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Procedures-Surgical**

Systematic Review of Ultrasound-Assisted Lipoplasty

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New Interventional Procedures – Surgical**

The Royal Australasian College of Surgeons

Systematic review of ultrasound-assisted lipoplasty

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Safety and Efficacy Classification for Ultrasound-Assisted Lipoplasty

The ASERNIP-S Procedure Classifications were revised in August 1999 by the ASERNIP-S Management Committee. As such, each of the four procedures already assessed by ASERNIP-S was allocated a new classification from the following list:

1. Safety and efficacy is established. Procedure is equal to, or better than the nominated gold standard. Procedure may be introduced into practice.
2. The safety and efficacy of the procedure cannot be determined due to an incomplete and/or poor quality evidence-base. One of the following recommendations is made:
 - 2.1 An audit is required.
 - 2.2 A Controlled Clinical Trial, preferably prospective with concurrent controls, is required.
 - 2.3 A Randomised Controlled Clinical Trial is required.
3. Safety and efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

The new classification for Ultrasound-Assisted Lipoplasty is 2.1. *An audit is required to assess both safety and efficacy.*

The ASERNIP-S Ultrasound-assisted Lipoplasty Review Group recommends that ultrasound-assisted lipoplasty should not be performed to contour female breast tissue.

References to previous classifications remain unchanged in the document.

Important Note: The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.

The Systematic Review of Ultrasound-assisted Lipoplasty,
Recommendations and Safety and Efficacy Classification were
ratified by the ASERNIP-S Management Committee:

ASERNIP-S Management Committee Meeting
August 8th 1999

The Council of the Royal Australasian College of Surgeons
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ASERNIP/S



**Australian Safety
and Efficacy
Register of New
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Review Protocol

Ultrasound-Assisted Lipoplasty

March 1999

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1. Objectives

To review the literature comparing traditional techniques of liposuction with ultrasound-assisted lipoplasty (UAL) to establish the best evidence for recommendations on the safety and efficacy of UAL.

2. Background

The development of traditional liposuction two decades ago provided plastic surgeons with a technique to remove localised areas of fat with small suction cannulae introduced through small incisions¹. This “dry” technique of fat removal has been largely replaced with a “wet” technique (also called tumescent) which involves the preparatory infiltration of fluids to help disperse the fat and thereby assist its removal. The tumescent approach allowed larger volume liposuction with reduced blood loss². Traditional liposuction has a low complication rate and a high patient satisfaction rate.

The concept of UAL involves the ultrasonic liquefaction of fat by cellular fragmentation³. A fatty emulsion is then extracted by low-vacuum suction. Proponents of UAL claim that it provides a more selective destruction of larger volumes of adipose tissue than traditional methods, it is less physically demanding for the surgeon, with minimal blood loss and little bruising for the patient⁴. Ultrasound-assisted lipoplasty also removes denser fibrous tissue and breast parenchyma than traditional liposuction⁵.

However, in addition to the equipment being more expensive, UAL has a different thermal effect on tissues, takes longer to perform, has the potential for oil emulsion retention, as well as having a longer learning curve^{6,7}. It is therefore necessary to determine the safety and efficacy of this new liposuction technique.

3. Inclusion Criteria for considering studies for this review

a. Types of participants:

Adult patients in any case setting described as having excess deposits of undesirable subcutaneous tissue were included. As the assessment of “excess and undesirable” may differ between trials, it was not possible to apply a standard definition to any study population.

If patients were recruited with deposits of subcutaneous tissue from a metabolic, pharmacological or known pathological condition, then they were included only if the results for patients with localised subcutaneous tissue collections were presented separately.

b. Types of intervention:

Ultrasound-assisted lipoplasty

Suction-assisted lipoplasty

c. Types of outcome measures:

Primary outcomes:

Independent measures of contour improvement

Surgical complications

Duration of operation

Blood loss

Patient recovery

Surgeon fatigue

Secondary outcomes:

Costs

Pain

Reliability and acceptability

Quality of life

4. Study Design

Types of studies:

Trials were included if the allocation of patients was described as randomised. Controlled clinical trials and case reports were considered only in the absence of randomised controlled trials.

There was no restriction on date of publication. Initially only studies published in the English language were included. Otherwise, references were only excluded if they did not meet the inclusion criteria.

Search strategy for identification of any existing reviews:

The trials register of the Cochrane Collaboration was searched for randomised trials of ultrasound assisted therapies. In addition, contact was made with companies who manufacture or distribute ultrasonic-assisted liposuction devices for any unpublished or ongoing studies.

Databases were searched and continually monitored to identify publications that met this study's inclusion criteria. Such databases included Medline, Embase, Current Contents and the Cochrane Library Database.

5. Literature Search Strategy for Review

Databases searched:

- SilverPlatter Medline (WinSpirs)
- Ovid Current Contents
- The Cochrane Collection (The Cochrane Library CD 1998, Issue 4)
- Lexis-Nexus Embase

Search Terms:

- Search strategies were devised by the ASERNIP-S Researcher and Protocol Surgeon.

Search terms used :

Ultrasound-Assisted Lipoplasty –

(ultraso* and (liposuction or lipoplasty or lipectomy)) and English language

Traditional Lipoplasty –

(liposuction or lipoplasty or lipectomy) and English language

NB: * is a truncation symbol, which receives variations of the indicated text.

ultraso* retrieves eg. ultrasound, ultrasonic ,ultrasonics or ultrasonically

The symbol is * (Medline), \$ (Current Contents), ! (Embase).

Results of Literature Searches: searched 8/1/99

Ultrasonic Liposuction

<i>Medline</i>	<i>1984-12/1998</i>	<i>38 references</i>
<i>Current Contents</i>	<i>1993-12/1998</i>	<i>32 references</i>
<i>Embase</i>	<i>1974-12/1998</i>	<i>27 references</i>

Traditional Liposuction

<i>Medline</i>	<i>1984-12/1998</i>	<i>877 references</i>
<i>Current Contents</i>	<i>1993-12/1998</i>	<i>376 references</i>
<i>Embase</i>	<i>1974-12/1998</i>	<i>808 references</i>

Literature Databases:

Ultrasoundlipo – 39 references formed this database in Reference Manager after exclusions of duplicates and articles that clearly did not meet the inclusion criteria.

6. Methods of the Review

Titles and abstracts of publications identified by the search strategies were assessed by the ASERNIP-S Researcher in terms of their relevance and design, according to the selection criteria. After satisfying this initial assessment, full versions of articles were obtained and checked by the Review Surgeon to identify those that fit the inclusion criteria. Using a data extraction checklist, the Review Surgeon categorised the studies to be included, and excluded those that did not meet the criteria. The Review Surgeon added additional background material if considered necessary.

