

Proven Safety of the VASER® (Vibration Amplification of Sound Energy at Resonance) Lipo System

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Background

Lipoplasty is the most common cosmetic surgical procedure performed in the United States, yet ultrasound-assisted lipoplasty (UAL) only represents less than 20% of these procedures. Despite the well-documented advantages of UAL, concerns about complications remain a significant barrier. While earlier iterations of internal ultrasound devices were associated with blood loss, seroma, and burns, among other complications, third-generation devices, such as the VASER Lipo System, have clearly demonstrated advances in efficiency and safety, including minimal blood loss and the safe extraction of large volumes.¹ The VASER Lipo System combines VASER technology refinements in energy delivery and instrumentation with improved clinical techniques to minimize tissue matrix trauma and deliver the desired clinical outcome with maximum safety and effectiveness.²

Evolution of Lipoplasty

Modern lipoplasty was introduced in the late 1970s by Dr. Yves-Gerard Illouz and featured the use of a blunt cannula accompanied by high-vacuum suction to promote the fat extraction.³ In the late 1980s, Jeffrey A. Klein described the tumescent technique, which added both high-volume fluid and a local anesthetic. These additions allowed the procedure to be moved to an outpatient surgery setting with only intravenous sedation, rather than general anesthesia, and blood loss was reduced to 8% – 30% of total aspirate.^{1,4} However, concerns about the high volume of fluid required and the potential toxicity of lidocaine led to the evolution of the lower-volume, super-wet technique. Using a 1:1 ratio of infiltrating solution to estimated aspirate significantly lowered blood loss to a single digit percentage of the total aspirate.¹ Some have advocated for increasing the ratio to between 3:1 and 6:1, aiming to achieve significant tissue turgor.⁵ However, while the appropriate use of wetting solution reduces blood loss and postoperative bruising and enhances patient comfort, overzealous use can result in systemic fluid overload, as evidenced by reported cases of pulmonary edema as well as toxic levels of local anesthetics and

adrenaline.^{5,6} In the late 1990s, ultrasound was introduced as a means of emulsifying fat prior to the aspiration phase, which decreased the amount of blood in the aspirate.¹

First- and Second-Generation Ultrasound Devices

First-generation ultrasound devices utilized solid, blunt-tipped probes (4-6 mm) to deliver continuous ultrasound and fragment fat before evacuation. Second-generation ultrasound devices utilized 5 mm hollow cannulae to allow for simultaneous fat fragmentation and aspiration. However, the inner lumen of second-generation devices was restricted to a diameter of only 2 mm, limiting the aspiration function. In addition, access incisions of up to 1 cm were required to accommodate the large instruments and skin protectors. Inadequate training and a poor understanding of these devices occasionally led to the excessive application of ultrasound energy, which in some instances adversely affected clinical outcomes and increased surgical complications such as seromas, prolonged dysesthesias, burns, induration, contour irregularities, hyperpigmentation, cellulitis, and prolonged swelling.^{5,7} While the complications associated with first- and second-generation devices are reportedly related to the excessive energy output associated with these devices or to extended application, improvements made with third-generation devices obviate these concerns.⁷ Third-generation UAL devices yield a cleaner aspirate with a higher percentage of supernatant fat.¹

The VASER Lipo System: A Third-Generation Ultrasound Device

The VASER Lipo System, a third-generation UAL device, was designed to improve safety and efficiency, reduce complications, and allow for faster patient recovery.⁵ VASER probes are constructed with a proprietary, solid, side-grooved design that redistributes ultrasonic energy from the tip to the region



VASER Lipo probe configurations

immediately proximal. This results in a 50% lower energy requirement as compared to older systems. The probes are blunt and pass through tissue easily with minimal trauma. Minimizing ultrasound output provides greater tissue fragmentation while decreasing the probability of complications. An array of probe diameter and ring combinations are available to accommodate a range of tissue types and treatment locations.^{8,9}

The VASER System offers a number of advantages over other lipoplasty platforms:

- The VASER solid titanium probes provide more efficient delivery of ultrasound energy, enabling the use of a smaller probe and a smaller incision.⁹
- VASER probes are available with 1, 2, or 3 groove tips, providing greater versatility and precision. VASER probes with more grooves allow for greater fragmentation, while VASER probes with fewer rings allow for greater penetration of more fibrous tissue.²
- The VASER System offers a choice of continuous or pulsating ultrasound energy delivery, allowing the surgeon to tailor the approach according to the extent of fibrosis.⁹ Continuous mode is appropriate for general use, for more fibrous tissue, and for higher-speed fragmentation. The pulsating VASER mode is appropriate for softer tissue and applications in which finer sculpting is required, such as with the face and neck.²
- VASER technology uses roughly half of the ultrasound energy of other platforms to emulsify the same amount of fat, thereby reducing the risk of thermal complications such as fibrosis and seroma.⁹
- No serious complications have been reported related to VASER technology in more than 70,000 procedures.

