Ultrasound-Assisted Lipoplasty: Past, Present, and Future

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The use of high-frequency vibrations in surgical instruments, commonly referred to as ultrasonic surgical instrumentation, typically involves a frequency of vibration in the range from 20,000 cycles per second (20 kHz) to 60,000 cycles per second (60 kHz). The metal probe or tip of the surgical instrument moves forward and backward at the aforementioned frequencies to create a desired surgical effect. The choice of frequency and the design of the tip of the metal probe determine the application of the instrument and how the device interacts with the targeted tissue.

Ultrasonic instrumentation for surgical application was first introduced for the dental descaling of plaque in the late 1950's and early 1960's by Balamuth (1). This technique and technology for dental descaling are still widely used today.

In 1969 Kelman (2,3) adapted the vibrating metal pobe to the phacoemulsifcation procedure. Aspiration and irrigation capability were were added to the basic vibrating device to facilitate the safe and effective removal of the cataract. Today, over 2 million cataracts each year are removed in the U.S. using this technology and associated technique (4). The clinical effect of the phacoemulsification device on the cataract has been attributed to a micro-chopping effect (5). Safe and effective techniques and technology for this ultrasonic instrumentation have evolved to the degree that the cataract removal portion of the phacoemulsification procedure is often finished in less than 5 minutes per eye and over 98% of all cataract removals in the U.S. are now done using the phacoemulsification technique.

In 1974 the phacoemulsification device was further modified and applied to neurosurgery for tumor removal. The objective of the device was to selectively remove pathologic brain and spine tissues with minimal residual trauma to remaining tissues. The CUSA (Cavitron Ultrasonic Surgical Aspirator) device, the first such instrument, is still in wide use today. Several companies produce ultrasonic aspirators for neurosurgery and account for approximately 200,000 procedures per year worldwide. The tissue selective nature of the devices, i.e., the ability to spare nerves and vessels, has been attributed to the device's ability to differentiate between tissues with different water contents and to a process called cavitation. The cavitation theory has never been proven and alternative theories have been presented that base the selective tissue effect more on mechanical actions (6,7,8) and view the cavitation process as an unavoidable consequence, but not the primary mechanism of tissue interaction.

In the late 1980's and early 1990's the concept of an ultrasonic instrument was adapted to a cutting and coagulating device with application to laparoscopic surgery in the abdomen. Techniques and technology were developed and are used today for laparoscopic cholesystecomies, laparoscopic appendenctomies, laparoscopic Nissen Funoplications, and other laparoscopic procedures. It is estimated that between 400,000 and 600,000 procedures per year are done using this technology (worldwide).

The application of ultrasonic instrumentation to body contouring surgery began in the late 1980's and early 1990's. Scuderi (9) and Zocchi (10,11,12,13,14) pioneered the application of ultrasonic vibration to fat emulsification and removal. The hope and objective of this effort was to create both technology and associated techniques that consistently produced a safer and more effective means of aesthetic body contouring when compared to known methods of the time, namely suction–assisted lipoplasty. The

benefits of tissue selectivity demonstrated and utilized in the previously mentioned surgical applications were expected to produce a method of lipoplasty that was more 'fat specific' than the existing and well-known suction cannula. This technology and technique were named UAL for Ultrasound-Assisted Lipoplasty.

The first generation UAL device was produced by the SMEI Company of Italy and utilized smooth, solid probes at a frequency of 20 kHz. The solid probes had a stepped design with diameters at the tip as small as 3.0 millimeters (small probe) and diameters at the base as large as 6.0 millimeters (large probe). The basic technique involved good surgical practice and two fundamental rules: 1) the essential use of a wet environment produced by infiltration of sufficient wetting solution and 2) a constantly moving the probe to prevent thermal injury (13). Initial surgical times were in the range from 10-12 minutes for a 250-300 cc removal or approximately 4 minutes of ultrasound time per 100 cc of aspirate (13).

Around 1995 a growing interest in UAL in the United States prompted the plastic surgery community leadership to create a UAL Task Force that included representation from the American Society for Aesthetic Plastic Surgery, Aesthetic Society Education Research Foundation, American Society of Plastic Surgery, Lipoplasty Society of North America, and Plastic Surgery Education Foundation. The mission of the Task Force was to evaluate the new ultrasonic instrumentation for lipoplasty and to assist in its teaching and introduction in the United States. Teaching courses were offered under the oversight of the Task Force with didactic and hands-on training. Subsequent to his Task Force efforts, Fodor (15) published his experience on 100 patients using a contra-lateral study model. His conclusions comparing SAL to UAL found no significant differences between SAL and UAL and failed to prove the claimed benefits attributed to UAL.

During the UAL Task Force period second generation UAL devices became available. These devices included the Lysonix 2000 (Lysonix Inc., Carpinteria, CA) and the Mentor Contour Genesis (Mentor Corporation, Santa Barbara, CA). The Lysonix system operated at a frequency of 22,500 Hz (22.5 kHz) and utilized hollow ultrasonic cannulae that aspirated emulsified fat simultaneously with the emulsion process. Cannula offerings were 'golf-tee' and 'bullet' designs with diameters of 4.0 millimeters and 5.1 millimeters. The 'golf-tee' tip design with a 5.1 millimeter diameter was the most commonly used design, in theory because of its 'higher' efficiency. The Mentor Contour Genesis was an integrated system with suction, infusion, and an ultrasonic generator all packaged in one moveable system. The ultrasonic frequency was 27,000 Hz (27.0 kHz) and also utilized hollow ultrasonic cannula similar to the Lysonix, with diameters offered from 3.0 millimeters to 5.1 millimeters. The shape of the tip of the Mentor cannulae was flat with side ports for aspiration for all tip diameters.

