

A Multicenter, Prospective, Randomized, Single-Blind, Controlled Clinical Trial Comparing VASER-Assisted Lipoplasty and Suction-Assisted Lipoplasty

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Background: No scientific comparative study has demonstrated any statistically significant clinical improvement attributable to a new lipoplasty technology relative to traditional suction-assisted lipoplasty. This prospective study used a contralateral study design to evaluate postoperative differences between vibration amplification of sound energy at resonance (VASER)-assisted lipoplasty and suction-assisted lipoplasty.

Methods: Twenty female patients between the ages of 20 and 48 years received contralateral treatment with suction-assisted lipoplasty and VASER-assisted lipoplasty in one or more anatomical regions for a total of 33 regions. Patients received suction-assisted lipoplasty on one side of the body and VASER-assisted lipoplasty on the contralateral side. Patients were blinded to technology application. Aspirate was analyzed for blood content, and skin retraction was analyzed by measuring changes in ultraviolet light tattoos.

Results: Regarding skin retraction, the VASER-assisted lipoplasty-treated side resulted in a statistically significant improvement in skin retraction of 53 percent relative to suction-assisted lipoplasty (17 percent per liter versus 11 percent per liter, $p = 0.003$) with 33 paired sites using a two-tailed t test. Regarding blood loss, VASER-assisted lipoplasty treatment resulted in a statistically significant reduction in blood loss of 26 percent (11.2 versus 14.0 cc blood/100 cc) relative to the suction-assisted lipoplasty side ($p = 0.019$ with $n = 20$ using a two-tailed t test). Subjective measures (i.e., pain, swelling, appearance, and patient and physician preference) showed no statistical difference between the two methods at the 6-month evaluation.

Conclusions: The VASER-assisted lipoplasty method demonstrated improved skin retraction and reduction in blood loss compared with suction-assisted lipoplasty. This is the first study to demonstrate statistically significant and clinically relevant improvements in a new lipoplasty technology relative to suction-assisted lipoplasty. (*Plast. Reconstr. Surg.* 129: 681e, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, I.

According to the procedure statistics report from the American Society for Aesthetic Plastic Surgery, there were over 283,000 lipoplasty procedures performed in the United

States in 2009, making lipoplasty one of the top surgical cosmetic procedures and second only to breast augmentation surgery. Patients seeking elective body contouring have several options available, with the majority of procedures in 2009 using suction-assisted lipoplasty. Other standard procedures include vibration amplification of

From the Personal Enhancement Center and private practice. Received for publication February 13, 2011; accepted October 3, 2011.

Presented at Plastic Surgery 2009, the 78th Annual Meeting of the American Society of Plastic Surgeons, in Seattle, Washington, October 23 through 27, 2009.

This trial is registered under the name "VASER-Assisted Lipoplasty Compared With Suction-Assisted Lipoplasty (Contra-Lateral)," ClinicalTrials.gov identification number NCT00731354 (<http://clinicaltrials.gov/ct2/show/NCT00731354>).

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DOI: 10.1097/PRS.0b013e3182442274

Disclosure: The authors do not have any stock ownership or equity interests with Sound Surgical Technologies. They do not hold any patent licensing arrangements and have not received any payment for conducting or publicizing the study described in this article.

sound energy at resonance (VASER; Sound Surgical Technologies, LLC, Louisville, Col.)–assisted lipoplasty, power-assisted lipoplasty, ultrasound-assisted lipoplasty, laser-assisted lipoplasty, and external ultrasound-assisted lipoplasty. VASER-assisted lipoplasty is a third-generation internal ultrasound system that incorporates significant design improvements over previous generations. VASER-assisted lipoplasty uses small-diameter, solid, multiple-ring probes (rather than a hollow cannula) to deliver a minimal level of power needed to specifically target and emulsify fatty tissues. The technologies available have not to date been comparably studied in the same patient using suction-assisted lipoplasty as the control.

The literature shows many prospective and retrospective lipoplasty studies using a single technology or technique in a series of patients.^{1–10} The literature further shows a smaller number of comparative population studies in humans where one selected technology was used on one population of patients and a second technology was used on a control population.^{11–15} The literature further shows an even smaller number of scientifically based, contralateral studies that evaluate different lipoplasty technologies in humans.^{16–20}

Because of the variability in patients and surgical techniques, it is difficult to compare different devices and/or technologies without properly constructed, scientifically designed studies. This protocol uses a contralateral study design in which the patient constitutes their own control. This design reduces or, where possible, eliminates variability between patients and thereby increases the resolving power of the study relative to the assessment of different devices or technologies.

The primary objective of this study was to assess postoperative differences in skin retraction in a group of patients using a contralateral model with suction-assisted lipoplasty and VASER-assisted lipoplasty methods of body contouring. Secondary measures included differences in aspirate blood content, postoperative comparisons between the suction-assisted lipoplasty side and the VASER-assisted lipoplasty side for pain and sensation, patient and surgeon preference, and the amount and/or degree of complications.

