhage control.

Recently, a novel certified medical 1,470 nm diode laser system has been introduced. Due to its absorbance profile within human tissue, the system is expected to offer both, good ablative, and coagulative tissue effects. It would therefore be useful for a full range of applications that could originally only be performed with two or more systems. Diode lasers also have lower acquisition and maintenance costs than the CO₂ devices, and they are more versatile in the clinical setting due to their smaller size, transportability and power supply requirements.

As already investigated formerly, a fiber guided 1,470 nm diode laser system is a suitable instrument for endonasal "non-contact" application for treatment of hyperplastic inferior nasal turbinates [16]. Due to its excellent cutting abilities observed in ex-vivo experiments (unpublished data) this prospective controlled clinical trial was initiated to compare ablative tissue effects using the 1,470 nm diode laser system and our standard practise (carbon dioxide laser) for tonsillotomy in an intraindividual manner.

MATERIALS AND METHODS

Twenty-one children aged 3–13 years (mean age 6.3 years) participated in this prospective, randomized, double blind feasibility trial. Informed consent was obtained from patients' parents prior to inclusion into the study. Full ethical approval was obtained to perform the trial at the Ethical Committee at University of Munich. All patients suffered from obstructive symptoms due to tonsillar hypertrophy as assessed by a standardized questionnaire using a visual analogue scale (0 = no impairment, 10 = massive impairment). The following symptoms were enquired: snoring, muffled speech, sleep apnea, impaired alimentation/development/prosperity. All patients/patients' parents received this questionnaire prior to laser treatment as well as on Days 1, 3, 7, 14, and 21 following surgery. Patients with examination findings of tonsillar asymmetry, bleeding disorders and those with

a history of recurrent tonsillitis or peritonsillar abscess were excluded.

After adequate preoperative work up (medical history, clinical examination, informed consent), patients were randomized for tonsillotomy procedure by lot with carbon dioxide laser on the one and 1,470 nm diode laser on the other side. All procedures were performed under general anesthesia and the patients were blinded towards the randomization result. For laser surgery, the surrounding tissue was protected with wet swabs according to laser safety regulations. The carbon dioxide laser was set to 12 W in continuous wave mode (Wavelength: 10,600 nm, Sharplan 20C, Laser Industries LTD, Tel-Aviv, Israel) and the fiber-guided 1,470 nm diode laser (Medilas D 1470, Dornier MedTech Europe, Wessling, Germany) was set at 15 W in continuous wave mode and used in contact mode according to the findings in the ex-vivo experiments (data not shown). The part of the tonsil protruding into the pharynx (Fig. 1) was removed exclusively. Intraoperative haemorrhage was controlled by punctual bipolar cautery (20 W) if necessary. No local anesthetics were used.

The length of the procedure, the cutting ability of the laser device, the occurrence of intraoperative bleeding and the frequency of bipolar cautery for intraoperative bleeding control were recorded for each treated side, respectively.

Post-operatively, the pain experienced in rest as well as pain while swallowing for each treated side, respectively, was subjectively assessed via standardized questionnaire (interval scale with 0 = no pain, 10 = massive pain), as even very young children can easily discriminate between pain on the right and left side [17]. Use of analgesics for post-operative pain control as well as persistency of obstructive symptoms (snoring, muffled speech) was documented. An independent physician, who was blinded towards the site-specific treatments, performed clinical examinations assessing the post-operative condition of the surgical areas (swelling tonsillar remnant, swelling of uvula, scab formation, infection, bleeding) on Days 1, 3, 7, 14, and 21 following surgery. On the last clinical

