Early Clinical Experience with the 1440 nm Wavelength Internal Pulsed Laser In Facial Rejuvenation (2 Year Follow Up)

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INTRODUCTION

The recent adoption of the internal 1440 nm pulsed laser has advanced the safety, efficacy and versatility of laser lipolysis and tissue tightening in face/body rejuvenation1-6. The longer wavelength provided increased localized photothermal and vaporizing effects in front of the fiber on fatty tissue and collagen fibers (water), achieving twenty times more absorption in adipose tissue than the 1064-nm/1320-nm and forty times more absorption than 924-nm/980-nm wavelengths7-11. In recent clinical studies4,6, the use of the 1440 nm wavelength has been shown to significantly increase skin thickness and elasticity 6-18 months from baseline measurements. The purpose of this paper is to report the early experience with the 1440-nm wavelength, using a specially designed side-firing fiber, in a four step approach primarily to the lower third of the midface and neck.

LASER DEVICE SYSTEM

The laser workstation delivered the 1440 nm wavelength pulsed laser from a 800 µm side-firing fiber that was enclosed and protruded 2mm from the tip of a temperature-sensing 1.2mm cannula. The side-firing fiber distributed about half of its energy perpendicular to the fiber axis and the other half transmitted along the fiber axis (Figure 1). Chevron markings on the handpiece designated the direction of the laser emission perpendicular to the fiber axis. This emission design permitted a more targeted delivery of laser energy to the structures of interest that included in turn fat, fibro-fascial layer of the muscle, and the skin-dermis. During treatment of the fatty tissue and deeper fibro-fascial muscle layer, the temperature-sensing cannula acted as a thermal switch by sensing temperatures set between 45-47°C at the immediate laser delivery point. When the recommended target temperature was attained, an audible signal was triggered. If the surrounding tissue temperatures exceeded the preset threshold level, a beeping audible signal warned the operator to move to another area to reduce excessive thermal injury. Maintenance of this thermal window distributed laser heat energy evenly to melt fatty tissue and denature collagen in a safe manner. When the laser fiber treated shallow subdermal tissue (5mm below the dermis), the temperature-sensing cannula was programmed at the same 45-47°C temperature range, which in turn produced a superficial skin temperature between 38-42°C, that was optimal for collagen denaturation and later delayed tissue tightening. An infrared thermal camera (FLIR ThermCAM E45, Niceville, Florida) obtained continuous skin temperatures between 38-42°C and ensured a uniform, real-time deliverance of heat by depiction of a confluent orange-red coloration.
within each treatment site. A hand-held infrared noncontact thermometer (MiniTemp MT6, Raytek Corporation, Santa Cruz, CA) was used simultaneously with the thermal camera to measure rapidly surface skin temperatures by spot-checking to ensure skin safety.

CLINICAL PROTOCOL

Patients were selected for isolated mild to moderate accumulations of fat to the lower third of the face and neck and mild to moderate tissue laxity of the muscle and skin. After review of their medical history, subjects were consented for their office procedure and the usage of local anesthesia. A preoperative physical examination, blood chemistry panels, and electrocardiogram were required from each patient within 2 days of surgery. Prior to surgery, patients were weighed, photographed by standardized digital imaging, and prescribed a pain medication and antibiotic. In four randomized patients, skin thickness was measured at the same spot three times with a 20-MHz high-frequency ultrasound probe (DermaScan C, Cortex Technology) at baseline and six months. In one patient, biopsies from opposing sides of the treated neck below the ear lobule were submitted for hematoxylin and eosin staining for assessment of tissues at completion of procedure.

The procedure was not recommended for correction of strong and separated bands of the platysma muscle. Exclusion criteria included pregnancy, uncontrolled diabetes mellitus, collagen disorders, significant cardiovascular diseases, bleeding disorders, smokers, and previous surgical procedures within a year to treatment sites. Aesthetic treatment efficacy from baseline to six months were rated by two independent investigators using the Investigator Global Aesthetic Improvement Scale (IGAIS) from standardized photographs (0 = no change, 1 = mild improvement, 2 = moderate improvement, and 3 = significant improvement). Patients used a Subject Global Aesthetic Improvement Scale (SGAIS) from their baseline to six months photographs (0 = no change, 1 = mild improvement, 2 = moderate improvement, and 3 = significant improvement).

