RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Laser Liposuction vs. Tumescent Liposuction: Multicenter Randomized Controlled Trial
PROTOCOL NO.:	LaserLipoRCT WIRB® Protocol #20110017
SPONSOR:	Jeffrey A. Klein, M.D. San Juan Capistrano, California United States
INVESTIGATOR:	Name Address City, State Zip Country
SITE(S):	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Telephone

You are encouraged to ask questions regarding this research study. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. If you prefer, you are welcome to take an unsigned copy of this consent form home with you and take your time to read it carefully, and discuss it with family or friends before making your decision. You can underline or highlight any section of this consent form which you find requires more detailed explanation.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you,

- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You will receive a signed and dated copy of this consent form for your records, if you agree to participate in this study. You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Part or all of your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What study drug or study device or study procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.
- If you take part in this research, you will be given a copy of this signed and dated consent form.

INTRODUCTORY INFORMATION AND PURPOSE

You are being asked to participate in this study because you have expressed an interest in having liposuction of your hips, thighs or knees. The purpose of this research project is to compare the benefits of two common liposuction techniques: Tumescent Liposuction and Laser Liposuction. The present research study, involving only female subjects, is a clinical study designed to scientifically determine if there are any significant differences between tumescent liposuction and laser liposuction.

Tumescent liposuction involves the use of very dilute solution of lidocaine, a local anesthetic, together with liposuction using relatively small stainless steel cannulas (narrow tubes). The use of tumescent local anesthesia permits liposuction totally by local anesthesia, with the patient awake and comfortable. Some surgeons prefer to do tumescent liposuction using additional sedatives or general anesthesia. Your surgeon will provide you with precise information regarding the type of anesthesia available and recommended for your surgery.

Laser liposuction is essentially the same as tumescent liposuction plus the additional use of a laser light energy applied within the targeted fat before or after liposuction is completed. Laser liposuction is a relatively new technique. Although laser liposuction is rather popular, there are no published multicenter scientific studies which support claims that laser liposuction is superior to tumescent liposuction.

Your participation in this research involves liposuction, questionnaires and follow-up visits. If you agree to participate in this clinical study, you will have liposuction of both hips, and/or both outer thighs on the same day, with tumescent liposuction randomly assigned to one side and laser liposuction to the other side. Subsequently, on three separate occasions, 1 week, 4 weeks, and 20 weeks after surgery:

1) Your areas treated by liposuction will be examined by your surgeon
2) You will answer a questionnaire concerning your judgment of the surgery results, and
3) You will be photographed and the results of the liposuction on the two sides will be compared by judges who will not know which side was treated by tumescent liposuction and which side was treated by laser liposuction.
4) Your pre-operative and postoperative photos will be displayed on a website called Liposuction.com where the public can judge the relative cosmetic differences of one side of the body compared to the other. Neither your face nor your identity will be revealed to those who are judging the results of your liposuction.

The main purpose of this research study is to compare the cosmetic benefits of tumescent liposuction and laser liposuction. Many experienced surgeons believe there is no significant difference between the cosmetic results produced by tumescent liposuction or laser liposuction. Some surgeons believe laser liposuction provides superior results. Other surgeons find no benefit in using lasers in addition to tumescent liposuction. There is no published objective evidence that

there is any significant cosmetic difference between the two techniques. This research study will scientifically compare these two liposuction techniques.

Another purpose of this research study is to compare the type and number of complications and undesirable side effects between tumescent liposuction and laser liposuction. Tumescent liposuction and laser liposuction are widely recognized as safe and effective but, as with any surgical procedure, there are definite risks. The relative degrees of safety between tumescent or laser liposuction are probably similar. Your liposuction surgeon will discuss these risks with you in detail.

This research does not involve experimental drugs or experimental surgical techniques. All surgical techniques and drug dosages used in this study are standard and have been well described in articles published in the journals of profession surgical societies.

The expected duration of subject participation for each individual volunteer, including follow-up visits for evaluation and photographs, is approximately five months. It is hoped that there will be approximately 400 individual volunteer subjects and approximately 20 to 40 or more surgical centers involved in this research project.

If you are considering the possibility of becoming a volunteer subject, it is appropriate for you to ask any and all questions which you may have. You can take this consent form home for consideration before making your final decision about participating in this research study.

Description of Study/Procedures

At each surgical center each volunteer subject will receive the same two treatments: tumescent liposuction on the hip and/or outer thigh one side and laser liposuction on the opposite side. The side to be treated with laser liposuction will be randomly assigned by the flip of a coin.

This study will require approximately five to six visits with the surgeon:

1) Initial Consultation Visit
2) Visit for a Pre-Operative Medical History, Physical Examination and Laboratory Tests (this Pre-Op visit may be combined with the initial consultation visit)
3) Day of the Surgical Procedure: you will be photographed and you will complete a detailed questionnaire.
4) Follow-Up Visit 1 week after liposuction surgery: you will be photographed and you will complete a brief but detailed questionnaire.
5) Follow-Up Visit 4 weeks after liposuction surgery: you will be photographed and you will complete a brief but detailed questionnaire.
6) Follow-Up Visit 20 weeks or 5 months after liposuction surgery: you will be photographed and you will complete a brief but detailed questionnaire.