This study is a multicenter, prospective, randomized, single-blind, controlled clinical trial. Each center used identical protocols and procedures. Patients were included if they were nonsmokers between 18 and 50 years of age; had a body mass index between 20 and 30; had good skin tone and excess fatty tissue in the arms, medial thighs, lateral thighs, or back, where the extra

tissue is expected to be composed of adipose tissue; and consented to comply with all study procedures and follow-up. Patients were excluded if they were undergoing body contouring for injury or disease or were currently enrolled in another study. All patients who elected to participate received treatment with both suction-assisted lipoplasty and VASER-assisted lipoplasty. Patients were allocated randomly to undergo suction-assisted lipoplasty on the left or right side of the body and VASER-assisted lipoplasty on the contralateral side. Patients returned for five follow-up visits, at which time skin measurements and photographs were taken of the treated areas and both patients and surgeons completed postoperative assessments.

PATIENTS AND METHODS

This prospective study examined 20 female patients over an 11-month period from September of 2007 to August of 2008. Ages ranged from 20 to 48 years, with an average of 38 years. Patients were recruited from office fliers and local newspaper advertisements at each of the independent study sites. All patients were healthy adults seeking contouring of one or more of the following areas: arms, upper back, flanks, inner thighs, and outer thighs. Patients had no previous lipoplasty in the areas being studied. All patients were nonsmokers, had a body mass index less than 30, and had good to moderate skin tone and heavy to moderate amounts of extra tissue in the surgical site where extra volume was expected to be composed of adipose tissue. Patients were followed for 6 months, with five postoperative study visits. All patients signed a written informed consent. The study protocol and informed consent for this prospective study were reviewed and approved by Liberty Institutional Review Board, Inc. (Deland, Fla.).

Preoperative Procedures

Before the scheduled operation, patients had photographs taken of the target areas, and a blood sample was taken to measure preoperative hemoglobin. Each area for which lipoplasty was planned was tattooed with three small (0.5 mm) ultraviolet dots to compare skin retraction preoperatively and postoperatively and between technology types.

The microdots were applied subcutaneously using a disposable three-point round needle and a single-use Click Stick Handle (SofTap Permanent Cosmetics, Livermore, Calif.). Ultraviolet-reactive black light ink (Chameleon Body Art Supply Company, Pittsfield, Mass.) was used to make three microdots approximately 5 cm apart and in

an equilateral triangle pattern, on each anatomical location of interest. A triangle was chosen, as the shape is the least invasive and is simple to measure, with a lower accumulated error than a figure with more sides, and the 50-mm size provides a compromise between the relative measurement error and the effect of more complex surface geometry. An accurate measurement between dots was recorded immediately after placement for use as a baseline.

Figure 1 shows the three microdots under natural and ultraviolet light. Three, clear, tape arrowheads indicate the location of each dot. The diameter of each dot is approximately 0.5 mm. With the use of a black light, the dots appeared very faint, allowing the surgeon to measure the distance between the dots (and thus skin stretch or retraction) at each follow-up visit. Patients were marked preoperatively by each surgeon of record to map surgical borders for the lipoplasty procedure on each side of the patient's body.

Randomization

The surgeon determined whether suction-assisted lipoplasty would be performed on the right or left side using a coin flip to random selection. The patient was unaware of which procedure was performed on each side. Regardless of the number of anatomical sites being contoured, the procedure type remained consistent for the entire side of the body divided by the median plane.

Surgery

Anesthesia. The type and method of anesthesia was determined by the surgeon of record in consultation with each patient.

Infusion. For both suction-assisted lipoplasty and VASER-assisted lipoplasty, similar infusion protocols were used. Tumescence solution, consisting of a mixture of 1 liter (less 100 cc) of lactated Ringer's solution, 10 cc of 1% plain lidocaine per liter of lactated Ringer's solution, and 2 cc of 1:1000 epinephrine, was infused into the anatomical site to minimize intraoperative blood loss and provide analgesia. The infusion rate ranged between 100 cc/minute and 400 cc/minute using a small-diameter blunt infusion cannula with a diameter of 12 gauge or smaller. The same infusion rate was used for both sides, suction-assisted lipoplasty and VASER-assisted lipoplasty. The solution was infused to achieve an approximate ratio of 1.5:1 for wetting solution into expected total aspirate out (superwet plus). It is important with the VASER-assisted lipoplasty procedure that a ratio of 1.5:1 be obtained. Suction-assisted lipoplasty infusion could be between 1:1 and 1.5:1 according to the surgeon's preference. A similar total infusion was performed on both sides. The tumescent solution was distributed throughout the anatomical site in an even and uniform manner, infiltrating fluid at all locations in the operative site and at least 1 cm beyond the marked field. Once infiltrated, a waiting period of 10 to 12 minutes was observed before either suction-assisted lipoplasty or VASER-assisted lipoplasty procedures commenced. Each side was treated completely before moving to the other side to ensure similar waiting periods and orientations between the two sides. Careful records were kept of the infusion volume and infusion finish time (to provide the start time for the wait period) for each anatomical region.

