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A Multicenter Study for a Single, Three-Step Laser Treatment for Cellulite Using a 1440-nm Nd:YAG Laser, a Novel Side-Firing Fiber, and a Temperature-Sensing Cannula

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Abstract

Background: Historically, treatments for cellulite have not been able to address all of its physiological components and require multiple sessions.

Objective: The authors evaluate the safety and efficacy of a single, subdermal procedure to treat the underlying structure of cellulite.

Methods: Fifty-seven patients underwent a 3-step cellulite treatment with a 1440-nm Nd:YAG laser with a side-firing fiber and temperature-sensing cannula. Efficacy was measured by the ability of blinded evaluators to distinguish baseline photos from those taken at 3 and 6 months posttreatment, as well as their rating of the results on a 5-point, 2-category ordinal photonumeric scale when comparing baseline photos to those taken at 2, 3, and 6 months posttreatment. Patient and physician satisfaction was assessed based on completion of a satisfaction survey at 2, 3, and 6 months posttreatment. Adverse events (AE) were recorded throughout the study.

Results: At 6 months posttreatment, blinded evaluators rated at least a 1-point improvement in the appearance of cellulite in 96% of treated sites. Blinded evaluators were also able to correctly identify baseline versus posttreatment photos in 95% of cases. At least 90% of patients and physicians reported satisfaction with the results of treatment throughout 6 months. AE were mild in intensity and transient to treatment.

Conclusions: A single, 3-step, minimally invasive laser treatment using a 1440-nm Nd:YAG laser, side-firing fiber, and temperature-sensing cannula to treat the underlying structure of cellulite proved to be safe and maintained effectiveness at least 6 months posttreatment.

Level of Evidence: 2

Keywords

cellulite, Nd: YAG laser, cosmetic medicine, minimally invasive treatment, cellulite laser treatment



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Previous histology and magnetic resonance imaging (MRI) studies have documented the underlying structure of cellulite.¹⁻³ The hypodermal fat layer in skin is normally divided into chambers by septae that are perpendicular to the skin surface. The fibrous tissue strands extend from the dermal layer, through the hypodermal fat layer, and connect to the underlying muscle layer. In at least 85% of postpubertal women, the septae eventually sclerose, contract, and harden, holding the skin at an inflexible length while hypodermal fat lobules extend upward into the dermis.² The integrity of the dermis is

also compromised as skin thickness and elasticity decrease with age.³ The combination of these structural changes yields a heterogeneous effect on the skin surface. Treating any or all of these anatomical features restores the skin surface to a more homogeneous state, reducing the appearance of cellulite.

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A time-honored treatment for cellulite is massage, which aims to improve impaired microcirculation. Developed in France during the 1970s, the Endermologie ESI device (LPG Systems, Valence, France) mechanically mobilizes subcutaneous fat and improves lymphatic drainage by kneading the skin between 2 revolving rollers.⁴ Since then, various devices using intense pulsed light, radiofrequency, diode laser, infrared light, and ultrasound with and without mechanical massage have been studied, along with mesotherapy and other types of injectables and topical agents. Results have shown mild and temporary improvement.⁵⁻¹²

In 2000, Hexsel and Mazzuco¹³ described a subdermal technique for treating cellulite that focused on the subcision of septae. Three action mechanisms come into effect when this technique is performed at the level of the subcutaneous fat: severing of the septa that retain the skin, formation of new conjunctive tissue from blood components, and redistribution of fat and of the mechanical forces between lobes.

In 2008, Goldman et al¹ reported the first use of a laser procedure to treat cellulite. Energy from a 1064-nm Nd:YAG laser was conducted through a straight optical fiber to the subcutaneous tissue, performing laser lipolysis in the superficial subdermal plane and also inducing neocollagenesis for subsequent skin tightening. The final step was performed in a deeper subcutaneous plane throughout the entire affected area for overall adipose volume reduction. The most depressed areas were then injected with the patient's autologous fat.

In 2011, one of the authors² published a study on 10 patients treated with a 1440-nm Nd:YAG laser and a newly developed fiber with side-firing capabilities (SideLight 3D; Cynosure, Westford, Massachusetts) enclosed in a thermal-sensing cannula (ThermaGuide; Cynosure). The side-firing technology permitted multidirectional firing, enabling the laser energy to be deposited into the anatomical structures underlying the cellulite. Of note, the 1440-nm Nd:YAG laser is absorbed by adipose tissue at a rate 127 times greater and absorbed by water at a rate 252 times greater than 1064-nm lasers.¹⁴ The thermal-sensing cannula provided the temperature measurement at the point of treatment and was used as a guide in distributing the laser energy more evenly.

In this study, we report on the experience with this same 1440-nm Nd:YAG laser treatment at 5 study sites, which enrolled and treated 57 patients using the same device and 3-step approach: (1) selective deplaning of fat cells to minimize expansion of tissue causing bulging, (2) selective thermal subcision of septae to release and regenerate connection of tissue to minimize skin being held

down, and (3) heating of the superficial layer for skin thickening to smooth the surface of the dermis and disrupt impregnated or herniated fat in the dermis.

