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Title:

Laser Liposuction vs. Tumescent Liposuction: Multicenter Randomized Controlled Trial

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Study Summary

Title	Laser Liposuction vs. Tumescent Liposuction: Multicenter Randomized Controlled Trial
Short Title	Laser Liposuction RCT
Protocol Number	LaserLipoRCT
Phase	Phase II / Phase III
Methodology	Double-blinded, Randomization, Repeated Measurement
Study Duration	Approximately 2 year
Study Centers	Multiple Centers
Objectives	Design a powerful, high quality clinical trial that will evaluate the objective merit of lasers in liposuction.
Number of Subjects	To be determined after the pilot study
Main Inclusion Criteria	Patients with generally good medical condition are recruited. Morbidly obese patients or those with systemic medical problems are not considered
Study Treatment	Laser Liposuction
Procedure	Symmetric areas of patients are targeted for traditional tumescent liposuction and laser assisted liposuction, respectively. Results from both sides are compared with each other to assess the merit of laser in liposuction.
Statistical Methodology	Generalized Linear Mixed Model (GLMM)

Introduction

1.1 Liposuction

Liposuction is a cosmetic surgical procedure which removes unwanted areas of subcutaneous fat using a small stainless steel suction cannula connected to a strong vacuum by plastic tubing. The cannula is inserted into subcutaneous fat through tiny incisions which eventually become imperceptible. When a strong suction is applied and the cannula is moved in a reciprocating in-and-out motion, subcutaneous fat is aspirated into a disposable canister.

Liposuction is not effective as a weight-loss technique. However, it is remarkably successful at removing diet-resistant and exercise-resistant fat deposits and producing and aesthetic improvement of a patient's profile. Liposuction has become increasingly popular over the last two decades and is now one of the most commonly performed cosmetic surgical procedures worldwide.

Tumescent liposuction involves the infiltration (injection) of tumescent local anesthesia, which consists of a large volume of very dilute solution of lidocaine (a local anesthetic) and epinephrine (a capillary vasoconstrictor), into the targeted subcutaneous fat. Some surgeons prefer to do tumescent liposuction under general anesthesia. However with skillful gentle infiltration technique, tumescent local anesthesia does permit liposuction totally by local anesthesia without general anesthesia, narcotic analgesia or heavy IV sedation. Tumescent liposuction permits liposuction with unprecedented safety, effectiveness and dramatically better cosmetic results compared to the pre-tumescent or old-fashioned liposuction techniques.

In recent years, laser liposuction has become popular largely as the result of direct-to-consumer promotional efforts sponsored by laser manufacturers. Those who promote laser liposuction claim the results are significantly better than the "traditional liposuction" techniques without ever defining the term "traditional liposuction".

Those who promote laser liposuction claim that lasers cause skin tightening; however there are there are no large randomized controlled clinical trials which compare skin tightening after laser liposuction to that of tumescent liposuction. Furthermore it is rarely mentioned that laser liposuction cannot be accomplished without tumescent local anesthesia. Ultimately it may be there is no real difference between the long-term results of tumescent liposuction and laser liposuction. It is the intention of the present randomized controlled trial (RCT) to critically and objectively compare laser liposuction to tumescent liposuction.

1.2 Laser Assisted Liposuction

Laser energy can be delivered into subcutaneous fat by means of a flexible optic fiber placed inside of a small ($\leq$ 2 mm diameter) stainless steel cannula which is inserted through a tiny skin incision into

subcutaneous fat. Laser as an adjuvant to liposuction was described for the first time by Apfelberg in 1994, who showed results of a multi-center study approved by the FDA in five different centers for cosmetic surgery [2]. Conducted by a flexible fiber optic delivered through a cannula, the laser energy is transmitted to the adipocytes, which absorb the light and heat energy, expand their volume, and rupture.

Publications by Blugerman [5], Schavelzon [14], and Goldman [7] demonstrated their experience with lasers used directly on adipose tissue in a procedure called laser-lipolysis. Later, Badin [3, 4] published his experience with laser-lipolysis, highlighting the important tissue retraction obtained with this technique. Ichikawa [9, 10] showed the histological evaluation in subjects and laboratory animals treated with laser lipolysis, which indicates the findings of tissue evaporation, destruction, heat coagulation, and rupture of the cell membrane. Recently, Goldman [8] suggested several positive benefits, which include skin retraction and a reduction in intra-operative and post-operative bleeding as well as in the population of adipocytes. Kim [12] asserted anecdotally that laser lipolysis offers excellent patient tolerance, quick recovery time, as well as the benefit of dermal tightening. Katz [11] asserted anecdotally that laser assisted liposuction is less traumatic to tissues, causing less swelling and bruising, with improved skin retraction when the technique was used in areas of flaccidity, however there were no clinical controls.
Most of the reported benefits of laser liposuction are based on anecdotal experience and clinical impressions. Many surgeons who are experienced with tumescent liposuction have found no significant benefit associated with the use of lasers in addition to tumescent liposuction.