7. Formulation of Recommendations of Safety and Efficacy

Based upon data from the review process, recommendations by the Review Surgeon in the form of a Draft Review were made on the safety and efficacy of ultrasound-assisted lipoplasty. The Draft Review was then disseminated amongst members of the Review Group who reviewed the document according to particular expertise. Any concerns were then discussed at the Review Group teleconference.

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Draft Review

on the Safety and Efficacy of

Ultrasound-Assisted Lipoplasty

July 1999

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Introduction

Ultrasound-assisted lipoplasty (UAL) is a relatively new surgical innovation available to Australasian surgeons. While traditional Suction-assisted lipoplasty (SAL) has been widely practised with low complication rates and high patient satisfaction levels, proponents of UAL claim it offers several advantages over traditional lipoplasty. Experience with this new technique in Europe and the United States of America has generally been positive but some reservation exists about the long-term effects of ultrasonic energy interaction with living tissue¹. Initial reports also raised concerns about high seroma rates, longer operating times, and skin burns²⁻⁴.

It is the purpose of this review to summarise existing international experience with UAL to provide a framework for recommendations on the safety and efficacy of this new liposuction technique. This will enable Australasian surgeons to make informed decisions about the procedure so that the Australasian patient population can be treated with maximal safety.

The review is prefaced with an overview of traditional SAL to place into perspective the potential advantages and disadvantages of the more novel UAL.

Overview of Suction-Assisted Lipoplasty

Suction-assisted lipoplasty (SAL) is a commonly used procedure for the removal of subcutaneous fat deposits and remodelling body contours.

The basic procedure involves a subcutaneous cannula connected to a power source, which generates sufficient suction to remove the fat without causing significant damage to neurovascular structures traversing the adipose tissue. To facilitate fat removal a number of modifications and refinements have been proposed and adopted in various ways as the technique of liposuction evolved.

Initially SAL was described as a “dry” procedure in which subcutaneous fat was mechanically avulsed with cannulae and external massage used to evacuate the fatty residue; however, this was brutal and haemorrhagic, so various “wetting” techniques became popular to prepare the fat with subcutaneous solutions.

The sharp tips of early cannulae facilitated fat removal at the expense of significant blood loss and neuropraxias from indiscriminate damage to neurovascular structures. Nowadays the cannulae for routine SAL are blunt tipped with side hole ports.

Suction-assisted lipoplasty is performed at one atmosphere of suction to minimise the risk of damage to vital structures within the fat, while still providing a sufficiently negative pressure to evacuate disrupted fat globules⁵.

Like any other surgical intervention, SAL has the potential to cause a range of complications. These may be related to:

- Anaesthesia employed
Infiltration solution - lignocaine toxicity
Intravascular fluid shifts - hypovolaemic shock

- Operator techniques
Cannula pathways
Scarring
Contour defects
Haematomas
Seromas
Skin loss
Paraesthesias, pain

- General complications
Swelling, bruising, impaired physical activity
Infection
Embolism – Thrombus
– Fat

Almost all complications of SAL can be averted if due care is given to patient selection, sensible choice of subcutaneous infiltration solution, careful operator technique, restriction of fat removal to modest volumes of tissue, and appropriate aftercare.

Suction-assisted lipoplasty has become one of the most common procedures performed for recontouring body shape. Apart from fairly predictable complications if reasonable guidelines are not followed, the procedure is safe and effective with a high rate of satisfaction.

The term “ultrasound” refers to mechanical vibrations of frequencies above the limit of human hearing, (*i.e.* above 16 kHz). Ultrasound-assisted lipoplasty involves the application of ultrasonic energy to subcutaneous adipose tissue in order to fragment the fat cells and facilitate the removal of fat as a liquefied aspirate. The fat is then removed in the same manner as SAL, so the pivotal difference between UAL and SAL is the application of ultrasonic energy. While this report will focus on techniques that deliver ultrasonic energies internally, it is possible to utilise external ultrasonic energy applied transcutaneously as a prelude to the cannula extraction of fat⁶⁻⁸.

In a surgical sense, the use of ultrasonic energy to aspirate tissue was not novel, because several other surgical applications existed. These include phacoemulsification of cataracts, ultrasonic aspiration of intra-cranial tumours, as well as applications in liver and renal surgery.

Although UAL has been performed for over a decade in Europe and South America since its introduction by Zocchi of Italy^{9,10}, only recently has it gained popularity elsewhere. Guaranteed benefits of UAL over SAL include: less injury to nerves and blood vessels, less overall tissue trauma, minimised blood loss, lesser diameter of channels formed in adipose tissue, smooth tunnels created in adipose tissue, more even shaping of overlying skin surfaces, accurate positioning of probe, and spot-specific tissue removal¹¹.

In contrast to these positive claims are the disadvantages that include: more operating room time, more expensive equipment, skin necrosis and burns, fat necrosis and fibrosis, hyper-pigmentation, sensory alteration and a longer learning curve¹².

Ultrasound-assisted lipoplasty equipment includes an ultrasonic generator that transmits electrical energy to a hand piece containing a piezo-electric crystal that converts the incoming electrical signal into a mechanical vibration at ultrasonic frequency. When the attached probe is in contact with fat, the adipocytes are lysed into an emulsion. The probe may be either a hollow cannula through which low-pressure suction can evacuate lipoaspirates, or a solid probe style that requires subsequent aspiration of emulsified fat through a separate hollow cannula, as per SAL.

After excitation by an electric field, the crystal in the hand piece produces sound waves in the ultrasonic frequency range of 20kHz to 30kHz. This sound wave energy or mechanical energy is imparted to the probe tip as a rapid piston-like action forward and backward in a longitudinal direction with cyclical displacement in the order of 100 microns.

When applied to adipose tissue these alternating waves cause compression and rarefaction that results in micro-cavities or bubbles. These bubbles can expand with each cycle until a critical diameter is reached beyond which they implode with disruption of the cell and the instantaneous generation of high levels of energy in various forms such as heat and light¹³, as well as the liberation of free radicals and other chemicals.

For more detailed accounts of the physics of ultrasonic energy using tissue fragmentation, refer to articles by Cimino and Bond^{14,15}, and the 1999 article by Zocchi¹⁶.

