Evaluation of the Safety and Efficacy of a Novel 1440nm Nd:YAG Laser for Neck Contouring and Skin Tightening Without Liposuction

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ABSTRACT

Background: Laser lipolysis is a less invasive approach to neck rejuvenation than open surgery or liposuction. Wavelengths utilized for lipolysis liquefy fat and induce collagen remodeling, which tightens skin. A new Nd:YAG device has recently been developed that emits energy at a wavelength of 1440nm; this wavelength is more highly absorbed by adipose tissue and water than other wavelengths currently available.
Objective: To test the safety and efficacy of a pulsed 1440nm Nd:YAG wavelength and side-firing fiber for the treatment of subcutaneous fat and skin laxity associated with the aging neck.
Methods: Twenty-four subjects aged 40 to 65 years underwent laser lipolysis of the submental and anterior cervical areas. An average of 1205J per 5x5cm square was delivered, with a maximum internal temperature setting of 47°C. Cervicomental Angle Score (CAS), Global Aesthetic Improvement Scale (GAIS), subject and investigator satisfaction, and safety were assessed.
Results: At six months post-treatment, 79% of subjects had a significant improvement in the CAS ($P<.001$) and 79% demonstrated an improvement on the GAIS. Clinical improvement was marked and evident for all but one subject, with physician and patient satisfaction scores indicating overall satisfaction with the procedure and outcomes. Adverse events were mild and transient with no incidence of burns, seromas, hematomas, infection, or nerve damage.
Conclusion: The 1440nm Nd:YAG device with the side-firing fiber was safe and effective for the treatment of subcutaneous fat and skin laxity in the neck. This device offers an alternative to selected individuals aged 40 and over who do not wish to undergo rhytidectomy.

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INTRODUCTION

Neck rejuvenation is becoming increasingly popular for individuals in their 40's and older. As the neck ages, it loses the well-defined contours seen in youth. One apparent change is in the cervicomental angle—the angle formed by the horizontal plane of the submental region and the vertical plane of the neck. In classical beauty, a cervicomental angle of 105° is generally considered the "ideal" representation of a youthful and beautiful neck.[1] Over time, the cervicomental angle becomes blunted and more obtuse, resulting in the loss of the youthful-appearing neck. In addition, descent of the skin and soft tissues of the lower face create jowls and the loss of a well-defined, youthful jawline. Subcutaneous and sub-platysmal fat deposits can progressively increase, leading to excessive fullness in the submental area.

Until recently, surgery has been the mainstay of neck rejuvenation.[2] However, many individuals are reluctant to undergo surgery due to various factors including the invasiveness and recovery time, while others may not be good candidates for surgery due to medical contraindications such as uncontrolled hypertension or use of anticoagulant medications.[3]

Laser lipolysis has emerged as a proven modality for treatment of excess fat and cellulite for those who do not wish to undergo open surgery. For neck rejuvenation, laser lipolysis provides the benefits of both removal of subcutaneous fat as well as tightening of the skin to reduce skin laxity. These results are achieved via two primary mechanisms: liquefaction of the adipose tissue and collagen remodeling.[4] The laser delivers energy in the form of heat to the tissue via an optical fiber within a cannula. This heat is absorbed by adipocytes resulting in damage to the cell membranes. The cell membranes rupture and the liquefied fat can then be removed via simple manual manipulation.[5] The laser energy also serves to denature adipose and dermal collagen, resulting in its remodeling and contraction. This becomes clinically evident as skin tightening.[5,6]

Multiple laser lipolysis devices are available. There are two main systems–diode and neodymium-dosed yttrium aluminum garnet (Nd:YAG)—with the primary difference being that the diode devices deliver shorter wavelengths in the electromagnetic spectrum than the Nd:YAG devices. The wavelengths delivered by these devices range from 920nm to 1444nm. There has been much dis-

cussion regarding the optimum wavelength for liquefying adipose tissue and reducing skin laxity.[4] While there has been speculation that lower wavelengths are better for melting fat and higher wavelengths are better for heat distribution and skin tightening, there have not been any well-controlled studies to support these claims.[4] It does appear, however, that the degree of heating and overall energy delivered may be critical in determining outcomes.[7]