The UAL technique continued to evolve with both the Lysonix and Mentor devices. Originally application times were long and significant complications and were reported and safety was questioned (16,17,18,19,20,21). As application times were reduced the complication rate declined. Application times were reduced to 1 minute of ultrasound per 100 cc's of aspirate (22,23). The concept of 'loss of resistance' became widely known as a realistic surgical endpoint. Rapid Probe Movement (23) was introduced as another means to safely control the energy presented by the second-generation machines.

Overall, results ranged from safe and effective use of UAL to high complication rates and questionable safety.

In July 1998 Topaz (24) published an article concerned with the long-term impact of UAL due to hypothesized sonoluminescence, sonochemistry, and free-radical generation. To study the safety issues raised by this publication, ASERF organized a Safety Panel Meeting, held in St. Louis in November of 1998, that included experts in biochemistry, ultrasonic surgery, cavitation physics, and experienced UAL users. A number of research efforts and studies were launched and completed to address issues identified at the meeting and a summary report was produced by the Safety Panel coordinator (25). Conclusions reached by the panel of experts record that 1) more needs to be known about the tissue interaction process; 2) hydrogen peroxide is the only reactive oxygen species potentially produced by UAL that is capable of inducing DNA damage, 3) that hydrogen peroxide was not detectable following direct sonication of wetting solution with a UAL machine (100 nmol resolution), and 4) that the authors must conclude that there is no significant risk of malignant transformation from H_2O_2 (or any other ROM) produced during UAL (25).

In the late 1990's the Lysonix Company and the Mentor Corporation, the 2nd generation device manufacturers and distributors, became involved in litigation concerning patent infringement. The lawsuit lasted until late 2001 at which time the Mentor Corporation prevailed and received a judgment against Lysonix. As a direct consequence, the Lysonix Company was subsequently absorbed by the Mentor Corporation. During this litigation period, technologic advancement and continued development of the equipment and accessories was literally frozen, resulting in a complete lack of response to clinical and market needs.

As a consequence of the Topaz article, the Lysonix/Mentor litigation, the generally less-than successful clinical success, and clearly visible feuding between the European progenitors of the UAL technique and the plastic surgery leadership in the United States, ultrasonic instrumentation for body contouring surgery began to fall into disfavor as a technique of choice for body contouring surgery. Analysis of this process showed that cost of the equipment, a long learning curve, manufacturer marketing without sufficient clinical and fundamental science, improper application techniques, larger incisions, longer surgical times, and conflicting results presented at major plastic surgery meetings resulted in confusion and disappointment in the surgical community worldwide.

A number of surgeons continued to use the ultrasonic instrumentation safely and effectively (26,27,28,29). Their evolving technique allowed them to get effective results without the complications noted at the introduction of the technology. Further, use of the ultrasonic devices was safely expanded to the face and breast (30,31).

In early 2001 a third generation of ultrasonic instrumentation for body contouring surgery became available. This technology was named VASER, for Vibration Amplification of Sound Energy at Resonance. The VASER technology and associated technique (Sound Surgical Technologies, Lafayette, CO), called VAL for VASER-Assisted Lipoplasty, was designed to minimize or eliminate known complications from earlier generations of UAL technology and to simultaneously realize the benefits of ultrasonic instrumentation as established in other surgical arenas. The guiding concept was to develop instrumentation

that would emulsify fatty tissue quickly and safely with the absolute minimum amount of energy, thereby achieving the desired result with little or no residual trauma to the remaining tissues. VASER instrumentation introduced the concepts of pulsed delivery of ultrasonic energy, small-diameter solid probes (2.2 millimeter to 3.7 millimeter), and grooved probe designs to increase efficiency. Gentle emulsion cannulae for the aspiration phase were introduced to preserve the delicate structure of the tissue matrix after the emulsion process was completed.

In 1999 and 2001 Cimino (8,32) published the first scientific studies that defined the amount of power delivered to the tissues by various ultrasonic surgical devices and clearly defined the variables under the control of the surgeon that determine safety and outcomes. This basic scientific information led to clearly understood relationships between 'causes' and 'effects' when using ultrasonic surgical instrumentation for body sculpting surgery. As a direct consequence, the suction aspect of ultrasonic instrumentation was eliminated (hollow ultrasonic cannulae) and replaced by solid probe designs, probe diameters were significantly reduced, efficiency was improved, and pulsed energy delivery was introduced, all of which significantly reduced the energy delivered to the patient. A pilot clinical (33) study on 77 patients using the VASER and the VAL technique (multi-center) showed zero complications and effective results.

At the time of this writing (early 2003) the use of ultrasonic energy for body sculpting surgery is in a transitional phase. Earlier 1st and 2nd generation technologies are exiting the marketplace and newer 3rd generation technology/techniques are being investigated and slowly introduced to the surgical community. Further research and clinical investigation will determine whether or not continued advancements will result in technology and techniques that will present the patient and the surgeon with a more 'fat specific' method for lipoplasty that, in the end, produces safer and more desirable aesthetic outcomes.

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