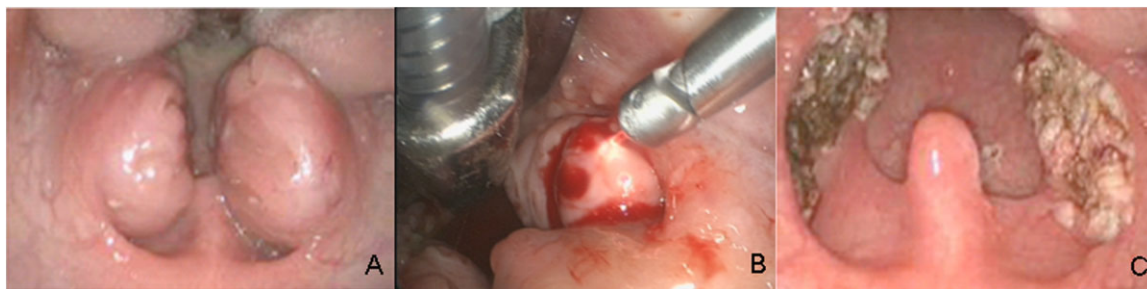


Fig. 1. Intraoperative site (wet swabs removed). The protruding part of the tonsil is to be reduced (A). Fiber-guided contact application of 1,470 nm laser light via bare fiber mounted onto ENT-fiber guidance system (B) and final post-operative view (1,470 nm diode laser on the right, carbon dioxide laser on the left side, C).

examination, all patients/patients parents were asked if they would have the procedure repeated and/or recommend it to a friend.

Statistical analysis was performed using Wilcoxon signed rank-test for non-parametric data. A P -value <0.05 was considered statistically significant.

RESULTS

Preoperative Parameters

Patients' symptoms and clinical findings. All patients suffered from tonsillar hypertrophy with the main symptom of "snoring" ($n = 21$) and 62% of patients from "muffled speech" ($n = 13$). Nine patients (43%) were preoperatively screened via polysomnography to rule out a sleep apnea due to apnea episodes as reported by parents on the initial visit. Average AHI (apnea/hypopnea index) amounted to 6,2/h (min. 2,4/h, max. 14,1/h) with an average desaturation of 82% (min. 90,3%, max. 73,3%). All patients presented hyperplastic tonsils as assessed by an ENT-specialist on the initial clinical examination. No "kissing tonsils" were detected. In three patients, an indication for simultaneous adenotomy was given due to recurrent middle ear effusion resulting in a persistent conductive hearing impairment.

Intraoperative Parameters

No immediate complications (e.g., major haemorrhage) related to the treatment were observed intraoperatively using either the carbon dioxide or the 1,470 nm diode laser system.

The mean total operation time including implementation of laser safety instructions was 7.6 min (± 4.7 min) for the whole tonsillotomy procedure. The mean duration of the operative treatment itself considered separately per treated site amounted to 2.7 min (± 1.9 min) using the 1,470 nm laser and 4.9 min (± 3.3 min) using the carbon dioxide laser, respectively ($P = 0.001$). The cutting abilities of the lasers were subjectively rated as 1 = insufficient, 2 = poor, 3 = moderate, 4 = good, and 5 = very good by the operating surgeon. The 1,470 nm laser scored $3.3 (\pm 0.9)$ compared to carbon dioxide laser scoring

$3.7 (\pm 1.2)$ with no statistically significant difference in cutting abilities between the laser systems.

Records of bleeding observed intraoperatively (0 = no bleeding, 1 = slight bleeding and 2 = bleeding requiring intervention) showed that the dissection of the tonsil using the 1,470 nm diode laser led to significantly less bleeding as compared to the carbon dioxide laser (0.5 ± 0.7 vs. 1.2 ± 0.7 , $P = 0.003$, see Fig. 2A). Consequently, the use of bipolar cautery (scoring 1 point for every use of a bipolar forceps) was significantly lower (1.3 ± 1.6 at the carbon dioxide treated side vs. 0.4 ± 0.7 at the 1,470 nm diode laser treated side, $P = 0.005$, see Fig. 2B).

Post-Operative Parameters

Patients' symptoms during the post-operative healing period. The mean pain score as determined by standardized questionnaire was slightly higher while swallowing (3.5 ± 0.6 on both sides on Day 1, see Fig. 3B) than at rest (0.9 ± 0.3 for 1,470 nm laser treated and 0.9 ± 0.7 for CO₂ treated side on Day 1, see Fig. 3A) as expected and prevailed predominantly on the first 3 days following surgery. No significant differences concerning post-operative pain were detected between the laser systems.

This is reflected by the pain medication required for pain control during the post-operative period. There was a moderate use of analgesics (paracetamol supp. or ibuprofen sirup in very young children or tablets respectively in older children) in the first 3 days post-operatively. 53% of patients required pain medication on Day 1, 47% of patients on Day 3 following surgery. On Day 7, two patients required pain medication for food intake. There were no analgesics used for pain control after Day 7 post-operatively.