In 2012, a new device was developed that uses the 1440nm wavelength, designed to liquefy adipose tissue and tighten skin. The 1440nm wavelength is key in this system as this wavelength has been shown to have greatly increased absorption by both adipose tissue and water than shorter wavelengths, and thus may have an advantage in achieving greater adipolytic activity compared with other wavelengths.[7] Due to the high intensity of the pulse and the increased absorption of 1440nm wavelength, micro-bubbles or "steam bubbles" are formed at the tip of the optical fiber. When these bubbles collapse, they induce strong mechanical stresses on the neighboring tissue, and cause greater disruption of the cell membranes. To date, the 1440nm wavelength has demonstrated significant improvements in the appearance of cellulite on the thighs at 12 months after a single treatment.[8] Such a system may offer advantages for the treatment of small anatomical areas such as the neck.

"Laser lipolysis has emerged as a proven modality for treatment of excess fat and cellulite for those who do not wish to undergo open surgery."

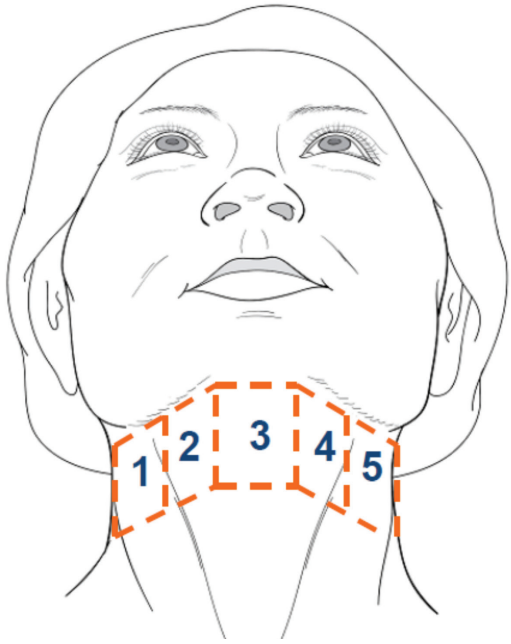
In this study, we tested the safety and efficacy of the 1440nm Nd:YAG wavelength and a side-firing optical fiber delivery system for the treatment of subcutaneous fat and skin laxity associated with the aging neck. This system is unique in that half of the energy emitted is delivered perpendicular to the long axis of the fiber and half is delivered ahead of the long axis of the fiber. The objective of the study was to develop a minimally invasive approach to neck rejuvenation in patients 40 years of age and older.

METHODS

Subjects

This study enrolled healthy male or female patients aged 40 to 65 years who presented with unwanted skin laxity and fat in the neck and submental areas. Subjects were excluded if they had: any procedures performed from the mid-face to the neck in the past six months; a significant systemic illness or immune disorder or any localized condition affecting the treatment area; a history of allergic reactions to local anesthesia; or any medical condition that, in the investigator's opinion, would interfere with participation in the study. In addition, subjects who smoked, had a history of a seizure disorder or keloid formation, those who were taking medications that could interfere with the treatment (including medications causing photosensitivity), or had a body mass index above 30 were excluded.

FIGURE 1. Treatment area markings. The submental area is divided into squares approximately 5x5 cm (25 cm^2). Image courtesy of Cynosure Inc.



Study Design

A single treatment was performed on each subject using a pulsed 1440nm wavelength laser and side-firing optical fiber described below. Follow-up assessments were conducted at one week, one month, three months, and six months post-treatment. Digital photographs were taken at baseline and at the last time point. The study was conducted at the author's private office. The protocol was approved by the International Institutional Review Board and all subjects provided written informed consent prior to study participation.

Procedure

A pulsed 1440nm wavelength laser (Smartlipo® TriPlex™, Cynosure, Inc., Westford, MA) was used for all treatments. The neck was divided into 4 to 5 squares of approximately 5x5cm (25cm^2) (Figure 1). The skin was disinfected using hexachlorophene washes. All subjects were offered diazepam (5mg) prior to the procedure if needed. The treatment area was injected with a tumescent solution (150-200cc) consisting of 500mg lidocaine, 1mg epinephrine, and 12.5mL 8.4% sodium bicarbonate per liter of normal saline.