METHODS

Patients

A total of 57 patients provided informed consent and were treated at 1 of 5 study centers between November 2009 and July 2010. The study was approved by the Independent Institutional Review Board in Plantation, Florida. This trial was intended to support application for US Food and Drug Administration (FDA) clearance for the 1440-nm Nd:YAG laser device used to treat patients.

The average age and body mass index (BMI) of the patients were recorded, along with Fitzpatrick skin types. Prospective patients were excluded from participation in the trial if any of the following were present: surgical/nonsurgical treatment for cellulite in past 6 months; history of thrombophlebitis, acute infections, heart failure, or keloid formation; recent antiplatelet, anticoagulant, thrombolytic, vitamin E, or anti-inflammatory therapy; intolerance to anesthesia or medications that produce a photosensitizing effect; pregnant, breastfeeding, or intended pregnancy; or inability to maintain a diet and exercise routine during the study period. Basic chemistry panels were assessed, which is standard preoperative practice, and patients were given antibiotics to be taken the evening prior to treatment and continued for 7 days posttreatment. Photographs were taken on the day of surgery prior to and after surgical treatment and at all follow-up visits.

Treatment

Patients underwent a single treatment in the bilateral thighs and/or buttocks. With the patient in a standing position, a grid of 5 × 5-cm squares was marked over the cellulite area. Lumps at least 3 × 3 cm and dimples at least 1 cm long were then marked with different colors (green for lumps and red for dimples). With the patient positioned either in the lateral decubitus or prone position, the skin was prepared with providone-iodine antiseptic. A small amount of lidocaine was injected at chosen sites. Using a small blade, 1-mm incisions were made. Distal incision points at the lower border of the marked grid were preferred for proper posttreatment drainage. Proximal incisions at the upper border of the marked grid were made as necessary. Each defined sector was infused with up to 60 mL of tumescent anesthesia mixture (50 mL of 0.5%

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lidocaine, 1 mg epinephrine per liter of warm saline, and 20 mL of 8.4% sodium bicarbonate). Although this tumescent formula was used throughout our study, other concentrations of tumescent solution mixtures may be employed. After 10 to 20 minutes, the cannula and side-firing fiber tip was passed through the incision, delivering energy at 8 to 10 watts and 25 Hz. The thermal-sensing cannula was set to sound when the temperature reached 47°C and to shut off at 52°C.

Four to 6 squares at a time were chosen for treatment. In the first step, the cannula-fiber was inserted perpendicular to the marked mounds in the *down* position, 1 to 2 cm below the dermis within the selected 5 × 5-cm squares. The cannula-fiber was then passed in a fan-shaped manner to melt the excess hypodermal fat, which reduced the expansion mound into the dermis at the dermal-hypodermal interface (300 J for mounds 3 × 3 cm; 600 J for mounds 5 × 5 cm). In the second step, the cannula-fiber was moved *sideways* in a zigzagging (back-and-forth) pattern, perpendicular to the marked depressions 3 to 5 mm below the dermis, subcising taut septal bands and releasing the dimples (100 J for dimples 1 cm; 300 J for dimples 3 × 3 cm; 600 J for dimples 5 × 5 cm). The fiber was then placed in the *up* position, 1 to 3 mm below the dermis, to heat skin in the entire 5 × 5-cm square (remaining joules after mounds and dimples treated) to increase skin collagen and elastin for tissue tightening and dermal thickening. Close proximity to the incision point was avoided to prevent overheating of the area.

Cannula placement and treatment direction were important in determining outcomes. When the cannula was placed vertically, the energy was distributed more evenly, especially when subcising the septae. When the cannula was placed horizontally, parallel to the horizontal depressed lines and folds, the energy deposition occurred in a smaller area and disrupted more fat than desired, leaving a groove or unevenness in that zone.

The 4 to 6 treatment squares were marked to optimize laser delivery without overheating the area. Previous clinical experience² demonstrated that working with 1 square at a time produced rapid heating of that area; however, if the treatment area was too large, inadequate heat would be retained in the tissue. Again, all lumps and depressions were treated first within the 4 to 6 squares and then finished by deploying the total recommended joules for the entire area with an overall superficial heating pattern. The total delivered energy per square for the completion of all 3 steps in the procedure was approximately 1000 J. Deposition of up to an additional 300 to 500 J/square was allowed at the investigator's discretion for more complex presentations in individual patients, such as thicker fibrous bands and larger fat lumps. Following treatment, moderate hand pressure was applied with a rolled towel in a top-to-bottom motion toward the access incision site(s), to assist in the removal of dislodged fatty tissues and tumescent fluid. A compression garment with sponge inserts was worn by each patient for the first few days posttreatment. Patients were then instructed to wear the garment alone (without sponges) for up to 3 weeks. Standard posttreatment instructions were given.

Patients were informed that typical side effects such as bruising, swelling, pain, numbness, and itching could occur.