There are certain requirements for participation in this study. These include:

- A subject must be healthy. Your health status will be determined by your individual liposuction surgeon. In some cases your surgeon may ask for a clearance-letter from one of your specialist or primary care physicians to confirm that you are sufficiently healthy for liposuction.
- You must not be pregnant (you must have a negative urine pregnancy test) on the day of surgery.
- You must agree to discontinue any oral medication which may interfere with a safe liposuction surgery. For example, medications containing NSAIDs (non-steroidal anti-inflammatory drugs) such as aspirin or ibuprofen may cause excessive surgical bleeding. Medications containing ketoconazole (Nizoral®), fluconazole (Diflucan®), sertraline (Zoloft®), erythromycin or clarithromycin (Biaxin®) and related drugs may interfere with the safe metabolism of the local anesthetic lidocaine.

Risks of Asymmetry

There may be risks of asymmetry or a visible difference between the left and right hips and outer thighs after this liposuction clinical study. However all of the surgeons who are participating in this clinical study believe that there is no scientific evidence that laser liposuction and tumescent liposuction give results which are significantly different. In the event that your liposuction does produce a noticeable irregularity then your surgeon will perform a touch-up liposuction procedure at a fee which will not exceed twenty percent (20%) of your original fee.

Risks and Discomforts

There may be risks of participation and risks of side effects which are still unknown. Liposuction surgery and the medications used for liposuction may be harmful to a fetus and therefore pregnant women are excluded from this study. If you suspect that you have become pregnant, you must notify the study doctor immediately.

Liposuction is associated with some degree of post-surgical risk and pain. Your surgeon will discuss and explain the standard well recognized risks and discomforts associated with liposuction. There is little evidence for any difference between tumescent liposuction and laser liposuction in terms of risks or discomfort. This research study will attempt to evaluate any differences between tumescent liposuction and laser liposuction in terms of risks of complications and post-operative pain (intensity, quality or duration).

Both the tumescent liposuction techniques and the laser liposuction techniques use tumescent local anesthesia which contains lidocaine and epinephrine in a physiologic saline solution. The Liposuction Guidelines of American Society for Dermatologic Surgery state that the maximum safe dosage of lidocaine is 55 milligrams (mg) per kilogram (kg) of patient's body weight. In the present laser liposuction clinical study the intended maximum dosage of tumescent lidocaine is 45 mg/kg and in no case will it exceed 50 mg/kg. The concentrations of medications in the

solution of tumescent local anesthesia will not exceed lidocaine 1 gram per liter, epinephrine 1 milligram per liter, sodium bicarbonate 10 milliequivalents per liter in physiologic saline or lactated Ringer's solution.

In the case of lidocaine and epinephrine, which are used for tumescent local anesthesia, these side effects, which are very uncommon, include:

Lidocaine injection may cause side effects:

Upset stomach
Numbness
Tingling
Drowsiness
Lightheadedness
Dizziness or spinning sensation
Ringing in ears
Difficulty thinking or concentrating
Nervousness or restlessness
Shaking muscles that you cannot control

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, call your study doctor immediately:

Difficulty breathing
Pounding, fast, or irregular heartbeat
Convulsions or seizures
Allergic reactions (itching, hives, swelling). Allergic reactions to lidocaine are extremely rare.
Some of these reactions could be life-threatening or fatal. Lidocaine injection may cause other side effects.

Epinephrine injection may cause side effects:

Upset stomach
Vomiting
Sweating
Dizziness
Nervousness
Weakness
Pale skin
Headache
Shaky hands that you cannot control
Blood pressure too high or too low

Some side effects of epinephrine can be serious. The following symptoms are uncommon, but if you experience any of them, call your study doctor immediately:

Difficulty breathing
Pounding, fast, or irregular heartbeat.
Epinephrine injection may cause other side effects.

Additional Optional Medications may be recommended by your liposuction surgeon for additional anesthesia and comfort. These drugs are not part of this research study. Your surgeon will discuss and answer your questions regarding these "elective" medications.

If you experience any of the following symptoms, call your study doctor immediately:

Skin rash or peeling
Unusual bleeding or bruising

The risks and discomforts associated with routine liposuction are outlined in a separate surgical consent form which your liposuction surgeon will provide to you and ask you to sign. You will be given a copy of that liposuction consent form.

Drawing blood may cause pain, bruising, lightheadedness, or, on rare occasions, infection.

Expected Benefits

There is no guarantee that you will receive any medical benefits from being in this study. What we learn in this study may help other surgical patients in the future.

Costs

Your liposuction surgeon will charge you a professional fee for performing your liposuction surgery.