Laser energy was delivered to the tissues using an 800 micron diameter unique side-firing optical fiber (SideLaze3D™, Cynosure, Inc., Westford, MA). This side-firing fiber delivers approximately half the laser energy perpendicular to the fiber

axis while the remaining energy distal to the long axis of the fiber. This permits the laser energy to be directed more precisely up or down to target the dermis above or the fat below, respectively. Three small incisions (2mm) were made—below the chin, and at the base of each earlobe. The fiber was inserted through each incision with the side-firing hand piece initially turned to direct the energy toward the subcutaneous adipose tissue. Energy delivered perpendicular to the fiber increases the efficiency for melting fat. After approximately half of the total energy had been delivered, the side-firing fiber was turned to direct energy upward toward the undersurface of the dermis for skin tightening. The maximum internal temperature was set at 47°C. A helium-neon aiming beam allowed the location of the fiber tip to be seen as a red translucent light through the skin. The laser display indicated the total energy delivered during use. Fat was removed via manual manipulation: a syringe was rolled over the skin of the submental region to push the liquefied fat out through the cannula incision sites. No mechanical aspiration or liposuction was used to extract the liquefied fat. The procedure took approximately one hour per subject. Post-treatment compression garments were applied to the treatment area continuously for three days, then at night for seven to ten days.

Assessments

The primary endpoint of the study was an improvement in a combination of the Global Aesthetic Improvement Scale (GAIS) and the Cervicomental Angle Scale (CAS). The GAIS is a subjective 5-point scale graded by the investigator as a comparison between current aesthetic appearance vs. baseline as follows: 1 (very much improved; optimal cosmetic results), 2 (much improved; marked improvement in appearance from initial condition, but not completely optimal for this subject), 3 (improved; obvious improvement in appearance from initial appearance, but a re-treatment is indicated), 4 (no change; appearance is essentially the same as the original condition), and 5 (worse; appearance is worse than the original condition). GAIS assessments were taken at baseline and at six months.

CAS scores were assigned using baseline and six-month photographs as follows: grade 1 (normal angle), grade 2 (mildly oblique), grade 3 (moderately oblique), and grade 4 (severely oblique). The best possible CAS improvement score is three grades. Subjects completed a satisfaction questionnaire at three months post-op, while a physician satisfaction questionnaire was completed at three and six months following treatment. Satisfaction was graded on a 6-point scale: 1=extremely dissatisfied, 2=dissatisfied, 3=slightly dissatisfied, 4=slightly satisfied, 5=satisfied, 6=extremely satisfied. Safety was self-assessed by subjects who were instructed to maintain a diary of any post-treatment events and graded them on a 5-point severity score from none=0 to severe=5 during the first week post-procedure.

TABLE 1.

Average Treatment Parameters of Lipolysis Procedure for all Subjects.

Treatment parameter	All subjects (N=24)
Minimum tumescence (cc)	140
Maximum tumescence (cc)	270
Average tumescence (cc)	201
Average deep joules per square	579
Average shallow joules per square	626
Average total joules per square	1205
Average total joules per subject	4232
Average temperature (°C)	45
Power (W)	10

Statistics

T tests were performed for CAS measures at baseline vs six months.

RESULTS

Twenty-four subjects (17 female, 7 male) with evidence of aging necks, including fat in the submental area, underwent the procedure. Ages ranged from 40 to 65 years, with an average age of 56 years. The majority of subjects were Caucasian, with 1 Hispanic subject. Fitzpatrick skin types were 3 type I, 12 type II, 8 type III, and 1 type IV.

