A Double-Blind, Randomized, Intra-Individual Controlled Feasibility Trial Comparing the Use of 1,470 and 940 nm Diode Laser for the Treatment of Hyperplastic Inferior Nasal Turbinates

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Introduction: Various laser systems have been used for volume reduction of hyperplastic nasal turbinates. For endonasal application, fiber controlled diode lasers are preferred over conventional laser systems for reasons of cost and practicability. This study compares coagulative tissue effects using $\lambda = 1{,}470$ nm and $\lambda = 940$ nm lasers in treatment of hyperplastic inferior nasal turbinates in an intraindividual manner.
Methods: Twenty patients underwent laser coagulation for hyperplastic inferior nasal turbinates in this prospective, randomized, double-blind, clinical feasibility trial. In each case, one nasal cavity was treated using 1,470 nm laser (4–5 W power), the other one with 940 nm laser (12 W power), endoscopically controlled in noncontact mode. Clinical presentation and patients symptoms were documented preoperatively and on day 1, 3, 7, 14, and 21 postoperatively using rhinomanometry, standardized questionnaires including SNOT 20 GAV (German adapted version), and separate endoscopic examination, respectively.
Results: No infections, hemorrhages, or other complications occurred intra- or postoperatively. The mean operation time was significantly shorter using the 1,470 nm diode laser as compared to the 940 nm laser. There was a significant reduction of nasal obstruction on day 21 postoperatively compared to the preoperative condition on both sides regardless of the laser system used. Evaluation of the SNOT-Scores as assessed before and 3 weeks after surgery showed significant subjective improvements.
Conclusions: 1,470 nm diode laser system offers an efficient method for tissue reduction in hyperplasia of inferior nasal turbinate. Compared with our standard practice (940 nm diode laser), 1,470 nm diode laser application provides an equivalent tissue reduction in shorter operation time using less total energy and a comparable relief of nasal obstruction postoperatively. Lasers Surg. Med. 43:881–886, 2011. © 2011 Wiley Periodicals, Inc.

Key words: diode laser; endonasal application; inferior nasal turbinate hypertrophy; intraindividual design; nasal obstruction

INTRODUCTION

Inferior turbinate hypertrophy is a common cause of nasal airway obstruction. Whilst the mainstay of treatment for this condition is with the use of pharmacologic therapy, there remains a cohort of patients that are refractory to this treatment and require surgery. Numerous surgical techniques have been employed over the years, including total or partial turbectomy, submucous resection, laser surgery, electrocautery, cryosurgery, and radiofrequency ablation [1]. It has been shown that endonasal laser treatments cause limited tissue trauma with little or no bleeding, and reach a high patient acceptance as they can be usually performed under outpatient conditions [2–5]. Since the early 1980s, laser systems of various types have been used for surgical endonasal applications. Systems most frequently used include the carbon dioxide (CO_2) and neodymium:yttrium-aluminium-garnet (Nd:YAG) lasers. The use of holmium:yttrium-aluminium-garnet (Ho:YAG), potassium titanyl phosphate (KTP), diode of different wavelengths, and argon ion lasers has also been reported [6].

The basic difference between the various common medical laser systems is the wavelength of the emitted light, leading to altering light-tissue interactions due to optical parameters of the tissue. Most of the commonly available diode laser systems provide light at wavelengths of $\lambda = 800$–$1{,}000$ nm, mainly causing coagulative tissue effects when applied in noncontact mode. Diode lasers also have lower acquisition and maintenance costs than the CO_2 or Nd-YAG devices. They are also more versatile

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in the clinical setting due to their smaller size, transportability, and power supply requirements.

Recently, a 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 may therefore be useful for a full range of applications that could originally only be performed with two or more systems.

This study aims to compare the coagulative tissue effects and patient symptom scores using the 1,470 nm diode laser system in the treatment of inferior nasal turbinate hypertrophy compared with our standard practice diode laser 940 nm in an intraindividual manner.