Among the disadvantage of laser liposuction are: 1) the high cost of the equipment and its maintenance, 2) a significant amount of extra time is required to perform laser liposuction compared to tumescent liposuction and 3) the risk of laser-associated thermal injury to tissues including vascular injury. Lasers also induce a significant degree of subcutaneous scarring and fibrosis which becomes clinically evident whenever a surgeon attempts secondary liposuction as a touch-up procedure following a previous laser liposuction. Complications following laser liposuction do occur but they are rarely reported and therefore a true risk-benefit of laser liposuction has yet to be published.

To date there have been no multicenter randomized controlled trials to substantiate claims that there is a significant difference between the traditional liposuction and laser assisted liposuction. There is a need for a scientifically objective evaluation the differences between laser liposuction and tumescent liposuction.

2 Study Objectives

The objective of this study is to design a statistically powerful, high quality multicenter clinical trial that will evaluate the objective merits of lasers in liposuction compared to simple tumescent liposuction.

Anecdotal reports based on the clinical impression or histological examination have asserted that laser assisted liposuction is superior to traditional liposuction, without specifically defining what is meant by “traditional liposuction.” It is implied that laser liposuction is better than tumescent liposuction. On the other hand, laser liposuction may be more dangerous than tumescent liposuction without providing any well-documented substantial benefits.

We propose a randomized controlled experimental design and sufficient statistical power to critically examine the validity of these conflicting views.

3 General Study Design

Multiple surgeons at multiple independent surgical centers will be involved in this study. For each patient will have symmetric areas treated by laser liposuction and tumescent liposuction. Each patient will be treated by one or preferably two surgeons. When two surgeons work together during their participation in this trial they will have separate roles to play as follows:

Surgeon #1 applies laser energy to targeted subcutaneous fat. One side is treated by relatively high laser energy; the contralateral side is treated with no laser energy; however surgeon #1 will use the optic-fiber cannula on both sides so that the mechanical effects of the cannula tunneling through the fat is equal on both sides. In other words, each side will receive the same number N of in-and-out strokes using the optic-fiber cannula. There is random assignment of the side to be treated by laser, where the allocation is determined by the flip of a coin, {Heads =Right Side Is treated First and with Laser} and {Tails=Left side is treated first and with laser}. The second side does not receive laser energy. However the second side does receive exactly the same number of strokes as the first side using the optic-fiber cannula without laser energy. Surgeon #1 will not be blinded with respect to which side gets higher energy. **Surgeon #2** does liposuction, and will be blinded to the treatment. The patient is also blinded with respect to treatment difference between both sides.

At research sites where **only one surgeon** participates in the clinical trial, this surgeon will deliver both the laser treatment and perform the liposuction surgery.

Clinical Assessment

A subjective assessment of the surgical results will be conducted sequentially over time by both the patient and by the liposuction surgeon who will compare left vs right sides by choosing one of the 3 possible responses:

A) The Left Side is Greatest
B) No Difference Between Sides
C) The Right Side is Greatest

This post-operative questionnaire/assessment will be repeated on the Day of Surgery, Week1, Week4, and Week20. The patient and surgeon will evaluate each of the following criteria by choosing the most accurate of the above 3 possible responses:

(1) Soreness (discomfort with movement)
(2) Tenderness (discomfort with touch)
(3) Pain (discomfort without movement or physical touch)
(4) Swelling / Edema
(5) Erythema (pink / red discoloration associated with inflammation)
(6) Numbness (decreased sensation)
(7) Paresthesias (altered or abnormal sensation in response to common sensory stimuli)
(8) Bruising intensity (deep v.s. light discoloration)
(9) Bruising extensiveness (large v.s. small area of involovement)
(10) Drainage volume
(11) Lumpiness / lack of smoothness
(12) Cosmetic and aesthetic improvement
(13) Skin Smoothness
(14) Skin Contraction

Split-Body Online Photo Comparison

The public will be able to view 20-week post-operative photos (4 views: front, back & both sides) and vote by choosing one of the 3 possible responses:

A) The Left Side Has the Best Cosmetic Result
B) There Is No Difference Between Sides
C) The Right Side Has the Best Cosmetic Result

4 Subject Selection

4.1 Inclusion / Exclusion Criteria

All the patients are to be screened through an initial office visit consisting of an evaluation of their general medical condition, body habitus, and lifestyle.