For further symptoms associated with obstruction (snoring, muffled speech) a general assessment was performed, as these symptoms cannot be assessed separately for each side. Regarding these symptoms, there was a significant, subjectively rated reduction in symptom severity on Day 1 post-operatively as compared to preoperative findings ($P < 0.001$, respectively, see Fig. 4A,B) followed

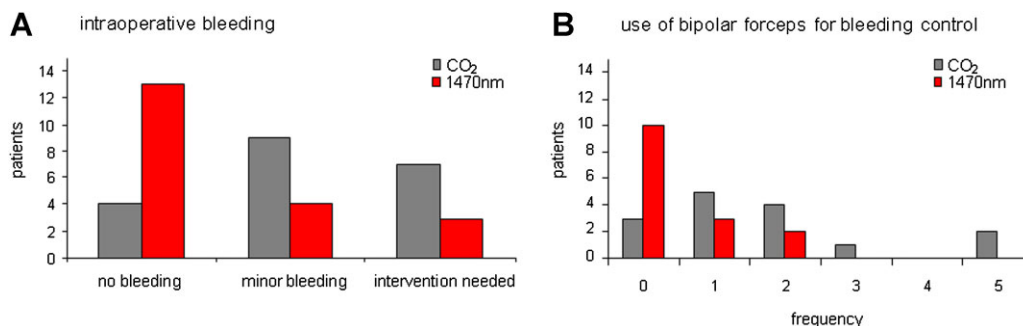


Fig. 2. Intraoperative bleeding (A) and use of bipolar forceps for intraoperative bleeding control (scoring 1 point for every use of the bipolar forceps, B) for CO₂- and 1,470 nm diode, respectively, as assessed intraoperatively, $n = 21$.

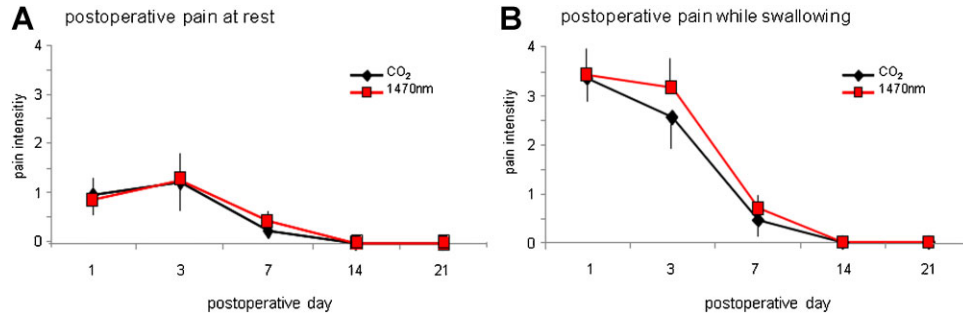


Fig. 3. Post-operative pain in rest (A) and post-operative pain while swallowing (B) for CO₂- and 1,470 nm diode laser treated side, respectively, as assessed during the post-operative period (average values with standard deviation, $n = 21$).

by a further, constant improvement in the course of the post-operative period to complete cessation of the symptoms on the final post-operative visit.

On the last examination (Day 21 post-operatively) all (100%) of patients/patients' parents declared to be content with the performed procedure and they would have it repeated again, 100% felt they would recommend the procedure to a friend.

Clinical findings during the post-operative healing period

No significant differences between the laser systems were detected concerning swelling of the tonsillar fossae/ tonsillar remnant, scab formation in the wound area as well as overall healing process in the course of the post-operative period (Fig. 5A,B).

No infection, bleeding or other complications were observed or reported on examinations of the patients in the course of the post-operative period.

As expected, the obstructive symptoms (snoring and muffled speech) reported after the laser treatment seemed to correlate with the extent of tonsillar remnant swelling as well as scab formation observed and showed corresponding improvement in the course the post-operative period. On both sides, an adequate and symptomatic

tissue reduction of the hyperplastic tonsils was witnessed after 3 weeks.

