

Study Title:

Evaluating the Efficacy of Two Laser Lipolysis Treatment Devices

Primary Investigator:

Robert J Troell, MD, FACS

Funding Source: None

Introduction/Background:

There are currently numerous medical technologies marketed as adjuvant therapies in liposuction procedures. This study is designed to compare two laser lipolysis technologies of different wavelengths.

The two laser technologies to be investigated are Smart Lipo (Cyanosure) end light fiber at 1064 nm (20 Watts), 1320 nm (12 Watts) and 1440 nm or variant of the above (Multiplex). This is a pulse laser wave form and the temperature at the laser tip can reach 850 degrees C. and the Slim Lipo (Palomar Medical Technologies) end light fiber at 924 nm and 975 nm. This is a continuous laser wave form and the laser tip temperature reaches about 70 degrees C.

The goal was to determine the efficacy and the side effects observed of each laser lipolysis device in a direct comparison on opposite sides of the same subject.

Patient Population:

All subjects were healthy woman 18 to 65 years of age who presented and requested liposuction therapy. Exclusion criteria included any medical condition where minimally invasive surgery under oral or mild intravenous sedation was contraindicated.

Methods:

The key to the study was a direct comparison on the same patient, where one side of the body undergoing one modality and the other a different modality determined randomly.

Laser Procedure Technique:

The history and physical examination including appropriate laboratory and cardiac testing are updated and the patient fully consented prior to the procedure. On the day of surgery photographs are taken. The skin of the area to undergo liposuction surgery is marked with a sharpie marking pen noting areas of excess fatty tissue and areas where there are indentations using different colors with circles for excess fat and lines for areas of indentations. The area is marked in grids of 4 x 10 cm to assist in laser energy delivery.

Patients are offered preoperative oral sedating and pain medication and received oral antibiotics. Team members and the subject were protected by special eyeglasses. A 3 mm incision below each zone permitted access for treatment. Each of the 4x10cm target zones is treated with the manufacturer recommended laser energy levels.

Deep and shallow subdermal temperatures, as well as surface skin temperatures, were recorded simultaneously in each panel by the manufacturers temperature control software. After the surgical procedure was completed, each incision was approximated with a single suture. Subjects were dressed with super absorbant pads over the incisions and a compression garment for at least 2-3 weeks. Postoperative antibiotic and pain medications were prescribed.

The patient is prepped with a prep solution, such as chlorhexidene, and sterile drapes applied. Anesthesia was delivered in the form of a wetting solution prepared in a one liter normal saline bag combined with between 80-100 cc of 1% lidocaine, 1.0 - 1.5 mg of 1:1,000 epinephrine and 10 cc of 8.4% sodium bicarbonate. The wetting solution is administered by an infiltration cannula to each of treatment areas using a superwet technique.

Laser energy needed to treat each area is determined by the surgeon with the amount of energy per treatment area of 5000-7000 Joules (J) with a treatment duration of about ten minutes for a 20 x 20 cm area. The skin target temperature is between 37-40 degrees C.

The outcome measures investigated will be:

1. visual appearance documented by video and/or still photography
2. skin thickness measured by non-invasive diagnostic ultrasound measurements (TouchView device)
3. skin elasticity measured by a Cutometer or Elastometer
4. skin tightening measured by surface skin ultraviolet dye tattoos in a triangle pattern changing in size using a black light for visualization
5. measurements of circumference changes using a tape measure at superior middle and inferior points
6. patient and physician observational surveys in a visual analog format regarding discomfort, swelling, bruising and aesthetic outcomes
7. surface skin temperature measurements by non-contact thermometer during the treatment sessions.
8. Some subjects may volunteer for pre and post-treatment 2.5 mm dermal punch histology biopsies of the treatment area (completed post-treatment at the 6 month time frame)

Patients will be observed at one month, three months, 6 and 12 months post-treatment.

Review of the Technique of the Outcome Measures:

1) 35 mm Photography

The key to photography is standard views, antero-posterior (AP) and lateral, which include the majority of the anatomical area in the photograph against a solid cobalt blue background. The lighting uses side and up down lighting to flash at the time of the camera shutter taking the photograph. This is the same setup for all the before and after photographs.

VIDEO

Using the same background and lighting, a video camera documents the subject at the same height as the treated area (thigh/buttock) in a 360 degree view spinning clock-wise.

2) Skin thickness and fat layer measurements

An external diagnostic ultrasound device, such as the TouchView, distributed by Sound Surgical Technologies, measures the thickness in millimeters (mm) with digital images stored within the system.

3) Elastometer or Cutometer

These medical devices are used to reliably measure skin elasticity. One company manufacturing both devices is Courage+Khazaka (Köln, Germany). The measurement is based on the worldwide acknowledged suction method. Skin is drawn by negative pressure slightly into the aperture of the probe, after some seconds the negative pressure stops and the skin relaxes. The penetration depth of the skin is determined optically during the suction and relaxation. There will be five measurements at each site to optimize accuracy. To ensure the measurement will be at the exact site for each subsequent treatment, an ultraviolet tattoo makes the center of the areas to be assessed.

ELASTOMETER PROCEDURE:

Skin is cleansed of makeup and any cream. The device is turned on. The probe is placed flat on the skin with a constant low pressure. When the probe is placed correctly on the skin, the measurement is started automatically. Skin is then sucked within 6 seconds with a negative pressure of 400 mbar. After this 6 second period, the negative pressure stops and the skin returns into its original state. The elasticity is expressed in percent (%) on the display and on the diode chain. This procedure is performed five times to each area for heightened accuracy.