Patient inclusion criteria: Healthy female requesting liposuction of hips and or outer thighs.

Each research site may specify its own additional inclusion criteria. Patients must have realistic expectations. Anticipated maximum volume of supernatant fat cannot exceed 3.5 Liters. Anticipate total mg/kg dosage of tumescent lidocaine should not exceed 45 mg/kg. Under no circumstances will the total dosage of lidocaine exceed 50 mg/kg. Patient must agree to participate in the Randomized Clinical Trial (RCT).

Patient exclusion criteria: A patient is exclude if she is pregnant or breast feeding, has a history of Hepatitis C or HIV/AIDS, or is excessively Obese. A patient is excluded if her anticipated volume of supranatant fat is expected to exceed 3.5 liters. Each research site may specify its own additional exclusion criteria.

4.2 Randomization

To avoid the latent bias to the surgical results, the allocation of the side to be treated by high laser energy should be random. In each center, a person, except for those involved in the surgical procedure, can be chosen to perform the following randomization procedure.

(1) Toss a balanced coin and record the result;

(2) Based on the coin toss result, Assign one side to be treated by high laser energy as follows.

"Head" = Right side is treated first and with laser

"Tail" = Left side is treated first and with laser

5 Clinical Trial Procedures

5.1 Tumescent liposuction using microcannulas

After marking the treatment site with a surgical marker, patients are prepped and draped in sterile fashion. The tumescent local anesthesia (TLA) is infiltrated into the target area(s). TLA consists of a large volume of saline solution with precise amounts of very dilute epinephrine, bicarbonate, and lidocaine, which is dispersed into the fatty tissue. The injected area then becomes locally anesthetized, vasoconstricted and distended. There is a 15 to 60 minute waiting period, allowing for diffusion of infiltrate and appropriate vasoconstriction. Tiny skin incisions (adits) are placed for the introduction of a stainless steel cannula. On the first side, laser energy is delivered to the tissues using back-and-forth movements of the optic-fiber cannula; the precise number N of in-and-out strokes of the cannula are counted by a nurse/observer. On the second side, the optic-fiber cannula is passed in-and-out of the tumescent tissue precisely the same number N of times as the on the first side but without using any laser energy. Fatty tissue is mechanically removed through a suction cannula with negative pressure aspiration pump. Postoperative discomfort is reduced with the tumescent technique since the local anesthesia remains in the treated tissue with residual numbness that may last for 12 hours or more after surgery.

5.2 Laser assisted liposuction

After the subcutaneous infiltration of tumescent fluid and a waiting period of 15 to 60 minutes, the laser energy is conducted to the adipose tissue through a optic fiber, delivered through a 1mm to 2mm diameter stainless steel micro-cannula of variable length. After the surgeon and patient are protected adequately with special eyeglasses, small (approximately) 1mm incisions are made in the desired sites, through which a microcannula is introduced advancing back and forth in fan-like movements, at different levels of depth, including the subcutaneous, similar to the superficial liposuction. The dosage of the laser energy is controlled through a LCD display control panel that expresses the energy quantitatively. For visualization purposes, a Helium-Neon (He:Ne) laser source is combined into the beam path, which allows precise visualization of the region where the energy is acting, due to cutaneous transillumination. When in contact with the previously infiltrated fatty tissue, the laser produces a photo-hyperthermia effect, transforming luminous energy into heat in adipocytes, thereby injuring the adipocyte by rupturing the cell membrane. Next liposuction removes fat tissue, cellular debris , an oily cell contents through a cannula using negative pressure from a vacuum pump.

6 Safety Considerations

Both laser liposuction and simple tumescent liposuction are surgical techniques used around the world. These techniques are generally considered to be very safe. This research project will not use any new or experimental device, medication, or dosage formulation. Each surgeon will use his or her safest surgical technique. Dosages of tumescent local anesthesia as well as laser energy will be within accepted standards.

7 Ethics Considerations

There is considerable equipoise in the present experimental design and protocol. Most surgeons believe there is little difference between the cosmetic results of these two liposuction procedures. If a surgeon firmly believes that either laser liposuction or simple tumescent liposuction is far superior to the other form of liposuction, then he or she should not participate as a surgeon in this clinical trial.

It is relatively unlikely that there will be any significant cosmetic/anatomic asymmetry resulting from a difference in technique. If such a difference does become evident, then the surgeon agrees to repair the situation by doing a touch-up liposuction procedure. The each surgeon will decide upon the appropriate fee for touch up procedures he or she will charge. As part of the signed informed consent each patient will agree to the maximum “touch-up” fee before participating in this research project.