VASER Lipo Safety in Clinical Studies

Several studies have explored the safety and efficacy of lipoplasty with the VASER Lipo System as compared to traditional procedures and devices. In 2002, Mark Jewell et al published the results of 77 patients who underwent VASER-assisted lipoplasty (VAL) by 3 different clinicians. No complications similar to those associated with traditional UAL, including seromas, prolonged dysesthesias, burns, indurations, contour irregularities, hyperpigmentation, or prolonged swelling, were reported. Recovery was uneventful and no patient required revisionary lipoplasty or other secondary body contouring procedures to improve results. Pain was reported as average, bruising and swelling were minimal, and both patient and surgeon satisfaction were high. The authors also performed a literature search and presented a statistical analysis of complications related to UAL (Table 1). The authors concluded that VASER technology is a safe and efficient body contouring modality and that the shorter fragmentation time, smaller probe diameters, and reduced ultrasound energy associated with the VASER System minimize collateral tissue damage.⁵

Garcia et al compared 27 consecutive female patients (ages 18.75 years to 54.5 years) receiving suction-assisted lipoplasty (SAL) for contouring of the back and posterior flanks with 30 consecutive female patients (ages 18.5 years to 70.3 years) receiving VAL for the back and posterior flanks. The average body mass index (BMI) for the SAL and VAL groups was 24.2 and 25.6, respectively. This patient cohort represents a larger-sized patient population seeking treatment in an area associated with a higher complication rate and a greater percentage of blood in the aspirate.¹

The mean hematocrit of aspirate in the SAL arm was 3.98%, compared to 0.61% for the VAL arm. The mean hemoglobin content of the aspirate was 7.5 times higher in the SAL arm

Table 1. Complication Rates Associated with First-, Second- and Third-Generation UAL Devices^{1,5}

UAL Technology	Total Complication Rate	Mean Complication Rate	Median Complication Rate
First- and Second-Generation UAL*	7.9%	13.5%	4.9%
VASER Lipo System [†]	0%	0%	0%
VASER Lipo System [‡]	0%	0%	0%

* Based on literature review that included 14 articles and 2,874 patients⁵

[†] Jewell et al study; includes 77 patients⁵

[‡] Garcia et al study; includes 57 patients¹

(2.23 g/dL vs 0.30 g/dL). Statistical analysis of the differences in aspirate hematocrit and hemoglobin was determined to be highly significant ($P < .0001$). When using bloody aspirate as the "endpoint" before removal of the desired amount of aspirate in posterior trunk lipoplasty, an average of 3.1 times more aspirate was removed from the back and posterior flanks with VAL than with SAL. No VASER-related complications were reported in this study. The authors concluded that VAL should be considered for patients undergoing large-volume lipoplasty procedures or lipoplasty of tight, fibrous areas such as the back and posterior flanks where increased blood loss is expected.¹

Summary

The VASER Lipo System is a safe and efficient device for emulsifying fat, allowing for easier aspiration with a higher degree of precision. It significantly reduces surgeon fatigue associated with high-volume extractions and yields a very clean, bloodless aspirate even in tight, fibrous anatomical areas. In more than 70,000 procedures with the VASER Lipo System, no serious complications have been reported.

References

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Dr. Onelio Garcia Jr. began private practice in South Florida in 1985 following completion of his residency training at University Medical Center in Jacksonville, Florida, under the tutelage of Dr. Bernard L. Kaye, a founder and past president of the American Society for Aesthetic Plastic Surgery. Dr. Garcia was president of the Miami Society of Plastic Surgeons in 1997, presided over the Florida Society of Plastic Surgeons in 2005, and is currently a member of the board of directors of that society. Dr. Garcia serves as a Voluntary Assistant Professor in the Division of Plastic Surgery at the University of Miami Miller School of Medicine. He is an active member of numerous plastic surgery societies including the American Society of Plastic Surgeons, American Society for Aesthetic Plastic Surgery, and American College of Surgeons. He is the founder and current president of Aesthetic Plastic Surgery Miami Inc. and a Diplomate of the American Board of Plastic Surgery.