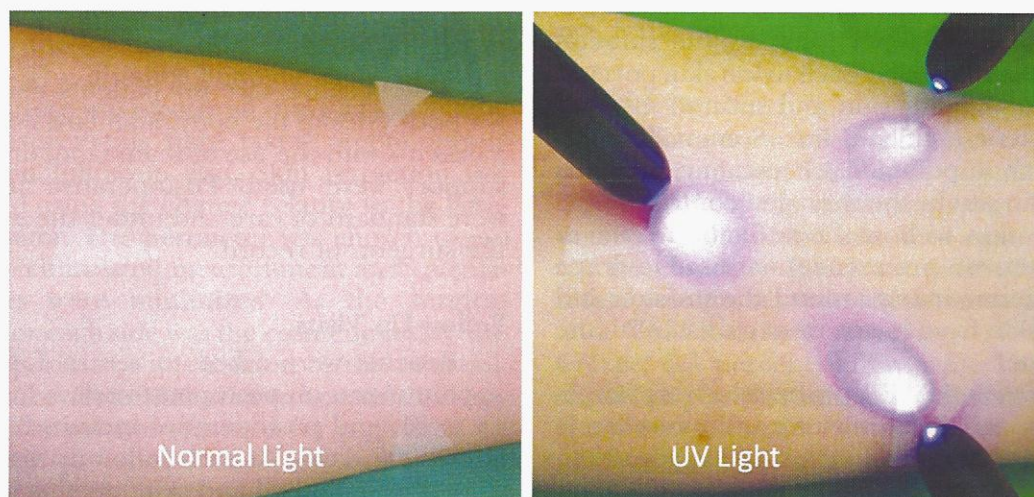


Fig. 1. The three microdots under natural (left) and ultraviolet (right) light. Three, clear, tape arrowheads indicate the location of each dot.

Surgeons preoperatively determined the maximum dosage of each solution medication to minimize the risk of potential local anesthetic toxicity or fluid overload. If the superficial layer was treated on one side with one technology, the superficial layer was treated to a similar extent using the other technology on the contralateral side.

Standard Suction-Assisted Lipoplasty Procedure

The surgeons completed the suction-assisted lipoplasty procedures using 3.7- or 3.0-mm Mercedes pattern suction cannulae. Other cannulae designs were used for final feathering at the discretion of the surgeon. Suction-assisted lipoplasty aspiration proceeded until a final contour was achieved to the surgeon's satisfaction. A single canister was used to collect the entire aspirate from study sites on one side of the body (e.g., the suction-assisted lipoplasty side), and a separate canister was used to collect the entire aspirate from study sites on the contralateral side of the body (e.g., the VASER-assisted lipoplasty side) to compare the lipocrit and aspirate content from each procedure type. This ensured that the total aspirate for each procedure was evaluated. The aspirate from any additional lipoplasty sites that were not part of this study were collected in separate canisters and discarded according to institutional policy.

Standard VASER-Assisted Lipoplasty Procedure

Skin ports (part of the VASER System) were used to protect all incision edges while using the VASER technology. The incision and the tissue below each incision were stretched using a hemostat to ease insertion of the skin ports. Ceramic skin ports were used in all cases by Dr. Vanek. Nylon skin ports were used in all cases by Dr. Nagy. The skin port style was chosen by the surgeon based on the surgical site. Each nylon skin port was placed in the stab incision and sutured in place with 4-0 Prolene (Ethicon, Inc., Somerville, N.J.) at three anchor points. Each ceramic port was maintained in situ by the threaded contour of the screw-type design, without suture fixation. A wet or dry towel (surgeon preference) was used to drape the patient immediately around the incision and protect the skin from inadvertent contact with the VASER probe.

Emulsification. VASER probe selection, amplitude setting, and pulse versus continuous mode setting were determined by the surgeon according to the characteristics of the localized fat deposits. The VASER was applied until the targeted fat was emulsified using the guideline of 1 to 1.5 minutes

of treatment time per 100 cc of infused wetting solution and based on surgeon experience.

Aspiration. VASER-assisted lipoplasty aspiration was conducted using only VentX cannulae (Sound Surgical Technologies), which are specific to the VASER-assisted lipoplasty procedure. Cannula size was chosen based on the region and characteristics of the localized fat deposits. Aspiration proceeded until the emulsified fluids/tissues were removed and a final contour was achieved to the surgeon's satisfaction.