PROCEDURE

In the sitting position, the patient’s treatment sites were marked with one 3 x 5 cm sector lateral to each marionette line and two 5 x 5 cm sectors on each side of the midline of the neck (Figure 2). Subjects received an oral sedative thirty minutes before surgery. After skin preparation with povidone-iodine antiseptic washes, a 1 cm incision was made behind each ear lobe and also at the transverse submental crease line. Twenty to thirty ml of tumescent anesthesia mixture (50 ml of 0.5% lidocaine, 1mg epinephrine per liter of warm saline, and 20 ml of 8.4% sodium bicarbonate) was infused into each sector through the access incisions at the deep and superficial levels of subcutaneous fat. After 20-30 minutes, the 800 um side-firing fiber, enclosed in its temperature sensing cannula, was inserted through one of the three access incisions.

Standard laser guidelines, as outlined by the American National Standard for the Safe Use of Lasers in Health Care Facilities, included the use of protective goggles for the patient and staff during phases of laser treatments. All procedures were performed awake with oximetry and electrocardiogram monitoring without need for external oxygen administration. The red aiming beam from a diode 630 nm laser source visualized the tip of the fiber during the three steps involving the laser with the fiber tip
either in the down or up direction. The intensity and distribution of the red-aiming beam during lasering in a darkened or dimmed room guided the surgeon to position optimally the laser’s energy and direction to the mid-level of fat, over the platysma muscle and under the skin-dermis. In the first step, the fiber was inserted through one of the access incisions in the down position (Figure 3). Once in place, the activated cannula-fiber was moved back and forth in a fan-like pattern in the mid-to-deep levels of the subcutaneous fat in each sector. Two sectors on one-half of the neck were treated at a time to optimize laser delivery. The power and pulse frequency settings were set between 6-10 watts and 25H, respectively. The endpoints of treatment were determined when 1) the total number of joules delivered ranged between 500-700 joules/sector, and 2) limited or no tissue resistance to the fiber’s passes while the temperature-sensitive cannula maintained a 45-47°C threshold. External skin temperature monitoring was performed with the thermal infrared imaging camera and the hand-held infrared noncontact thermometer.

In the second step, liposuction with a 1.2 mm round two-hole cannula to the lower third of the face and with a 3.2 mm two-hole flat cannula to the neck evacuated the liquefied fat, tumescent solution, and tissue debris under a low vacuum pressure of 350-500 mm Hg in the six sectors. Liposuction permitted immediate contour assessment and created an environment with less debris that facilitated more rapid elevation of threshold subdermal temperatures during the subsequent shallow lasering.

In the third step, the activated fiber-cannula was inserted in the down direction (Figure 4), reciprocated in a fan-like motion, and deposited a total of 200-300 joules on the fibro-fascial surface of the platysma muscle in each sector. It was anticipated that the denatured collagen fibers would eventually reorganize and tightened the muscle unit.

In the fourth step, the activated fiber-cannula was turned in the up direction (Figure 5), moved in a fan-shaped pattern, and delivered about 300 joules at 2-5 mm below the dermis in each sector. The endpoint of treatment was determined when a total of 200-300 joules was administered per sector or when the surface skin temperature was recorded between 38-42°C at the temperature-sensitive cannula threshold was set at 45-47°C. Cold compresses were applied immediately to hot spots, designated by the infrared thermal camera, in order to return temperatures to the desired levels. When laser treatment was completed, the liquefied fat and debris was removed by gentle rolling through the incision sites. Quarter inch penrose drains were inserted in each post-lobule incision sites to facilitate further drainage and removed within 24 hours. Compression garments with sponge inserts were applied for 7-10 days after which a series of weekly external ultrasound treatments were given to reduce irregularities and swelling.