Safety and Efficacy of Ultrasound-Assisted Lipoplasty

General Considerations

The earliest clinical data on UAL were reports by Scheflan and Tazi¹⁷ describing their experience in 800 patients, and Kloehn's¹⁸ commentary on over 600 patients. Scheflan and Tazi reported 4% fat necrosis and fibrosis, 6% sensory alteration (which they speculated might result from sensory nerve damage by ultrasound), 4% skin necrosis and 4% skin pigmentation. Kloehn's complication rate was less than 3%, with the most common problem being surface irregularities and asymmetries. Thermal and friction burns at incisional sites were also recorded prior to the use of a skin protector.

More recently, comparative studies of UAL and SAL led Fodor and Watson¹², and Igra and Satur¹⁹, to conclude that no benefit could be attributed to UAL.

In contrast, however, Kenkel *et al*²⁰, used a porcine model to compare the tissue effect of SAL and UAL and concluded that UAL treatments generated more lipid aspirate per haemoglobin lost, and better preservation of vascular structures.

Some enthusiastic supporters of UAL report their large clinical experiences with few complications and strongly endorse the safety and efficacy of this technique²¹⁻²³. Most however caution that there is a learning curve associated with the procedure and that proper hands-on instructional courses are essential²¹.

These considerations bear particular relevance to large volume lipoplasties (*i.e.* > 5 litre lipoaspirates) for which significant preoperative and postoperative attention to detail is required to avoid problems²⁴.

Subcutaneous Wetting Solutions

One of the major changes in liposuction over the past few years has been in the preparation of the fat layer with various solutions. The history of subcutaneous infiltrations preparatory to liposuction is well covered in an historical overview by Bussien and Maillard²⁵, who document the main contributors and define their individual formulae. It is appropriate to consider these solutions carefully, because SAL is more effective if the adipose tissue is infiltrated to tumescence, and perhaps more importantly, UAL's effectiveness is critical to such an environment. From a safety and efficacy perspective, the solutions to be infiltrated are of prime importance in the light of a recent report by Rao *et al*²⁶ on liposuction deaths related to these infusions.

Enthusiastic proponents of large volume fat removals have used increasingly large volumes of wetting solutions, and as the volume of lipoaspirate has steadily increased in day surgery lipoplasties, so too has the amount of lignocaine and adrenaline. To clarify nomenclature of wetting solutions, Fodor²⁷ has delineated the following terms:

- The wet technique
- The superwet technique
- The tumescent technique

The “wet” approach is when 200 - 300 cc of isotonic solution, usually containing adrenaline in low dose, is infused subcutaneously into each site regardless of the volume of aspirate.

In the “superwet” technique, the volume of wetting solution equals the proposed aspirate volume; the isotonic infusate (*e.g.* Ringer’s lactate) contains low dose adrenaline (*e.g.* 1:1,000,000 to 1:2,000,000). As this type of liposuction is usually performed under general anaesthesia, local anaesthetic is not included in the infusate.

The “tumescent” technique uses the wetting solution as the primary mode of anaesthesia by the addition of large amounts of lignocaine. Tissue turgor is used as the endpoint of subcutaneous infiltration, which may lead to volumes of infusate far in excess of the volume of aspirate.

Proponents of the tumescent technique advocate that the mechanical and pharmacological properties of this subcutaneously injected fluid prevent the massive shifts of intravascular fluids usually seen in liposuction under general anaesthesia. With tumescence under local anaesthesia, only small amounts of IV fluid may be advisable²⁸.

Care must be taken to recognise that the fluid and lignocaine load of the tumescent technique can be dangerously large, particularly when combined with sedative anaesthetic agents (*e.g.* midazolam) that are degraded by the same saturable system of hepatic metabolism as lignocaine. Once saturation occurs, lignocaine levels rise sharply because absorption exceeds elimination²⁶. Signs of lignocaine toxicity may be masked by the concomitantly administered neurolepts.

However, large doses of lignocaine under local anaesthesia have been used in tumescent anaesthesia without signs of toxicity. This may be explained by fat partitioning of the lignocaine and its subsequent removal in the lipoaspirate²⁹. Caution is advised in the extrapolation of this data to the routine clinical situation, because lignocaine levels may reach peak plasma levels several hours after infusion²⁶.

For patient safety in all types of lipoplasty, and particularly UAL, which is usually performed with tumescent techniques, the composition and volume of subcutaneous wetting solutions should be based on good evidence as per the recommendations of Bussien and Maillard²⁵ (see over page).

In choosing an appropriate tumescent formula, there are several controversial options:

- Isotonic or hypotonic,
- Normal saline or lactated Ringer's solution,
- The doses of lignocaine, adrenaline and bicarbonate, and
- The temperature of the fluid to be infiltrated²⁵.

Surprisingly, large volumes of solution containing high concentrations of lignocaine have been infiltrated rapidly with peristaltic pumps. Although a slow infusion of 35 mg/kg of lignocaine has been accepted as safe, (even though this far exceeds the recommended maximum of 7 mg/kg for lignocaine administered with adrenaline), dermatologic surgeons have reported safety with 55mg/kg with one report allegedly demonstrating "safety" using 70-90 mg/kg³⁰!

After careful consideration of these variables, and based upon a three-year experience with ultrasonic liposuction, Bussien and Maillard²⁵ make the following recommendations:

- Lactated Ringer's solution be used as the subcutaneous infiltration solution because it mirrors the composition of the interstitial compartment.
- Lignocaine be used as the standard local anaesthetic at a maximum dose of 35 mg/kg if infused over 45 minutes into the subcutaneous fat.
- Adrenaline 0.5 mg/l to 1.0 mg/l be used for vasoconstriction to retain the lignocaine and the adrenaline at the site of infiltration.
- Sodium bicarbonate 8.4%: 5 mEq/l be used to adjust the solution's pH to the pKa (pH 7.9) of lignocaine.
- Room temperature infusions are preferred.

Fluid Resuscitation Guidelines

From an analysis of 53 consecutive patients undergoing liposuction, Trott *et al*³¹ suggest the following guidelines for fluid resuscitation:

Small volume liposuctions (< 4 litre aspirates)

Give IV maintenance fluid plus subcutaneous wetting solution.

Large volume liposuctions (> 4 litre aspirates)

Give IV maintenance fluid plus additional 0.25 cc of crystalloid per cc of aspirate removed after 4 litres plus subcutaneous wetting solution.

Other authors^{28,32} however, caution against embarking on major fluid replacements without due regard for the type of anaesthetic used.

Ultrasound Related Issues

The precise mechanism in which ultrasonic energy interacts with living tissue is only partially understood. It is this incompleteness in our understanding that underpins the reticence of some clinicians to fully embrace this technology¹.

