Safety and Effectiveness of the Combined Nd:YAG and Er:YAG Laser-assisted TightSculpting® Body Contouring Procedure

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ABSTRACT

BACKGROUND: High-power lasers are a new option for non-invasive reduction of localized fat deposits.

AIM: The aim of this study was to evaluate the safety and efficacy of a combined Nd:YAG and Er:YAG laser-assisted body contouring procedure.

METHODS: 12 patients with abdominal fat and 20 patients with submental fat received 3–6 sessions of a two-step TightSculpting® laser body contouring procedure (SP Dynamis, Fotona, Slovenia). The first, Nd:YAG laser step provides deep tissue heating leading to hyperthermic laser lipolysis, whereas the second, Er:YAG step provides superficial skin tightening. Patients with abdominal fat also received supporting treatment including post-treatment massage and cycling exercise and use of a compressive garment. They were also instructed to diet and perform regular exercise. Abdominal and submental skinfold was measured at baseline and after treatment in both groups. Additionally, weight and waist circumference were measured at baseline and after treatment in patients with abdominal fat.

RESULTS: Skinfold thickness decreased significantly in both groups. In patients with abdominal fat, weight and waist circumference also decreased significantly compared to baseline. Results improved with the number of laser sessions applied. No complications were observed.

CONCLUSION: The combined Nd:YAG and Er:YAG laser-assisted tight-sculpting procedure is a safe and effective minimally invasive option for patients with localized subcutaneous fat deposits.

Key words: Nd:YAG, Er:YAG, non-invasive, laser assisted, body contouring.

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I. INTRODUCTION

Liposuction is the most common cosmetic surgery, with 1,453,340 procedures having been performed worldwide in 2016[1]. The risks, financial costs and lengthy downtime associated with surgical procedures for fat reduction and the development of a number of non-invasive techniques[2] have led to an increasing demand for non-invasive body contouring worldwide. 433,351 non-surgical fat reduction procedures were performed in 2016. Low-level laser therapy (LLLT), cryolipolysis, radio frequency (RF) and high-intensity focused ultrasound (HIFU) are currently the leading non-invasive techniques for reducing localized subcutaneous adipose tissue[2]. Non-obese to moderately obese patients who wish to avoid the risk of surgery or the long downtime associated with it are suitable candidates for non-invasive procedures[3].

Adipocyte viability is significantly reduced after short (1 minute) exposure to temperatures above 50°C[4]. At prolonged exposure a relatively small temperature increase is sufficient to cause hyperthermic death of adipocytes[3]. Three minutes at 45°C resulted in 40% viability[4]. At 15 minutes, 43–45° in subcutaneous tissue is sufficient for the effect[3]. High-power lasers are the latest method of achieving adequate temperature increase in subcutaneous tissue. A feasibility study in a porcine fatty tissue model showed that using 1,064 nm Nd:YAG laser with concomitant surface cooling, a subsurface temperature peak sufficient to trigger the hyperthermic cell death of adipocytes is reached at a depth of 5.7 mm, while a safe surface temperature of 38°C is maintained[3]. Clinical tests with 1,060 nm diode laser showed good efficacy and no serious side effects[5–8].

The combined Nd:YAG and Er:YAG TightSculpting® procedure (Fotona, Slovenia) consists of two steps (Table 1). Nd:YAG deep heating is used to induce deep tightening and fat thickness reduction. The Er:YAG step induces superficial skin tightening[9], thus improving the overall aesthetic effect. While case reports using this procedure have been published before[10], the effects have not been quantified on a larger number of patients in a systematic way. The aim of this pilot study was to assess the safety and efficacy of the combined non-invasive Nd:YAG and Er:YAG laser body contouring procedure for reducing abdominal and submental fat deposits.

Table 1. Treatment parameters

TightSculpting®	Step 1: 1064 nm Nd:YAG	Step 2: 2940 nm Er:YAG
Pulse mode	PIANO (6.4 s)	SMOOTH
Handpiece	S-11 L-runner	R11
Spot size	20 mm	7 mm
Fluence/ Power	1.2 W/cm²	2 J/cm²
Frequency	auto	3.3 Hz

II. MATERIALS AND METHODS

a) Patients

Patients attending our clinic between October 2016 and March 2018 seeking targeted body reshaping in the abdominal or submental area were screened for inclusion.