Aspirate Blood Content: Lipocrit

The volume of decanted fat and the volume of infranatant fluid were recorded for each canister. Samples of the infranatant were taken using a long cannula attached to a syringe. Infranatant samples from both procedures were frozen for a minimum of 12 hours and shipped to a central laboratory for testing. The hemoglobin concentration of the infranatant was multiplied by the total infranatant volume and divided by the preoperative hemoglobin concentration to yield the volume of whole blood in the infranatant.

These values were normalized using the total volume of decanted fat to yield blood volume in the infranatant per volume of removed (decanted) fat. The results of three separate samples collected simultaneously were averaged to calculate the amount of whole blood in the infranatant.

Wound Management

All incisions were closed with subdermal Monocryl (Ethicon) and subcuticular Prolene. Steri-Strips (3M, St. Paul, Minn.) were applied and left on for 5 to 7 days postoperatively.

Postoperative Care

Postoperative care for patients was the same for both sides of the body. Standard compression garments with the use of foam tape/dressing and support were used. Postoperative instructions were standard of care and under the direction of the surgeon of record.

Follow-Up Visits

Patients were asked to return for follow-up appointments on postoperative days 1, 4 to 5, and 14 to 21, and postoperative months 3 (± 7 days) and 6 (± 7 days). At each follow-up visit, patients were photographed and skin measurements were taken, and then both patient and surgeon completed a postoperative assessment.

Patient's Assessment

The patient's assessment consisted of questions to rate each side of the body for pain, numbness, tingling, burning sensation, comparative bruising, and swelling using an ordinal rating scale of 0 to 6 (0 = none and 6 = severe) and 1 to 5 (1 = very dissatisfied and 5 = very satisfied) for the overall assessment. Patients (still blinded to the assignment to each side) were also asked to determine which side they preferred. Patients who had surgery on their back were not required to complete the assessments during the first 2 weeks postoperatively because of the potential for fluids to migrate preferentially to the side on which the patient rests, thus contaminating measured data. All other anatomical sites were evaluated by the patient at each follow-up visit.

Surgeon's Assessment

The surgeon's assessment was completed at each postoperative visit and was used to assess comparable anatomical sites for appearance and irregularities. The assessments were made using an ordinal rating scale, with scores of 0 to 6 for induration, edema, and ecchymosis (0 = none and 6 = severe) and 1 to 5 (1 = very dissatisfied and 5 = very satisfied) for the overall assessment. Surgeons who completed postoperative assessments of the back were not required to complete the assessments during the first 2 weeks postoperatively because of the potential for fluids to migrate preferentially to the side on which the patient rests, thus contaminating measured data. Postoperative evaluations were conducted based on left versus right sides, to avoid reference to the treatment method used.

Skin Retraction

A small ultraviolet light was used to assist the surgeon in the location of the previously placed microdots. The distance between each leg of the triangle pattern was measured using a clear plastic ruler. Measurements were taken preoperatively and at each follow-up visit. Skin retraction was determined using the change relative to the baseline perimeter. The perimeter was chosen to ensure that accumulated measurement and calculation errors were minimized. As the surgical endpoint for each side was the cosmetic result, the measured perimeter was divided by the total volume aspirated from that area to account for any differences in volume removed for each area.

Statistical Analysis

Patient and surgeon questionnaires used a quasi-interval scale. For paired comparisons of in-

terval variables, statistical significance was determined using a two-tailed paired *t* test. Nonparametric data were analyzed using the two-sided Wilcoxon matched-pairs signed rank test. For paired comparisons of interval/ratio variables such as skin retraction, statistical significance was determined using a paired two-tailed *t* test. Statistical analysis was conducted using the commercially available statistical software SYSTAT (Systat Software, Inc., San Jose, Calif.).

RESULTS

Twenty female patients aged between 20 and 48 years received contralateral treatment with suction-assisted lipoplasty and VASER-assisted lipoplasty in one or more anatomical regions for a total of 33 regions under two surgeons. Each surgeon enrolled 10 subjects. Nine subjects were randomized to be treated on the left with suction-assisted lipoplasty; 11 were randomized to be treated on the right. Summary results are listed in Tables 1 and 2.

Skin Retraction

The absolute percentage retraction was normalized with the volume of aspirate removed from each site before statistical analysis. The VASER-assisted lipoplasty-treated side resulted in a significant improvement in skin retraction of 53 percent relative to suction-assisted lipoplasty (17 percent per liter versus 11 percent per liter) at the 6-month follow-up ($p = .003$). Skin retraction was also significantly greater on the VASER-assisted lipoplasty-treated side at 1 day postoperatively ($p = 0.04$). Figure 2 shows the time course of the mean normalized skin retraction for both suction-assisted lipoplasty and VASER-assisted lipoplasty. A subset analysis was conducted, and there was no significant difference between the two treating surgeons.

