

Nonsurgical Minimally Invasive Er:YAG Laser Snoring Treatment

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ABSTRACT

This report describes a one year clinical experience performing the NightLase™ laser treatment on patients with snoring and other SDB symptoms. The NightLase treatment is based on a minimally invasive photo-thermal effect using Er:YAG laser light on oral mucosa.

In a period of one year we treated 57 patients having snoring and other SDB symptoms. All patients received three sessions of the NightLase laser treatment. Discomfort during the treatment was evaluated by the patients and potential side effects were monitored. Results were measured using a snoring questionnaire during follow-ups at 14 days and 45 days. Long-term effects for up to 15 month after the treatment were followed up on by performing telephone interviews. The majority (74%) of patients responded positively to the treatment, with an average improvement of snoring severity and SDB scores of 50% and 45.9%, respectively. Only mild discomfort during the treatment was recorded, and there were no other adverse effects.

The NightLase Er:YAG laser method has been found to be an effective, minimally invasive and safe method for treating patients with snoring and other SDB symptoms.

Key words: snoring, Er:YAG laser, laser treatment

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I. INTRODUCTION

Snoring is a very common and generally non-desired form of Sleep-Disordered Breathing (SDB) which affects more than 30% of the adult population and a significant number of children [1]. The prevalence of snoring was higher among men than women with an approximate ratio of 2:1 [2,3] and is higher among older than younger populations [4]. One study of a Polish middle age population (35-69 years)

found that 46% of Polish males and 25% of females are habitual snorers [5].

There are several factors which could contribute to snoring, among them nasal congestion, the anatomy of the patient's mouth, obesity, sedatives and drug use as well as smoking and alcohol consumption.

Snoring is known to cause sleep deprivation to snorers and those around them, as well as daytime drowsiness, irritability, lack of focus and decreased libido [6]. It has also been suggested that it can cause significant psychological and social damage to sufferers. Multiple studies reveal a positive correlation between loud snoring and the risk of heart attack and stroke [7], therefore it is beneficial to snorers (even to light, occasional, non-habitual ones) to get a consultation regarding their health risks and possible treatment options.

Quite often, snorers also suffer from Obstructive Sleep Apnea (OSA), a cessation of breathing caused by a repeatedly closed upper airway during sleep. During breathing cessation the patient usually exerts respiratory effort, resulting in a re-establishment of breathing, often followed by arousal and fragmented sleep. OSA symptoms include sleep disruptions, snoring, choking, esophageal reflux, nocturia and heavy sweating. Several studies confirmed that the obstructive sleep apnea syndrome significantly increases the risk of stroke or death from any cause, and that the increase is independent of other risk factors, including hypertension [8-12].

Many patients suffering from snoring and sleep apnea experience daytime somnolence, morning headaches, automatic behavior, mood alterations, sexual dysfunction, even short-term memory loss and hypnogenic hallucinations [13]. These symptoms alone are sufficient reason to seek medical help, but when they are comorbid with hypertension, the patient's health risks should be assessed by a qualified physician.

There is a whole range of treatment options for snoring, starting with behavioral options like diet and exercise (reduction of weight, alcohol and sedatives),

cessation of smoking, changing the sleeping position (from back to side) and some other lifestyle changes (like exercising the throat with singing lessons or playing some wind instruments [14]). The main problem associated with lifestyle changes is patient motivation, which is usually very low unless the problem becomes life threatening.

The next category of treatment options is oral or dental appliances used to advance the lower jaw, thus opening the upper airway to reduce or eliminate snoring. Oral appliances are cheap but their use is associated with certain problems like TMJ discomfort, sore teeth and gums. These devices are rated as class 2 medical devices which means they require a prescription from a doctor.

The first line treatment for heavier cases of sleep apnea are Continuous Positive Airway Pressure (CPAP) devices which provides a constant flow of air into the mouth and nose, keeping the airways open so the patient can breathe more easily during sleep. CPAP devices are effective in the treatment of sleep apnea, reducing snoring, improving breathing during the sleep, lowering daytime sleepiness and lowering blood pressure. However, many patients find the CPAP machine uncomfortable and are unable to wear them for longer periods. The most common complaints are discomfort and dry mouth, nasal congestion, skin irritation and nightmares.