4) Skin Tightening measured by surface skin triangle size changes using ultraviolet dye to produce micro-dots at the 3 pts of the equilateral triangle.

The micro-dots will be applied subcutaneously most commonly using a disposable 3-point round needle and a single use Click Stick Handle (SofTap® Permanent Cosmetics). UV-reactive black light ink (Chameleon Body Art Supply Company) will be used to make the micro-dots. The dots that comprise the triangle will be exactly either 30 mm or 50 mm in length apart. The size of the triangle will be chosen based on the size of the area with indentations caused by the cellulite where the triangle is completely within this area. An accurate measurement between each dot will be recorded immediately after placement for use as a baseline and then at the normal follow-up schedule.

The diameter of each dot is approximately 0.5 mm. With the use of a black light (Wood's light), the dots appear faintly glowing white in darkness, allowing the surgeon to measure the distance between the dots (and thus skin stretch or retraction) at each follow-up visit.

TATTOO PROCEDURES: (three basic methods available)

Method #1 – *(Supplies are available through any Aesthetician ordering supply company, MEDI Point Blood Lancet-single use)*

1. Clean the area with alcohol swab.
2. Position the triangle (5cm) on the of treatment area to identify the three points of the triangle.
3. Pour the ink into the ink well and dip the lancet in the ultraviolet ink.
4. Puncture the skin with lancet a couple of times on the indicated triangle points
5. Use the ultraviolet light to ensure tattoo success.
6. Mark the triangle points with marking pen to proceed to treatment.

Method #2 – *(Supplies available through Sound Surgical Comfort System -3R Prong Needle- Single use)*

1. Clean the area with alcohol swab.
2. Position the triangle (3 or 5 cm) on the treatment area to identify the three points of the triangle.
3. Assemble the handle and the needle head.
4. Pour the ink into the ink well and dip the needle in the ultraviolet ink.
5. Puncture the skin with the needle a couple of times on the indicated area.
6. Use the ultraviolet light to ensure tattoo success.
7. Mark the triangle points with marking pen to proceed to treatment.

Method #3 – *(The tattoo gun can be purchased at www.trilabproducts.com or 877-Tri.Labs, Tri-Lab Product, Inc- Sapphire Pro 110V Gun- Hi Tech Micro pigmentation, Professional tattoo Artist Gun)*

1. Clean the area with alcohol swab
2. Position the triangle (5 cm) on the treatment area to identify the three points of the triangle.
3. Assemble the gun with all of the needed attachments.
4. Pour the ink into the ink well and dip the needle 3mm in the ultraviolet ink.
5. Pull out of the ink well and power up for a second. This allows fresh pigment into the tip.
6. Position the gun and fire the application of ink into the designated area.
7. Use the ultra violet light to ensure tattoo success.
8. Mark the triangle points with marking pen to proceed to treatment.

***NOTE:** The best method of identifying the triangle prior to treatment and after treatment is by using a wood lamp. This method proved to be the most accurate and best method of all. Other ultraviolet lights after the tattoo fades away it creates more of a challenge for an untrained eye.*

Supplies needed: Different method of puncture supplies, gloves, cotton balls, alcohol swabs, triangles with circular perforation for consistent results, ultra violet ink and ink wells and ultraviolet light and or a wood lamp.

1) Circumferential measurements (in centimeters) using a tape measure at the superior middle and inferior pts of treatment noted before each treatment.

2) Patient and physician observational surveys.

The visual analog scales are given to the patient to complete prior to administering the other scale surveys.

- a. Overall satisfaction survey
 - i) five point scale (0-worse, 1- poor, 2- moderate, 3- good, 4- excellent)
 - ii) 0-100 on a visual analog score (poor to excellent)
- b. Localized fat reduction survey
 - i) five point scale (0- no change, 1- 25% improvement, 2- 50% improvement, 3- 75% improvement, 4- near complete resolution)
 - ii) 0-100 on a visual analog score (poor-excellent)
- c. Skin texture survey
 - i) five point scale (0-worse, 1- poor, 2- moderate, 3- good, 4- excellent)
 - ii) 0-100 on a visual analog score (poor to excellent)

- 3) A non-contact temperature gun (example; Ryobi, Anderson, SC) at maximum output of <math><1\text{mW}</math> at between 630-670 nm (Class II laser product) is used to determine an accurate surface temperature during the treatment session.**

The recommended target temperature from the manufacturer of each cellulite treatment modality will be attained during each treatment session. The laser gun documented the final tissue temperature by pointing the gun to the area to be evaluated and reading the LCD screen.

- 4) Patients volunteering to undergo biopsies had histologic stains performed on the tissue specimens.**

BIOPSY TECHNIQUE

About 2 cc's of 1% lidocaine with epinephrine is injected to the proposed biopsy site. A dermal punch (2.5 mm) is placed the flat against the skin, gently pushing downward and twisting in a clockwise-counter-clockwise direction until the skin is detached. If needed, a scissor is used to amputate any residual tissue. The defect is then closed with a suture. The specimen is sent to determine thickness. It is measured with a caliper prior to placing in 10% neutral buffered formalin (NBF) and again at the time of the histologic evaluation. (Note: Placing in formalin fixative will shrink the tissue specimen, however, the same amount for all specimens). The tissue will undergo a stain for elastin fibers (VVG stain) and collagen fibers (Masson trichrome). A qualitative assessment is performed by a board certified dermatopathologist (Dr. Narciss Mobini, MD, Quest Diagnostics) and graded using a 0-10 score comparing before and after treatment biopsies. The dermatopathologist will be blinded to the treatment method used.

Patients will be observed at one month, three months, 6 and 12 months post-treatment.