Blood Loss

Aspirate from each different region treated was collected and each total volume measured. The lipocrit of the infranatant was then used to determine the blood lost from each area. There was no clinically significant difference in the aspirate volume between suction-assisted lipoplasty and VASER-assisted lipoplasty (781 cc versus 671 cc; 6.4 percent difference). The VASER-assisted lipoplasty treatment resulted in a statistically significant reduction in blood loss of 26 percent (11.2 versus 14.0 cc blood per 100 cc) relative to the suction-assisted lipoplasty side ($p = 0.019$). Figures 3 and 4 show representative samples of aspirate volumes during the study.

Table 1. Summary of Enrollment

Patient*	Treated Area	VAL Side	Probe Size (mm)	No. of Rings	Aspirate (cc)	
					SAL	VAL
301	Inner thigh	Right	3.7	3	850	850
	Outer thigh	Right	3.7	3	1150	1150
302	Inner thigh	Left	3.7	3	1200	1300
	Outer thigh	Left	3.7	3	1500	1550
303	Inner thigh	Right	3.7	3	600	700
304	Inner thigh	Right	3.7	3	725	725
	Outer thigh	Right	3.7	3	800	1000
305	Arms	Left	2.9	3	575	575
401	Inner thigh	Left	2.9	3	300	350
402	Inner thigh	Left	3.7	3	1200	1200
	Outer thigh	Left	3.7	3	1200	1100
403	Inner thigh	Right	3.7	3	300	300
404	Outer thigh	Left	3.7	3	700	700
405	Inner thigh	Right	3.7	3	800	800
501	Arms	Right	3.7	2	600	450
	Upper back	Right	3.7	2	500	300
	Flanks	Right	3.7	2	700	500
502	Inner thigh	Right	3.7	2	850	1100
	Outer thigh	Right	3.7	2	700	700
503	Inner thigh	Left	2.9	2	1050	650
	Flanks	Left	2.9	2	600	550
504	Inner thigh	Left	3.7	2	800	600
505	Inner thigh	Left	3.7	2	1350	1000
	Outer thigh	Left	3.7	2	1000	950
	Flanks	Left	3.7	2	1200	850
506	Inner thigh	Right	3.7	2	500	450
507	Inner thigh	Left	3.7	2	450	500
	Outer thigh	Left	3.7	2	500	300
508	Inner thigh	Right	3.7	2	300	300
	Outer thigh	Right	3.7	2	300	300
509	Inner thigh	Left	3.7	2	450	475
	Outer thigh	Left	3.7	2	500	400
510	Outer thigh	Left	3.7	2	750	500

VAL, VASER-assisted lipoplasty; SAL, suction-assisted lipoplasty.

*All patients were female. None were smokers.

Table 2. Summary of Results of VASER-Assisted Lipoplasty versus Suction-Assisted Lipoplasty

	Normalized Skin Retraction (% per liter)		Normalized Blood Loss (%)
	3 Mo	6 Mo	
VAL	15.4	17.0	9.6
SAL	10.1	11.1	13.0
VAL improvement (%)	52	53	26

VAL, VASER-assisted lipoplasty; SAL, suction-assisted lipoplasty.

Subjective Measures

Patient-reported sensations of pain, sharp pain, numbness, and burning showed no statistical difference between the two technologies through 6 months (Table 3). After the first week, average sensation scores were "minor" or less for both the suction-assisted lipoplasty and VASER-assisted lipoplasty sides. The similarity of subjective measures was repeated when the data were analyzed as medians, with no difference in median scores in 26 of

the 35 measure/time points. The remaining nine medians differed only by scale point. Larger, future studies will be required to determine whether this small difference is both statistically and clinically meaningful.

Surgeon-reported induration, edema, and ecchymosis reflect results similar to the patient-reported sensations, with no differences seen between suction-assisted lipoplasty and VASER-assisted lipoplasty through 6 months (Table 4). After the first week, average scores were "minor" or less for both suction-assisted lipoplasty and VASER-assisted lipoplasty.

Both patients and surgeons were asked for overall satisfaction levels at each follow-up, and the average reported data show no difference between suction-assisted lipoplasty and VASER-assisted lipoplasty (Table 5).

Complications

There were no complications reported during the study.