Among other non-surgical snoring therapies, there are also pharmaceuticals – various decongestants, delivered orally or in a form of nasal spray, but these medications are not advised to be used on a routine basis due to side effects (like rhinorrhea) and because these agents lose effectiveness after a few days of usage.

Most of the severe cases of snoring and apnea are treated with one of many surgical methods, mostly involving the uvula and soft palate, and sometimes also the back wall of the pharynx. Among the more commonly used less invasive surgical procedures are the pillar procedure, the injection snoreplasty procedure and various radiofrequency procedures.

The pillar procedure is used to stiffen the soft palate by placing several (usually three) small longitudinal implants into the soft palate. This procedure is performed in physician's office under local anesthesia. Complications associated with this procedure are post-op pain, foreign body sensation and partial extrusions (one or more implants get extruded during the first postoperative year in 25% of patients [15]).

Injection snoreplasty also uses the principle of palatal stiffening by creating scar tissue in or on the palate. Several different sclerosing agents are in use [16], which are injected submucosally into the central soft palate, where they create a bulla-shaped lesion. The procedure is usually done under local anesthesia. Aside from the sensation of swelling and several days of post-op pain, the sclerosant causes palatal ulceration and sloughing, resulting in scar tissue, which is the final goal of the procedure [17].

Among various radio frequency treatment methods, Coblation (cold ablation) is considered to be the most minimally invasive and most common. The same principle of palatal stiffening is used. Radio frequency bipolar single-use probes are used to form channels in the tissue of the soft palate. The body's natural response is to form scar tissue in these channels, which stiffens the soft palate over a period of several weeks. In this procedure local anesthesia is also used, and there is similar post-op healing accompanied with swelling and at least one week lasting pain [18, 19]. Although the coblation treatment is effective in reducing the snoring, its effect is not permanent and requires repetitions of the procedure.

Lastly there are many variants of surgical treatment for snoring, among which the best known are: uvulopalatopharyngoplasty (UPPP), for laser-assisted uvulopalatoplasty (LAUP) and radiofrequency tissue volume reduction (RFTVR). The UPPP procedure is performed under general anesthesia and patients are hospitalized at least for the first night after surgery. LAUP and RFTVR are considered less invasive and are performed under topical and local anesthesia using an ablative laser (like CO₂) and RF probe (with, for example, 460 kHz alternating current flow). There are many potential postoperative side effects, aside from prolonged pain [19], like problems with smell and taste, pharyngeal dryness, globus sensation, vocal change, and pharyngonasal reflux. UPPP may be associated with some significant complications ranging from respiratory complications, re-intubation and pneumonia to cardiovascular complications, hemorrhage and even death [20]. Although much more invasive, and considering the above mentioned complications, these surgical treatments have rather low success rates – in the range of 40% [21-24] as well as a quite significant number of relapses. Some studies found no significant change in the AHI (Apnea-Hypopnea Index) in patients who had LAUP compared to those who had no surgery [25,26]. Others have shown that UPPP and related procedures may not only fail to improve patient symptoms, but may, in fact, result in a worsened patient condition [27,28].

So, in spite of all of the available treatment methods, patients and physicians are still searching for less invasive, more effective treatment methods for snoring and sleep apnea reduction.

Recently a new minimally invasive, nonsurgical method using an Er:YAG laser was proposed for the treatment of snoring, and promising preliminary results were presented [29,30]. As a clinic involved in various treatments of snoring and sleep apnea in our everyday practice, we decided to make a clinical evaluation this new method, the results of which we have presented here in this paper.

II. MATERIALS AND METHODS

In the period of one year (January 2012 - January 2013) we treated and followed 57 snoring patients.

Before being recruited for this trial, all patients applying for treatment of snoring were examined and consulted by an ENT specialist experienced in snoring diagnosis and therapies. The new laser therapy was presented to all patients and explanations were given regarding the potential risks and benefits. Alternative therapies were presented as well, and patients who decided to undertake the laser treatment all signed informed consent forms.