MATERIALS AND METHODS

Twenty otherwise healthy individuals (10 female and 10 male, aged 18–70 years, mean 45.4 years) with bilateral inferior nasal turbinate hypertrophy participated in this prospective, randomized, double-blind feasibility trial after giving an informed consent. Full ethical approval to perform the trial was obtained from the Ethical Committee of Ludwig-Maximilian-University of Munich. All patients suffered from nasal obstruction and were therapy-refractory to conservative medical treatment. To fit the intraindividual trial design, a standardized questionnaire with an interval scale (0 = no impairment, 10 = massive impairment) was generated, assessing the severity of nasal congestion and nasal obstruction under physical exertion for each nasal cavity separately. Only patients with minimum score of 7 on less symptomatic side and a score difference with a maximum of two score points between both sides were included. The following secondary nasal symptoms were further implemented in this questionnaire with no separate assessment for each side using an interval scale (0 = no impairment, 10 = massive impairment): snoring, xerostomia, and nasality. All patients received this questionnaire prior to laser treatment as well as on day 1, 3, 7, 14, and 21 postoperatively. In addition, preoperatively and 3 weeks postoperatively the patients' symptoms were documented by means of Sino-Nasal Outcome Test (SNOT 20 German adapted version), which is a multiple-choice 20-item instrument validated for quality of life assessment in nasal disorders [7,8].

Preoperative endonasal findings prior to and after decongestion with 0.5% xylometazoline were documented endoscopically. In addition, patients were asked to give feedback on improvement of nasal airflow after application of decongestant drops to rule out a major osseous/cartilagenous component of inferior turbinate hypertrophy. Patients with a grossly deviated nasal septum, acute rhinitis/sinusitis, chronic rhinosinusitis, nasal polyps, and those with history of a surgical treatment of the nose were excluded.

After adequate preoperative work up (medical history, clinical examination including rhinomanometry prior and after decongestion, informed consent), topical anesthesia was applied for 10–15 minutes, using cotton pads soaked with a 4% tetracaine and 0.5% xylometazoline solution (1:1). For documentation and visualization purposes, a rigid endoscope (0°/4 mm, Karl Storz, Tuttlingen, Germany) was mounted to a photo- and video-documentation device (Image 1/AIDA System, Karl Storz). For a direct comparison of the two laser systems, one nasal cavity was treated using the 1,470 nm diode laser and the other one using the 940 nm diode laser (intraindividual design). After blinded randomization of patients' nasal cavities for treatment with 1,470 or 940 nm diode laser system, respectively, the application of laser light was performed in a "noncontact" mode using a flexible silica fiber (600 μm core diameter) fixed onto a custom-designed device for precise endonasal fiber guidance [9] (ENT-Fibre Guidance System, Karl Storz). Laser parameters were set to 12 W for the 940 nm diode laser system (Medilas D MultiBeam, Dornier MedTech Europe, Wessling, Germany) and to 4–5 W for the 1,470 nm diode laser system (Medilas D 1470, Dornier MedTech Europe) according to the findings gained in a series of *ex vivo* experiments (data not shown). Laser light application itself was performed via guiding the fiber from the posterior to the anterior free edge of the inferior turbinate under endoscopic control (Fig. 1). Laser light was applied until adequate blanching of the tissue was obtained as judged by the operating surgeon. In cases where the head of inferior turbinate seemed especially prominent, some single laser spots were directed solely onto the head of the turbinate.

Records of intraoperatively experienced pain (interval scale with 0 = no pain and 5 = distinct/considerable pain) were conducted for each treated site, respectively.

