

# Clinical Application of VASER–assisted Lipoplasty: A Pilot Clinical Study

**Mark Laurence Jewell, MD; Peter Bela Fodor, MD; Ewaldo Bolivar de Souza Pinto, MD; and Mussab Abdulrahman Al Shammari, MD**

**Background:** Although lipoplasty is the most frequently performed aesthetic surgical procedure, ultrasound-assisted lipoplasty (UAL) has not been widely adopted because of its increased potential for complications, complex and bulky instrumentation, additional cost, and steep learning curve.

**Objective:** We report on the use of the VASER ultrasound device in lipoplasty procedures and compare the clinical outcomes obtained by means of VASER-assisted lipoplasty with those of other UAL devices.

**Methods:** A superwet technique was used, and the wetting solution was uniformly distributed in the intended treatment area. Skin protection measures included use of specially designed skin ports to protect the incision edges and wet towels adjacent to the port locations. Access incisions were 3 to 4 mm in length. The VASER device was used in VASER (pulsed ultrasound) mode by 2 investigators (P.B.F. and M.L.J.); the continuous ultrasound mode was used by these investigators only if tissue emulsification was not readily achieved by using the VASER mode. A third investigator (E.B.d.S.P.) primarily used the continuous mode. Effective fat fragmentation in either mode was achieved by a maximum of 1 minute of treatment time per 100 mL of infused wetting solution.

**Results:** In a series of 77 patients treated by 3 different clinicians, satisfactory results were obtained with no major complications. This contrasts with an incidence of complications of 7.9% (median, 4.9%) for first- and second-generation UAL devices as determined by statistical analysis of the literature.

**Conclusions:** The initial clinical experience with VASER-assisted lipoplasty indicates that it is a safe and efficient technique for body-contouring surgery. (Aesthetic Surg J 2002;22:131-146.)

Although lipoplasty is the most frequently performed aesthetic surgical procedure,<sup>1,2</sup> ultrasound-assisted lipoplasty (UAL) has not been widely adopted because of an increased potential for complications,<sup>3,4</sup> complex and bulky instrumentation, additional cost,<sup>5</sup> and steep learning curve.<sup>6</sup>

Historically, a variety of approaches have been used to evacuate fatty deposits during lipoplasty. Initially, improvements in lipoplasty outcomes were linked to advances in aspiration cannula tip design and changes in diameter. Despite these improvements, limitations of the technique included blood loss, postoperative ecchymosis, limited effectiveness in fibrous areas of the body, and surgeon fatigue.

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## Wetting Solutions

The next significant advance in lipoplasty was the introduction and use of wetting solutions. Illouz is credited as the first to use wetting solutions during lipoplasty procedures. Currently, the infusion of wetting solutions containing epinephrine and local anesthetics is an integral part of lipoplasty techniques. Lipoplasty performed without the infiltration of wetting solutions (“dry technique”) produces significant surgical blood loss (aspirate contains 20% to 45% blood) and postoperative bruising.<sup>7-9</sup> The “wet technique” involves the infiltration of small amounts of saline solutions, regardless of the volume of aspirate, with or without pharmacologic additives. Hetter<sup>10</sup> first reported that the use of solutions that contained dilute epinephrine reduced blood loss to 15% to 30% of the aspirate. Fodor<sup>11</sup> expanded the concept of wetting solutions to the “superwet technique,” in which larger amounts of solutions were used during lipoplasty (infiltration-to-aspiration ratio of 1:1). When this technique is used, blood loss in the aspirate, measured as lipocrit, is usually less than 1%.<sup>12</sup> UAL and suction-assisted lipoplasty (SAL) have similar lipocrits.<sup>13,14</sup> Klein advocated even higher volumes of infiltration (infiltration-to-aspiration ratio of 3 to 6:1), to the point that the tissue developed significant turgor; this was generally defined as the “tumescent technique.”

The proper use of wetting solutions results in diminished blood loss, reduced postoperative bruising, and enhanced patient comfort. On the other hand, overzealous use of wetting solutions can result in systemic fluid overload, and excessive amounts of local anesthetics intended as regional anesthesia may have deleterious systemic effects.<sup>15-17</sup> Before the introduction of the tumescent technique in the early 1990s, traditional limited SAL was a very safe and effective procedure.<sup>18</sup>

Unfortunately, much confusion regarding wetting solutions in lipoplasty still remains despite multiple previous publications.<sup>19-23</sup> A detailed description is beyond the scope of this article. Nevertheless, a definition of terminology can be found in a recently published editorial.<sup>20</sup>

## Energy-based Devices

Another major advance in lipoplasty involved the addition of techniques that used energy-based devices such as UAL, external UAL, and reciprocating cannula lipoplas-

ty, known generally as *power-assisted lipoplasty (PAL)*. The mechanism of tissue interaction for the PAL devices appears to be similar to that of traditional lipoplasty in that it involves suction-assisted blunt avulsion/aspiration of fat through the ports of a mechanically reciprocating cannula.<sup>23-25</sup> Other technologies, such as the application of laser and microwave energy<sup>26</sup> for fat fragmentation, have been tried experimentally.

The use of continuous ultrasound to produce fat fragmentation in lipoplasty was first popularized by Scuderi et al.<sup>27</sup> First-generation devices (SMEI, Casale Monferrato, Italy) delivered continuous ultrasound through solid, blunt-tipped probes (4 to 6 mm in diameter) to pretreat (fragment) fat before evacuation.<sup>28</sup> Second-generation UAL machines—as popularized by Lysonix, Mentor, and other manufacturers—used 5-mm diameter hollow cannulas that would allow for simultaneous fat fragmentation and aspiration.<sup>29,30</sup> Even by using a cannula with this external diameter, the internal lumen has a diameter of only 2 mm, making the aspiration function generally inefficient. Although there were slight differences in function, both the Lysonix and the Mentor devices were designed to produce continuous ultrasound energy to accomplish fat fragmentation and both incorporated the simultaneous aspiration function. Access incisions for traditional UAL were relatively long (ie, up to 1 cm in length) to accommodate large UAL instrumentation and skin protectors.<sup>28,30</sup> UAL devices that simultaneously infiltrate wetting solutions through an external sheath (sheath systems) do not provide any additional benefits during UAL procedures. In addition, the sheath-style UAL cannulas are reported to have more resistance to passage through tissue.<sup>31</sup>