DISCUSSION

Based on recent post-tonsillectomy haemorrhage data/cases, the younger the child, the more restrictive the indication for tonsil removal should be established [2]. Due to the risk of secondary bleeding, tonsillotomy is often preferred over tonsillectomy in pure obstructive tonsillar hyperplasia without recurrent infections. Besides the risk of haemorrhage, the post-operative pain represents the major issue in tonsillectomised patients as a result of disruption of mucosa and glossopharyngeal and/or vagal nerve fibers with consecutive inflammation and spasm of pharyngeal muscles leading to ischemia and a protracted cycle of pain [18]. In tonsillotomy, the tonsillar capsule and pharyngeal muscle remain untouched and the resulting pain is therefore less. As extensively studied by Hultcrantz et al. [5], both risk for haemorrhage and post-operative pain are significantly reduced and the quality of life increased when tonsillotomy is performed rather than tonsillectomy [19,20]. At present, the most frequently applied technique for tonsillotomy is, besides monopolar electrosurgery and radiofrequency, the carbon dioxide laser [4,15]. Carbon dioxide laser light at $\lambda = 10,600$ nm is

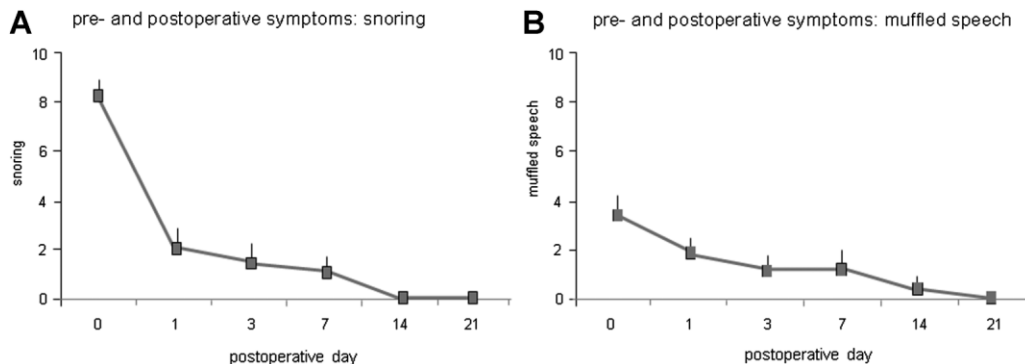


Fig. 4. Preoperative assessment (time 0) and changes symptoms (snoring [A] and muffled speech [B]) in the course of the 3 weeks post-operative period (average values with standard deviation, $n = 21$).

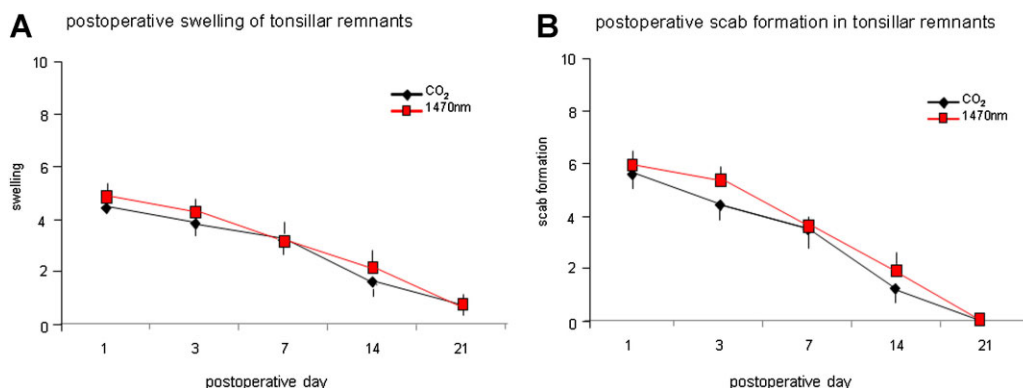


Fig. 5. Post-operative assessment in the course of the 3 weeks post-operative period of clinical condition of the operation wound areas (swelling [A] and scab formation [B]) for each treated side, respectively. Average values with standard deviation, $n = 21$.

easily delivered via mirror arm and special handpiece, and disposes of good cutting as well as haemostatic effects, so it is well established for this indication.