Inclusion criteria were: baseline BMI 20–30, significant unwanted localized abdominal and/or submental fat deposits, and willingness to sign informed consent. Exclusion criteria were pregnancy, uncontrolled hypertension, heart disease, recent or current history of cancer, or actively undergoing radiation or chemotherapy treatment, liver/kidney disease, or photosensitivity.

b) Treatment

In order to increase the energy absorption of the target treatment area, the patients were asked to drink 500 ml of water 30 minutes before each treatment, because laser energy is better absorbed in hydrated fat tissue[11]. No anesthetic was required. Treatment areas of approximately 64 cm² were marked on the skin. There were 12–15 areas per typical abdominal patient and 3 areas per typical submental patient.

The TightSculpting® procedure consists of two steps. First, 1064 nm Nd:YAG is applied to the treatment area in a super-long PIANO pulse modality (SP Dynamis, Fotona, Slovenia; scanner L-runner, 1.2 W/cm²). Maximum surface temperature is set to 40°C for treatment of the abdomen and 39°C for treatment of submental fat. Minimum T is set to 38°C. Zimmer cooling is applied at level 1 throughout this step. The temperature is maintained for 15–20 minutes at four areas. Each treatment area is the size of the scanner (7.6 x 8.4 cm). Deep bulk heating of the skin is achieved in this step, inducing fat cell apoptosis.

In the second step, a prolonged 2940 nm Er:YAG non-ablative thermal Fotona SMOOTH® mode pulse (SP Dynamis, Fotona, Slovenia; R11 handpiece, 2 J/cm², 3.3 Hz, 7 mm spot) is used for superficial tightening of the skin. The area is treated for 3 minutes immediately after step one of the treatment. Patients received treatment every 2–4 weeks; 3–6 treatments were applied.

Supporting treatments were applied to the 12 patients who received abdominal and/or waist fat reduction treatments to increase the effectiveness of fat reduction by laser and provide additional treatment at areas which the laser cannot expose, such as visceral fat and fat outside of laser-exposed areas. Among these 12 patients, there were 8 who received both abdominal and submental fat reduction treatments.

In order to increase the effectiveness of fat reduction by laser, adipocyte removal from the lased adipose tissue was assisted by providing 20 minutes lymphatic drainage massage right after each treatment[12]. The consumption of the liberated fatty acids and their removal by increased blood circulation were stimulated by cycling on a stationary bicycle for 20 minutes immediately after each treatment. The use of a compressive garment after the first treatment 12 h per day for one month and 6 h per day for another month prevented the fat deposits from forming again at the same location and provided support after the Er:YAG skin tightening.

Patients were instructed to diet and exercise for 30 minutes daily[13] to help to reduce body fat in general, including visceral fat and fat in areas not exposed to laser treatment. They were also instructed to drink 2 liters of water per day.

c) Outcome measures

For abdominal fat patients, age, height and BMI were recorded at baseline, whereas weight, waist circumference and abdominal skinfold size measured by caliper were recorded at baseline and 2 weeks after the final treatment. For submental fat patients, age was recorded at baseline and submental skinfold size was recorded at baseline and 2 weeks after treatment.

The number of treatment sessions required to achieve the final effect was also recorded for each patient in both groups, along with any side effects or adverse reactions.

d) Statistical analysis

Pairwise differences between baseline and post-treatment values for the outcome measures at each location were tested by paired t-tests. Bonferroni step-wise correction was used to account for multiple comparisons. Of secondary interest, correlations between the patients' age, baseline BMI, the number of sessions and the change in outcome measures were tested by bi-variate non-parametric Spearman correlation. Correlations were also used to detect relationships between the patients' age and baseline values and the number of sessions required to achieve the final effect. All tests were conducted at two-sided α=0.05 with IBM SPSS Statistics 20 (Figure 1).