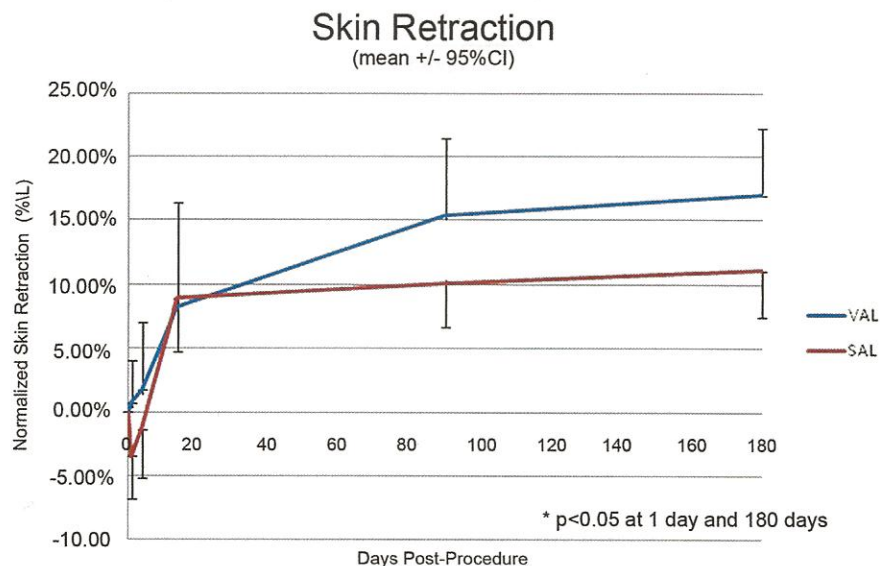


Fig. 2. Time course of the mean normalized skin retraction for both suction-assisted lipoplasty and VASER-assisted lipoplasty. *CI*, confidence interval; *SAL*, suction-assisted lipoplasty; *VAL*, VASER-assisted lipoplasty.

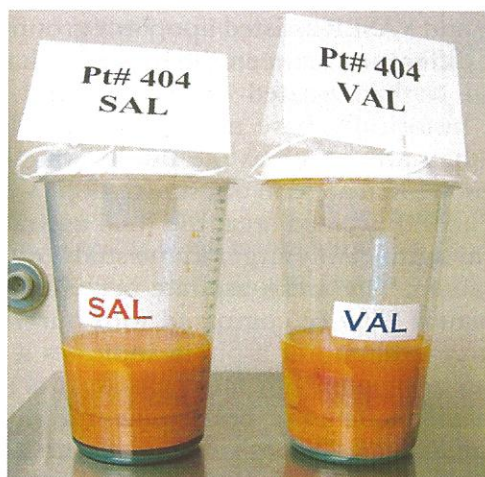


Fig. 3. Representative samples of aspirate volumes during the study from site 4. *SAL*, suction-assisted lipoplasty; *VAL*, VASER-assisted lipoplasty.

DISCUSSION

This study is the first to objectively compare results of ultrasound-assisted and traditional liposuction and to show that ultrasound-assisted liposuction not only has superior skin tightening but that the skin tightening is sustained through 6 months after the procedure. The postoperative subjective assessments did not show a significant difference; however, these assessments are, by necessity, made in reference to the preoperative aesthetic condition. The greater the amount of physical change, the less that subtle changes will be

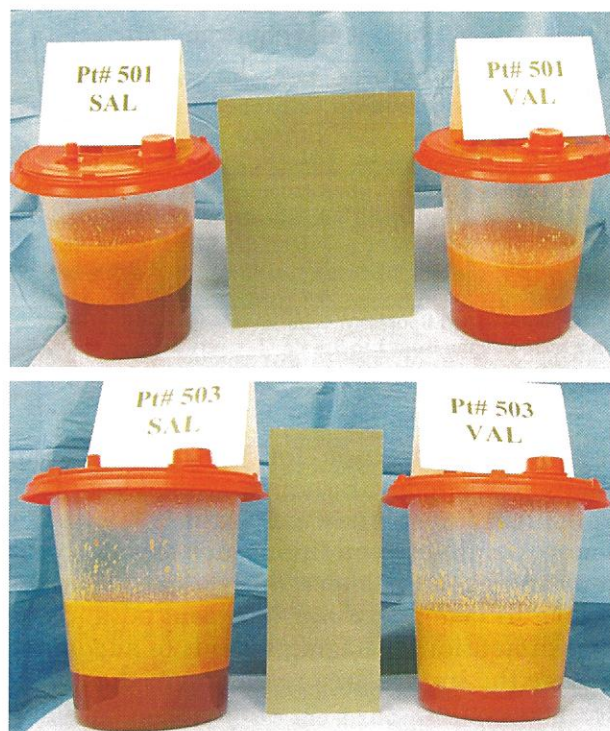


Fig. 4. Representative samples of aspirate volumes during the study from site 5. *SAL*, suction-assisted lipoplasty; *VAL*, VASER-assisted lipoplasty.

assessable by purely subjective means. By the nature of the procedure, with similar volumes of aspiration, both sides on a gross evaluation should appear similar. This study demonstrates a greater

Table 3. Patient-Reported Subjective Measures*

Days	Pain		Sharp Pain		Numbness		Tingling		Burning Sensation		Swelling		Bruising	
	SAL	VAL	SAL	VAL	SAL	VAL	SAL	VAL	SAL	VAL	SAL	VAL	SAL	VAL
1	2.4	2.6	1.2	1.8	1.5	2.0	0.5	0.5	0.7	1.0	2.4	3.0	2.7	2.6
4	2.3	2.7	1.1	1.7	2.2	2.6	0.8	1.0	1.0	1.3	2.4	3.0	2.9	3.2
14	1.4	1.9	0.7	0.9	1.5	2.1	0.7	0.8	0.6	0.9	1.5	2.1	1.3	1.2
90	0.3	0.7	0.3	0.4	0.6	1.0	0.3	0.5	0.2	0.3	0.5	0.7	0.2	0.3
180	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.1

SAL, suction-assisted lipoplasty; VAL, VASER-assisted lipoplasty.