Ultrasound, when applied internally to fatty tissue by a metallic probe or cannula, is thought to break down cells by means of 3 mechanisms: cavitation, thermal effect, and direct mechanical effect.<sup>32-36</sup> It nevertheless can affect other components of the tissue matrix. The ability of ultrasound to produce skin retraction during UAL is not predictable and is potentially dangerous.<sup>37,38</sup>

The UAL technique was taught through a standardized curriculum at regional instructional symposia sponsored by the UAL Task Force, a coalition of major plastic surgery organizations that represented the American Society for Aesthetic Plastic Surgery, the Aesthetic

Surgery Education and Research Foundation, the American Society of Plastic and Reconstructive Surgeons, the Plastic Surgery Educational Foundation, and the Lipoplasty Society of North America. Approximately 2000 surgeons received training in 41 courses, which included both didactic and bioskills instruction. UAL is a multistep process that involves infiltration of wetting solutions, internal application of ultrasound to fragment fatty tissue, and evacuation of fragmented fatty tissue emulsion by SAL or PAL cannulas.

Despite the voluminous material covered in UAL training courses, there appeared to be a poor understanding of the basic science of ultrasound and its effect on tissue.<sup>39-41</sup> Few studies have addressed ultrasound's effect on tissues and attempted to quantify the amount of ultrasound power necessary for safe clinical outcomes.

Importantly, many surgeons did not understand the relationship between ultrasound power and efficiency of fat fragmentation. As a result, many relied on larger-diameter UAL cannulas to shorten operating-room time, a choice that also increased the amount of energy applied to tissues. Lengthy application times of ultrasound energy was noted in multiple published articles.<sup>28,38,42</sup>

Without a sufficient understanding of power, probe efficiency, and probe design, it was possible to inadvertently apply excessive ultrasound power to fragment fatty tissue, often at the expense of clinical outcomes and increased surgical complications. Until the work published by Cimino,<sup>41</sup> there had not been a qualitative or quantitative study examining the differences among UAL devices and the power that they can deliver to tissues. His article also defined the variables controllable by the surgeon that can ultimately affect clinical outcomes.

Despite initial enthusiasm for UAL, it became apparent to those who used these devices that there were both technical (equipment) limitations and surgical complications attributable primarily to application of excessive amounts of ultrasound energy during lipoplasty. Complications with second-generation ultrasound lipoplasty devices were related to the amount and duration of energy applied to fragment adipose tissue. Most UAL cannulas required high levels of ultrasound energy for fat fragmentation. Excessive application of ultra-

sound energy can produce internal cavity formation that could lead to seroma or even pseudobursa formation or delayed resolution of swelling, or both.<sup>43</sup> Lateral movement of UAL cannulas or probes could produce thermal damage to deep tissues along the sides of the cannulas. In addition to prolonged tissue induration, painful dysesthesias and sensory changes caused by ultrasound injury have been reported.<sup>42,44</sup> It has been postulated that such adverse effects are a result of the demyelination of sensory nerve fibers.<sup>45,46</sup> End-hits against the dermal undersurface can produce burns.<sup>37,47</sup> Full-thickness skin loss and hyperpigmentation have also been reported.<sup>48,49</sup> These complications are related to the excessive, inefficient, or improper application and delivery of ultrasound energy.

Outcomes from UAL performed with traditional UAL devices varied from excellent results to significant complications not ordinarily encountered with SAL or PAL.<sup>28,37,38,50</sup> In the meantime, there has been, comparatively speaking, minimal investigation to determine the cause of UAL-related complications. Although hard data do not exist, the clinical use of traditional UAL seems to be declining in the United States, as it has already internationally. As of September 2001, SMEI (first-generation devices) had made a business decision not to actively distribute in the United States, whereas The Lysonix Corporation had ceased selling UAL devices in the United States because of patent-infringement issues.

Beginning in 1995, the senior author (P.B.F.) gained extensive experience with early-generation internal UAL devices. A clinical study was conducted on 100 cases making use of a number of different devices.<sup>51</sup> Although no complications were reported, no appreciable advantage over traditional lipoplasty was found and this author gradually abandoned the use of UAL in his practice.

### **The VASER Device**

From a theoretical perspective, ultrasound energy as used within lipoplasty should be viable for the safe and efficient fragmentation of adipose tissue. The search for an improved ultrasound device that would overcome the limitations in UAL has continued. To this end, a "wish list" was developed to help guide engineering efforts to create a third-generation ultrasound device, which would focus on safety, improved design (efficiency), reduced

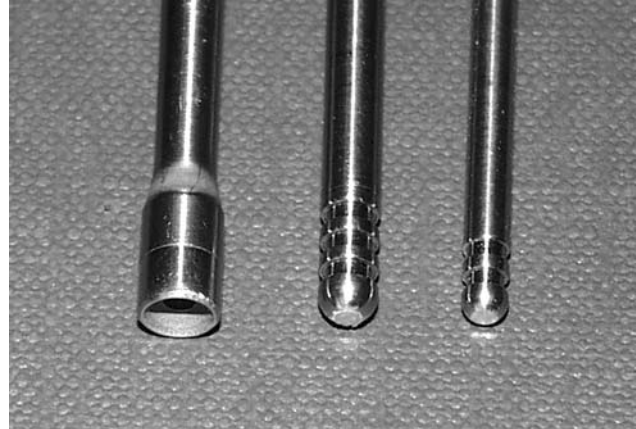


**Figure 1.** A 2.9-mm VASER probe and handle with skin protector and wet towel.

complications, and faster recovery (Fodor PB, oral communication to W.W. Cimino 1998). The clinical objective was to achieve better results and fewer complications attributable to excessive ultrasound exposure.

