White Paper

Treatment of Grade II-III Cellulite using a Minimally Invasive 1440nm Pulsed Nd:YAG Laser with Eighteen-Month Follow Up

Gordon H. Sasaki, MD, FACS
Professor, Loma Linda Medical University Center Private Practice: Pasadena, California USA

Ana Tevez, Surgical RN
Connie Ha, Surgical LVN
Erica Lopez Ulloa, CST
Chelsea Knutson, CST

INTRODUCTION

In the majority of post-pubertal women, cellulite represents a prevalent cosmetic concern of multifactorial genesis, exhibiting classical findings primarily to the posterior-lateral thighs and buttocks. This gender-specific condition is characterized structurally by thickened hypodermal fat that stretches the vertically oriented fibrous septae bands and herniates into the weakened dermis. Currently, there are a number of available treatments and FDA-cleared devices approved for temporary improvement in the appearance of cellulite. These modalities have nuanced advantages in value, but whether they are actually a value remains largely unknown, since most require multiple treatments. In contrast, the introduction of the 1440nm pulsed Nd:YAG laser, using a specially designed side-firing fiber, defined for the first time a three-step approach to affect the underlying structures in cellulite. This minimally invasive single treatment Cellulaze™ procedure has improved the appearance of cellulite for a duration of at least one and one-half years, with minimal adverse events.

CLINICAL DESIGN

Twenty-five healthy women were recruited for the treatment of moderate-to-severe cellulite on their thighs (posterior, lateral, or both) in a prospective, consecutive study at the author’s private plastic surgery clinic—in accordance with International Conference of Harmonization good clinical practice guidelines and approved by an independent Institutional Review Board. After adherence to exclusion criteria, each subject reported her medical history, underwent a pre-operative physical examination and chemistry panel and furthermore, agreed not to undergo other procedures at the anatomical areas during the study period. Height and body weight were recorded for each subject to calculate BMI.

In the standing position, each subject’s treatment areas were divided into square sectors (5 x 5cm). The horizontally raised and depressed irregularities were marked precisely to locate them during treatment, as shown in Figure 1. After skin preparation with povidone-iodine antiseptic, the patient was placed either in the lateral decubitus or prone position for surgery. Through less than a 1cm incision at the midpoint of the lower border of the outlined thigh, a small cannula was inserted and an average of 50 to 60ml of tumescent anesthesia mixture (50ml of 0.5% lidocaine, 1mg epinephrine per liter of warm saline, and 20ml of 8.4% sodium bicarbonate) was infused into each sector. After 20 to 30 minutes, a 1000 µm side-firing fiber (SideLaze3D™, Cynosure, Inc.), enclosed in a 2.1mm temperature-sensing cannula (ThermaGuide™, Cynosure, Inc.) was passed through the access incision. The red aiming beam tip indicated the bidirectional manner in which the laser energy was delivered. The power and pulse frequency settings with the system were delivered at 8 to 10 watts and 25Hz, respectively. The ThermaGuide™ temperature-sensing cannula monitored subdermal temperature readings averaging below 47°C. Skin temperatures reached about 38-42°C during treatment.
The red aiming beam from the laser system aided visualization of the tip of the side-firing fiber (Side-Laze3D, Cynosure, Inc.) during the three steps of treatment, with the fiber tip in the down, sideways, and up directions. Once in place, the cannula-fiber was inserted perpendicular to the marked mounds in the down position within the selected 5 x 5cm squares and passed in a fan-shaped manner to melt the excess hypodermal fat, thus reducing the expansion-mound into the dermis at the dermal-hypodermal interface. In the second step, the cannula-fiber was moved sideways in a back and forth direction, in a fan-like pattern, perpendicular to the marked depressions to subcise and release the dimples. The fiber was then positioned in the up position 2 to 3mm below the dermis to heat the skin in all the 5 x 5cm squares in order to increase skin collagen and elastin for tissue tightening through tissue coagulation and dermal thickening through collagen remodeling. Total joules of energy delivered per sector was approximately 1000 joules, including all three steps of treatment. Up to an additional 500 J/square were delivered for more complex presentations, such as thicker fibrous bands and larger fat mounds. Treatments beyond transitioned curved zones (posterior to lateral thighs/lateral to anterior thighs) were approached by separate inferior access incisions. Vigorous rolling massaging from top-down to the access incision site(s) removed clumps of dislodged fatty tissues and tumescent fluid.

To optimize laser delivery without overheating, four to six squares were treated at a time. Working with one square at a time will cause rapid heating of that area; however if too large an area is treated, the heat will not be retained enough. Treat all mounds and depressions first within four to six squares and then finish depleting total joules for the entire area with overall superficial heating. A soft ¼ inch long Penrose drain(s) is(are) inserted from the access incision(s) and threaded to the upper ⅓ of the treated area in order to serve as an effective conduit over time in reducing seromatus fluid collections and inflammatory responses from liquefied fat that has not been evacuated. The drain was removed two to three days later. A compression garment with sponge inserts was worn for the first few days and then the garment alone was worn for three to six weeks.