**RESULTS**

Between September 2010 and March 2012, nineteen consecutive patients (two men, seventeen women; 41-74 years old, mean age 51.1 years) were indicated for laser lipolysis and tissue lifting for facial rejuvenation (Table 1). The mean pretreatment weight was 72 kg (range 46.6-103.6 kg) with a mean body mass index of 27.4 (range 20.5-36.9). At the 3rd and 6th month evaluation periods, each patient demonstrated no significant change from baseline weight and body mass index.
An average of 200ml of tumescent solution (range 125-280) was infiltrated into the deep and superficial subcutaneous layers within the lower third of face and entire neck. Within the mid-to-deep subcutaneous fat in each sector, the delivered energy ranged from 6-10 Watts at 25 Hz, averaging 695 joules/sector (range 500-700 joules/sector). The endpoints of treatment were determined when 1) the average number of joules occurred between 500-700 joules/sector, 2) the internal temperature consistently obtained varied between 45-47°C, and 3) increased ease of passing the firing laser fiber through the tissues (Figure 6). Depending on preoperative findings, liposuction removed between 50-125ml aspirate, of which about 55%/volume consisted of fat. Heating of the fibro-fascial layer of the platysma muscle (Figure 7) averaged about 275 joules/sector (range 200-300 joules/sector). Shallow subdermal heating distributed an average of 285 joules/sector (range 250-400 joules/sector) at 1-5mm below the dermis. The endpoint of treatment was determined when 1) the total amount of 300 joules/sector was delivered and 2) the fiber-cannula passed with minimal resistance. The achievement of surface temperature skin recordings between 36-42°C is regarded as a secondary endpoint in order to prevent over-delivery of joules and heat (Figure 8). The total average joules delivered per patient was about 7380 joules, which translated to about 1230 joules/sector. In patients with moderate skin laxity, the skin was retreated with additional lasing, averaging 150 joules/sector, to temperatures between 38-42°C for possible increased tissue tightening based on clinical findings. The surgical time averaged about 1 hour (range 45-75 minutes) with immediate postoperative recovery time less than an hour. Compression garments were continued to another 7-10 days to reduce any incidence of exudative or seromatous collections.

In four patients, who were randomly selected for DermaScan C measurements, all demonstrated an average of 23% increase in skin thickness compared to baseline at six months (Table II). Mean increases were significant (p < 0.01) at each time point. The ultrasonic images of the dermis at baseline changed to a thicker, more compact dermis at six months, indicating possible enhancement of collagen deposition within the dermis after treatment (Figure 9).

OUTCOMES and SIDE EFFECTS

Patients were very satisfied with their changes at 6 months especially in the definition of their mandibular-neck outlines with reduction of the prejowls, marionette folds and submental fullness (Figures 10-12). The incidence of bruising and swelling was low and resolved completely within two weeks. No patients developed hematomas, sensory or motor nerve injuries, striations, blisters or dyschromias after three layers of laser treatment. Three patients developed small fibrous nodules within the subcutaneous fat in the neck that resolved within 6 weeks with postoperative ultrasound treatments. Postoperative discomfort was mild to moderate with patients using analgesic products such as extra-strength acetaminophen or lowest doses of hydrocodone/acetaminophen. Most patients were able to resume normal activities within two weeks. There were no unanticipated significant adverse events. Patients experienced about an 80% improvement by 6 months with progressive tissue lifting and contouring thereafter.

Patients and two independent investigators were asked to evaluate global satisfaction results at 3 and 6 months after treatments in the nineteen patients on a five point scale (0, worse; 1, no change; 2, mild; 3,
The mean scores at 3 months were 2.75 and 3.0, respectively, with improvements in contour, fat reduction and tissue laxity. The mean scores at 6 months were 3.0 and 3.5, respectively, with continued progressive tissue tightening, contouring and definition. All patients would recommend the procedure to others.