In response to the “wish list,” Sound Surgical Technologies LLC (Lafayette, CO) developed an ultrasound surgical system, the VASER device. This system uses small-diameter solid probes (ie, of 2.9 mm and 3.7 mm) with grooves near the tip to increase fragmentation efficiency. The grooved probe design redistributes the ultrasound energy, transferring some of the vibration energy from the front of the tip to a region just proximal to the tip. Because the efficiency of the fragmentation/emulsification process has been improved by using the grooved design, smaller-diameter probes can be used to achieve rapid and effective fragmentation.

Ultrasound power delivered to the tissues is a strong function of the diameter of the probe.<sup>41</sup> Therefore, smaller-diameter probes deliver less energy to the tissues but still achieve the desired fragmentation and emulsification because of the grooves at the tip and resulting higher efficiencies. For example, the most commonly used clinical settings for the Lysonix 2000 machine (continuous mode) are the 5-mm bullet probe at amplitude settings of 5 to 6, resulting in powers applied to the tissues of 20 to 25 W<sup>41</sup> and efficiencies of 145 to 165 mJ/mm<sup>3</sup>. By comparison, the 3.7-mm single-groove solid VASER probe at amplitude settings of 70% to 90% (continuous mode) results



**Figure 2.** Comparison of a 5-mm “golf tee” UAL cannula (left), a 3.7-mm 3-groove VASER probe (center), and a 2.9-mm 2-groove VASER probe (right).

in 11 to 13 W applied to the tissues for an efficiency range of 155 to 175 mJ/mm<sup>3</sup>. These data show that probe design can result in a nearly 50% reduction in applied power, with improved fragmentation and emulsification capability.

The VASER mode (pulsed ultrasonic energy delivery) reduces the applied power still further while maintaining efficiency. This approach of pulsed delivery of energy is used to achieve the benefits of higher probe vibration amplitudes, but only for short bursts of time. The vibration energy is essentially “off” more than 50% of the time in the VASER mode. For the same 3.7-mm single-groove solid VASER probe, at settings from 80% to 100%, the applied power is 6 to 8 W, with efficiencies from 135 to 155 mJ/mm<sup>3</sup>. The VASER mode results in a nearly two-thirds reduction in applied power (compared with that of the Lysonix 2000) with only a slight loss of efficiency. The 2.9-mm diameter probes achieve further reductions in applied power with very high fragmentation efficiencies. Thus, the efficiency of the probe design is critical to the delivery of low levels of applied power. Simply turning down the power on first- and second-generation equipment will not achieve the desired result, because the efficiency of fragmentation falls off so rapidly with decreased amplitude.<sup>41</sup>

In addition, the VASER ultrasound handpiece and its instrumentation are smaller, lighter, less cumbersome, and therefore more “user-friendly” than those of earlier devices. Curved probes have also been developed that



**Figure 3.** In all cases, the supernatant fat exceeded 80% of the total volume of aspirate.

incorporate these technologic advances and are expected to eliminate many of the objections related to probes that cannot be bent or shaped.

### Objectives

As with any new form of surgical technology, it is important to examine whether the new approach is superior to the currently existing methodology with respect to the efficiency, safety, and quality of the clinical outcomes. It is also important to compare complications and clinical outcomes with the findings of other reports in the medical literature that involve traditional UAL devices to validate the benefits alleged to be attributable to newer ultrasonic surgical technology. From the perspective of the surgeon, advances in surgical instrumentation also must be superior to the already existing technology with regard to ease of use. In addition, the new device should have an adequate service life. Ideally, if improvements in technology occur, new equipment should contain an upgrade pathway. For that matter, VASER technology is currently being investigated for surgical uses other than lipoplasty. To the best of our knowledge, traditional UAL equipment has not been upgraded, nor have additional surgical applications been developed.

### Methods

Three investigators (P.B.F., M.L.J., and E.B.d.S.P.) practicing in different locations and using a standardized approach as much as possible participated in the study.



**Figure 4.** In some cases, the supernatant fat was 95% of the total volume of aspirate.

A protocol for the use of the VASER device for VASER-assisted lipoplasty (VAL) was developed. Worksheets were used for data collection. Information was collected concerning the anatomic location of lipoplasty, the amount of wetting solution infiltrated, the amount of supernatant fat, VASER device settings (probe, amplitude, and time), and time required for fat evacuation. During follow-up visits, patient photographs were taken at predetermined postoperative intervals and information was collected regarding ecchymosis, pain, and complications, as well as patient and surgeon satisfaction. Patients with “common lipoplasty indications,” including excess fat in the abdomen, hips, lateral thighs, back, and breasts (men only, treated for gynecomastia), were selected for this first study. On the basis of initial results, other anatomic areas were included, such as inner thighs and knees.

### Wetting solutions

The superwet technique was used (1:1 volume of infiltrate/volume of aspirate). The wetting solution was uniformly distributed in the intended treatment area and was infused slightly beyond marked lipoplasty boundaries and in all areas of planned port locations. Once a body area was infiltrated, a minimum 10-minute wait elapsed before emulsification was performed with the VASER device. To minimize the risk of potential local anesthetic toxicity or fluid overload, we did not infiltrate all the body areas to be treated at the same time. The amount of lidocaine infused did not exceed 35 mg/kg of body weight in any case.



**Figure 5.** **A, C,** Preoperative views of a 20-year-old man with gynecomastia. **B, D,** Postoperative views 2 weeks after a VAL procedure that included 500 mL of wetting solution infiltrated per side, application of a 2.9-mm probe for a treatment time of 5 minutes 30 seconds at 90% power, and removal of 350 mL of aspirate per side (90% fat).

### Skin protection

Skin protection was achieved during the delivery of ultrasound energy through the use of specially designed skin ports to protect the incision edges and wet towels adjacent to the port locations (Figure 1). The towel protected the skin from inadvertent contact (external burns) with the shaft of the vibrating probe. The probe movement was performed with a simple axial back-and-forth motion. Levering (applying torque) of the probe was strictly avoided. Levering occurs when the skin port is used as a fulcrum, which focuses the vibration energy at a point of contact with the skin to the extent that a single layer of towel may not provide sufficient skin protection. Access incisions were 3 to 4 mm in length, significantly shorter than necessary with traditional UAL devices.