Assessments

A camera system Nikon D90 (Canfield Scientific, Fairfield, New Jersey) was set up in a dedicated photo room in each of the 5 clinical centers. In addition, fixed lighting was mounted in the ceiling in each center with an attached string to ensure consistent light-to-patient distance, along with a level to ensure consistent light angles. A lumen meter was used to record the exact amount of light falling on each patient. A mat was used to repeat positioning. Patients stood in a relaxed manner with no muscle tightening, with equal weight on both legs, and with arms folded and resting at their abdomen. All photographs were taken in a standardized manner, in the same room at each clinic, with the same camera fixed at the same location by the same person hired for reproducibility. Photographs of thighs and buttocks were taken pretreatment (baseline) and at each of the follow-up visits, which occurred at 2, 3, and 6 months after the single initial treatment.

A goal end point was also established: a 1-point level of improvement in the appearance of cellulite at 2, 3, and 6 months posttreatment, relative to baseline photos; treatment sites with a 1-point improvement were considered "responders." The 1-point improvement was based on a 5-point, 2-category ordinal photometric scale (described below) specifically designed and validated for this study. Improvement was represented by a decline on the scale, reflecting a decrease in the number of dimples or number and/or depth of contour irregularities. A 1-point level of improvement was considered a success for either category per treatment site as agreed upon by the FDA.

An end point of an 80% success rate was also set for correctly identifying baseline photos compared with 3- and 6-month posttreatment photos. A success rate of 80% would statistically exceed the likelihood of a 50/50 chance of picking correctly. Satisfaction was measured based on a 6-point Likert scale¹⁵ at 2, 3, and 6 months posttreatment, and safety was assessed through the recording of all adverse events (AE), including physician and patient observations throughout the course of the study.

Scale Design and Validation

A scale depicting discernable levels of the clinical appearance of visible cellulite was designed by Cynosure (the study sponsor and manufacturer of the laser) in conjunction with 3 physicians (2 board-certified plastic surgeons and 1 board-certified dermatologist) (Figures 1 and 2). Two key clinical morphologic features of cellulite (categories) were identified: (A) number of evident dimples and (B) severity of linear undulations (contour irregularities). The severity of each category was graded from 0 to 4. Five photos were then selected to represent each level of severity for each category.

