

# NightLase™ – a New Laser Treatment Method for the Reduction of Snoring and Sleep Apnea – a Pilot Study

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## SUMMARY

A novel method for the treatment of snoring and sleep apnea was recently proposed that utilizes laser beam photothermal effects on the mucosa tissue in the oropharynx.

The objective of this study was to assess the efficacy of this method using both subjective patients' assessments and objective polysomnographic measurements of snoring and apnea levels.

Eleven patients were treated at a single center, DKC Dental and Surgery Center in Ljubljana, Slovenia, using a Fotona Fidelis Plus III d laser and the proprietary NightLase™ protocol. Prior to and post treatment, all patients were submitted to night-long measurements by polysomnograph (Respironics, Alice 5 Diagnostic Sleep System) at the Sleeping Lab of the University Clinic of Respiratory and Allergic Diseases in Golnik, Slovenia. The second measurement was executed one month after the last treatment session and three months after the first measurement.

Snoring levels were measured by total duration of snoring time (in minutes) while sleep apnea was measured by RDI (Respiratory Disturbance Index). There were many other sleep parameters measured and recorded (like oxygen desaturation, heart beat, leg and body movements, etc.) but were not analyzed in this beginning phase of the study.

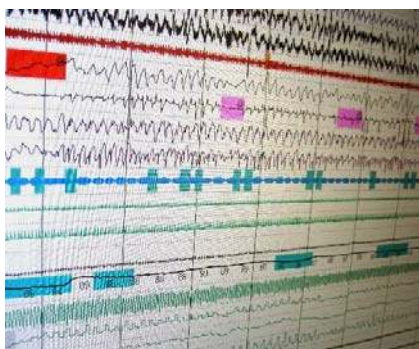


Fig. 1: An example of polysomnograph measurements.

All patients were also asked to subjectively assess the results of the treatment by responding to a special questionnaire, taking into account snoring, sleep apnea, sleepiness and other sleep disorder elements.

All patients reported an improvement of their sleep in general as well as their snoring. The patients assessed an average snoring reduction after the second session of the laser treatment to be around 23%. The change in the total questionnaire score reported by patients showed an average reduction of 30%, presenting an important improvement in sleeping quality, which was also reflected in the high degree of the patients' satisfaction with this treatment.

There were no adverse effects noticed after the treatment, which was very well tolerated by all patients and reported to be virtually painless.

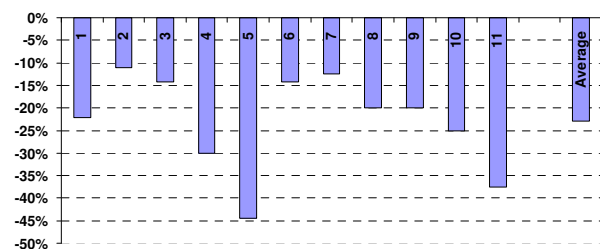


Fig. 2: Snoring reduction as assessed by patients.

On the other hand the results of polysomnographic measurements showed more dispersed data. For two of the patients (reported by themselves as well as by their sleeping partners to be heavy snorers – both with grades 9/10 on the questionnaire scale) measured snoring values were extremely low (0.6 min and 1.0 min) indicating either very high variability in night-by-night snoring or possible error in the measurement. Among the remaining 9 patients, one didn't have any changes, five had reductions in snoring duration ranging from 9% to 100% and three patients had an increase in snoring duration. The average reduction of measured snoring duration for these nine patients was 11%, as shown on Fig. 3.

Measurements of the RDI index identified three patients as having a severe level of sleep apnea (30 and higher) that would require further medical care, while another eight patients had no-to-mild apnea (below 15 points).

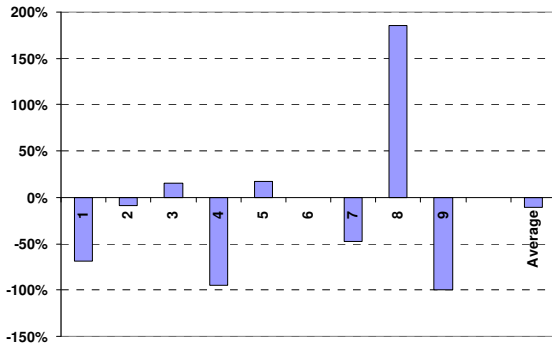


Fig. 3: Measurements of the change of snoring duration after laser treatment showed dispersed results with an average reduction of 11%.

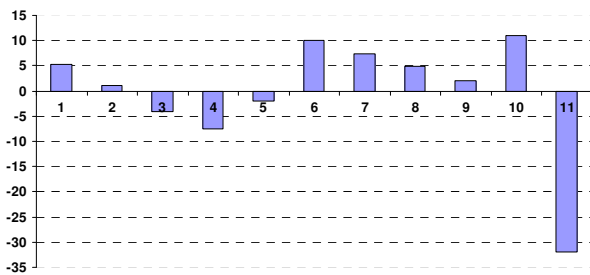


Fig. 4: Measurements of the change of RDI index scores after laser treatment. The last three patients (9-11) are the ones with severe degrees of sleep apnea.

According to the results of this pilot study, NightLase™ laser therapy for snoring and sleep apnea is a safe and easily tolerated treatment for patients, without noticed adverse effects.

Assessment of the treatment efficacy showed significant improvement reported by patients, which was also partly confirmed by the results obtained with polysomnography.

For a better and more reliable objective assessment of the efficacy of this therapy, some changes should be introduced in further studies: the introduction of inclusion and exclusion criteria (like AHI > 30/h) for patient selection and multiple measurements (at least two diagnostic nights both before and after therapy) for better measurement reliability. Furthermore, overall upper airway anatomy of the patient (nose patency) should be taken into account.

A new study with a larger number of patients and longer follow-ups, which will take into consideration all of the experiences obtained in this pilot study, is currently in preparation and we hope to be able to report new findings soon.