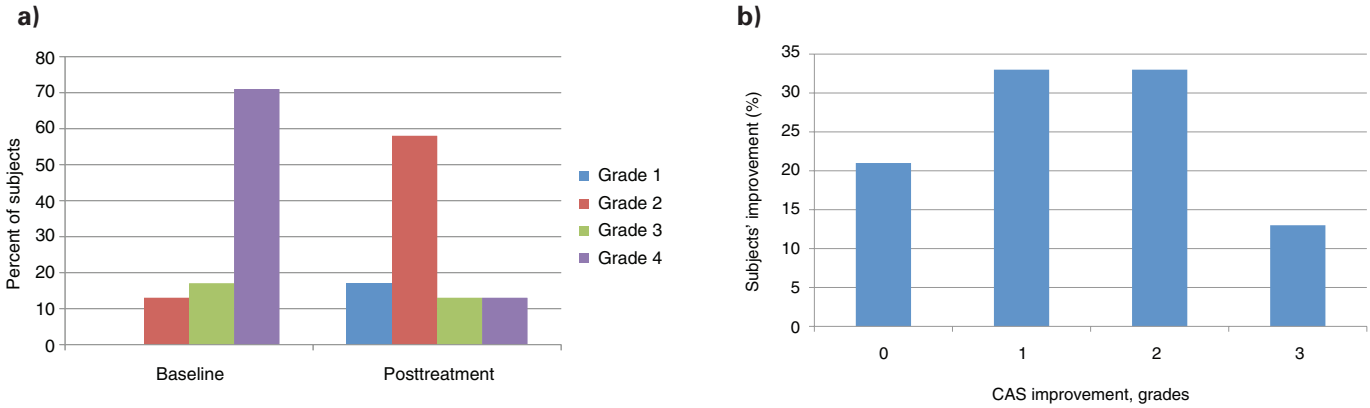
Laser lipolysis was performed as described above. Parameters of the procedure were adjusted according to each subject's anatomic presentation. Average parameters are shown in Table 1. The total energy delivered per patient ranged from 3678 to 6964J, with an average of 4232J. An average of 1205J per 5x5cm square was delivered. Energy delivery in the adipose tissue averaged 579J per 5x5cm square and in the superficial sub-dermal tissue averaged 626J per 5x5cm square. Liquefied fat was expressed through manual manipulation as described above.

At baseline, 71% of subjects had a CAS grade of 4, indicating a severely oblique angle. At six months post-treatment, 79% of subjects had a significant improvement in their CAS ($P<.001$) (Figures 2A and 2B). The majority of subjects saw an improvement of two or three grades, with 75% having a final CAS grade of 1 (normal) or 2 (mild). The average improvement was 1.4±1.0. Examples of improvements in CAS are shown in Figure 3.

Similar to the CAS, 79% of subjects (n=19) showed an improvement on the GAIS (Figure 4). Average improvement was 2.6±1.0, indicating that an obvious to marked improvement in appearance was noted by the investigator compared with the original presentation.

The physician satisfaction score was reported as an average of 4.3 (out of a maximum of 6) one month after the procedure and 4.6 at three months. Subjects reported an average satisfaction score

FIGURE 2. a) Cervicomental Angle Score (CAS) at baseline and 6 months post-treatment. CAS grades: 4=severely oblique, 3=moderate, 2=mild, 1=normal angle. **b)** CAS improvement. Improvement was measured as baseline grade – grade at 6 months post-treatment. The percentages of subjects showing improvements of 1, 2, and 3 grades are shown. Maximum improvement is 3 grades. Average improvement was 1.4 grades (N=24). *P*<.001.



of 4.5 at three months. Ninety-four percent of satisfaction scores ranged from 4 (slightly satisfied) to 6 (extremely satisfied). The majority of subjects were satisfied with the outcome of the procedure (61%), with 6% extremely satisfied and 28% somewhat satisfied. Only one subject was dissatisfied with the outcome. Similar results were seen when subjects were asked about the likelihood of returning for similar treatment, with 11% extremely likely, 61% likely, 22% somewhat likely, and 6% (n=1) somewhat unlikely.

Subjects reported the incidence and severity of adverse events that occurred in the seven days post-procedure. The incidence of swelling, numbness, and bruising appeared to peak between days three and five, and then decrease by day seven. However, all events were mild in nature throughout the first seven days and resolved within one to two weeks following the procedure. There was no incidence of burns, seromas, hematomas, infections, or nerve damage (Table 2).