Due to the observations made in the *in vitro* experiments (data not shown), it was expected that the a novel, CE-marked 1,470 nm diode laser system might also (and apart from its coagulative capabilities as described in our previous study [16]) dispose of excellent tissue cutting abilities in contact mode due to the high rate of tissue ablation. This current work is the first to show the safety and efficacy of this fiber guided diode laser system emitting a light at a wavelength of 1,470 nm for tonsillotomy procedure in a small number of patients.

Although there was no significant difference in pain sensation experienced by the patients post-operatively between the two methods, there was a statistically significant difference in frequency and severity of intra-operative haemorrhage. On the carbon dioxide treated side bipolar coagulation had to be applied more frequently than on the 1,470 nm diode laser treated side because of bleeding from small vessels. The tissue damage due to carbon dioxide laser appears more superficial and the coagulation zone reaching the surrounding tissue is less pronounced than in the 1,470 nm diode laser system. This could be explained by the different tissue absorption coefficients of these wavelengths. For 1,470 nm light the absorption coefficient is about $\mu_a(1,470) = 25 \text{ cm}^{-1}$ compared to $\mu_a(10,600) = 800 \text{ cm}^{-1}$ [21]. The optical penetration is thus limited and differs by factor of 30 for these wavelengths being way more superficial for the carbon dioxide laser. Therefore, the coagulative and haemostatic effect of carbon dioxide laser might be not as efficient in the well perfused tonsillar tissue as that of the 1,470 nm diode laser.

The duration of surgery differed significantly and took about half the time using the 1,470 nm diode laser as compared to the carbon dioxide laser, mainly due to easier intraoperative handling and fewer interventions required for bleeding control.

The present study demonstrates that there is no difference in post-operative pain between laser tonsillotomy with either one of the two laser systems used during the 3 week post-operative period. Over all, the post-operative pain after tonsillotomy is very low compared to tonsillectomy. A strict analgesia regime for pain control was not needed. Most children were pain free with paracetamol suppository or ibuprofen liquid. Pain levels during food or beverage intake were higher compared to pain levels at rest, presumably due to the mechanical forces affecting the recently treated tissue, although in some studies less pain was observed while swallowing [22]. In the intra-individual design used in this work the subjects acted as their own controls, which reduces the problems caused by inter-individual variation in the perception of pain and the bias caused by peri- and post-operative administration of analgesics.

In the presented clinical case series, the 1,470 nm diode laser system disposed of good cutting ability as compared to the conventional system (i.e., carbon dioxide laser) with comparable post-operative clinical results. Speaking for both systems, there were no minor or major complications (neither intra- nor post-operatively) witnessed in the treated group of patients ($n = 21$), which corresponds well with the scientific literature for carbon dioxide and diode laser tonsillotomy [4,15,23,24]. On both treated sides the post-operative pain was mild and the post-operative recovery quick and therefore the patient acceptance and satisfaction were exceptionally high.

One of the major drawbacks of the current clinical case series is the fact that it does not provide long term follow-up data, as a recurrent hyperplasia of the reduced tonsils in up to 10% may occur when conventional methods are applied [5,19,22,23]. For the 812 nm diode laser system, however, Sedlmaier et al. [24] have shown promising long term results for this indication. Due to the small patient numbers and the lack of long term data, it is furthermore not feasible to directly compare the method to other novel approaches for a reduction of tonsillar volumes in

obstructive tonsillar hypertrophy such as radiofrequency surgery, which have also been reported to provide satisfying results [8,19,20].

A larger clinical study incorporating both radiofrequency and the 1,470 nm diode laser for tonsillotomy is therefore anticipated.

CONCLUSION

The intra-individual design of this study allows the direct comparison of carbon dioxide laser and fiber guided 1,470 nm diode laser for tonsillotomy in obstructive tonsillar hyperplasia. No differences in post-operative pain, the post-operative healing process and morbidity between these two techniques were detected. Compared to the carbon dioxide laser, the 1,470 nm diode laser provides excellent cutting abilities combined with less intraoperative bleeding leading to shorter operation times. Taking into account that it is also well suited for coagulative endonasal applications, the 1,470 nm diode laser system offers a highly efficient alternative to the conventional carbon dioxide laser in clinical practise.

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