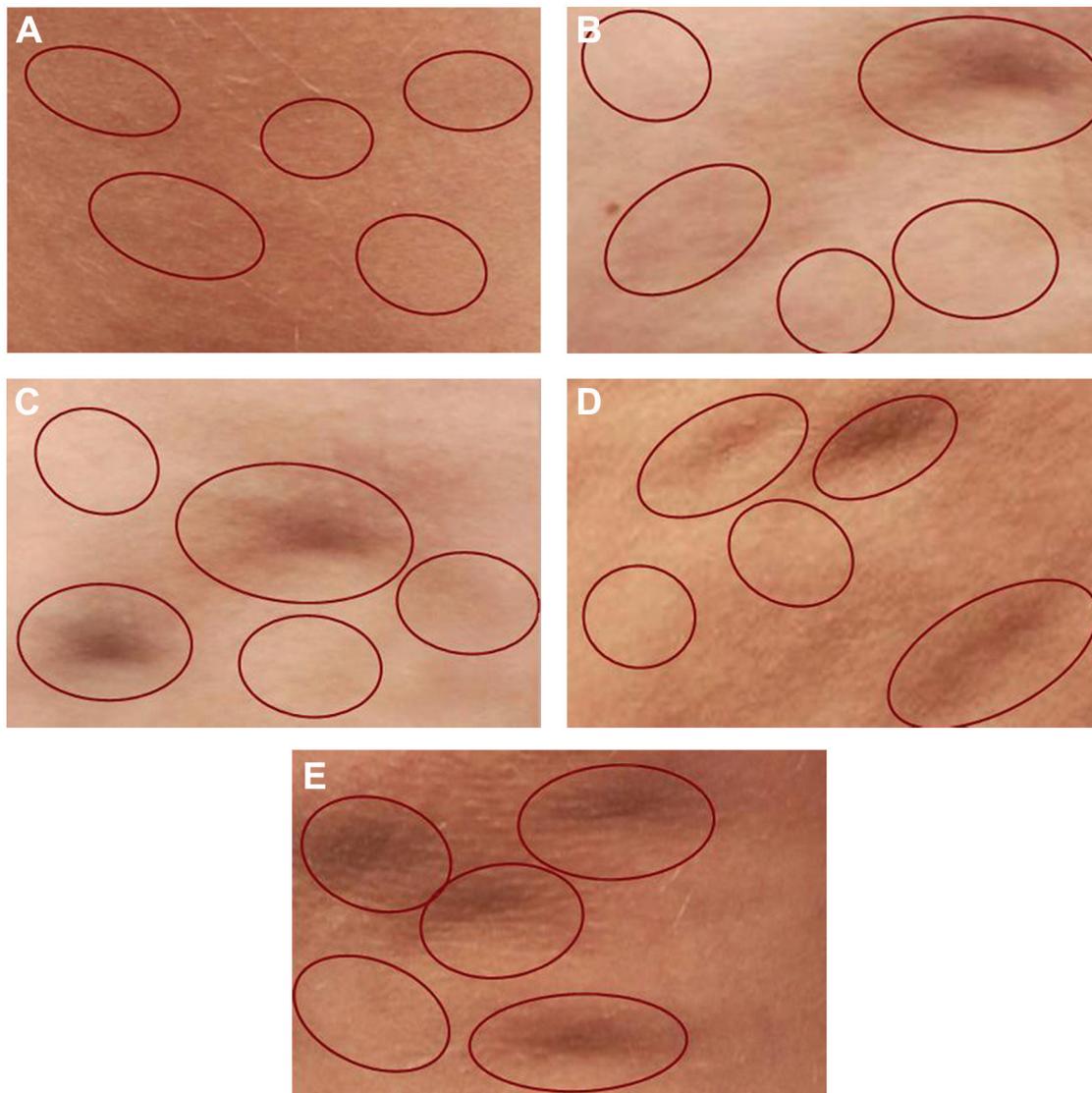


Figure 1. Scale for evaluating cellulite dimples, in which a dimple is an isolated circular or oval-shaped depression on the surface of the skin. Each photo represents a number of dimples. Five circles are placed in each photo for evaluation purposes. The circle may or may not contain a dimple. This is done so the evaluator is not confused by nondimpling irregularities but not biased by being told exactly where the dimples are located. (A) Score 0 (no dimples); (B) score 1 (1 dimple); (C) score 2 (2 dimples); (D) score 3 (3 dimples); (E) score 4 (4 or more dimples).

Three clinically trained evaluators who were not involved in the development of the scale were chosen and trained. The evaluators were independent from the study physicians and authors of this article. This device was only available to sites approved by the FDA for the study, and therefore the evaluators did not own the device, nor were they familiar with the procedure. The evaluators were asked to provide their own score for preselected, prescored (but blinded) test photos. If any photos were not properly scored, the evaluator was retrained and asked to rescore the test photos until the correct scores were given. Once trained, the evaluators were presented with

125 photographs (60 dimples and 65 contour irregularities) from this series that represented the full range of the cellulite scales. Photos were randomized. Each evaluator scored the photos and recorded the results on a standardized score sheet. Interrater reliability (consistency among evaluators) was determined by comparing paired evaluators' scores and was expressed as a weighted kappa value. In addition, the percent of evaluators in agreement was calculated. Intrarater reliability (consistency of each evaluator) was determined by a comparison of the matched scores (initial assessment score and reassessment score). The same evaluators scored the same photos using the