### Tissue type and probe selection

VASER probe selection was determined according to the characteristics of the localized fat deposit to be treated. In general terms, the 3.7-mm probes are intended for rapid debulking of larger volumes of fat. The 2.9-mm probes are intended for smaller volumes and for contouring (Figure 2).

Probe diameter and the number of side grooves on the tip influence how the probe will pass through any given tissue type. For a given diameter, probes with more grooves fragment tissue more efficiently but do not penetrate fibrous tissues as easily because a significant amount of the ultrasonic energy is transferred to the sides of the probe, where the rings are located. Therefore, for a given diameter, probes with fewer grooves are more appropriate for fibrous tissues. Smaller-diameter probes will also

**Table 1. Tissue type, probe selection, and amplitude setting**

Tissue type	Continuous mode	VASER mode	Amplitude 2.9 mm (3-groove, L or S)	Amplitude 3.7 mm (3-groove)	Amplitude 3.7 mm (2-groove)	Amplitude 3.7 mm (1-groove)
Very soft	Yes	Yes	60-80	70-90	70-90	Not recommended
Soft	Yes	Yes	60-90	80-100	70-90	70-90
Medium	Yes	Yes	70-100	80-100	80-100	70-90
Fibrous	Yes	2.9 mm only	80-100	Not recommended	80-100	80-100
Very fibrous	Yes	No	80-100	Not recommended	Not recommended	80-100

L or S, Long or short probe length (ie, 24 cm/17 cm).

penetrate fibrous tissues more readily than larger-diameter probes, irrespective of the number of rings. For example, if fibrous tissue impeded the passage of a 3.7-mm (3-groove) probe, a 3.7-mm probe with fewer grooves (2 or 1) or a 2.9-mm probe (3-groove) would be selected.

Recommended settings for the VASER device are dictated by tissue type, ultrasound mode, probe selection (diameter and number of side grooves), and amplitude settings. These are summarized in Table 1.

#### VASER mode versus continuous mode

Throughout this study, the VASER mode (pulsed ultrasound) was found to be sufficiently powerful and, therefore, it was used as the designated method of fat fragmentation by 2 investigators (P.B.F. and M.L.J.). One investigator (E.B.d.S.P.) primarily used continuous ultrasound mode in his series of patients. It was necessary to evaluate the clinical safety, efficacy, and patient outcomes that involve both modes of ultrasound as produced by the VASER device and its solid, grooved probes.

Continuous ultrasound mode was used (P.B.F. and M.L.J.) only when tissue emulsification was not readily achieved with the VASER mode, such as in extremely fibrous tissue. Cross-tunneling was used where possible for more uniform fragmentation and to facilitate subsequent aspiration. Each body area was treated once with wetting solutions, fat fragmentation, and aspiration. Repeat fragmentation after aspiration was not performed. Additional aspiration (in part of the nonemulsified fat) was carried out as necessary for optimal aesthetic refinement by means of the SAL or the PAL technique.

#### Lipoplasty technique

Until an understanding of how efficiently the VASER mode worked was achieved, initial application times were based on an arbitrary minimum of 1 minute of treatment time (continuous or VASER mode) for each 200 mL of wetting solution infused. We found that at times this produced only partial fragmentation of the targeted volume of fat. Subsequently, with experience and depending on the anatomic site, it was determined that effective fat fragmentation could be accomplished by using the guideline of a maximum of 1 minute of treatment time per 100 mL of infused wetting solution with the VASER or the continuous mode.

Loss of resistance to probe movement was used as the primary end point of emulsification, which usually occurred somewhere between the time guidelines described earlier. As one would expect, areas of the body that contained less fibrous fat took less time to reach the desired end point than more fibrous areas. Aspiration was accomplished by using the SAL technique (M.L.J.) or a PAL device (P.B.F. and E.B.d.S.P.). Access incisions were closed with sutures. Topical silicone-backed foam was applied under a compressive garment.

#### Evaluation of VASER lipoplasty outcomes

Follow-up examinations were conducted at specific intervals on postoperative days 3 to 4 and 7 to 10, as well as 1 to 3 months postoperatively (as much as this was practical). Patient postoperative pain was rated on a scale of 1 to 5, with 1 representing minimal and 5 representing severe pain. Ecchymosis was rated as 1 to 5, with 1 representing no ecchymosis and 5 representing maximal ecchymosis. Patient and surgeon satisfaction were also rated on a scale



**Figure 6. A,** Preoperative view of a 32-year-old woman. **B,** Postoperative view 6 weeks after VAL of the thighs and subgluteal areas with 2200 mL of wetting solution total infiltrate (330 mL for the abdomen, 330 mL for each inner thigh, 300 mL for each trochanteric region, 300 mL for each subgluteal “banana roll”); application of a 2.9-mm probe for a treatment time of 2 minutes 30 seconds per area at 80% power; and removal of 2100 mL of total aspirate (90% fat; 300 mL from abdomen, 300 mL from each inner thigh, 300 mL from each trochanteric region, 300 mL from each subgluteal area [90% fat]).

**Table 2. Clinical outcome of 77 VASER-assisted lipoplasty patients (scale of 1-5)**

Category	Outcome rating	Reference scale
Postoperative pain	1-3	1 = no pain; 5 = maximum
Ecchymosis	1-2	1 = none; 5 = maximum
Patient satisfaction	4-5	1 = dissatisfied; 5 = completely satisfied
Surgeon satisfaction	4-5	1 = dissatisfied; 5 = completely satisfied

of 1 to 5, with 5 being completely satisfied. Patients were examined for the presence of other known complications of traditional UAL, SAL, and PAL, such as seroma, infection, burns, dysesthesias, hyperpigmentation, contour irregularities, and prolonged swelling or induration.