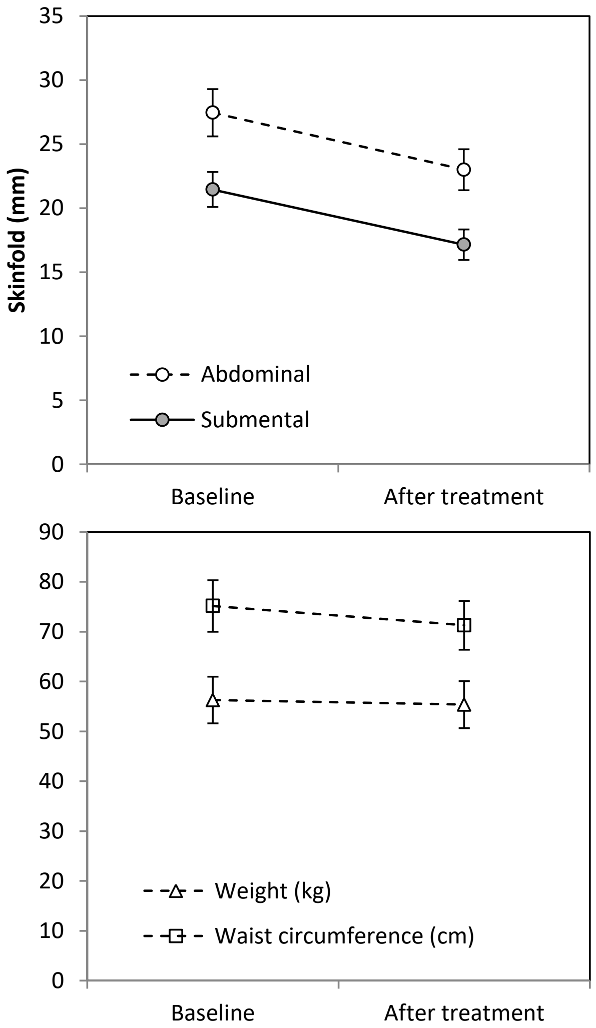

Fig 1: A) Skinfold thickness at baseline and after 3–6 sessions of combined Nd:YAG and Er:YAG laser treatment. Mean±SD of 11 patients with abdominal fat (open symbols) and 20 patients with submental fat (grey symbols) treated. **B)** Weight and waist circumference at baseline and after laser treatment for patients in the abdominal group only (mean±SD, n=11).

One patient in the group with abdominal fat had significant weight loss (5 kg) during the study and a correspondingly high waist circumference and skinfold thickness reduction, and there was some concern that this may skew the results (Fig. 2). Boxplot analysis identified this patient as an outlier. Sensitivity analyses were therefore conducted for all tests for the primary outcome measures by including or excluding this patient, which showed that excluding the high-weight-loss patient did not qualitatively change the results. To be conservative, the analysis results that were reported excluded this patient.

III. RESULTS

a) Patients

24 female patients aged 34–72 years (mean 46 years) were included in the study. 12 patients were treated in the submental area only, 4 patients were treated in the abdominal area only and 8 patients had both areas treated.

For abdominal patients, treatment of the 12–15 areas took 48–60 minutes for step 1 and 30–40 minutes for step 2. For submental patients, treatment of 3 areas took about 10 minutes for each step. Patients reported no pain or discomfort, only a feeling of warmth in the treated areas. No edema was observed. Post-treatment erythema lasted about an hour. No other side effects were observed or reported.

Subcutaneous fat was significantly reduced after laser treatment in both groups (Table 2). A reduction of superficial wrinkles and cellulite was observed post-treatment (Figure 2); however, it was not quantified.

Table 2. Decrease in skinfold thickness, weight and waist circumference after laser treatment in patients with abdominal or submental fat. Mean change and 95% confidence interval (CI) reported. Significance of the difference between baseline and post-treatment values obtained by paired t-tests. Bonferroni step-wise correction was used to account for multiple comparisons. Original p values are reported, with those still significant after correction printed in bold.

	Abdominal (n=11)			**Submental** (n=20)		
	Decrease vs. baseline (95% CI)		***p***	**Decrease vs. baseline** (95% CI)		***p***
Skinfold (mm)	4.5	(3.2–5.7)	**<0.001**	4.3	(3.7–4.9)	**<0.001**
Weight (kg)	0.9	(0.3–1.5)	**0.005**			
Waist circumference (cm)	3.9	(2.7–5.0)	**<0.001**			

b) Abdominal fat

Paired t-tests confirmed that the change from baseline was significant for body weight, waist circumference and skinfold size (Table 2) even though one patient, who lost 5 kg during the study, with a correspondingly large waist circumference reduction and skinfold reduction (Fig. 2), was excluded from the analysis.

Fig. 2: This is the most extreme case in our study; this female lost 5 kg of body weight during the study after 6 laser treatment sessions and adjunctive measures, with concomitant high reduction in waist circumference (-9 cm) and abdominal skinfold (-14 mm). However, 12 months after end of treatment she regained the weight and abdominal fat deposits.