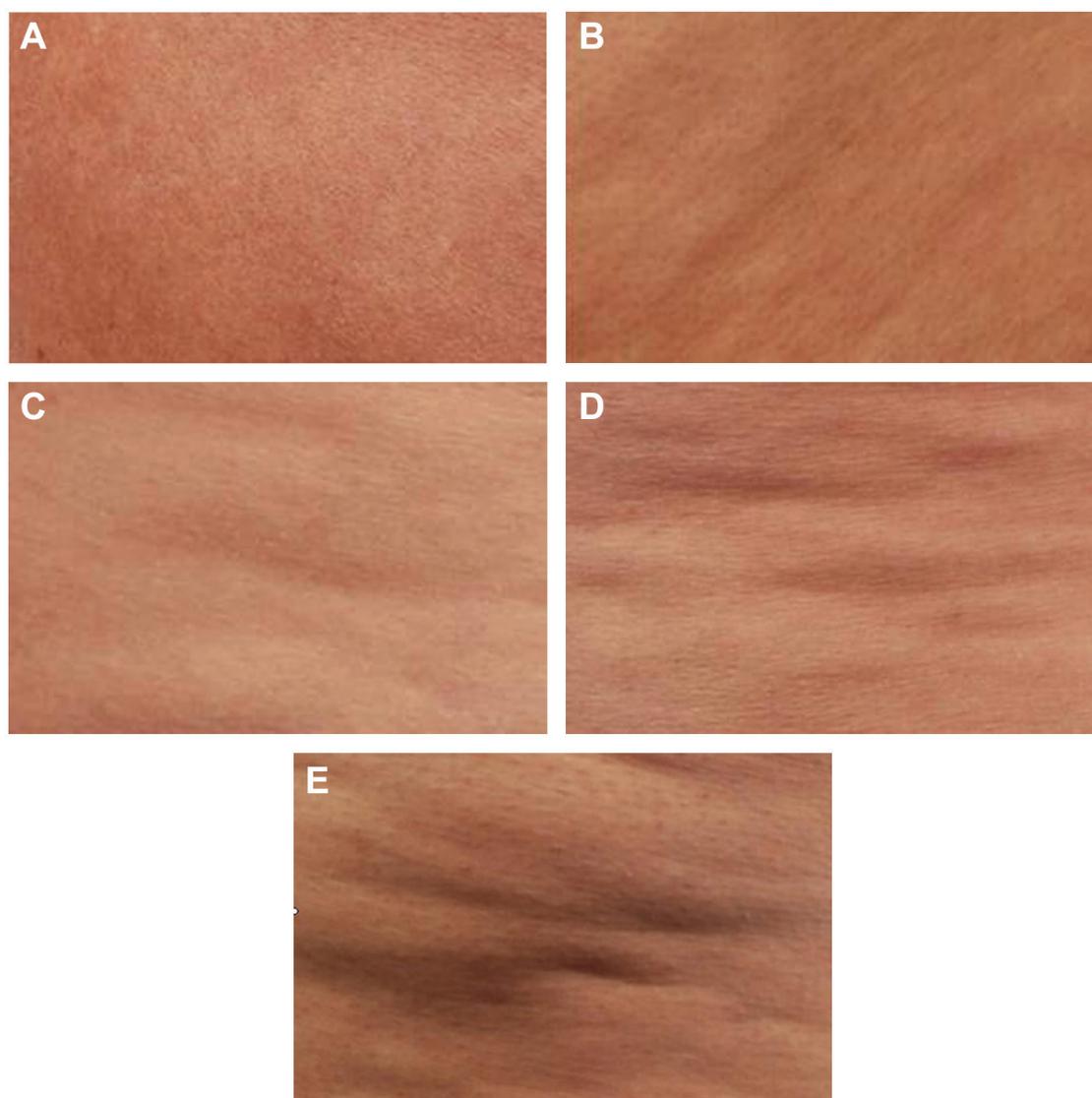


Figure 2. Scale for evaluating contour irregularities. The irregularities become more severe as more concavity and convexity occur in the linear undulations. (A) Score 0 (none—no depressions or raised areas); (B) score 1 (superficial: generalized, small depressions with no protuberances); (C) score 2 (mild: pattern of mild linear undulations with alternating areas of protuberances and depressions); (D) score 3 (moderate: pattern of moderate linear undulations with alternating areas of protuberances and depressions); (E) score 4 (severe: severe generalized linear undulations with alternating areas of protuberances and depressions).

same process 2 weeks after the initial assessment. Intrarater analysis was expressed as a weighted kappa value. In addition, the percent of evaluators in agreement was calculated. Kappa values above 0.50 were generally recognized as demonstrating reasonable agreement for both interrater and intrarater categories.

RESULTS

All 57 patients in this study were women. Average patient age was 43.3 years (range, 21-55 years), and average BMI

was 25.1 (range, 20-33). The patient population had Fitzpatrick skin types of mostly type II and III and was of Caucasian and Hispanic descent.

Interrater weighted kappa values ranged from 0.69 to 0.90 for all paired evaluator comparisons for each category (0.88-0.90 for dimples and 0.69-0.70 for contour irregularities). Evaluators were found to be in agreement 59% to 85% of the time (81%-85% for dimples and 59%-63% for contour irregularities).

Intrarater weighted kappa values ranged from 0.75 to 0.92 for each of the 3 evaluators' scores for 2 time points (initial assessment and reassessment) for each category (0.88-0.92

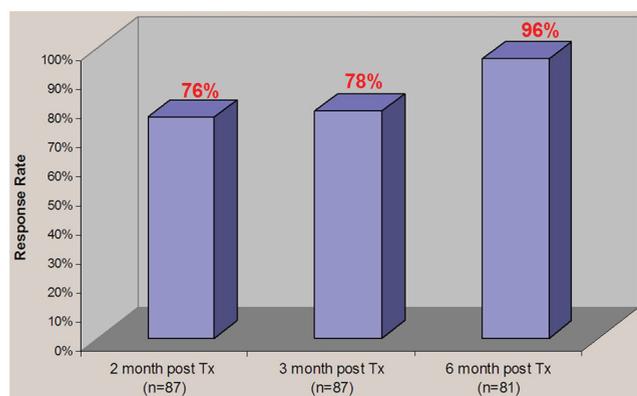


Figure 3. Treatment sites with at least a 1-point score improvement in either dimples or contour irregularities. Percentages are averages as reported by 3 blinded evaluators.

for dimples and 0.75-0.85 for contour irregularities). Evaluators were found to be in agreement 68% to 88% of the time (83%-88% for dimples and 68%-78% for contour irregularities) from initial assessment to reassessment.

Level of improvement from baseline photos to photos taken 2, 3, and 6 months posttreatment was assessed based on the validated scale. Ninety-one percent of treatment areas were considered “responsive” (at least a 1-point improvement on the scale) in either dimples or contour irregularity categories, exceeding the efficacy end-point goal of 80% at 2, 3, and 6 months (Figure 3). Figures 4 and 5 show detail per category for the response rate. Table 1 shows scores where a greater than 1-point improvement was achieved in both categories. Total improvement scores averaged 2.4, 2.4, and 2.7 at 2, 3, and 6 months, respectively.

Evaluators were also asked to identify the pretreatment (baseline) photos from photos taken at 3 months and then 6 months posttreatment. Ninety-nine paired baseline and 3-month posttreatment photos were assessed. For the 6-month posttreatment sets, 81 paired photos were used. Table 2 shows that an average of 93% of baseline versus 3-month photos and 95% of baseline versus 6-month photos were correctly identified by the 3 evaluators. These values exceed the efficacy end point of an 80% success rate. Clinical results are shown in Figures 6 and 7.