In addition you may be charged for routine laboratory tests and standard post-operative elastic compression garments. If an anesthesiologist provides professional services then you may be charged a fee for the professional anesthesiology services.

In addition you will be expected to pay for medications which you will take at home such as antibiotics, acetaminophen (Tylenol®), and perhaps a sleeping pill. If it is mutually decided that you stay overnight in a hotel, then you will pay your own hotel expenses. There is no charge for the clinical care and medical services provided by your surgeon and his/her staff for follow-up care associated with this research study. Because liposuction is an elective cosmetic procedure, expenses associated with liposuction are generally not covered by insurance.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

Payment for Participation

You will be paid in three installments for your participation in this study.

The first payment of $ _____ will be paid when you return for the scheduled 1-week follow-up visit, one week after your surgery.

The second payment of $ _____ will be paid when you return for the scheduled 4-week follow-up visit, four weeks after your surgery.

The third payment of $ _____ will be paid when you return for the 5-month follow-up visit, three months after your surgery.

If, for any reason, you are removed from the study by the surgeon or if you decide to withdraw from the study after liposuction but before completing the entire study, you will be allowed to keep each of the payments paid to you up to that point in time.

Payment will be made at the end of each of the three scheduled follow-up visits: at one week, four weeks and five months.

Alternative Procedures

You do not have to participate in this study to have liposuction. You may choose to have tumescent liposuction or laser liposuction without participating in this study.

Confidentiality of Records and Information Identifying Research Subjects

Information from this study will be maintained and kept in confidence by your surgeon and his/her study staff. Your surgeon and his/her staff will not share research information about you with anyone during and after the study, except where required by law.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by your surgeon and may be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries; and
- Western Institutional Review Board (WIRB)

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records including photographs
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Compensation for Injury

In the event of complications associated with this research study, you will be billed fees charged by other physicians or hospitals. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

Source of Funding

The sponsor of this laser liposuction clinical study, Jeffrey A. Klein, M.D., is helping this research study by paying for the data analysis (test) and statistical consultation services provided by the UCR Statistical Collaboratory, University of California, Riverside.

Each individual surgeon is responsible for all of his or her own expenses which are incurred while participating in this research study. Each individual participating surgeon is responsible for covering the cost of doing liposuction and gathering the data for this research study.

HK Surgical, Inc. (hksurgical.com) is helping this laser liposuction clinical study by supplying (at no charge) all of the black panties which will be used to assure uniformity of pre-operative and post-operative photographs.

iiResearch.Org is non-profit website designed to facilitate communication and collaboration between clinicians, patients, scientists and statisticians. The present laser liposuction clinical study will rely on iiResearch.Org to organize the study and to conduct the online judging of post-operative photos.

There are no outside corporate or government funding for this research study.

Questions

If you have questions about your participation in this study or in case of injury or complications, or if you have questions, concerns, or complaints about the research, or if further information is desired, contact your surgeon.

In addition, you may contact the sponsor for this study: Dr. Jeffrey A. Klein, 30280 Rancho Viejo Road, San Juan Capistrano, California 92675

Office Telephone: 949-248-1632
Office After Hours: 949-248-2414
Office Fax: 949-248-9339
Home Telephone: 949-548-9532
Cell Telephone: 949-283-1070
E-mail: jeffkleinmd@yahoo.com

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you decide to end participation in the research study at any time, your surgeon will continue to provide the same routine follow-up care that is provided to all of his patients following liposuction.

Your participation in this research study may be ended by your surgeon or the sponsor at any time, without your consent, for any of the following reasons:

- It is in your best interest.
- You do not consent to continue in the study after being told of changes in the research that may affect you.
- Your continued participation is unsafe.

- Your expectations are unrealistic.
- In the surgeon's opinion, it would be unethical to continue.
- Or for any other reason.

New Findings

If there is any new information that might change your decision to be in this study, the study doctor will provide such information to you. You may be asked to sign a revised consent form if this occurs.

Consent

I have read the information in this consent form. My surgeon and the study staff have explained the nature, purpose, possible alternative methods of this research study, the risks involved, and possible complications associated with local anesthesia and liposuction surgery. All my questions about the study and my participation in it have been answered. No guarantee has been made as to the results. Liposuction is performed strictly for cosmetic purposes, is not medically necessary, and is not a covered benefit of health insurance. I freely consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

To Be Signed at the Time of the Pre-Operative Examination

By signing this consent form, I have not given up any of my legal rights.

Printed Name of Subject:_____

_____
Subject's Signature Date

_____
Witness' Signature Date

_____
Signature of Person Conducting Informed Consent Discussion Date

Print Name(s) of Surgeon(s):_____

_____
Signature of Surgeon(s) Date
(if different from above)

To Be Signed on the Day of Surgery

Subject's Signature (To be signed on date of surgery) Date

Surgery Date/Time Signed

Witness Signature Date

Subject's Telephone # on the Night of Surgery