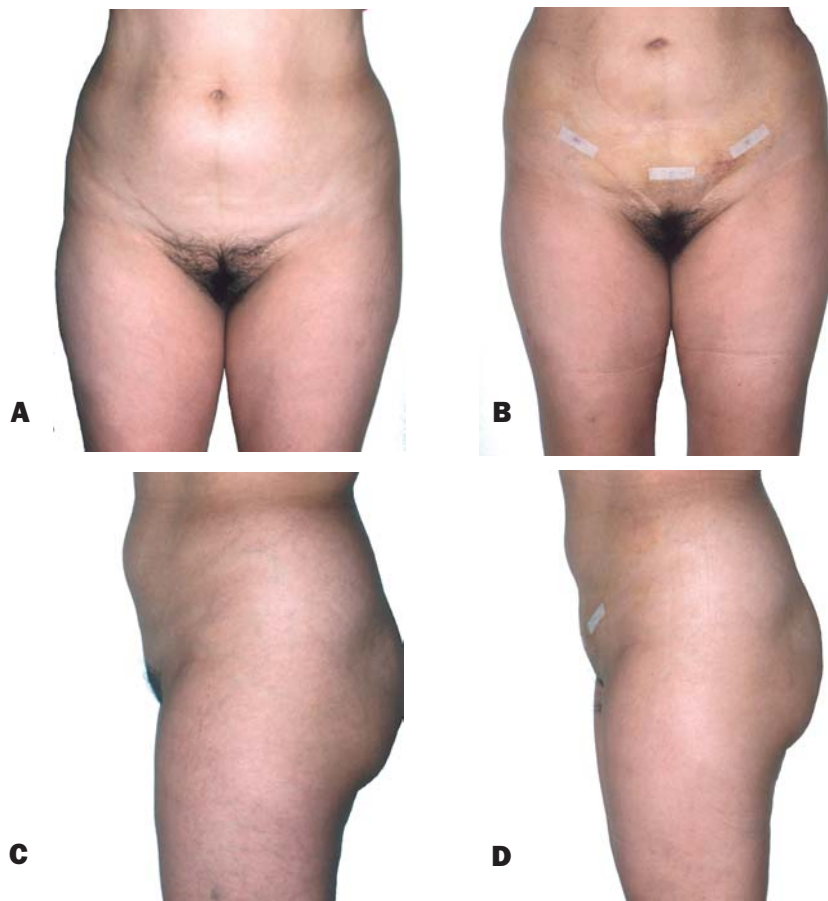
#### Literature search and statistical analysis of traditional UAL complications

To evaluate the safety and efficacy of VASER technology, it was important to compare our clinical experiences, including the incidence of complications in VAL patients, with those in published articles on UAL. We searched the PubMed databases for all clinical articles from indexed journals that appeared in English from 1980 to the present with the keywords *assisted*, *ultrasound*, and *liposuction*, obtaining 73 articles. We also searched any references given in these articles that had the same keywords, as well as the keyword *complication*. In addition, we searched the *Aesthetic Surgery Journal* from January/February 1989 to

November/December 2001 for any articles containing these same keywords, including the keyword *complication*. The yield from this last search was 20 additional articles. Therefore, the total number of articles found through our literature search was 93. All these articles were reviewed. Major and life-threatening complications were not included in our analysis. We specifically looked at the following 9 complications: (1) seroma, (2) induration, (3) alteration in sensation (dysesthesia and hyperesthesia), (4) burns (access site), (5) distant burns (end hits), (6) skin necrosis, (7) cellulitis, (8) pigmentary changes, and (9) prolonged swelling.

We found 17 articles in which these complications were reported. We assumed that the complication rate was 0 for any of these individual complications that were not reported in each of the 17 articles (ie, in the articles that reported at least some type of UAL-related complication).

In some of these articles, although reference was made in



**Figure 7. A, C,** Preoperative views of a 52-year-old woman. **B, D,** Postoperative views 2 weeks after VAL of the abdomen with 750 mL of wetting solution infiltrate (total), application of a 2.9-mm probe for a treatment time of 4 minutes at 90% power, and removal of 500 mL of total aspirate (90% fat).

the text to various complications, the authors did not specify the percentage of patients in whom these complications were observed. Similarly, in some articles, induration was mentioned in the body of the article but was not listed as a complication. Complications appear to be reported in these papers on a per-patient basis. In the end, 14 articles appeared to have valid data regarding UAL-related complications that could be subjected to statistical analysis. In one article by Lack,<sup>4</sup> 10 complications were reported in 6 patients. This was classified as a 100% incidence of complications in this specific series for the purposes of statistical analysis.

Three of the 17 articles were not used. A study by Kloehn<sup>30</sup> reported only an overall 3% complication rate without categorizing complications. A study by Commons et al<sup>50</sup> reported 217 seromas, which occurred in 1085 surgical sites in 117 patients. This article was not included in the statistical analysis because of incomplete categoriza-

tion of reported complications. A chapter by Gingrass<sup>52</sup> was not used because it appeared to be a review article.

## Results

### Clinical outcomes

Within the context of this pilot study, the emphasis was on the evaluation of a new lipoplasty technology (the VASER device) with regard to its safety, efficacy, and patient outcomes as compared with the reported experiences of other investigators who have used traditional UAL. Data on volumes of wetting solutions and fat aspirate, mode of energy used (pulsed versus continuous), time of application of ultrasound, and evacuation of fat were collected; however, the statistical analysis of these findings was not the primary emphasis of this pilot study and therefore will be mentioned only in general terms. The maximum length of follow-up time with respect to outcome of VAL has been 6 months (as long as practically feasible).

**Table 3. Complication rates per report from 14 articles\***

Author	No. of UAL patients	Total no. of complications	Overall complication rate (%)
Beckenstein and Grotting <sup>28</sup>	100	15	15
Lee et al <sup>53</sup>	35	0	0.0
Tebbetts <sup>55</sup>	70	0	0.0
Ablaza et al <sup>38</sup>	55	13	23.6
Rohrich et al <sup>42</sup>	114	5	4.4
Gilliland et al <sup>57</sup>	766	13	1.7
Maxwell and Gingrass <sup>58</sup>	250	33	13.2
Fodor and Watson <sup>51</sup>	100	0	0.0
Schefflan and Tazi <sup>37</sup>	800	112	14.0
Agaoglu and Erol <sup>59</sup>	37	2	5.4
Lack <sup>4</sup>	6	10	100 <sup>†</sup>
Tebbetts <sup>56</sup>	70	0	0.0
Kenkel et al <sup>54</sup>	296	7	2.4
Baxter <sup>43</sup>	175	16	9.1
Analysis			
Totals	2874	226	7.9 incidence
Maximum	800	112	100
Minimum	6	0	0.0
Median	100	8.5	4.90
Mean	205.3	16.1	13.5 average

UAL, Ultrasound-assisted lipoplasty.