**DISCUSSION**

As demonstrated previously with the laser treatments with 1064 nm and 1320 nm wavelengths, laser-assisted lipolysis and tissue lifting for facial and neck rejuvenation can be done safely and efficiently utilizing the advantages of the 1440-nm wavelength to produce selective fat destruction and to shorten collagen fibers by denaturation in the fibro-fascial layer of the platysma muscle and dermal structures for eventual lifting. Monte Carlo simulation study with three different wavelengths (1064-nm, 1320-nm, and 1440-nm) demonstrated that the 1440-nm wavelength produced the highest fat and dermal tissue ablation efficiency, with minimal localization of heat over depth compared to the other two wavelengths. In a randomized, controlled study on the lower half of the abdomen, acute histologic findings with the 1440-nm wavelength energy (1000J, 55°C) in the deep subcutaneous fatty tissue (10-20mm below the dermal-fat junction) demonstrated marked immediate fat cell disruption and necrosis and profound collagen fiber denaturation in the reticular dermis and septae. When the 1440-nm wavelength energy was delivered in the shallow depth of the subdermal fatty tissue (<5mm depth), significant acute denaturation was confined to the collagen fibers in the reticular dermis and septae at skin temperatures between 40-42°C with 10W (830 joules). At the 6th week, progressive collagen fiber fibrosis and reorganization within the reticular dermis and septae were observed histologically and are believed to contribute to delayed optimal tissue lifting at three months and thereafter.

In this clinical study, controlled lipolysis with the 1440 nm laser in the down and forward directions resulted in a spectrum of adipocyte damage from swelling, rupture of cellular membrane, dispersed lipids and coagulative necrosis, as demonstrated by previous histologic studies. The lipolytic debris was removed by liposuction that contributed to fatty reduction and contouring along with skin accommodation. The present study also delivered heating of collagen fibers with the 1440nm laser in the down and forward locations in the fibro-fascial layer of the platysma muscle to stimulate shortening and tightening of collagen fibers. There were no direct or indirect findings that heating the superficial musculo-aponeurotic system (SMAS) resulted in dysfunctions (paresis, asymmetries, pain, or spasms) after this therapeutic maneuver. Similar clinical findings were observed after focused ultrasonic thermal coagulation points were precisely delivered to the imaged SMAS layer of the lower third of face and neck. This small clinical experience also suggested that laser treatments to the reticular dermal layer with the 1440 nm laser in the up position resulted in beneficial tissue tightening effects beyond that would be expected from accommodation after liposuction alone, in some of the skin-challenged patients. The stimulation of collagen fiber deposition and remodeling resulted in increased dermal thickness by comparing ultrasonic images at baseline and at three and six months. Although skin elasticity was not measured, other publications for the treatment of cellulite, utilizing the 1440 nm laser, have demonstrated increased skin elasticity and dermal thickness over six months to a year. A clinical study, using the 1320nm and 1064 nm wavelengths with less affinity to heat water and collagen
fibers in the dermis of abdominal skin than that observed with the 1440 nm wavelength, has reported an increase in tissue tightening versus controls by 3D Vectra Analyses over 3 months.

The present clinical experience demonstrated persistence of clinical benefits at 6 months in all patients by objective and subjective analyses. Adverse events were limited to transient swelling and bruising, the severity of which was mild and completely resolved by 2-3 weeks. Treatment burns were not observed because the internal and skin temperatures were monitored real time. The treatment endpoint was the number of joules of energy delivered and the skin surface temperature. Limitations of this preliminary study include the small number of patients and short follow up duration. The encouraging results of the present study warrant more studies in treating larger number of patients of greater severity to optimize the treatment parameters.

CONCLUSION

The incorporation of the 1440-nm wavelength offered increased benefits for laser lipolysis and tissue lifting for facial rejuvenation in nineteen patients who presented with fat accumulations in the lower third of their faces and neck. Most of these patients exhibited moderate degrees of tissue laxity and sagging. Photographic analyses and subjective responses from Investigator and Patient Global Aesthetic Improvement Scales indicated that the 1440-nm wavelength achieved high thermal absorption within fat and collagen (water) leading to fat reduction and collagen denaturation, and progressive tissue lifting by 3-6 months. The combination of the 1440-nm wavelength, side-firing fiber, and the thermal-control systems provided a safe and effective means for facial rejuvenation. Further studies are needed to validate these initial findings.