It is known that the interaction of ultrasound with human tissues *in vivo* produces three different effects:

- i. Thermal
- ii. Cavitation
- iii. Direct tissue interactions

While there are numerous medical uses of ultrasound, the desired and undesired effects are determined by such variables as:

- Frequency,
- Power intensity,
- Peak amplitude,
- Duration of exposure, and
- Whether it is delivered as a pulse or in a continuous fashion.

For example, in tumour ablative therapy, an externally focused ultrasonic beam (frequency: = 1 MHz, power 0.5 – 3 W/cm²) uses the thermal effects to cause spot-specific tissue heating. In contrast, ultrasonic diagnostic imaging (frequency: 1 - 10 MHz, power < 0.05 W/cm²) relies on the absorption and scattering differences at tissue boundaries to generate images. Ultrasound-assisted lipoplasty (frequency: 20 - 50 kHz, power 10 – 300 W/cm²) has the cavitation effect as its principal mode of action¹¹.

i. Thermal Effects

Absorption of ultrasound in human tissue depends on the molecular composition of that tissue, with the absorption coefficient increasing as a function of protein content. For water and body fluids, there is little absorption in acoustic conditions so there is little risk of heating³³. Tumescence conditions for ultrasonic liposuction create an essentially fluid medium allowing for little absorption and theoretically little heat gain, but the extent of ultrasound-induced tissue heating depends on the balance of heat gain and heat loss.

Vascularity and tissue composition determine heat loss rate, and as perfusion is poor in fatty tissue, heat dissipation may be limited and the net effect may be tissue overheating. Tissues with higher collagen composition have higher acoustic absorption coefficients and as liposuction is usually performed within areas of adiposity bounded by skin and fascia, care must be exercised to avoid “end hits” of the ultrasonic probe against these structures to avert thermal damage.

In response to concerns of heat-related problems and following reports of burns and ischaemic skin injuries in the literature, Ablaza *et al*³⁴ investigated whether significant temperature elevations occurred in the clinical setting. Using subcutaneous transducers, they measured temperatures in the area of liposuction; before infusing tumescent fluid, after tumescent fluid infusion, and at five-minute intervals until the UAL was completed.

Although subcutaneous temperatures did rise with the application of ultrasonic energy, the average subcutaneous temperatures remained below the core temperature at all time intervals.

The recommendations from that study were:

- i. Room temperature tumescent fluid enhances the thermal safety zone without lowering core body temperature.
- ii. Although heat is a natural by-product of the energy transfer involved in UAL, the risk of thermal injury is negligible when experienced operators (*i.e.* qualified surgeons who have successfully completed a training course in UAL) perform the procedure. Ablaza *et al*³⁴, interpret the previously reported ischaemic skin injuries to be the result of damage to the subdermal plexus, rather than a thermal injury. They caution that a complete understanding of UAL techniques with strict adherence to the basic principles of flap vascularity should ensure safe and effective UAL performance.

ii. Cavitation Effects

Cavitation is the generation, growth and collapse of bubbles in a sound field. During the pressure phases of a sound wave, stable bubbles of dissolved gas in living tissues will grow and shrink due to the cycles of compression and decompression; this is termed “stable cavitation”. If the pressure changes between cycles of compression and decompression are sufficiently large, gas pockets form within the tissues, and contract within the sound field, and shearing forces can fragment the cells^{11,35}.

A more violent form of cavitation, called “transient cavitation”, occurs when higher acoustic energies cause the gas bubbles to collapse during the compression phase of vibration. This sudden, violent collapse of the gas bubbles generates locally intense shock waves with the release of dramatic amounts of heat and pressure¹¹.

The mechanism of cavitation and other non-thermal effects are poorly understood, as all forms of cavitation have only been studied in simple liquids and cell suspensions. These are not truly representative of living tissues that are linked via cellular structures to form a more complex structure, which in turn may be susceptible to greater damage than a single cell. The paucity of *in vivo* toxicity work means little information is available about the effects of cavitation in human tissue. However, cavitation effects can result in sufficient energy to disrupt chemical bonds and produce chemically reactive free radicals with the potential to interfere with DNA and thereby lead to chromosomal damage. Although this has never been observed in either patients or laboratory animals, several studies have been undertaken in cell culture experiments where cells are isolated from the effect of surrounding tissue, so that thermal effects are less likely than cavitation effects.

The potential carcinogenic potency of chemically active free radicals has to be considered whenever cavitation occurs within cells³³. Genetic effects include chromosomal aberrations as well as point mutations and sister chromatid exchanges (SCEs). Although chromosomal aberrations and point mutations are clinically adverse, the significance of SCEs is not clear. Liebeskind *et al*³⁶ attested that ultrasound of diagnostic intensities can affect the DNA of animal cells. *In vitro* acoustic shock studies on mammalian cells with the generation of inertial cavitation have demonstrated the production of ultraviolet light, which is known to be mutagenic. Such observations in cell lines cannot be directly extrapolated to mammalian tissue³³.

There is the potential also for the demyelination of peripheral nerves from the cavitation effects of UAL. However, a study comparing the sensory changes of SAL and UAL found no significant difference at ten weeks postoperatively³⁷.

iii. Direct Tissue Interactions

In an effort to understand the physical effects of UAL on adipose tissue, Adamo *et al*³⁵ compared the results of UAL (20 kHz, 65 W delivered by solid titanium probes) and SAL by a microscopic analysis of the evacuated tissue using a small study of five patients treated by each technique. They analysed samples of the evacuated material by centrifuging samples at 300 rpm followed by an examination of the supernatant with optical and scanning electron microscopy. This facilitated an examination for signs of cellular damage, signs of cavitation, and gas micro bubbles. The SAL derived tissue was composed of fat globules in their original organised form, whereas the UAL sonicated tissue showed cells ruptured at several sites with all the intercellular junctions destroyed. No evidence of the cavitation phenomenon was noted.

While postulating that the UAL effects are produced by micro-streaming tissue movement, Adamo *et al*³⁵ suggest that a direct ultrasonic effect on tissue produces disruption of macromolecules and cellular structures and may produce accelerated chemical reactions, free radicals and chromosomal disruption.

These researchers cautiously recommended that further research was needed to clarify the end-points of sonication:

- i. It's effectiveness, and
- ii. The possibility of hazards lest we expose "the patient to a physical agent that we have not thoroughly investigated"³⁵.

Certainly when ultrasonic energy was used in the treatment of malignancies in the past, vascular complications were frequent, and occasionally massive metastases resulted. Recent evidence on the stimulation by therapeutic ultrasound of angiogenic factors, *e.g.* interleukin-8 (IL-8), basic fibroblast growth factor (bFGF) and vascular endothelial growth factor³⁸ (VEGF), suggest that ultrasonic energies can stimulate cellular activity.