DISCUSSION

The 1440nm Nd:YAG laser lipolysis procedure performed in this study resulted in significant clinical improvement in the appearance of the neck in study participants. The vast majority of subjects experienced an improvement in their cervicomental angle scale score with 75% of subjects achieving a score of 1 or 2, corresponding to a normal or mildly oblique cervicomental angle. This result was confirmed by the GAIS, where the investigator observed a marked improvement in appearance for 79% of subjects. No subjects worsened in their appearance.

Several circumstances can predispose an individual to achieving suboptimal outcomes with laser lipolysis of the neck. These include having an anterior larynx, a low hyoid bone, a weak chin, excess sub-platysmal (as opposed to subcutaneous) fat, or very lax skin with minimal fat. Individuals should be reviewed for such conditions as they may not be suitable candidates for laser lipolysis.

The maximum desired internal temperature setting was 47°C. Previous small studies of laser lipolysis of the neck have reported external temperatures ranging from 32.2° to 40°C, with internal temperatures not reported.[6,9] The maximum internal temperature reached is important and correlates with surface temperatures. Surface temperatures greater than 47°C (equivalent to 50° to 55°C at a 5mm depth) can result in thermal injury, with blistering occurring at 58°C.[4] The laser cannula used in this study has an embedded thermistor that monitors the internal temperature delivered to the treated areas and cuts off once the maximum set temperature is reached (ThermaGuide™, Cynosure, Inc.). While the temperature must not be high enough to cause excessive external skin injury, some analyses have indicated that internal temperatures should reach 48° to 50°C in order to denature collagen and obtain optimal tightening.[4]

The average energy administered per box was 1205J, with the split between deep and superficial being approximately 50:50. The total energy received per patient ranged from 3678 to 6964J, with an average of 4232J. The ideal total energy required to achieve the desired adipocyte rupture and skin tightening is currently unknown. A few studies have been published on laser lipolysis of the neck, which have listed the total joules administered. These studies report the typical total energy ranges from 2586 to 4988J[6,9] and 5000 to 7000J.[10] With examples shown in these reports all demonstrating favorable outcomes, the optimal total energy cannot be deduced from these studies. For the benefit of those wishing to conduct laser lipolysis using this technology, the energy administered per box is probably a more useful metric to guide recommendations. An evaluation of laser-tissue interaction on *ex vivo* abdominal tissue using laser lipolysis concluded that deep tissue heating is recommended at 1675 to 3325J per 25cm^2 sector,[5] although it should be noted that neck skin is thinner than abdominal skin and adipose thickness in the neck is less than that seen in the abdomen.

FIGURE 3. Digital photographs before and after laser lipolysis. Subjects are shown prior to treatment and at 6-8 months post-treatment.

Baseline

8 Months

Baseline

8 Months

Baseline

8 Months

As previously described, the side-firing fiber used with this 1440nm wavelength laser delivers approximately half its laser energy perpendicular to the fiber axis while the remaining energy is emitted distal to the tip of the fiber and along the fiber axis. This design utilizes the high water and lipid absorption of the 1440nm pulsed laser to form a transient steam bubble at the distal tip of the fiber, which then creates an air–glass interface in the tissue and deflects a portion of the beam at a 90° angle. This feature, unique to the 1440nm wavelength, permits more targeted delivery of laser energy to the structures of interest.[8] In addition, the software allows the number of squares and total joules of energy to be delivered to be pre-programmed into the device. The treatment end-point is a combination of total energy delivered, surgeon judgment and a lack of resistance felt throughout the treatment area.

This study reports on the first time the 1440nm Nd:YAG wavelength has been used for neck rejuvenation. Previous studies on the neck have used 1064 and 1320nm wavelengths.[6,9,11] Human adipose tissue is approximately 75% lipid and 25% water.[12] Based on the main chromophores in this tissue, coefficient of absorption data indicate that 1440nm would be absorbed at much higher levels than shorter wavelengths by both adipose tissue and the dermis.[12]

The technique of performing laser lipolysis is also important. Consistency of cannula movement is important to treating the entire area appropriately for even and stable delivery of energy while preventing any thermal damage. The laser device used was equipped with a motion-sensing microchip accelerometer (SmartSense™, Cynosure, Inc., Westford, MA); if hand piece motion ceases, the laser stops firing to prevent overheating of a single location and then resumes firing when motion resumes. This assists in the safe, effective and even administration of energy across the treatment area.