Postoperatively, both nasal cavities were treated with an antibiotic and steroid-containing ointment (Jellin-Neomycin® containing 0.25 g fluocinolone acetonide/

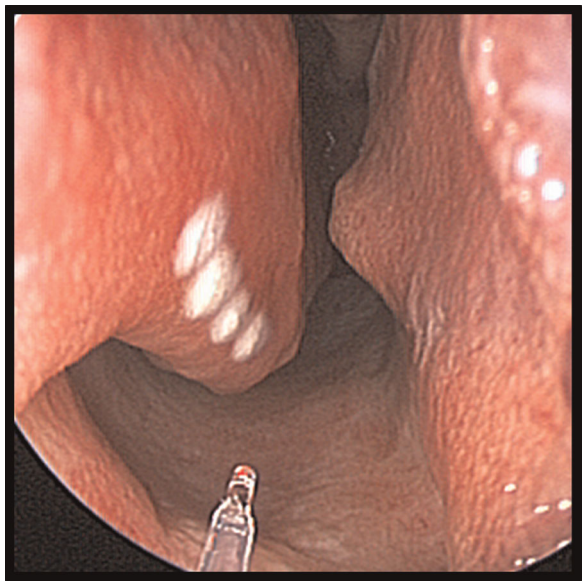

Fig. 1. Fiber-guided noncontact application of laser light via bare fiber mounted onto ENT-fibre guidance system.

4.25 g neomycin sulfate). Patients received prescriptions for nasal ointments and nasal decongestants.

After completion of the surgical procedure, the time of laser surgery, laser power settings, total amount of energy applied as well as coagulation capability as rated by the surgeon were recorded for each treated site separately. An independent physician that was blinded to the intervention performed clinical examinations and questioning of the patients using the standardized questionnaire on day 1, 3, 7, 14, and 21 following laser treatment. On the last clinical examination, all patients were asked if they would have the procedure repeated and/or recommend it to a friend.

Statistical analysis was performed using two-tailed Student's *t*-test for continuous data. A *P*-value <0.05 was considered statistically significant.

RESULTS

Intraoperative Parameters

No immediate complications (e.g., major hemorrhage) related to the treatment were observed intraoperatively using either the 940 nm or the 1,470 nm diode laser system.

The mean total operation time after application of local anesthesia including implementation of laser safety instructions was 10.53 minutes (±5.89 minutes) for the whole procedure. The mean duration of operative treatment itself considered separately per treated site amounted to 2.42 minutes (±1.54 minutes) using the 1,470 nm laser and 3.30 minutes (±1.89 minutes) using the 940 nm laser, respectively ($P = 0.03$, *t*-test). The total amount of energy used to treat the turbinates was 149 J (±68 J) on the 1,470 nm laser treated side and 697 J (±192 J) on the 940 nm laser treated side ($P < 0.001$, *t*-test). The coagulative capabilities of the lasers were recorded as 1 = poor, 2 = sufficient and 3 = very good. The 1,470 nm system scored 100% at very good compared to 940 nm system scoring 20% very good, 75% sufficient, and 5% poor.

Records of intraoperatively experienced pain (interval scale with 0 = no pain and 5 = distinct/considerable pain) revealed that this procedure was well tolerable for all patients conducted under local anesthesia. In detail, 25% of patients reported minimal pain sensation (=1) and 75% of patients perceived no pain during the procedure on the 1,470 nm treated side. During the treatment with the 940 nm laser, 40% of patients reported minimal (=1), 10% slight (=2), and 50% of patients reported no pain.

Pre- and Postoperative Parameters

SNOT 20 (GAV). Mean overall symptom score as determined by Sino-Nasal Outcome Test 20 GAV for 20 assessed items averaged preoperatively at 1.93 (±0.81) and on day 21 postoperatively at 1.10 (±0.41), showing a significant symptom reduction ($P < 0.001$, *t*-test). This total score refers to a broad range of health and health-related quality of life items with no domains or subscale differentiation, for example, nasal, sleep, or social/emotional concerns. Regarding the nasal domain separately as shown in Figure 2, the item 1 ("need to blow nose") and 3 ("runny nose") improved significantly. In the sleep domain the items 11, 12, 13, 14, and 15 ("difficulty falling asleep," "wake up at night," "lack of a good night's sleep," "wake up tired," and "fatigue") showed significant improvement.