Analysis of Regression Toward the Mean

At the 3-month evaluation, photos from nontreated areas were introduced into the evaluation to assess regression toward the mean. Twenty-six paired photos representing baseline and 3 months posttreatment were used (Table 3). Percentage of correctly identified baseline photos ranged from 42% to 54% for the 3 evaluators (average, 50%). The data suggest there was no bias caused by either the evaluation process or photography being conducted at different time points.

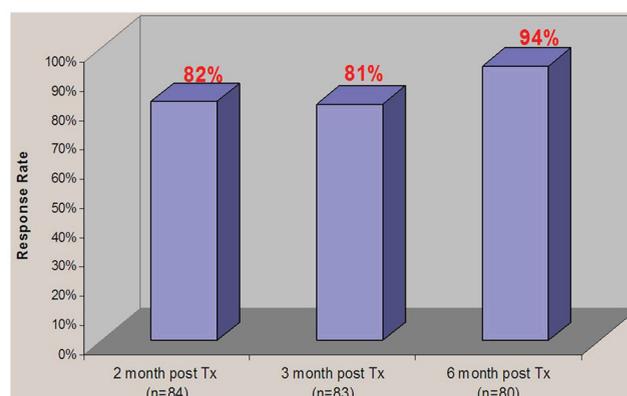


Figure 4. Treatment sites with at least a 1-point score improvement in dimples.

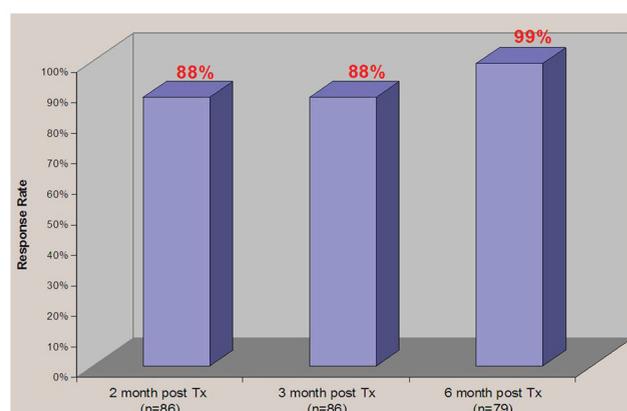


Figure 5. Treatment sites with at least a 1-point score improvement in contour.

Table 1. Blinded Evaluator Results in Dimples and Contour Irregularity Categories

	Posttreatment Time Period		
	2 mo	3 mo	6 mo
Total sites	87	87	81
Dimples at baseline	2.44	2.44	2.26
Dimples posttreatment	0.99	0.99	.72
Average improvement score of dimples (<i>P</i> value)	1.45 (<.001)	1.45 (<.001)	1.54 (<.001)
Contours at baseline	2.32	2.32	2.07
Contours posttreatment	1.37	1.39	0.93
Average improvement score of contour (<i>P</i> value)	0.95 (<.001)	0.93 (<.001)	1.14 (<.001)
Total improvement score (dimple + contour)	2.4	2.4	2.7

Patients and physicians were asked to rate their level of satisfaction at each follow-up visit based on a 6-point