A key benefit of the laser lipolysis procedure is that it is less traumatic to the tissue than traditional liposuction. Liposuction uses negative pressure to avulse adipose tissue; this causes more trauma to the tissue, more bleeding, bruising and more postoperative pain. In contrast, laser lipolysis gently melts the fat and, in this study, no negative pressure was applied. This results in less pain and trauma to the tissues. Histological studies have indicated that the energy delivered causes the coagulation of small blood vessels, leading to less blood loss and bruising,[5,11] therefore resulting in a shorter recovery period. In addition, because of the miniaturization of the laser lipolysis fibers and cannulae, the incision through which the cannula is inserted is typically smaller than that necessary with conventional liposuction. Finally, the laser lipolysis procedure causes coagulation of adipose and dermal collagen, resulting in skin remodeling, retraction, and reduced skin laxity.[5,11]

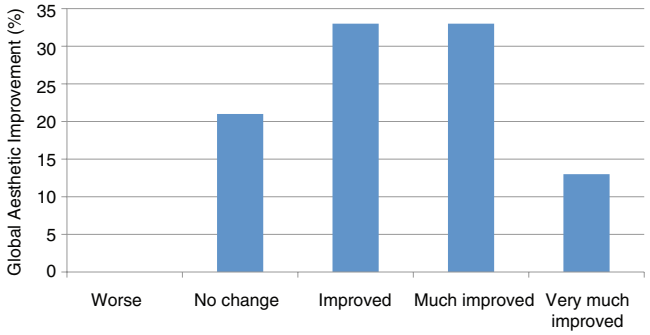
Overall, the treatment was very well tolerated with few, transient adverse events. All adverse events were graded as mild. Subjects were satisfied with the treatment, with many indicating they would be willing to undergo a similar treatment in the future.

TABLE 2.

Adverse Events Experienced During 7-Day Post-Procedural Period (Average)						
Post-treatment	**Numbness**	**Bruising**	**Itching**	**Pain**	**Redness**	**Swelling**
Day 1	0.8	0.8	0.6	1.5	0.9	1.6
Day 2	1.1	1.2	1.0	1.5	1.0	1.8
Day 3	1.4	1.5	1.3	0.9	0.9	1.9
Day 4	1.4	1.7	1.3	0.7	0.8	1.5
Day 5	1.5	1.5	0.9	0.8	0.4	1.4
Day 6	1.4	1.3	1.6	0.5	0.2	1.4
Day 7	1.0	1.0	0.3	0.5	0.2	1.3

Severity score: 0=none, 0.1 to 1.0=very mild, 1.1 to 2.0=mild, 2.1 to 3.0=moderate, 3.1 to 4.0=severe.

FIGURE 4. Global Aesthetic Improvement Scale (GAIS). Percentages of subjects shown for each grading on the GAIS. Average improvement was 2.6±1.0 (N=24).



This study was limited by the small number of subjects included and by the qualitative nature of the treatment outcomes. Further studies could explore the efficacy of this technique using higher overall energy (total joules) or assess the benefit of longer postoperative compression. Additional studies with larger numbers of subjects could measure outcomes more objectively using ultrasound to determine if the thickness of the skin is increased while the thickness of the fat layer is decreased. Histologic studies could be used to evaluate changes in collagen and elastin fibers and whether these changes correlate with clinical findings. Another area to investigate is whether a series of treatments would improve overall results.

Laser lipolysis offers several advantages over liposuction or open surgery for neck rejuvenation; it is less traumatic, produces less bruising, and proffers a shorter recovery time. Moreover, in properly selected patients, laser lipolysis provides additional benefits over rhytidectomy. In addition to being less invasive and traumatic, laser lipolysis can be performed easily under local anesthesia. The recovery time is shorter and more convenient for many potential patients who are averse to surgery due to cost, downtime, or incompatibility with intravenous sedation or general anesthesia. With further analysis, this procedure may provide a viable alternative to rhytidectomy for selected patient populations aged 40 years and over.

DISCLOSURES

Dr. Deborah S. Sarnoff is an investigator for Cynosure, Inc.

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