*On a scale ranging from 0 to 5 scale (0 = none and 5 = severe).

Table 4. Physician-Reported Subjective Measures*

Days	Induration		Edema		Ecchymosis	
	SAL	VAL	SAL	VAL	SAL	VAL
1	3.0	2.8	3.1	3.0	2.8	2.7
4	2.5	2.5	2.7	2.6	2.8	2.8
14	1.8	1.7	1.6	1.5	1.0	0.8
90	0.5	0.3	0.3	0.4	0.1	0.1
180	0.1	0.0	0.1	0.0	0.1	0.0

SAL, suction-assisted lipoplasty; VAL, VASER-assisted lipoplasty.

*On a scale ranging from 0 to 5 scale (0 = none and 5 = severe).

Table 5. Overall Patient and Physician Satisfaction

Days	Patient Satisfaction		Surgeon Satisfaction	
	SAL	VAL	SAL	VAL
1	3.8	3.6	2.8	3.1
4	3.5	3.1	3.2	3.4
14	4.1	3.4	3.5	3.5
90	4.1	3.6	4.1	4.2
180	4.3	4.0	4.3	4.3

SAL, suction-assisted lipoplasty; VAL, VASER-assisted lipoplasty.

*On a scale ranging from 1 to 5 scale (1 = very dissatisfied and 5 = very satisfied).

level of skin retraction for VASER-assisted lipoplasty compared with suction-assisted lipoplasty. A potential future study may include liposuction of more pendulous conditions such as gynecomastia or areas such as knees. Such a study may also be able to take advantage of recent advances in three-dimensional imaging systems to adequately evaluate the surface area reduction in these complex geometries.

In addition, we showed that the blood loss associated with ultrasound-assisted lipoplasty is less than that with traditional liposuction. In comparison, DiBernardo²⁰ showed in a 10-patient study a skin shrinkage improvement of 54 percent after 3 months' follow-up comparing laser-assisted liposuction and traditional liposuction; however, no long-term follow-up is reported. Garcia and Nathan in 2008²¹ published a study comparing suction-assisted lipoplasty to VASER-assisted lip-

oplasty. In the Results, they report a sixfold to sevenfold difference in the hemoglobin value measured in the suction-assisted lipoplasty aspirate as compared with the VASER-assisted lipoplasty aspirate. The study consisted of two sequential cohorts of 27 and 30 patients, respectively. The authors do not report the amount of time between the treatments of the two groups. In comparison, this study was a patient-controlled contralateral study where bleeding can be expected to be similar for the suction-assisted lipoplasty and VASER-assisted lipoplasty groups. The largest difference between the studies is that Garcia and Nathan treated only flanks and backs which, historically, have more issues with loss of blood than areas such as the thighs, which were the most treated areas in our study. Along with the differences in treated area, the total aspirate volume was significantly larger in the study by Garcia and Nathan. The mean aspirate per side was approximately 2300 cc compared with our 700 cc. The larger volume of aspirate indicates a more complex and potentially more bloody procedure. These differences aside, both studies indicate that for procedures both large and small, the VASER-assisted lipoplasty procedure results in a significantly lower blood loss across a range of treatment areas. The results of this study indicate that the ultrasonic energy delivered by this new technology not only provides a less traumatic means by which to perform this procedure, it also contributes to superior sustained skin retraction after the procedure. In Figure 2, we show not only a significant improvement in tightening at 6 months, but also that aspiration alone results in a postprocedure swelling through the first postoperative week, inferred from the negative retraction at 1 and 4 days. By comparison, the ultrasound-assisted arm showed no swelling on average, indicated by a zero or positive skin tightening through follow-up. The difference shown in the objective measures was not as evident in the subjective measures. A larger study may provide more insight into the clinical

significance of the difference between the objective and subjective measures. In this study, we extracted volumes between 300 and 1550 cc, demonstrating the utility and safety of this technology for both small- and large-volume lipoplasty.

The VASER-assisted lipoplasty method demonstrated a 53 percent improvement in skin retraction per cubic centimeter of aspirate removed relative to the traditional suction-assisted lipoplasty method and an average reduction of 26 percent in blood loss compared with suction-assisted lipoplasty. This is the first study to demonstrate statistically significant and clinically relevant improvements in ultrasound-assisted lipoplasty technology relative to suction-assisted lipoplasty. In summary, the advantages of ultrasound-assisted liposuction over traditional liposuction alone are less postoperative swelling, lower blood loss, and a greater and sustained skin tightening through longer term follow-up.