When one probes more deeply into the potential effects of the violent collapse and intense heat generated during the bubble implosions, the potential for problematic interaction becomes evident. These released free radicals could cause DNA damage³⁹. However although the genotoxic effects have been demonstrated *in vitro*, the special conditions under which these effects have occurred may not be representative of a clinical situation.

Recent evidence would suggest that ultrasound could alter cell division rates and influence apoptosis. Using an 8 MHz scanner on 12 mice for 15 minutes, there was a 22% reduction in the rate of cell division in cells of the small intestine and a doubling of apoptosis when examined 4½ hours after ultrasound exposure. One hypothesis for these observations was that ultrasound might be switching on the p53 gene that helps cells recognise DNA damage; the cells may stop dividing or undergo programmed cell death⁴⁰.

In view of these observations, it seems sensible to advise against the use of UAL to contour breast tissue. Interestingly, Maillard *et al*⁵ have reported such an application for UAL but they caution that:

- i. While highly improbable, a theoretical spread of an *in situ* breast cancer may be possible, and
- ii. The long-term ultrasonic effects on fat and breast tissue have not been studied⁵.

Concerns linger about the long-term complications that may arise from UAL as a consequence of tissue exposure to;

- Sonoluminescence (conversion of sonic energy into light)¹³,
- Sonochemistry (which produces free radicals),³⁵ and
- Thermal effects¹.

Recommendations

General

Ultrasound-assisted lipoplasty is not a replacement for SAL but complements it by allowing body contouring in areas not possible with SAL⁴¹. Ultrasound-assisted lipoplasty has proven benefit in the contouring of fibrous areas and in scarred secondary liposuction cases. It also reduces surgeon fatigue and allows more thorough fat removal in the fibrous male patient²¹. As with any new surgical procedure, adequate training, experience and attention to detail are the keys to predictable success. Because of the significant differences between UAL and SAL, and the potential complications associated with UAL, special training is considered an imperative prerequisite to performing UAL safely and effectively⁴².

Training

In March 1995, the major American plastic surgery organisations formed a task force to evaluate the safety and efficacy of UAL and to develop an educational curriculum to introduce and teach this new technology. To acquire UAL “privileges” it was recommended that:

Surgeons not fully trained in UAL techniques should successfully complete a training course of didactic lectures as well as a laboratory component with cadaveric dissection. The course should cover instrumentation and a demonstration of ultrasonic equipment and techniques to ensure safety.

Technical

Specific to UAL is the recommended use of submaximal amplitude settings except in very fibrous zones, and adherence to well defined end points for the ultrasonic phase of the operation. Suggested end points include loss of resistance to cannula movement and change in aspirate colour from yellow to pink². By avoiding excessive applications of internal ultrasound energy, cavity formation and hence, seroma development should be lessened. Although some authors advocate shortened treatment times (from 15 to 20 minutes per site to 2 to 5 minutes per site) to decrease the incidence of post operative swelling and dysaesthesia, others doubt the clinical effectiveness of such a truncated exposure time².

Patient Selection

The selection of patients for any liposuction procedure should be limited to those in good health and close to their ideal weight. Furthermore, liposuction should be restricted to specific areas of excess fat that have not reduced with diet and exercise⁴³.

Informed Consent

The omnipresent medico-legal issues of informed consent and risk minimisation require that patients be given factual information on SAL and UAL, particularly if UAL is used to complement SAL. Some risks are common to both techniques, and some are unique to each technique. Preoperative information should cover the following topics⁴²;

Thermal Injury

Risks include;

- Incision site burns from friction,
- Ultrasound-induced thermal injuries,
- Dermal 'end-hits'.

Precautions to reduce risk;

- Skin protectors to overcome skin burns at incisions¹⁸,
- Adequate wetting solution,
- Cannula tip control with constant movement²¹,
- Time limitation of ultrasound energy,
- Lower amplitude settings.

Skin Necrosis

Risks include;

- Thermal or ischaemic skin loss.

Precautions to reduce risk;

- Maintaining adequately 'wet' subcutaneous environment,
- Avoidance of aggressive undermining of skin in a superficial plane.

Seromas

Risks include;

- Fat liquefaction and cavity formation.

Precautions to reduce risk;

- Thorough evacuation of fatty emulsion,
- Insertion of drains in large volume lipoplasties (> 1.5 litres),
- Conservative liposuction in areas of marked skin laxity,
- Appropriate compression garments postoperatively.

Contour Irregularities

Risks include;

- Uneven skin contours from insufficient removal,
- Grooving or tunnelling defects from over enthusiastic removal in focal superficial regions,
- Skin laxity.

Precautions to reduce risk;

- Accurate markings preoperatively,
- Adequate wetting solutions,
- Attention to liposculpting technique,
- Avoidance of aggressive superficial treatment.

Infiltration Solution Related Problems

Risks include;

- Hypovolaemia,
- Fluid overload,
- Lignocaine toxicity,
- Adrenaline overdose,
- Electrolyte imbalances,
- Hypothermia,
- Death from combinations of the above risks.

Precautions to reduce risk;

- Sensible lipoaspirate volumes to limit lignocaine infused subcutaneously to 35mg/kg,
- Physiological solutions,
- Sodium bicarbonate to bring solution's pH to the pKa of lignocaine,
- Adrenaline limited to ≤ 0.5 to 1 mg/litre,
- Room temperature solutions³⁴,
- Safe fluid resuscitation³¹.

Nerve Damage

Risks include;

- Hypoaesthesias,
- Dysaesthesias.

Precautions to reduce risk;

- Restricting UAL energy application times,
- Avoid prolonged superficial treatments,
- Advise patients that by 10 weeks 90% of liposuction patients will have normal sensation³⁷.

Ultrasound-Induced Biological Effects

Risks include;

- Potential chromosomal damage from DNA disruptions,
- Carcinogenic potential of chemically active free radicals,
- Altered cell division,
- Architectural distortions of breast tissue impeding breast cancer screening.

Precautions to reduce risk;

- Avoid prolonged exposures to ultrasonic energy in one location,
- Use UAL only as an adjunct to SAL,
- Exclude pregnancy,
- Avoid female breast recontouring with UAL.

It is theoretically possible that cavitation activity in adipose tissue may generate free radicals and other reactive molecules that could interact with DNA to produce an endotoxic effect. Some consider this risk to be negligible because the adipocytes would need to:

- Survive the cavitation pressures and heat,
- Avoid being removed by aspiration, and
- Be stimulated to undergo replication, even though adipocytes are considered to be terminally differentiated cells¹¹.