REFERENCES:


Table 1. Demographic Data

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Table I. Demographic Data of sex, age, ethnicity, weight and BMI in 19 patients enrolled in 6 month study.

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Table II. Mean percentage increases in neck skin thickness from baseline during six months study period in 4 patients.

Figure 1. The side-firing 800µ fiber delivers about half of his laser energy in the forward direction to the fiber axis and the remainder moves perpendicular to the fiber axis.
Figure 2. Presurgical markings of the six sectors are outlined with the patient in the sitting position. Sectors 1 and 6 were rectangles (3 x 5 cm) in each lower third of face; sectors 2,3,4 and 5 were squares (5 x 5 cm) in the neck.

Figure 3. In the first laser treatment step, the 800µ side-firing fiber is positioned about 1 cm below the dermis in the down position on activation, laser energy is released in a forward and down direction to melt excess subcutaneous fat. Illustration courtesy of Margaret Gaston.
Figure 4. In the second laser treatment step, the 800µ side-firing fiber is positioned above the fibro-fascial layer of the platysma muscle. On firing, the laser energy is emitted in a down and forward direction to stimulate thermal collagen thickening and tightening of the fascia by remodeling. Illustration courtesy of Margaret Gaston.

Figure 5. In the third laser treatment step, the 800µ side-firing fiber is positioned less than 5mm below and parallel to the dermis. On activation, its laser energy is released in a forward direction in the subdermal fat and also upward to the undersurface of the reticular dermis to stimulate dermal thickness and tightening by collagen stimulation and remodeling. Illustration courtesy of Margaret Gaston.

Figure 6. Marked necrosis and disruption of adipocytes in the subcutaneous fat of the lateral neck were observed down to 10-20mm below dermal-fat junction after immediate exposure to 1440 nm wavelength (8W, 25 Hertz, 700 joules @45-47°C) at the completion of the procedure. 10x magnification, H&E staining.
Figure 7. Moderate coagulation necrosis of fibro-fascial layer of the lateral platysma muscle after immediate exposure to the 1440 nm wavelength (8W, 25 Hertz, 250 joules @45-47°C) at the completion of the procedure. 10x magnification, H & E staining.

Figure 8. Moderate thermal denaturation of the lower level of the reticular dermis and collagen fibers within septae at 1-3 mm below dermal-fat junction of the lateral neck after immediate exposure to the 1440 nm wavelength (8W, 25 Hertz, 275 joules @ 45-47°C) at the completion of the procedure. 10x magnification, H & E staining.
Figure 9. Ultrasound images of the mid-neck dermis (green), and hypodermis (black), and dermal-hypodermal interface showing thinner (mean 0.36 mm) and less compact dermis at baseline (left) and 25% thicker (mean 1.46 mm) and more compact dermis six months after treatment (right) of patient 4, as listed in Table II, and shown in Figure 11.

Figure 10. This 65 year old patient presented with significant fat accumulations to the jowls and neck with marked tissue laxity. Preoperative markings delineate the sectors to be treated (moderate-deep fat 700 j/sector; SMAS 350 j/sector; subdermal layer 280/sector with skin temperature 38-39°C; 175 cc lipoaspirate).
Figure 11. This 50 year old patient presented with significant fullness to the prejowl areas and to her entire neck with moderate degree of tissue laxity. Preoperative markings delineate the 6 sectors to be treated (moderate-deep 650j/sector; SMAS layer 275j/sector; subdermal layer 223j/sector with skin temperatures 38-39°C; 125ml lipoaspirate).
Figure 12. This 47 year old patient presented with a moderate amount of fullness to her prejowl and neck areas with mild-moderate tissue laxity. Skin markings delineated the six sectors (moderate-deep fat 542j/sector; SMAS layer 282j/sector; subdermal layer 275j/sector with skin temperature 39-40°C; 80ml lipoaspirate).
CONFLICT OF INTEREST STATEMENT

Dr. Sasaki is a researcher and training consultant for Cynosure, Inc. (the manufacturer of the device discussed in this chapter). Dr. Sasaki received limited funding under an unrestricted research grant for the study. No financial support was provided for the writing of this chapter.

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