During the consultation, the patients' throats were examined and the patients were classified according to Mallampati classification (I-IV)(Fig. 1).

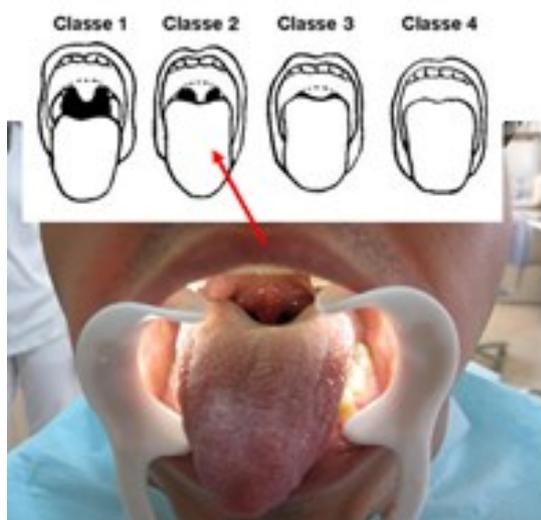


Fig.1: Example of Mallampati Class II throat: visibility of the hard and soft palate, the upper portion of tonsils and uvula. Courtesy of Dr. Jovanovic.

Patients using photosensitive drugs were excluded from this study. The other major exclusion criteria for the female patient population was pregnancy.

Efficacy of the treatment was evaluated with the NightLase™ questionnaire [31], consisting of eight questions, assessing the severity of snoring (the first question) and other problems associated with sleep-disordered breathing (SDB) (questions 2-7). Answers were graded on 11-point scales (0-10) and two scores were taken as the main outcome measure: the snoring severity alone (Q1) and the total questionnaire (SDB) score (Q1-Q8, maximal score = 80).

Assessments with the NightLase™ questionnaire were done before the treatment and at both successive visits, before the second and third treatment sessions were performed, and during follow-ups at 14 and 45 days respectively. After each treatment session patients were interviewed about treatment discomfort with a six-point scale (0 - 5). Patients were also asked to report about any other adverse effect they notice during the treatment or in the post-treatment period.

After the last treatment session patients were followed-up with telephone interviews in which they were asked to assess their improvement in snoring and their level of satisfaction with the treatment. For both questions, a four point scale was used (0 = no improvement / satisfaction, 1 = some improvement / satisfaction, 2 = significant improvement / satisfaction, 3 = excellent improvement / satisfaction). In this phone interview patients were also asked about adverse effects they had in the post-op period and about the sustainability of the treatment effect. This last (phone interview) follow-up was done in the first half of April 2013, representing a variable interval follow-up, between 3 and 15 months.

All patients were treated with an Er:YAG 2940 nm laser (SP Dualis, Fotona, Slovenia) using a PS03 handpiece with a patterned beam (Fig. 2). The laser beam was delivered in non-contact mode, enabled by the collimated beam of the PS03 handpiece [32]. Laser energy was applied to eight mouth and throat regions: the anterior pillar extending to the outer face up to the retromolar region and posterior third of the cheek (two regions – one left and the other right); the soft palate and uvula with the lower part of hard palate (two symmetrical regions); the posterior pillars and tonsils (two regions); the lateral and bottom sides of the tongue (also two regions).

We used the laser parameters and the treatment protocol according to the manufacturer's proprietary description and performed the coverage of the defined regions in the so-called manual brushing technique. This laser therapy is non-ablative and the mechanism of action is a photo-thermal effect causing heating of the treated areas to well controlled temperature levels

of between 45 to 65 degrees C. This in turn causes shrinkage of the collagen fibers in the treated oral mucosa and initiates, through heat shock proteins (HSP) action, neo-collagenesis [33-36].



Fig. 2: Er:YAG laser treatment of snoring, using the PS03 handpiece in non-contact, non-ablative mode.