Anterior rhinomanometry. Average rhinomanometry volumes on inspiration without decongestion on the 1,470 nm laser treated sides improved from 320 ml (±68 ml) preoperatively to 364 ml (±82 ml) on day 21 postoperatively, yet without statistical significance. The 940 nm laser treated sides showed rhinomanometry volumes of 332 ml (±57 ml) preoperatively and 361 ml (±79 ml) on day 21 postoperatively. This improvement in nasal patency was again not statistically significant.

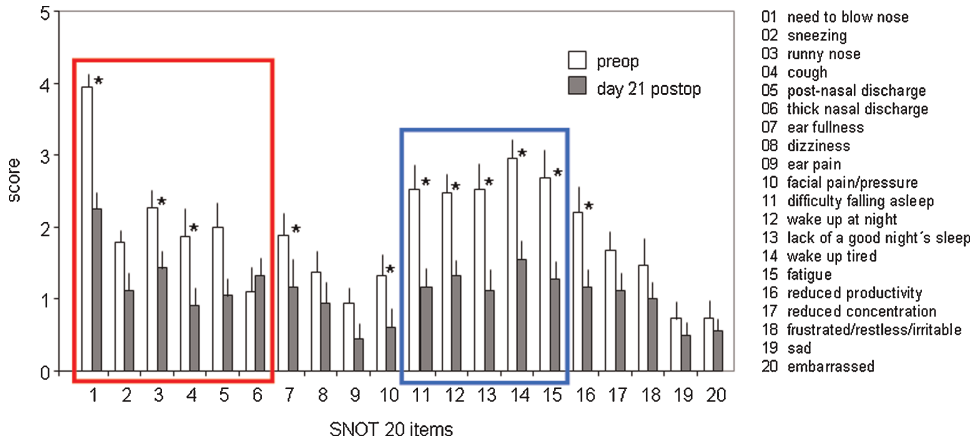

Fig. 2. Twenty items included in SNOT 20 (GAV) as assessed preoperatively and on day 21 postoperatively (average values with standard error of mean SEM, $n = 20$). Nasal (red) and sleep domains (blue) are depicted. Significant differences are indicated with asterisk ($P < 0.05$).

Standardized questionnaire: patients' symptoms. There was a significant reduction of the subjective general nasal congestion as well as reduction of the nasal obstruction during physical exertion on day 21 postoperatively as compared to preoperative findings regardless the laser system used (both $P < 0.001$, t-test). The preoperative assessment of patients' symptoms concerning nasal congestion and the obstruction during physical exertion was carried out for each nasal cavity separately. The severity of separately assessed symptoms at the preoperative visit was comparable for all patients. For further symptoms associated with nasal obstruction (snoring, xerostomia, and nasality) a general assessment was performed, as these symptoms cannot be assessed separately for each side. Regarding these symptoms, there was a significant reduction in symptom severity on day 21 postoperatively as compared to preoperative findings ($P < 0.01$, t-test, respectively).

No significant differences between the laser systems concerning subjective nasal congestion as well as nasal obstruction during physical exertion were observed in the course of the postoperative period (Fig. 3a and b).

No infection, bleeding, or other complications were reported on endoscopic examinations and questioning of the patients in the course of the postoperative period. The initial nasal obstruction after the laser treatment seemed to correlate directly with the extent of mucosa swelling and lasted for up to 3 weeks with considerable inter- and intra-patient variations. On both sides, an adequate and symptomatic tissue reduction of the inferior nasal turbinates was witnessed after 3 weeks. Eighty-five percent of all patients declared the performed procedure under topical anesthesia to be acceptable and they would have it repeated again, 90% felt they would recommend the procedure and the mode of anesthesia to a friend.