\*All reports were reviewed for the following 9 complications: (1) seroma, (2) induration, (3) alteration in sensation (dysesthesia and hyperesthesia), (4) burns (access site), (5) distant burns (end hits), (6) skin necrosis, (7) cellulitis, (8) pigmentary changes, and (9) prolonged swelling. Other complications, if present, were not included.

<sup>†</sup>Each of the 6 patients reported multiple complications.

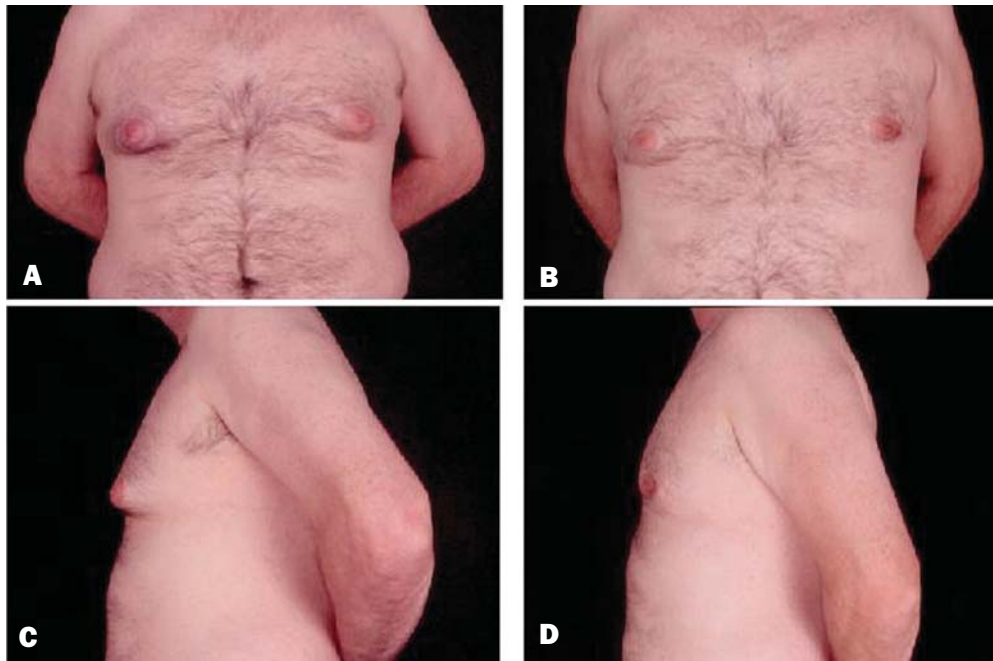
The clinical outcome of each patient was tabulated with regard to the subjectively rated parameters of pain, ecchymoses, patient satisfaction, and surgeon satisfaction.

The maximum amount of fat aspirate did not exceed 4000 mL in any one patient. In all cases, the supernatant fat exceeded 80% of the total volume of aspirate (Figure 3). In some cases, it was as high as 95% (Figure 4). Neither blistering from the silicone-backed foam nor pressure-induced ulcerations from surgical garments were encountered in any patients.

In addition, for the 77 patients who underwent VAL by 3 different clinicians, no complications of the sort that were analyzed in this article with respect to traditional UAL were found. No complications such as seromas, prolonged dysesthesias, burns, induration, contour

irregularities, hyperpigmentation, or prolonged swelling were observed in any of 77 patients involved in this study. Recovery was uneventful. There was 0 incidence of revisionary lipoplasty or other secondary body-contouring procedures to improve results obtained in this series.

Clinical outcomes from treatment with VAL are summarized in Table 2 and illustrated in Figures 5 through 11. Pain was average, with ratings in the 1 to 3 range. Bruising and swelling were minimal, with ratings in the 1 to 2 range. Patient satisfaction and surgeon satisfaction were both good, with ratings in the 4 to 5 range for each. One patient who underwent VAL of the thighs and trunk also underwent SAL of the calf and ankle regions. She developed significant ecchymoses in the calf region from the SAL, but did not have any complications from the VAL component of her treatment.



**Figure 8. A, C,** Preoperative views of a 33-year-old man with gynecomastia. **B, D,** Postoperative views 6 weeks after VAL with 250 mL of wetting solution infiltrated per side, application of a 2.9-mm probe for a treatment time of 1 minute 7 seconds/1 minute 41 seconds at 80% power, and removal of a total of 230 mL of aspirate (85% fat).

### Literature search results

Statistical analysis of complications involving UAL in the 14 selected articles revealed a rate of complications of 7.9% overall (total complications divided by total patients), a 13.5% overall mean rate (average of individual rates), and a median rate of 4.9% when first- or second-generation UAL devices were used (Table 3). By comparison, the complication rate for the 77 patients in this pilot study was 0% in all categories. These essentially complication-free VAL results compare very favorably with reports of complications such as seroma, prolonged dysesthesias, tissue induration, and burns at the access incisions and at distant locations concurrent with the use of traditional UAL devices (Table 4).

### Discussion

Within the context of this multicenter pilot study, we have used the VASER device to pretreat fatty deposits in 77 patients seeking improvement in body contour through lipoplasty. Our results indicate that the pretreatment (fragmentation) of fat by using pulsed or continuous ultrasound delivered through grooved, small-diameter solid probes is efficient and safe. Satisfactory to excellent clinical outcomes were observed in all patients enrolled in the study.