There was no post-op care prescribed, except that all patients were warned that on the following morning they may have a sensation of a sore throat, which usually occurs only on the first morning after the treatment. Patients were also instructed to report on any other potential adverse effect they may have notice in the post-treatment period.

III. RESULTS

Fifty seven patients aged 27-74 (average 44.8 years, 47 males and 10 females), completed all three sessions of laser therapy and responded to the final (telephone) follow-up. Most patients were of Mallampati class III (40 or 70.2%), 13 were class IV (22.8%) and 4 were class II (7%). The average snoring severity score measured with the NightLase questionnaire before the treatment was 8.1 and the average total SDB score was 31.4. The Nightlase questionnaire scores of fifteen patients (26.3%) did not change at repeated assessments before the second and third treatment, while the remaining 42 patients (73.7%) reported an improvement in snoring severity between 1 and 7 points (average 3.9 points) and in total SDB score between 2 and 53 points (average 16.7 points)(Fig. 3).

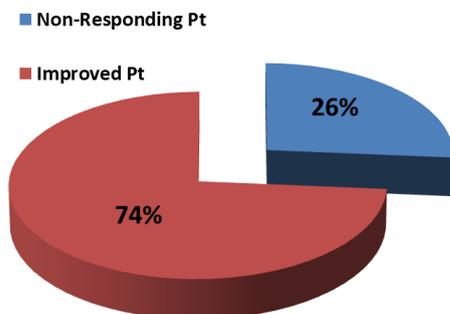


Fig. 3: Results of the NightLase questionnaire assessment: 74% of patients reported improvement, while 26% of patients didn't reported changes after the treatment.

For further analysis and follow-ups, we took into account the 74% of patients that responded to the treatment.

Average snoring severity scores before and at the first two follow-ups (at 14 and 45 days) improved by 50.5%, while the average total SDB score went from 30.9 points to 23.4 and to 14.2, thus improving by 46% (see Figs. 4 and 5).

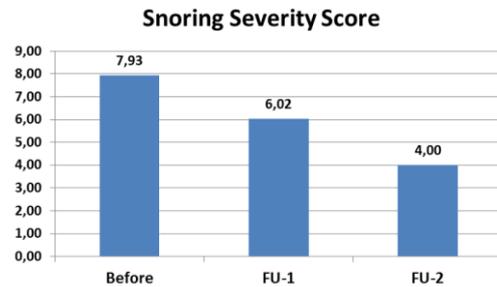


Fig. 4: The average snoring severity score improved after two sessions of treatment by 50.5% (dropping from 7.9 to 4.0).

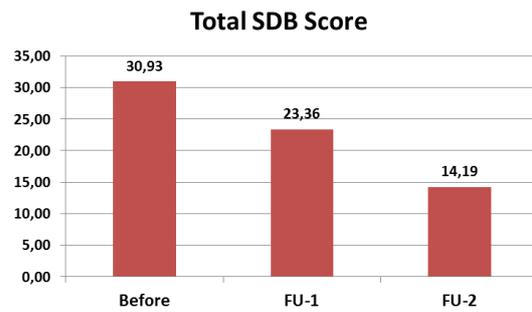


Fig. 5 The average total SDB score improved after two sessions of treatment by 45.9% (dropping from 30.9 to 14.2).

All patients evaluated the pain during the therapy. After the first session the average pain was 1.6 points, after the second it was 1.5 and after the third it was 1.4 points on the 0-5 scale, so treatment pain was in general assessed as mild. There were no other adverse effects of this laser therapy noted at any of the three performed sessions.

The telephone interview follow-up was performed at one time for patients at different stages after the last, third treatment session, namely at 3, 6, 9 and 12-15 months. Seven patients were interviewed at 3 months, 8 of them at 6 months, 10 at nine months and 32 (56.1%) at 12 to 15 months.

Improvement of snoring was assessed using scales with categories: no change, mild improvement, significant improvement and excellent improvement. 24 patients (57.1%) assessed their improvement as significant or excellent, 16 (38.1%) as mild and just 2

(4.8%) patients didn't mark an improvement (although on previous follow-ups both of them showed improved snoring severity and SDB scores)(Fig. 6).