DISCUSSION

To date, the diode laser system emitting light of the wavelength $\lambda = 1{,}470$ nm was reported to be used for endovenous application as well as for treatment of benign prostatic enlargement in experimental as well as clinical settings [10–12]. As observed in our own series of *ex vivo* experiments (data not shown), the 1,470 nm diode laser system is suitable for treatment of well-perfused tissue due to its good coagulation capabilities at relatively low energy settings. However, systematic *in vivo* investigations for endonasal applications, particularly direct comparisons to established treatment methods for hyperplastic inferior nasal turbinates, are lacking.

The current trial is the first to show the safety and efficiency of 1,470 nm diode laser system for volume reduction of hyperplastic turbinates as intraindividually compared to our standard practice (940 nm diode laser system) in a prospective, randomized, and blinded manner. The macroscopically visible tissue effect produced by the 1,470 nm laser using an identical bare fiber of 600 μm core diameter as observed by the operating surgeon by means of tissue blanching was equivalent to the effects of the commonly used 940 nm laser system, yet it required a significantly shorter treatment time and total energy amount. This seems to contribute to surgeons' intraoperative assessment of the coagulation capabilities of the lasers expressing a noticeable difference in favor of the 1,470 nm diode laser.

In all cases, the treatment could be performed under local anesthesia as an outpatient procedure, and therefore the patient acceptance and satisfaction were exceptionally high. The overall pain sensation was very moderate for both laser systems used, with a treatment trend towards less intraoperative pain with 1,470 nm diode laser system.

With regards to both laser systems, there were no minor or major complications (neither intra- nor postoperatively) witnessed in the treated group of patients, which corresponds well with the published literature for diode laser coagulation of inferior nasal turbinates [13–15].

The main symptoms due to hyperplastic inferior turbinate (nasal congestion and nasal obstruction during exertion) were significantly improved as assessed by means of a standardized questionnaire comparing pre- and 3 weeks

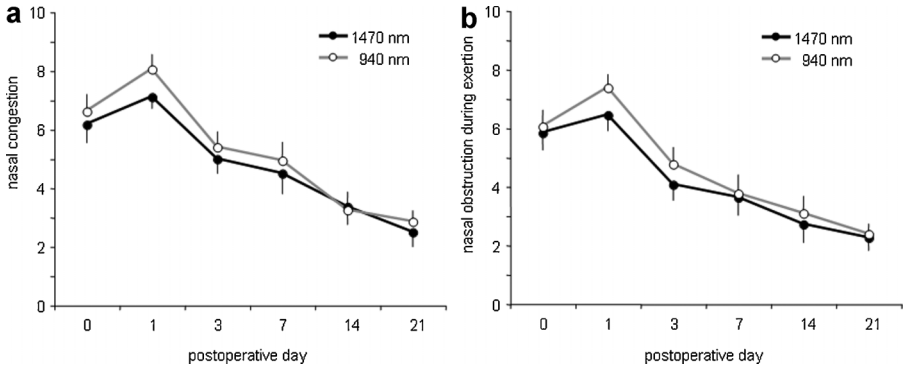

Fig. 3. Preoperative assessment (time 0) and changes in separately assessed symptoms (nasal congestion [**a**] and nasal obstruction during exertion [**b**]) in the course of the three weeks postoperative period for each treated site (average values with standard error of mean, $n = 20$).

postoperative ratings for both lasers. Corresponding to that, a significant symptom improvement was also shown concerning the first item included in the validated assessment tool SNOT 20 GAV ("need to blow nose"). Although meant for quality of life assessment in patients with rhinosinusitis, the SNOT 20 was used, because concerning its items for assessment of primary nasal symptoms ("need to blow nose," "sneezing," "runny nose," "thick nasal discharge") as well as general quality of life items (sleep, social/emotional concerns, for detailed disclosure see Fig. 2) it is a validated tool available in German [7]. As the structure of this validated clinical tool does not allow a differentiation between the two sides of the nose, an additional, standardized questionnaire was generated for a separate assessment of the nasal symptoms on each side to fit the intraindividual trial design. In the 3-week follow-up period, the nasal congestion as well as the obstruction under physical exertion did show significant improvements, yet without a difference between the two laser symptoms used.