A liposuction site however, is not composed solely of adipocytes. Moreover, some tissues such as glandular tissue have a high propensity for cellular replication and for this reason UAL would be best avoided for breast contouring.

Anaesthetic Related Problems

Risks include;

- General anaesthetic, regional anaesthetic, neurolept anaesthetic, local anaesthetic.
- Pressure points and neuropraxias.

Precautions to reduce risk;

- Attendance of a specialist anaesthetist with experience in anaesthesia for liposuction patients,
- Appropriate monitoring and resuscitation equipment,
- Formal agreements between day surgeries and major centres for transfer in case of emergency,
- Thorough understanding of the fluid shifts with various types of anaesthesia²⁸,
- Appropriate patient positioning⁴⁴.

Bruising and Postoperative Pain

Risks include;

- Significant bruising and pain,
- Long term skin staining by haemosiderin.

Precautions to reduce risk;

- Careful evacuation of liposuction sites,.
- Compressive garments applied at end of procedure.
- If anatomically feasible, analgesia with regional blocks incorporating long acting local anaesthetics, taking due care with the cardiotoxicity of local anaesthetics like bupivacaine.
- Adequate regular oral analgesia.

Skin Scarring

Risks include;

- Longer incisions for UAL (compared to SAL) to accommodate skin protector.

Precautions to reduce risk;

- Judicious placement of incisions,
- Meticulous skin closure and scar management.

Documentation

In addition to preoperative and postoperative photographs, clinical examination data and operative details should be recorded accurately with worksheets such as those prepared for the Lipoplasty Effectiveness And Patient Safety (LEAPS) study being conducted by the American Society of Plastic and Reconstructive Surgeons Plastic Surgery Education Foundation (ASPRS/PSEF) in the USA⁴⁵. Documentation of intraoperative fluid loss from each anatomical zone by analysing the lipoaspirates has also been suggested to gauge blood loss²⁹.

Conclusion

In conclusion, the technical aspects of UAL can be carried out safely if certain fundamental principles are observed⁴⁶;

- Appropriate patient selection,
- Appropriate anatomical sites,
- Attention to operative technique,
- Careful selection of infiltrating solutions,
- Adequate fluid management,
- Good patient monitoring and documentation,
- Postoperative compression garments.

Caution

While UAL appears to be a *technically* safe and efficacious procedure, there remains the persisting doubt about potential hazards long term, as a result of the high-energy interactions with tissue¹. This is particularly so for female breast contouring.

Future Research

Future *in vivo* studies could be undertaken on a transgenic animal model that has a high propensity to develop chromosomal aberrations in response to exogenous factors. Exposure to UAL level energies could be followed by an analysis of any chromosomal alterations to determine whether the UAL treated group had more DNA damage when compared with animals in a control group not exposed to UAL. This type of animal model^{47,48} is currently available and is central to an ongoing study to elucidate the *in vivo* effects of mobile phone signals. The importance of undertaking such a study is underpinned by the uncertainty of the significance of the ultrasonic tissue effects, particularly at the levels delivered to human tissue with UAL.

Procedure Classification

ASERNIP-S allocates each procedure a classification from the following list:

- I. Safety and efficacy is established. Procedure may be used.
- II. The procedure is sufficiently close to a procedure of established safety and efficacy to give no reasonable grounds for questioning the safety and efficacy. The procedure may be used subject to continuing audit.
- III. Safety and efficacy of the procedure is not yet established. The procedure requires further evaluation and may be used only as part of systematic research; comprising either an observational study or a controlled clinical trial.
- IV. Safety and/or efficacy of the procedure is shown to be unsatisfactory. Procedure should not be used.

The assigned ASERNIP-S classification for Ultrasound-assisted Lipoplasty is II.

Review Group Comments

The ASERNIP-S Ultrasound-assisted Lipoplasty Review Group recommends that ultrasound-assisted lipoplasty should not be performed to contour female breast tissue.

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METHODOLOGICAL ASSESSMENT REPORT

ULTRASOUND-ASSISTED LIPOPLASTY

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Introduction

Closed liposuction began in the late 1970's and since then, modifications have been made to the original idea. A significant improvement was the use of tumescent infiltration of the treatment areas prior to liposuction¹. In the early 1990's, Zocchi described the use of ultrasonic energy for the destruction of adipose tissue². The technique is thought to be based on the phenomenon of 'cavitation' whereby ultrasound energy causes vapour bubbles in liquid to implode, thereby disrupting tissues³. Cavitation acts on the fluid in fat cells and if used correctly is thought not to effect vascular, nerve or connective tissue components.

Ultrasonic energy must be applied in a 'wet' environment⁴. The tumescent technique has surpassed the earlier techniques of 'dry' (no infiltrating fluid), 'wet' (a few hundred millilitres of normal saline and lignocaine) and 'super wet' (larger volumes of infiltrating fluid)³. The tumescent technique utilises large volumes of infusate (> one volume wetting solution: one volume aspirate) to pressurise the tissues and is used both with suction-assisted lipoplasty (SAL) and ultrasound-assisted lipoplasty (UAL). This solution is aimed at being osmotically similar to that of the interstitial compartment, and commonly Lactated Ringer's solution is used. Bicarbonate is added as a buffer. Lignocaine is added as a local anaesthetic to a maximal dose of 35 mg/kg infused as a dilute solution over 45 minutes (care must be taken to avoid toxicity). Adrenaline can also be added to cause vasoconstriction, retain the anaesthetic at the site of infiltration and purportedly, to reduce bleeding⁵.

In ultrasonic lipoplasty a tumescent solution is infused, and following ultrasound treatment the liquefied fat is evacuated by suction. The proposed advantages of this technique include reduced trauma and blood loss, allowing massive fat removal in obese patients. It was recognised early that there was a steep learning curve for use of this technique².

Safety Issues

Potential complications of SAL include adverse effects on intravascular fluid volume (including hypotension and hypovolaemic shock), coagulation (including pulmonary embolism and thrombosis), nerves and nerve conduction, and circulation to skin; excessive blood loss, haematoma or seroma and infection. In the tumescent technique there is a risk of systemic lignocaine toxicity. Other risks include those to operating theatre personnel, who may be exposed to infectious or chemical contaminant aerosols.

The biological effects associated with the generation of ultrasonic energy are thought to be exerted by thermal mechanisms, which cause localised heating. Alternatively non-thermal mechanisms such as cavitation result in intense heat production and generation of free radicals and other chemically reactive species, which potentially can cause genotoxic effects in cells adjacent to those destroyed by the cavitation. Evidence of these has been found in cell lines *in vivo* under specialised conditions^{6,7}. However, there are no validated models for predicting whether such cavitation effects are likely in human tissues⁸. Bond and Cimino⁹ found no evidence of cavitation in fresh pig tissue exposed to ultrasound energy.