In most instances, the aspirate contained approximately 80% or greater supernatant fat. Blood loss appeared minimal, judging from the pale infranatant component of the aspirate. Postoperative edema and ecchymosis, determined through analysis of patient photographs and subjective clinical observations, were also quite minimal. Postoperative pain appeared average for lipoplasty patients. The patient recovery rate appeared similar to that encountered when traditional SAL or PAL is performed, along with use of the superwet technique. Importantly, there were no occurrences of the prolonged discomfort and burning sensations that have been reported for earlier-generation devices.<sup>37,43,44</sup>

We believe that this device represents a technologic advance over earlier generations of UAL equipment. The most important effect of these improvements (probe design and pulsed delivery of energy) is greater fragmentation efficiency and reduction of complications and side effects such as internal burns, seroma formation, skin necrosis, rippling, and painful dysesthesias, which have been reported in conjunction with the use of other UAL devices. We believe that with the use of good clinical judgment and precise surgical technique, surgical complications formerly attributed to continuous-wave UAL devices can be significantly reduced or eliminated with VASER technology.

**Table 4. Individual UAL complication rates from 14 articles**

Complication type (2874 UAL patients)	No. reported	Maximum incidence per series (%)	Minimum incidence per series (%)	Median incidence per series (%)	Mean (average of individual rates) (%)	Overall total incidence (%)
Seroma	62	21.8	0	1.25	4.8	2.2
Sensation change	66	83.3	0	0.20	7.0	2.3
Induration	3	50	0	0.00	3.6	0.1
Burns at access site	2	1	0	0.00	0.1	0.1
Distant burns	4	3	0	0.00	0.2	0.1
Skin necrosis	43	16.7	0	0.00	1.6	1.5
Cellulitis	2	0.3	0	0.00	0.0	0.1
Hyperpigmentation	35	4	0	0.00	0.5	1.2
Prolonged swelling	8	4.6	0	0.00	0.3	0.3

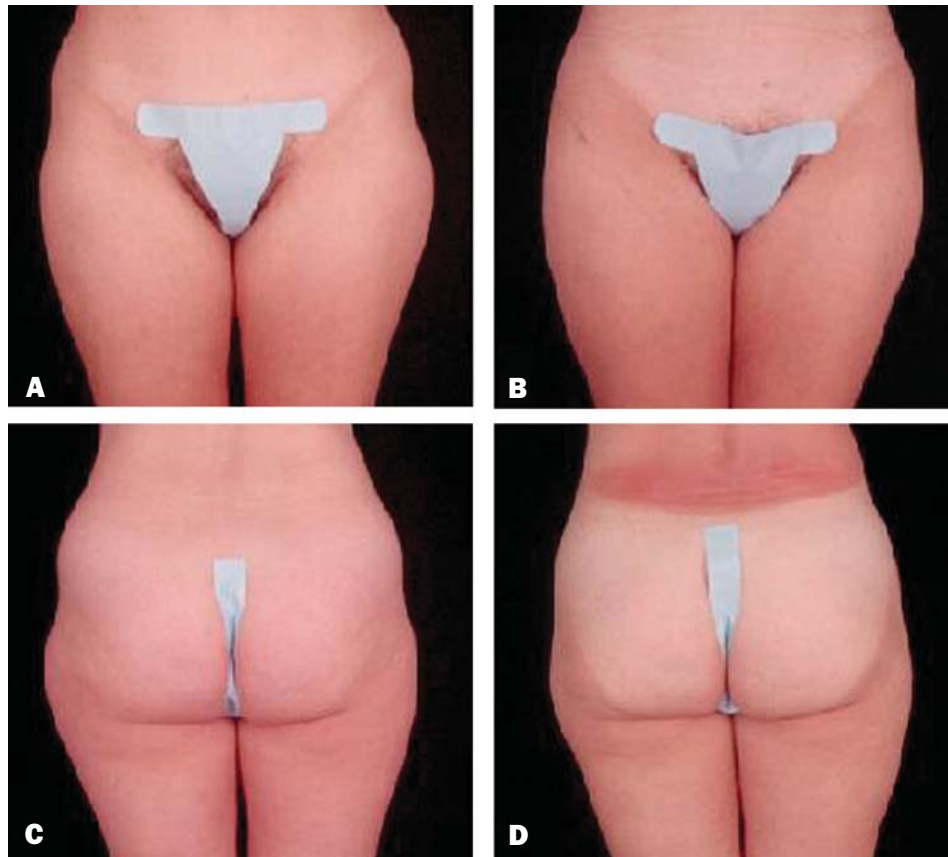
In addition, we noted that the time necessary for fragmentation and removal of fatty tissues using the VASER equipment is no longer—and in many cases is shorter—than the time required for removal of the same amount of tissue by means of traditional lipoplasty. One of the major objections to the earlier-generation UAL devices/techniques was the length of the procedure compared with that of traditional lipoplasty.<sup>60</sup> The VASER also significantly reduces the surgeon's effort, especially in treating more fibrous tissues. To date, we have not observed any mechanical failures of the VASER equipment or any tip degradation of the VASER probes. According to the manufacturer, a single probe should have a service life of approximately 100 VAL cases, depending to some degree on the complexity of the average case.

Having used the solid-probe technology of VAL, we believe that it is worthwhile to consider abandoning simultaneous fat fragmentation and aspiration through hollow UAL cannula designs. Traditional UAL devices combine inefficient probe designs, which require high levels of power to fragment subcutaneous fat, owing to their very limited aspiration capability because of their small internal lumens.<sup>61</sup> In addition to the targeted adipocytes, other structures such as nerves, collagen fibers, vessels, and lymphatics may be drawn (pulled) to the cannula port, exposing them to damage by ultrasound energy. Moreover, some of the hollow cannula designs (“golf tee”) have sharp leading edges that can inflict additional mechanical injury to tissue.<sup>51</sup>

In retrospect, the choice of hollow UAL instrumentation, aiming at simultaneous emulsification and suction as the preferred method, which was advocated initially and taught at the UAL courses, is potentially more hazardous and less efficient than the use of a solid probe for fat fragmentation followed by a separate, and much more efficient, aspiration phase. Traditional UAL cannulas simultaneously remove not only the emulsified tissue but also the fluids that protect adjacent tissues from the ultrasound energy. We disagree with earlier statements that visual feedback of emulsified fat with use of a hollow UAL cannula offers a benefit in terms of determining clinical end points for fat fragmentation.<sup>58,61,62</sup> The “loss of resistance” and time guidelines discussed earlier provide much more intuitive and effective feedback/guidelines. Repeated application of UAL to the undersurface of the dermis after evacuation of the emulsified fat for the purposes of stimulating skin retraction (the so-called fourth step) appears hazardous and unpredictable at best.<sup>37,63</sup>