The number of sessions was not significantly correlated with weight loss (r=-0.33, p=0.327, n=11) or skinfold reduction (r=-0.51, p=0.107, n=11), but it was correlated with waist circumference reduction (r=-0.73, p=0.011, n=11). Age and baseline BMI were not significantly correlated with any of the outcomes (p>0.05).

c) Submental fat

Paired t-test showed significant reduction in submental skinfold from the baseline (Table 2). Age was not correlated with skinfold decrease (r=-0.25, p=0.293, n=20), but it was correlated with the number of sessions required for the final effect (r=-0.54, p=0.014, n=20). The number of treatment sessions was correlated with skinfold decrease (r=-0.75, p<0.001, n=20).

There was no significant difference in submental skinfold reduction between patients who also received abdominal treatment (-4.5±0.9 mm, n=8) and those who received submental laser treatment alone with no additional measures (-4.1±1.4 mm, n=12, t-Test: p=0.530).

Typical results are presented in Fig. 3.

Fig. 3: Reduction in submental fat.

IV. DISCUSSION

Waist circumference, abdominal skinfold and submental skinfold were significantly reduced after 3–6 combined Nd:YAG and Er:YAG laser sessions. Abdominal skinfold was reduced on average by 19%, submental skinfold by 20% and waist circumference by 6%. For comparison, caliper measured fat thickness was reduced by 15–27% in different cryolipolysis studies[2]. Similar levels of reduction were observed also for other minimally invasive alternatives as reported in a recent review2. The only included study of cryolipolysis to measure abdomen circumference showed a 6.9 cm reduction. Most LLLT studies reported reductions of 2.2–2.9 cm in the abdomen, with one reporting a 6.8 cm reduction. RF studies showed reductions of 1.4–4.9 cm. Three HIFU studies showed reductions of 4.1–4.7 cm and four showed reductions of 2.1–2.5 cm 2. In this study, waist circumference was reduced through laser treatment and adjunctive measures by 4 cm on average.

One of the weaknesses of this study is the lack of a control group. However, as the outcome measures are not subjective, the placebo effect can be expected to be minimal[14]. Another issue is the use of adjunctive treatments in patients with abdominal fat. It is consequently difficult to ascertain how much of the treatment effect can be attributed to any of the measures alone. Irradiation with Nd:YAG laser can only reduce localized subcutaneous fat at the treatment area. Post-treatment exercise and massage are aimed at improving the metabolic removal of the destroyed adipose cells[12]. Diet and regular exercise provide additional treatment at areas that were not exposed to laser such as visceral fat and fat outside of the lased areas. Aerobic exercise has been shown to cause major reductions in belly fat in numerous studies[15]. Diet is also important; a lower-carbohydrate diet was particularly effective in reducing intra-abdominal fat[16]. Good results in patients with submental fat who did not receive adjunctive treatment can serve as an indication that laser treatment had an important contribution to the total effect.

While laser treatment can help reduce the subcutaneous fat tissue it cannot completely prevent deposition of new fat. A healthy lifestyle is necessary to maintain the results and this should be made clear to patients. A study on 97 women who lost 12 kg on a 800 kcal/day diet showed that as little as 80 minutes per week aerobic or resistance training helped reduce weight regain during a 1 year follow-up[17].

The Er:YAG step of the combined laser treatment provides superficial skin tightening, resulting in a more pleasing aesthetic appearance by reducing the sagging of excess skin after fat reduction. A precisely controlled sequence(s) of sub-ablative Er:YAG laser pulses that are delivered to the tissue achieve a controlled heating of the collagen without overheating the surface. Temporarily increasing the temperature of collagen induces collagen shrinkage [18,19] and initiates neocollagenesis [20,21], leading to the contraction and shrinkage of the irradiated bulk tissue and an overall improvement of its tightness and elasticity. A reduction in wrinkles and cellulite can be observed in clinical photographs. This is an advantage of laser treatment over alternative non-invasive body contouring modalities.

Laser body sculpting presents minimal risks to participants. There are no complications associated with the treatment. While lipolysis or laser lipolysis can provide more dramatic effects, it is also associated with greater risk and longer downtime[22]. The estimated mortality rate of liposuction is 1 in every 5000 procedures performed[22]. Non-invasive laser body-contouring should be offered to patients with localized fat deposits willing to accept a more gradual effect achieved over several treatment sessions, or for patients with contraindications to or concerns about more invasive procedures.

The combined Nd:YAG and Er:YAG laser-assisted tight-sculpting procedure is a safe and effective minimally invasive option for patients with localized subcutaneous fat deposits. It merits further investigation in controlled trials.

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