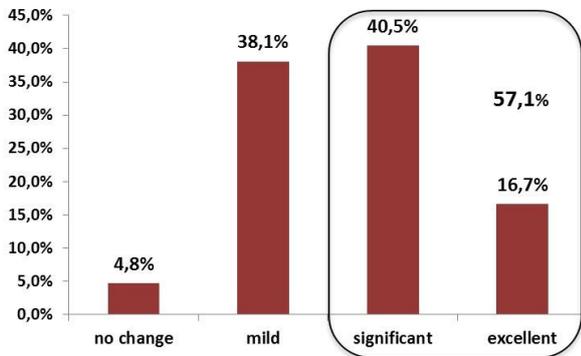


Fig. 6: Improvement of snoring assessed by patients: 95.2% of patients recognized improvement of their snoring, with 57.1% evaluating it as significant or excellent.

Patient statements about the sustainability of the achieved improvement showed that for the majority of patients (62.5%) the effect was sustainable or was still improving at 6 months after the treatment. The percentage of still sustainable effect at 12-15 months was 31.3%.

Almost 80% of the patients said they were satisfied with the treatment, 13 (31%) being somewhat satisfied, 16 (38.1%) being satisfied and 4 (9.5%) being very satisfied (Fig. 7).

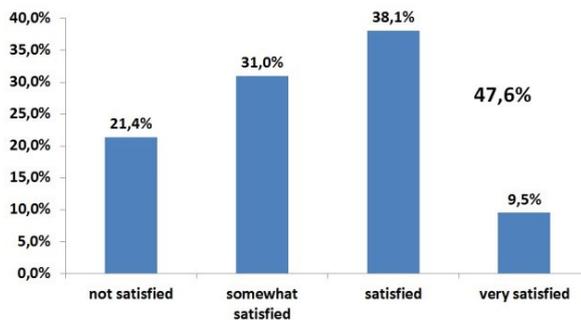


Fig. 7: Patients' satisfaction with the treatment and the results – 79.6% of patients expressed satisfaction with the treatment. Almost half of them (47.6%) assessed their evaluation as satisfied and very satisfied.

There were just two patients (3.5%) who remembered some transient adverse effects (sore throat) in the post-op period.

IV. DISCUSSION

While the 74% positive response rate to the NightLase treatment represents a satisfactory outcome, similar to that achieved with other, more aggressive treatment options, the question remains why certain patients did not respond to the treatment.

From data collected during the execution of this study, we were not able to identify factors contributing to this non-responsiveness. Patients age, sex, Mallampati throat types and other concurrent sleep (or non-sleep) related diseases from patient medical history charts were considered. In this study, we did not collect information on the patient's body mass index, which could influence the effectiveness of the treatment [37-39]. It is also possible that variations in response to the treatment are a consequence of variations in the patients' collagen remodelling capacity [32].

One of the factors may also be the patient's inability to objectively evaluate and compare the severity of snoring before and after the treatment. Objective measurements of snoring before and after the NightLase treatment using a polysomnograph have shown patients' subjective evaluations to be lower than objectively measured [30].

V. CONCLUSIONS

Our study confirmed that by performing a non-ablative, minimally invasive Er:YAG treatment of oral mucosa (the NightLase treatment), the resulting shrinkage of collagen and neo-collagenesis changes the throat configuration and consequently reduces snoring and other problems with sleep disordered breathing.

A majority (74%) of patients responded positively to the NightLase treatment, with an average improvement of snoring severity and SDB scores of 50% and 45.9%, respectively. Only mild discomfort during the treatment was recorded, and there were no adverse effects.

The NightLase Er:YAG laser method has been found to be an effective, minimally invasive and safe method for treating patients with snoring and other SDB systems. The response rate to the treatment may still be improved by developing appropriate criteria to exclude non-responding patients.

In conclusion, the NightLase minimally invasive laser method represents a good alternative to more aggressive standard treatment options for the treatment of snoring.

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