## Conclusion

Historically, we as surgeons have witnessed the expanded application of medical lasers when the concept of pulsed-energy delivery was discovered and applied to these devices (Coherent Ultrapulse Laser). Laser technology has evolved from the development of a continuous-wave, high-power device to the development of a device that efficiently delivers pulsed laser energy capable of a more selective effect within the target tissue (eg, for skin resurfacing, laser hair removal, vascular



**Figure 9. A, C,** Preoperative views of a 29-year-old woman. **B, D,** Postoperative views 2 weeks after VAL of the trochanters and hip regions with a total of 1600 mL of infiltrate, application of a 3.7-mm probe for treatment times of 1 minute 26 seconds per side for the trochanters and 1 minute 16 seconds/1 minute 51 seconds for the hips at 80% power, and removal of a total of 1831 mL of aspirate (85% fat).

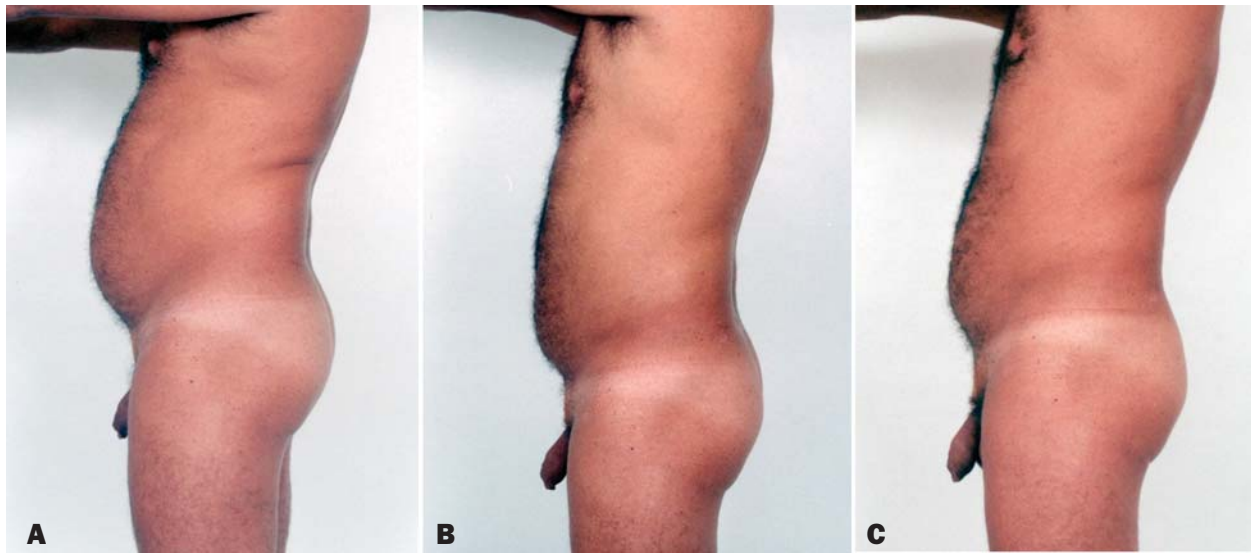
laser). A similar paradigm has occurred with the development of the VASER, as compared with that of traditional UAL devices.

We believe that the use of ultrasound for lipoplasty deserves to be revisited because of technologic advances incorporated in the VASER. From the results of this pilot study, it appears that this device, in the hands of a surgeon who is trained in UAL, can produce excellent results with a lower risk of complications than has been reported for earlier UAL equipment. The VASER appears to function in a complementary fashion when used with the SAL and PAL techniques.<sup>25</sup>

The VAL approach brings us closer to all of the theoretical and practical benefits of safe and efficient fat fragmentation without the high complication rates observed and reported with the use of traditional UAL devices. This is the result of improvements in instrumentation and

surgical technique, proper use of wetting solutions, and understanding of how to best use ultrasound energy for fat fragmentation. We agree with Courtiss<sup>64</sup> that new technologies must be evaluated by means of scientific methods as opposed to market-driven forces.

UAL education efforts in future training courses should discuss how ultrasound power is delivered to tissue in terms of probe design and efficiency, as well as in terms of the quantitative amount of energy that will be applied. The most important underlying theoretical concept with regard to success is that the surgeon should use the minimum amount of ultrasound power necessary to fragment/precondition fatty tissue for subsequent aspiration and to prevent damage to other elements of the tissue matrix and surrounding tissues. Irrespective of the approach selected for lipoplasty (SAL, UAL, PAL, VAL), complications can potentially occur if these technologies are improperly used.



**Figure 10.** **A**, Preoperative view of a 34-year-old man. **B**, Postoperative view 3 months after VAL of abdomen with a total of 1700 mL of infiltrate, application of a 3.7-mm probe in continuous mode for a treatment time of 9 minutes 18 seconds at 90% power, and removal of 1100 mL of aspirate (80% fat). **C**, Postoperative view 6 months after treatment.



**Figure 11.** **A**, Preoperative view of a 35-year-old woman. **B**, Postoperative view 25 days after abdominal lipoplasty/limited abdominoplasty with a total of 2000 mL of infiltrate, application of a 3.7-mm probe in continuous mode for a treatment time of 3 minutes 35 seconds at 90% power, and removal of 1000 mL of aspirate (85% fat).

In judging by our initial clinical experience with VAL, we believe that VASER technology is a safe and efficient body-contouring modality. On the basis of our evaluation, we believe that the strategy of maximizing probe efficiency to shorten fragmentation time, while reducing probe diameter and ultrasound energy, will minimize collateral tissue damage. In conclusion, we believe that

VASER technology, when used correctly, is a powerful lipoplasty tool.

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