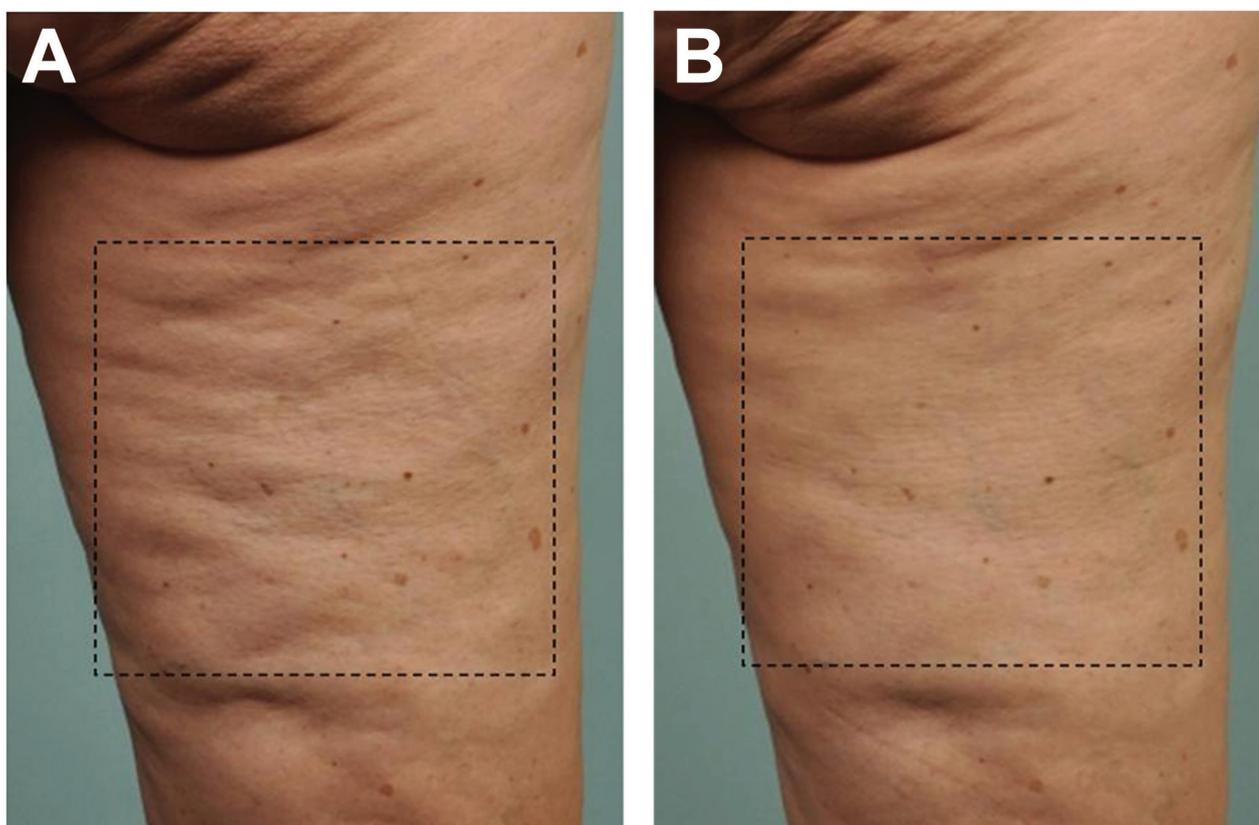


Figure 6. (A) This 54-year-old woman presented with mild cellulite. (B) Six months after a single treatment with the 1440-nm Nd:YAG laser. The dotted line encloses the treatment area.

scale: extremely satisfied, satisfied, slightly satisfied, slightly dissatisfied, dissatisfied, and extremely dissatisfied. At least 90% of patients and physicians reported high satisfaction with the results of treatment through 6 months posttreatment (Table 4).

Incidence of all AE (by both physician and patient evaluation), including patient and physician assessments, was recorded throughout the course of the study. Most were resolved by the 3-month follow-up visit, and no events were reported at 6 months (Table 5).

DISCUSSION

This single, 3-step cellulite treatment approach was both safe and effective in our study, as it has been in previous reports.^{1,16} This multicenter study demonstrated that the efficacy of treatment could be validated on a photographic scale by comparing results at 2, 3, and 6 months to baseline assessments. Blinded evaluators rated at least a 1-point level of improvement in 96% of treated sites at the 6-month follow-up (Figure 3).

Since the morphological features of cellulite are inconsistent, it was difficult to assess the overall improvement

of appearance. The Nürnberger-Müller scale¹⁷ captures general features, while the Hexsel scale¹⁸ provides a more detailed approach. The scale designed for this study was a combination of both, addressing 2 of the key features of cellulite appearance (dimples and contour irregularities).

It should be noted that the operative approach in this study was individualized for the 2 grades of cellulite. The topical effects of *peau d'orange* without lumps and dimples should only be treated with the third of the 3-step approach for superficial treatment and subdermal heating. Cellulite that includes dimples and lumps should be treated with the entire 3-step approach. It is also important that the 3 steps are conducted in the sequence described in this article. Since heat rises, it is crucial to treat the fat layer first, septae second, and superficial third. Subcision of septae and deplaning of fat should be limited to marked areas to avoid excessive tissue separation and fluid collection. Future studies will evaluate the addition of the SmoothShapes System (Cynosure)—a noninvasive, dual-wavelength laser-suction and massage device¹⁹—for side effect resolution and improved outcomes. Further studies with longer follow-up and more objective assessments of appearance improvement are also being conducted.