Objective measurement of nasal patency via anterior rhinomanometry showed no significant changes. However, anterior rhinomanometry as an objective method for nasal patency assessment is controversial as it strongly depends on the person performing the measurements. In addition, mucosal swelling of the inferior turbinates is part of the physiologic vascular changes which take place during the nasal cycle and is therefore not easily ascertained objectively. As a matter of fact, there is no definition of what constitutes an enlarged turbinate in terms of objective measurement, and the diagnosis is normally made by exclusion criteria when dealing with the sensation of nasal obstruction [16]. Subjective assessment of nasal obstruction provides important information about how the patient senses the severity of the symptoms. The lack of correlation of subjective scores of nasal obstruction with objective measures of nasal obstruction have partly led to the conclusion that objective measures such as rhinomanometry may be of limited clinical value [17].

One of the major drawbacks of the current trial is the fact that it does not provide long-term follow-up data. Especially the long-term outcome seems to be the critical issue with the laser treatments of the turbinates [18,19]. For the 940 nm system as well as the Ho:YAG laser system, however, a previous study has shown promising long term results for this indication [20]. 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 turbinate volumes in nasal congestive disease such as alternative laser systems, argon plasma coagulation, or radiofrequency surgery, which have also been reported to provide satisfying results [1,21,22]. Moreover, there is currently no clear consensus or "gold standard" in the literature indicating the most optimal technique for turbinate reduction and even the selection of an operative procedure remains controversial [23,24]. This makes an appropriate evaluation or a comparison of novel techniques challenging. Nevertheless, laser reduction and radiofrequency reduction seem to be standing out as methods that can be applied under local anesthesia providing minimal morbidity (very low risk of intra- and postoperative bleeding and other complications) combined with high patients comfort (time-saving application, outpatient procedure, no nasal packing). For these reasons, we have been using the 940 nm diode laser for more than a decade for this indication and therefore we regard this procedure as our standard practice [6,13,14,20].

A further, minor shortcoming of this trial is the lack of histological studies to assess ultrastructural effects on the inferior turbinate mucosa to support or explain the novel laser system excellent coagulation capabilities as subjectively assessed by the operating surgeon intraoperatively. To date, there is no histological examination of tissue specimens treated with the 1,470 nm diode laser. However there is some published data on 940 nm diode laser tissue effects, showing that in contrast to carbon dioxide laser ($\lambda = 10{,}600$) that causes a superficial vaporization of the tissue with a broad carbonization zone and penetration depth of 0.1 mm, it provides deeper tissue penetration with a rather thin carbonization layer and pronounced coagulation zone up to 1–3 mm as evaluated by means of optical microscopy (hematoxylin and eosin staining) and scanning electron microscopy [25]. Concerning histopathological changes following laser surgery, it could be shown that the lamina propria was occupied by fibrous tissues, and that the number of vessels and seromucinous glands in the turbinates had decreased [26–28]. Some authors found that laser assisted turbinate surgery disturbed mucociliary function [29,30], whereas Willat et al. [31] found the postoperative mucociliary clearance to be unchanged.

Due to the observations made in *in vitro* experiments (data not shown), it may be expected that the new 1,470 nm diode laser system should also (and apart from its coagulative capabilities) dispose of excellent tissue cutting abilities in contact mode due to the high rate of tissue ablation. A clinical feasibility trial to compare the system's ablative tissue effects to another, conventional laser system is therefore currently anticipated.

CONCLUSION

The 1,470 nm diode laser system offers a highly efficient alternative to conventional diode laser systems in treatment of nasal obstruction due to hyperplastic nasal turbinates. The high efficacy of the 1,470 nm diode laser system leads to comparable clinical results with relatively less energy consumption as well as a significant reduction of treatment time as compared to the conventional system (i.e., 940 nm diode laser).

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