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ACKNOWLEDGMENTS

This study was sponsored by Sound Surgical Technologies, LLC (Louisville, Colo.). The sponsor provided funding for institutional review board fees, facility fees, surgical fees, advertisements, and patient compensation.

REFERENCES

1. Fischer A, Fischer G. First surgical treatment for molding body's cellulite with three 5 mm incisions. *Bull Int Acad Cosmet Surg.* 1976;62:305-306.
2. Illouz YG. Body contouring by lipolysis: A 5-year experience with over 3000 cases. *Plast Reconstr Surg.* 1983;72:591-597.
3. Kloehn RA. Liposuction with "sonic sculpture": Six years' experience with more than 600 patients. *Aesthet Surg J.* 1996;16:123-128.
4. Rohrich RJ, Beran SJ, Kenkel JM, Adams WP Jr, DiSpaltro F. Extending the role of liposuction in body contouring with ultrasound-assisted liposuction. *Plast Reconstr Surg.* 1998;101:1090-1102; discussion 1117-1119.
5. Perez JA, van Tetering JP. Ultrasound-assisted lipoplasty: A review of over 350 consecutive cases using a two-stage technique. *Aesthetic Plast Surg.* 2003;27:68-76.
6. Badin AZ, Moraes LM, Gondek L, Chiaratti MG, Canta L. Laser lipolysis: Flaccidity under control. *Aesthetic Plast Surg.* 2002;26:335-339.
7. Graf R, Auersvald A, Damasio RC, et al. Ultrasound-assisted liposuction: An analysis of 348 cases. *Aesthetic Plast Surg.* 2003;27:146-153.
8. Beckenstein MS, Grotting JC. Ultrasound-assisted lipectomy using the solid probe: A retrospective review of 100 consecutive cases. *Plast Reconstr Surg.* 2000;105:2161-2174; discussion 2175-2179.
9. Tebbetts JB. Minimizing complications of ultrasound-assisted lipoplasty: An initial experience with no related complications. *Plast Reconstr Surg.* 1998;102:1690-1697.
10. Jewell ML, Fodor PB, De Souza Pinto EB, Al Shammari MA. Clinical application of VASER-assisted lipoplasty: A pilot clinical study. *Aesthet Surg J.* 2002;22:131-146.
11. Baxter RA. Histologic effects of ultrasound-assisted lipoplasty. *Aesthet Surg J.* 1999;19:109-115.
12. Katz BE, Bruck MC, Coleman WP III. The benefits of powered liposuction versus traditional liposuction: A paired comparison analysis. *Dermatol Surg.* 2001;27:863-867.
13. Latrenta GS, Mick SL. Endermologie after external ultrasound-assisted lipoplasty (EUAL) versus EUAL alone. *Aesthet Surg J.* 2001;21:128-135.
14. Gupta SC, Khiabani KT, Stephenson LL, Zamboni WA. Effect of liposuction on skin perfusion. *Plast Reconstr Surg.* 2002;110:1748-1751.
15. Araco A, Gravante G, Araco F, Delogu D, Cervelli V. Comparison of power water-assisted and traditional liposuction: A prospective randomized trial of postoperative pain. *Aesthetic Plast Surg.* 2007;31:259-265.
16. Fodor PB, Watson J. Personal experience with ultrasound-assisted lipoplasty: A pilot study comparing ultrasound-assisted lipoplasty with traditional lipoplasty. *Plast Reconstr Surg.* 1998;101:1103-1116; discussion 1117-1119.
17. Fodor PB, Vogt PA. Power-assisted lipoplasty (PAL): A clinical pilot study comparing PAL to traditional lipoplasty (TL). *Aesthetic Plast Surg.* 1999;23:379-385.
18. Rohrich RJ, Morales DE, Krueger JE, et al. Comparative lipoplasty analysis of in vivo-treated adipose tissue. *Plast Reconstr Surg.* 2000;105:2152-2158; discussion 2159-2160.
19. Cárdenas-Camarena L, Andino-Ulloa R, Mora RC, Fajardo-Barajas D. Laboratory and histopathologic comparative study of internal ultrasound-assisted lipoplasty and tumescent lipoplasty. *Plast Reconstr Surg.* 2002;110:1158-1164; discussion 1165-1166.
20. DiBernardo BE. Randomized, blinded split abdomen study evaluating skin shrinkage and skin tightening in laser-assisted liposuction versus liposuction control. *Aesthet Surg J.* 2010;30:593-602.
21. Garcia O Jr, Nathan N. Comparative analysis of blood loss in suction-assisted lipoplasty and third-generation internal ultrasound-assisted lipoplasty. *Aesthet Surg J.* 2008;28:430-435.