Ultrasound aspiration devices have been used in other surgical techniques including liver resection for cancer, laparoscopic cholecystectomy, laparoscopic removal of intraperitoneal masses, laparoscopic adrenalectomy, removal of central nervous system tumours and transurethral resection of the prostate³. It is important with any surgical technique that

patients are aware of all potential risks including theoretical concerns regarding the long-term effects of ultrasonic energy exposure¹⁰.

From the systematic searches defined in the protocol for the review of ultrasound-assisted lipoplasty the studies have been stratified based on their level of evidence (see pages 7 - 8).

Hierarchy of evidence – NH&MRC

- I Evidence obtained from a systematic review of all relevant randomised controlled trials.
- II Evidence obtained from at least one properly designed randomised controlled trial.
- III-1 Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
- III-2 Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
- III-3 Evidence obtained from comparative studies with historical control, two or more single arm studies or interrupted time series without a parallel control group.
- IV Evidence obtained from case series, either post-test or pre-test and post-test.

Two studies^{16,25} have been added to those originally obtained, by searching Current Contents from Week 1 to 28, 1999, to update the previous searches. The most common complication that arose in the tabulated studies included thermal entry site burns¹¹⁻¹³ which should be avoidable if appropriate care is taken, seromas^{4,13,14}, Reston foam (placed between treated area and overlying compressive garment) blisters^{4,14} and temporary neuropraxia¹¹. No deaths were reported in this series, however there are literature reports of a small number of cases of death with SAL¹⁵ where lignocaine toxicity or lignocaine-related drug reactions were thought to play a part. With the UAL procedure three deaths were reported from different countries⁵, with one death due to an inappropriately high dose of lignocaine having been administered.

Assessment Table

Ref #	Year	Authors	Study Location	Study Type	Study Level	Procedure	Equipment Type	Time of ultrasound application	Sample Size	Statistics used	Follow-up	Adverse Outcomes/ Comments on Safety	Comments on efficacy
11	1997	Igra H; Satur NM	CA, USA	RCT: (randomisation of treatment site: computer generated); blinded non-operating surgeon	II	UAL vs SAL	Morwell Ultra-style Ultrasonic Aspirator system, irrigated cannula	Not stated	28 (25F)	Paired student t-test(volume fat), non-parametric sign test (physician/patient rating)	Day 2-4; 1 week; 1, 3, 6 months	3.6% temp. neuopraxia, 3.6% thermal entry injury; physician/patient ratings mostly nsd (UAL:SAL).	Easier cannula motion for operating physician (UAL); nsd volume fat removed (UAL:SAL).
17	1997	Cook-WR Jr	CA, USA	RCT (treatment side randomised); operating physician blinded, patients not blinded	III-1	SAL +/- external US one side following infusion of tumescent solution; IM sedation (not IV sedation or GA)	External US (Rich-Mar) 2W/cm2, 1 MHz	10 - 15 min per body area	30 (25F)	Not performed	Day 2 post-op	No complications seen, external US side less bruising/swelling (18/30 cases).	External US side-easier on surgeon (21/30), less patient discomfort (16/30), aspirate looser & milky white (external US side).
20	1998	Fodor PB; Watson J	CA, USA	RCT (treatment side randomised); patients blinded	III-1	UAL vs SAL	Surgitron 3000, Sebbin, Lysonix 2000 (94 cases)	< 10 minutes per region	100 UAL(73F), 63/100; 10 patients randomly selected for independent evaluation	McNemar Chi squared test	Day 3-4, 7-10; 1-3 months longest 22mo	No complications - seromas, skin burns; UAL - less blood loss, better for fibrotic areas; post-op. ecchymosis most moderate, UAL disadvantage - longer incision, nsd postop. ecchymosis/swelling	No differences in post-op. skin retraction/contraction or sensory pigmentation changes/surface irregularities between 2 sides; UAL - post-op discomfort mostly minor, UAL - increased op. time, increased learning curve, UAL not superior to SAL.
18	1997	Havoonjian HH; Luftman DB; Menaker GM; Moy RL	CA, USA	RCT (treatment site randomised) non-blinded	III-1	SAL +/- external US one side following infusion of tumescent solution	1 MHz Rich-Mar Model X US unit	Approx. 10 min over treatment area	10	Not performed	1, 3, 7, 12 week	No intraop complications; 4/10 less swelling/bruising, 5/10 less postop. pain.	US side: 5/10 operator ease, 3/10 higher degree skin retraction, higher av. volume supernatant fat in US.
21	1997	Adamo C; Mazzocchi M; Rossi A; Scuderi N	Rome, Italy	Prospective comparative study (2 arms)	III-2	UAL vs suction lipoplasty (SAL); manual compression for fat removal	Brand not stated; 20kHz, 65W, solid probe	Not stated	10 - (5 + 5)	Not performed	Not stated	No adverse outcomes; need to assess possible hazards of US - accelerated chemical reactions, chemical changes, free radical formation, chromosome disruption.	SAL > infiltrate per unit time than UAL; UAL disruption of fat cells while SAL intact fat cells.
12	1998	Kenkel JM; Robinson JB Jr; Beran SJ; Tan J; Howard BK; Zocchi ML; Rohrich RJ	TX, USA , Torino, Italy	Animal (pig) controlled comparative study (2 arms) & non-liposuction control	III-2	UAL +/-sheath, non-liposuction control (under GA)	Mentor Contour Genesis	Not stated	8; 4 (-sheath), 3 (+sheath), 1 (non-liposuction control)	Independent t-test; repeated measures analysis of covariance	Not applicable	1 pig thermal entry site burn (12.5%); sheath requires GA; no biochemical evidence of fat, muscle, nerve damage; UAL + sheath - less Hb lost, less blood per triglyceride lost.	UAL: more lipid aspirated and better preservation of vascular structures. SAL: more aspirate per unit time; UAL sheath has protective effect.