**POST-PROCEDURAL ANALYSES**

Treatment efficacy was assessed with both high-resolution digital photography, taken under standardized conditions, and subjective patient and physician evaluations at two-, three-, six- and eighteen-months post procedure. Measured changes were assessed for skin elasticity at baseline, two-, three- and six-month intervals (Refer to Figure 1; Dermalab Elasticity Module, Cortex Technology, Hadsund, Denmark) and for skin thickness images (2MHz high-frequency ultrasound probe, Dermascan C) at baseline, and at two-, three-, and eighteen-months post procedure. For both elasticity and ultrasound, three to five measurements were taken at the center of each 5 x 5cm square. An average of the measurements was used to represent the findings for each measurement per subject. Comparisons were made with the Paired Student Test. Biopsies were taken on a select number of subjects at baseline and two months post treatment.

**RESULTS**

**SUBJECTS TREATED**

Twenty-five women (27-67 years old, average 40) presented with cellulite II-III, grading on their posterior or lateral thighs (Table 1). There were Caucasian (n=9) and Hispanic (n=16) subjects with Fitzpatrick skin types III (n=8), IV (n=12), and V (n=5). Median baseline body weight and BMI values did not differ significantly before treatment and at the follow up evaluations for patients who completed the eighteen-month study (n=15). (See Table 1.)

**SKIN ELASTICITY**

Subjects that presented for follow up at two-, three- and six-months post treatment showed at least a 22% improvement in skin elasticity. Nineteen subjects returned for a six month follow up and showed improvement of 40%, proving a continued statistically significant increase compared to baseline (Refer to Figure 2).

**SKIN THICKNESS**

Subjects achieved an average increase in skin thickness compared to baseline of approximately 14% at two months, remaining stable near 14% at three months, and 13% at eighteen months (in Figure 3). Increased dermal thickness was verified by ultrasound imaging.
Histocytes surrounded the adipocytes which intruded into the dermis. Histocytes are markers of fat necrosis.

New collagen deposition at dermal/hypodermal junction. Histocytes surrounded the adipocytes which intruded into the dermis. Markers of fat necrosis.

Figure 5  Histology: H&E Stain Two Months Post Treatment

Figure 6  New Collagen Deposition Two Months Post Treatment
SAFETY
Adverse events were recorded up to six months post treatment. As expected, most events were observed at one week and continued to improve with time. The most frequent effects were purpura, edema and numbness. Edema declined the most rapidly, while numbness and pruritis subsided more gradually.

DISCUSSION
This innovative procedure suggests that a single Cellulaze™ treatment with the side-firing SideLaze 3D fiber and 1440nm pulsed laser safely improves the appearance of moderate-to-severe cellulite for at least eighteen months with a satisfactory safety profile. The side-firing SideLaze 3D fiber enabled the operator to anatomically treat the three structural features of cellulite using a three-step approach. The subjective physician and subject evaluation were supported by objective measurements of skin elasticity, skin thickness and ultrasonic imaging.

Figure 7  Average Scores of Satisfaction Questionnaire

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Extremely Satisfied</td>
</tr>
<tr>
<td>5</td>
<td>Satisfied</td>
</tr>
<tr>
<td>4</td>
<td>Slightly Satisfied</td>
</tr>
<tr>
<td>3</td>
<td>Slightly Dissatisfied</td>
</tr>
<tr>
<td>2</td>
<td>Dissatisfied</td>
</tr>
<tr>
<td>1</td>
<td>Extremely Dissatisfied</td>
</tr>
</tbody>
</table>
Figures 8-10 Patient Pre and Eighteen Months Post Treatment Photographs
ULTRASOUND IMAGING

The images in Figure 4 show the dermis as the bright image and the dark/black area represents adipose tissue. One can see the fat intrusion into the dermis in the baseline image. At the eighteen-month follow up, less fat intruding into the dermis and a thicker, more dense and uniform dermal layer can be observed.

HISTOLOGY

Histology at two months post treatment show necrosis (Figure 5) of intruding fat and formation of new collagen (Figure 6) in areas treated with laser energy, resulting in changes seen in the ultrasound image.

EFFICACY

Satisfaction for both physician and subject were measured using a six-point scale to rate aesthetic improvement. Physician and patient evaluations continued to be favorable for efficacy over a follow up period of eighteen months (Figure 7); and evaluation of pre- and post treatment photo images also demonstrate lasting results at eighteen months (Figures 8 to 10).
Figure 1 Patient Pre-Treatment Markings: The photo above is of a patient marked using a template for 5 x 5cm squares. All obvious depressions and mounds are marked. Patient marking is an important step in the pre-treatment process.

<table>
<thead>
<tr>
<th>DEMOGRAPHICS</th>
<th>FITZPATRICK SCORE</th>
<th>AGE</th>
<th>GENDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>8</td>
<td>Min Age</td>
<td>27</td>
</tr>
<tr>
<td>Hispanic</td>
<td>16</td>
<td>Max Age</td>
<td>67</td>
</tr>
<tr>
<td>1/2 Cauc/1/2 Hisp</td>
<td>1</td>
<td>Ave Age</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>III</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>V</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WEIGHT (LBS)</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min</td>
<td>106</td>
</tr>
<tr>
<td>Max</td>
<td>236</td>
</tr>
<tr>
<td>Median</td>
<td>159</td>
</tr>
</tbody>
</table>

Table 1 Patient Demographics
REFERENCES