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Outline: Details of Protocol LaserLipoRCT

A) Objective: to compare the cosmetic outcome of simple Tumescent Liposuction versus Laser assisted liposuction techniques.

1) Control Technique: Simple tumescent liposuction using tumescent local anesthesia plus simple vacuum assisted liposuction with or without general anesthesia, narcotic analgesia or IV or IM sedation. Power assisted liposuction using mechanical (vibrating or reciprocating) powered device qualifies as Simple Tumescent Liposuction. The identical formulation and dosage of tumescent local anesthesia will be used on both sides of the patient

2) Treatment Technique: Any laser assisted liposuction technique which may vary among clinical research sites according to the equipment available to the surgeon. There is no consensus about optimal laser parameters which vary from surgeon to surgeon. For each patient the laser dosing parameters will be determined at the discretion of the surgeon.

The following independent (predictor) variables for laser liposuction will be recorded:

a) Manufacturer of Laser

b) Order of Laser Use: Laser used before or after or (before & after) liposuction.

c) Maximum Desired Peak Tissue Temperature

d) 1st Wave Length of Laser

d1) Power 1st Laser Wavelength: Rate of Energy Delivery=Watts=Joules/Second

d2) Average Energy Density: Joules per Unit Area = Average Joules/Unit Area

e) 2nd Wave Length of Laser (Some laser devices deliver two wavelengths concurrently)

e1) Power 1st Laser Wavelength: Watts = Joules per Second

e2) Average Energy Density: Joules per Unit Area = Average Joules/Unit Area

3) Alternative techniques of liposuction are excluded for this clinical trial:

a) Ultrasound (Vasar) liposuction cannot be used

b) Water-jet assisted liposuction cannot be used

B) Clinical Trial Design: Bilateral Comparison Within-Patient Control, Randomized Treatment Allocation, Patient and Judges of Results are Blinded to Treatment,

1) Control Within-Patient, side-by-side (split side, left vs. right side) study

2) Random Allocation of Laser Side: a flip of a coin by someone other than a surgeon, will determine which side (left or right) will receive treatment with laser energy:

Heads = {Right Side Treated with Laser}

Tails = {Left Side Treated with Laser}

3A) If Laser is Used <u>Before</u> Liposuction then exactly the same number of strokes using the laser optic-fiber cannula (symmetric or bilaterally equal) will be delivered to each side of the patient. The intention is to equalize the mechanical effects (pre-tunneling strokes) of the laser cannula.

a) Laser-side is treated first: The side to be treated using the full-laser-dose will be the first side to be treated so that the total number N of strokes with the laser cannula can be counted.

b) Count Total Number N of Strokes by laser optic-fiber cannula while laser energy is being delivered: count the optic-fiber cannula thrusts, strokes or in-and-out tunnels created by optic-fiber cannula which delivers laser energy. A designated nurse/observer will count and recorded the total number N of strokes

c) Deliver Equal Number N of Strokes to both sides. The side not treated by laser (side treated only by simple tumescent liposuction) will receive exactly the same number N of in-and-out strokes or tunnels created by optic-fiber cannula. The designated nurse/observer will count (keep a running total) of the number strokes of the optic fiber cannula during this phase of the. No more and no less than N strokes will be delivered to the non-laser side.

d) "Non-laser" side will receive no laser energy

3B) If Laser is Used <u>After</u> Liposuction then the side which receives no laser energy will not need to be treated with an equal number of optic-fiber cannula strokes.

4) Blinded Participants: There will be double or triple blinding.

a) Patient will be blinded to which side is treated by laser

b) Liposuction surgeon may or may not be blinded

c) If there is only one surgeon participating in the protocol, then the surgeon will deliver the laser lipolysis to the first side (determined by coin-flip: Heads=right side first, Tails=left side first) and the non-laser tunneling to the second side. This surgeon will liposuction each side in the same order.

d) Some research centers may use the two surgeon protocol (When two surgeons are participating in this study, the surgeon who does the liposuction should be blinded to (not aware of) the side which was treated with laser). Thus

i) The laser (1^{st}) surgeon will perform the laser lipolysis on the first side (determined by coin-flip: Heads=right side first, Tails=left side first) then treat the second (non-laser) side using the same laser optic-fiber cannula but without laser energy

ii) The liposuction (2^{nd}) surgeon will be blinded to which side had laser treatment.

iii) The judges who evaluate the post-op photographs will not know which side of the patient received laser liposuction and which side had standard tumescent liposuction.