Ref #	Year	Authors	Study Location	Study Type	Study Level	Procedure	Equipment Type	Time of ultrasound application	Sample Size	Statistics used	Follow-up	Adverse Outcomes/ Comments on Safety	Comments on efficacy
16	1999	Albin R; deCampo T*	Not stated	Controlled series (historic controls)	III-3	Large volume liposuction UAL, SAL	Lysonix 2000	Not stated	181; 31 SAL, 150 UAL	Not stated	Not stated	0.6% deep vein thrombosis, 1.1% pulmonary emboli.	Not stated
4	1996	Ablazer VJ; Gingrass MK; Perry RN; Fisher J and Maxwell GP	TN, USA	Prospective case series	IV	UAL; (50 GA, 4 epidural, 1 LA + sedation)	Medical Device Alliance Inc.	mean: 51 min (10-118 min)	55/96 temperature measured (45F)	Not stated	Day 1, 5; 2, 4, 6 week; then 3 - 9 months (mean 3.4 months)	Seroma, 12 (22%), Reston foam blister(16%), scrotal haematoma (2%); plastic sheath minimise skin burns, use UAL in 'wet' environment, minimal elevation of subcutaneous temperature, advocate use of room temperature tumescent fluid.	None
22	1996	Budo JA	Liege, Belgium	Prospective case series	IV	UAL; (45 GA, 11 LA)	Lipetron US Lancet, Medicon US liposuction device	Not stated	56 (54F)	Not performed	Not stated	Blood loss insignificant (max. 50ml), UAL less pain/haematoma, more postop. swelling.	Total op. time: 1.5hr - 2.5hr, UAL 10% longer than SAL (compared with reviews), UAL more complicated machinery, but more selective exeresis, treat difficult areas.
23	1998	Lack EB	IL, USA	Prospective case series	IV	UAL (non-water cooled cannula), post suction by SAL, IV sedation, skin protector	Not stated	Range 1 - 8 min per area	6 (4F)	Not performed	1, 4 week	Considerable morbidities - numbness, swelling, pain, seroma, necrosis, bruising (higher than that reported for SAL).	Skin retraction effects not proven, no reduction in blood loss compared with SAL (microcannula).
24	1997	Maillard GF; Scheflan M; Bussein R	Switzerland, Israel	Single case report	IV	UAL then SAL (Breast) (IV sedation)	Not stated	Not stated	1	Not performed	1, 6 week	Postop oedema, possible risk of spread of <i>in situ</i> breast cancer, aspirate little blood, no haematoma/ bruising at 1 week.	Symmetry nearly achieved at 6 weeks.
14	1998	Maxwell GP; Gingrass MK	TN, USA	Consecutive case series	IV	UAL; (94% GA; LA & Epidural)	SMEI, Sonic Sculpture, Sebbin, Surgitron Series 2000, Lysonix 2000	29 min (abdomen), 14' min (hip), 12' min (thigh)	250 (209F)	Not performed	1, 2, 4 week; 3, 6 months	Reston foam blisters (14%), seroma (11%), abdominal skin necrosis (1.2%).	Suggest final contouring with SAL; UAL learning curve.
13	1998	Rohrich RJ; Beran SJ; Kenkel JM; Adams WP Jr; DiSpaltro F	TX, USA NJ, USA	Consecutive case series	IV	3 stage technique - Infiltration, UAL, SAL	Lysonix 2000	2 - 11 minutes	114 (91F)	Not performed	Day 5; 3, 6 week; 3, 6 months	1% abdominal dysaesthesia (due to long US time), 2.6% abdominal seromas (long US & inadequate fat emulsion evacuation), 1% access site skin burn.	Aspiration rates: SAL - 58ml/min, UAL 36ml/min.

Ref #	Year	Authors	Study Location	Study Type	Study Level	Procedure	Equipment Type	Time of ultrasound application	Sample Size	Statistics used	Follow-up	Adverse Outcomes/ Comments on Safety	Comments on efficacy
19	1998	Tebbetts JB	TX, USA	Consecutive case series	IV	UAL (GA as outpatient)	Lysonix 2000, dual E & aspiration functions	1 - 6 min per side	70 (58F)	Not performed	Day 1, 2, 3; 1, 3 week; 3, 7 months	No peri/postop. Complications relating to US, no seromas, skin burns/blistering, vascular insufficiency, skin loss, neuralgia, skin pigmentation, infection, haematoma.	Reduce surgeon fatigue, no malfunction with US generator, probe replaced after 42 cases, Total UAL op. Time < traditional SAL times.
25	1999	Trott SA; Beran SJ; Kenkel JM; Adams WP Jr; Robinson JB Jr*	TX, USA	Case series	IV	UAL (3 stages)	Not stated	Not stated	21	Not stated	2, 6, 10 week	In general – SAL areas normal by 6 week, UAL by 10 week; 90% all patients normal sensation by 10 weeks.	Not stated

* Abstract only sighted; Abbreviations: RCT - randomised controlled trial, UAL - ultrasound-assisted lipoplasty, SAL - suction-assisted lipoplasty, US - ultrasound, GA - general anaesthetic, LA - local anaesthetic, IV - intravenous, F - female, nsd - no significant difference, op. – operative.

Efficacy Issues

The ultrasonic probe moves easily through tissue and thus requires less force to be applied by the surgeon compared to the standard SAL technique. It has therefore been considered safer and more efficacious due to reduced surgeon fatigue. A technique of lipoplasty entirely performed by UAL has proven to take longer than SAL, however much larger volume lipoplasties¹⁶ are possible via this technique due to the reduced blood loss. It has been suggested that UAL should be used to complement SAL and not necessarily to replace it.

In the tabulated studies, reduced surgeon fatigue¹⁷⁻¹⁹ is noted for the UAL procedure, however generally increased operating times^{20,22}, slower aspiration rates^{12,13} and the increased learning curve^{14,20}, were noted. Ultrasound-assisted lipoplasty has been reported to be useful in areas difficult to treat and in fibrotic tissue^{20,22}.

Conclusions

Despite the fact that four of the tabulated studies were randomised controlled trials^{11,17,18,20}, they were of poor quality. In two studies only, the assessing physician/surgeon was blinded and in one only, the patients were blinded as to which side was treated with ultrasound. However in all cases, most measures were subjective and without blinding their worth is dubious. In two of these studies external ultrasonic energy was applied to the infiltrated treatment area^{17,18}, however no other reports of this technique are evident in the current review. In other controlled studies^{12,16,21}, small patient numbers^{12,21} or historical controls¹⁶ were used. The remaining eight studies were case series^{4,13,14,19,22,23,25} and a single case report²⁴.

It is evident that the UAL procedure requires more extensive and rigorous evaluation. The prospects of the potential damaging effects of ultrasound energy application need investigation. Given the already widespread use of UAL it is considered imperative to collect data on this procedure, particularly focusing on safety issues. A prospective multi-centre cohort study to be conducted over a six-month period, with a single treatment group is soon to begin in the United States of America. It is anticipated to enrol about 2,000 patients from 40 - 50 plastic surgery practices. It may be worthwhile for ASERNIP-S to consider coordinating selected Australian surgeons who are performing ultrasound-assisted lipoplasty for participation in this study²⁶.

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