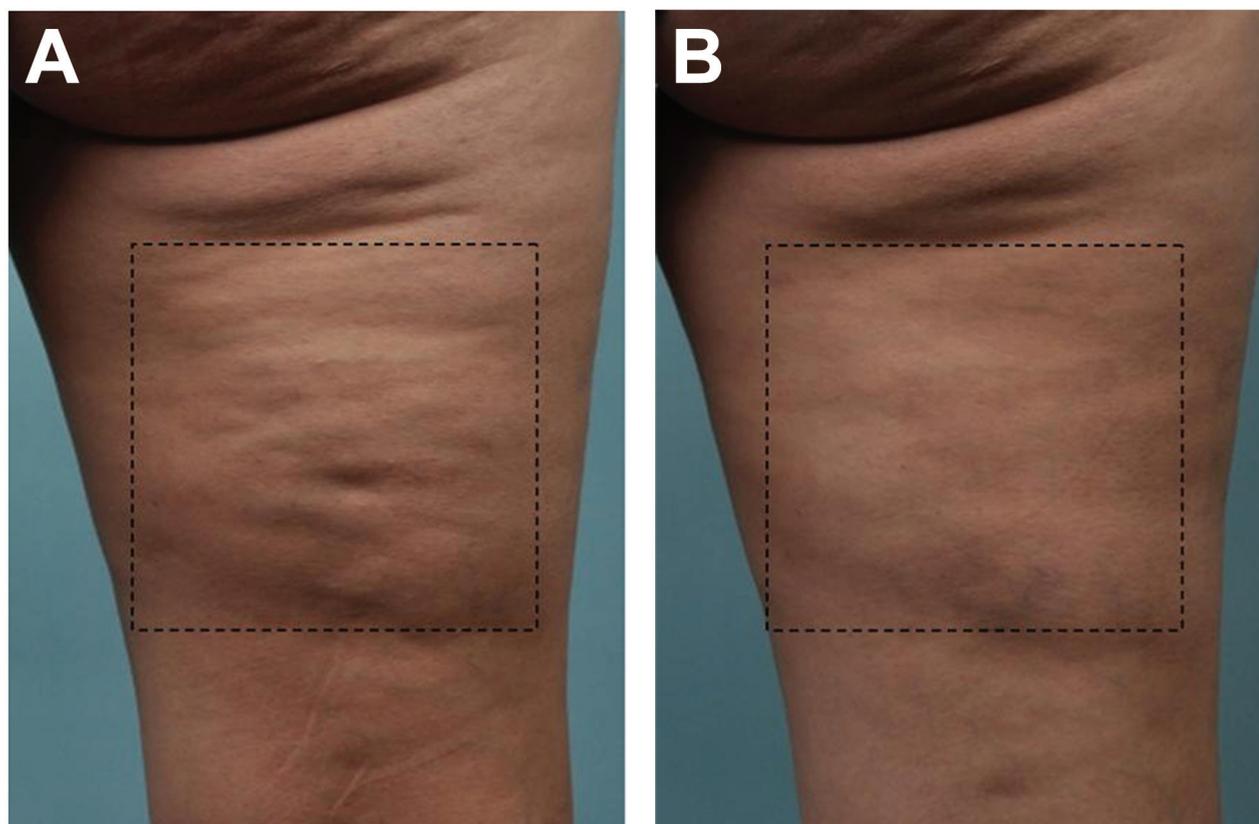


Figure 7. (A) This 35-year-old woman presented with mild cellulite. (B) Six months after a single treatment with the 1440-nm Nd:YAG laser. The dotted line encloses the treatment area.

Table 2. Correctly Identified Photos at Each Follow-Up Point vs Baseline Photos

Evaluator	3 mo (n = 99), No. (%)	6 mo (n = 81), No. (%)	<i>P</i> Value ^a
1	94 (95)	78 (96)	<.0001
2	91 (92)	76 (94)	<.0001
3	90 (91)	76 (94)	<.0001
Average % evaluators	93	95	

^aThe *P* value is based on a chi-square test to assess the null hypothesis that the rate that the evaluators can identify the pretreatment (baseline) photos is greater than 50%. A *P* value less than .001 meant that the chance of choosing the baseline photo statistically exceeded a 50/50 chance.

Table 3. Identification of Control Photos at 3 Months Posttreatment

Evaluator	No. (%) of Control Sites Correctly Identified as Baseline (n = 26)	<i>P</i> Value ^a
1	11 (42)	.43
2	14 (54)	.69
3	14 (54)	.69
Average % evaluators	50	

^aThe *P* value is based on a chi-square test to assess the null hypothesis that the rate that the evaluators can identify the pretreatment (baseline) photos is greater than 50%. A *P* value greater than .001 means that the chance of choosing the baseline photo does not statistically exceed a 50/50 chance.

Table 4. Physician and Patient Satisfaction Results Through 6 Months Posttreatment

	Posttreatment Time Period					
	Physician, 2 mo	Patient, 2 mo	Physician, 3 mo	Patient, 3 mo	Physician, 6 mo	Patient, 6 mo
Total patients	48	48	47	50	45	45
Average score	5.2	4.7	5.4	4.6	5.4	5
≥4, No.	48	43	47	45	44	42
≥4, %	100	90	100	90	98	93

CONCLUSIONS

In this multicenter study, a single treatment with the 1440-nm pulsed laser with a novel side-firing fiber improved the appearance of cellulite in the thigh and buttocks through 6 months of follow-up with minimal adverse effects.

Disclosures

All authors are paid research consultants for Cynosure, Inc (the manufacturer of the product discussed in this article).

Table 5. Incidence of Adverse Events at 3 Months

Event	No. (%) of Patients (n = 55)			
	Mild	Moderate	Severe	Total Patients
Pain	0 (0)	0 (0)	0 (0)	0 (0)
Redness	0 (0)	0 (0)	0 (0)	0 (0)
Swelling	1 (2)	0 (0)	0 (0)	1 (2)
Purpura	2 (4)	0 (0)	0 (0)	2 (4)
Itching	2 (4)	0 (0)	0 (0)	2 (4)
Numbness	0 (0)	0 (0)	0 (0)	0 (0)
Blisters	0 (0)	0 (0)	0 (0)	0 (0)
Hardness	0 (0)	0 (0)	0 (0)	0 (0)
Seroma	0 (0)	0 (0)	0 (0)	0 (0)
Necrosis	0 (0)	0 (0)	0 (0)	0 (0)

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