5) Multicenter Prospective Meta-Analysis: Robust with respect to protocols variations

a) Independent variables are allowed to be somewhat dissimilar (for example, each research center can include additional independent variables (data measurements).

b) Dependent or outcome variables are similar or nearly identical

6) Patient inclusion criteria

a) Healthy female requesting liposuction of

i) Hips

ii) Outer thighs

b) Each research site may specify its own additional inclusion criteria

c) Patients must have realistic expectations

d) Anticipated maximum volume of supernatant fat cannot exceed 3.5 Liters

e) Anticipate total mg/kg dosage of tumescent lidocaine should not exceed 45 mg/kg

d) Patient must agree to participate in the Randomized Clinical Trial (RCT)

7) Patient exclusion criteria:

a) Patients who are pregnant or breast feeding

b) History of Hepatitis C or HIV/AIDS

c) Excessively Obese

d) Aspirated volume of supranatant fat exceeding 3.5 liters will exclude patient from this study

e) Each research site may specify its own additional exclusion criteria

8) Independent Variables

a) Standardized pre-op questionnaires

b) Standardized pre-op digital photographs

c) Patient specific data (age, height, weight, history of significant weight gain/loss)

d) Surgeon & research site specific variables

e) Surgical device specific variables (including laser manufacturer and dosages)

f) Post-op care technique specific variable (open/closed drainage, elastic compression garments, duration of compression garment usage, etc)

9) Outcome variable data

a) Questionnaire completed by patient on

(Pre-op demographic data; post-op day of surgery, 1 week, 4 weeks, 20 weeks)

b) Physical examination & questionnaire completed by surgeon (post-op 1 week, 4 weeks, 20 weeks)

c) Digital photographs of anterior and posterior views (post-op 1 week, 4 weeks, 20 weeks)

d) Cosmetic improvement subjectively be judged by Patient, Surgeon & Public by voting either

i) Left side is better

ii) Right side is better

iii) No cosmetically significant difference between left & right sides

e) Public judges who will assess online photo taken 20 weeks post-op will be told that some patients might have had laser liposuction on both sides, some patients might have had tumescent liposuction on both sides and some patients had laser liposuction on one side with tumescent liposuction on the opposite side.

C) Data Collection & Analysis

1) Preoperative baseline measurements

2) Post-operative follow-up measurements: to be repeated

(pre-op & post-op day of surgery, weeks 1, 4 & 20).

3) Photographic Documentation: All photographs to be taken with

a) Patient standing erect, arms abducted symmetrically at approximately 45 degrees.

b) Superior edge of photograph should be the just proximal to the bra/horizontal bra strap

c) Inferior edge of photos should be approximately 5cm to 10 cm distal to the tibial plateau or popliteal fossa

d) Photographs must use evenly balanced lighting which does not favor one side or the other; shadows should be more or less symmetric.

e) Unequal Lighting in Before & After photos will be sufficient criteria to exclude patient from online public judging.

D) Surgeon Eligibility

1) Experienced Liposuction Surgeon

a) Has performed liposuction on at least 50 individual liposuction patients

b) Has performed liposuction of hips & outer thighs at least 12 individual patients

c) Has performed laser liposuction on at least 12 individual patients

2) No history of national or state or local disciplinary actions or ethical "blemishes" and no on-going state or hospital medical investigations or pending disciplinary actions.

3) Each surgeon must have completed an appropriate online ethics training course for clinicians engaged in human research. See http://phrp.nihtraining.com/users/login.php

4) WIRB approval as a research site: Physicians must obtain Western Institutional Review Board approval as a qualified site in a multicenter Study (www.WIRB.com)

5) Physician and investigators cannot have been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority, or are any currently the subject of such a proceeding.

6) If a surgeon firmly believes that either laser liposuction or simple tumescent liposuction is far superior to the other form of liposuction, then he or she should not participate as a surgeon in this clinical trial.
7) Each surgeon must conform to standard dosage limitations for tumescent lidocaine and manufacturer recommendations of dosages of laser energy.
8) Each surgeon will maintain careful and complete documentation of history & physical examination, anesthesia records, surgical procedures and post-operative follow-up care.
9) Each surgeon will use his or her own standard liposuction consent form in addition to the present research consent form.

E) Judge Eligibility

1) Any member of the public can go to the online website and judge the results of all patients by completing an online questionnaire.
2) One vote per person (e.g. no more than one vote per email address or IP address)

10 Statistical Plans (See Doc 3 110101 Statistical Plans)

10.1.Statistical Methodology

10.2 Sample Size Determination