The use of ultrasound for cosmetic fat reduction

Basic Terminology

liposuction (also referred as liposculpture, lipoplasty or suction-assisted lipectomy) – Removal of fat via a cannula using an applied vacuum. The procedure involves e. g. ultrasound (internal or external), water jets or Laser.

lipolysis – Metabolic degradation of lipids. In the context of cosmetic surgery often synonymous with liposuction.

HIFU – High Intensity Focused Ultrasound is a therapeutic ultrasound modality using focused ultrasound to apply high intensities to the human body, through the skin, to heat and destroy tissue (e. g. cancerous tissue) in a well-defined region.

Introduction

Many people are overweight and are trying more or less successfully to reduce their weight by various methods. A drastic method for achieving this aim consists of the use of surgical procedures [1]. More and more patients are seeking minimally invasive body sculpting treatments to improve health and body image. Body sculpting is one of the fastest-growing areas in cosmetic dermatology. The American Society of Dermatological Surgery published data showing that in the U.S.A. in 2014 more than 207,000 procedures were performed. This was an increase of 16 % over 2013, and 53 % over 2012. Tumescent liposuction (which infiltrates a local anaesthetic) is currently the standard of care [2]. Cryolipolysis, Radio Frequency or LASER-assisted lipolysis [3], and also ultrasound-assisted lipolysis (UAL) are becoming increasingly important. The ultrasonic procedures can be divided into invasive (internal ultrasound) and non-invasive (external ultrasound) methods. The latter include physiotherapeutic ultrasound, HIFU and also, more recently, shock waves.

Satisfactory assessment of the methods in use concerning the ultrasonic safety has so far failed, in particular because (i) the effects and side effects have not yet been adequately investigated; (ii) too few reliable independent studies have been carried out; and last but not least, (iii) the manufacturers are very reluctant to release the acoustic output parameters of their devices.

In this tutorial the ultrasonic procedures of fat reduction will be described briefly and some aspects of ultrasound safety will be considered.

Technical Aspects

Internal Ultrasound

Internal ultrasound-assisted liposuction (iUAL) is designed to work in conjunction with traditional tumescent liposuction. In this method a saline solution, which also contains specific pharmaceutical additives, is infiltrated into the fatty tissue, and is subsequently removed using appropriate cannulae of different sizes and shapes. The resulting mixture is then aspirated using a vacuum pump. The use of wetting solutions diminishes blood loss, enhances patient comfort, and improves the safety profile of the procedure [4].

In the case of iUAL the cannula used is part of an ultrasound system (Fig. 1), which oscillates at 20-30 kHz [5]. An emulsion of the fat with the wetting liquid caused by cavitation and direct mechanical mechanisms is produced by the application of ultrasound, [6].

Data published on the acoustic output parameters of the devices in use are extremely sparse. Jewell et al. [7] quote a maximum

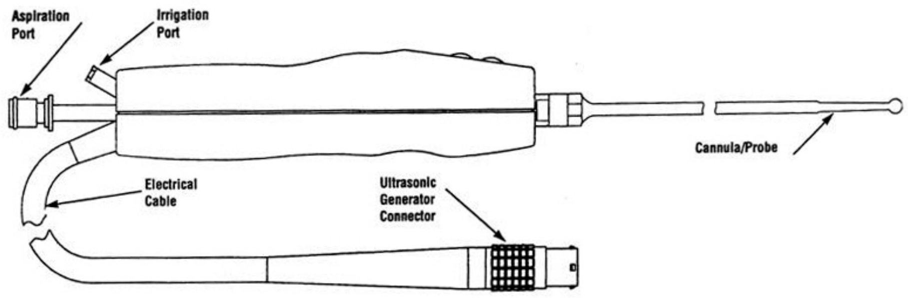

Fig. 1: iUAL Handpiece (Mentor Corp., Santa Barabara, USA)

acoustic power of 13 W cw, corresponding to a maximum energy density of 175 mJ/mm³ and a maximum amplitude of the cannula of 100 µm, respectively for the VASER system of Sound Surgical Technologies LLC (Louisville, USA)

External Ultrasound

For the external method of ultrasonic liposuction the fat tissue is treated through intact skin. The methods are referred to as being "non-invasive" and the amount of fat extracted is only moderate. The focus of the process is more on body sculpting than on the quantitative fat removal. Different ultrasound modalities are used.

Low-intensity, low-frequency ultrasound

In this method, frequencies between 100 kHz and 1 MHz are used. A focused ultrasound system (Contour I, UltraShape, Israel), frequently used operates at (200 ± 30) kHz with a maximum sound pressure of 459 kPa at the focus, and a focal depth of 15 mm, focal length 20 mm and focal diameter 8 mm, respectively [8].

Studies in gel phantoms and animal preparations have shown that thermal effects can be excluded. Based on microscopic images of ultrasonically exposed fatty tissue, it is concluded that cavitation must be the primary mechanism of the fat cell disintegration [8]. It induces significant reduction in the size of the adipocytes, the appearance of micropores and triglyceride leakage and release in the adipose tissue interstitium. Appreciable changes in microvascular, stromal, and epidermal components and in the number of apoptotic adipocytes were not found. Clinically the ultrasound treatment caused a significant reduction of abdominal fat [9].

Milanese et al. [10] reported on the application of external US at 150 kHz and 1.65 W/cm². After 10 weeks, the reduction of the layer thickness of gluteal and thigh sites was (2.03 ± 2.79) % and in the trunk and lower limb was (3.48 ± 3.97) %. Frequently, as in this example, the effects obtained are small and the measurement uncertainty is large.

Teitelbaum et al. [11] reported on the treatment of 164 volunteers (of whom 27 were in the control group). A single sonication in different areas of the body caused reductions in the circumference by about 2 cm and thickness of the fat layer around 2.9 mm, respectively.

Other results are summarized in the work of Sklar et al. [12].

Physiotherapy ultrasound

In this application non-focused ultrasound as commonly used in physiotherapy is employed, i.e., the frequencies are in the range between 1 and 3 MHz and the sound intensity is a maximum of 3 W/cm². The application is carried out by treating the areas concerned with ultrasound prior to surgery (liposuction). Generally, external ultrasound is used in conjunction with superficial subdermal liposuction.

Published results are found to be contradictory. Gasparoni et al. [14] sonicated for 10-20 minutes at 3 MHz and 3 W/cm² and as a result, they note that ultrasound improves skin retraction, reduces the skin irregularities and the "cellulitic" effect, making superficial subdermal liposuction easier and more effective. Mendes [15] found less resistance to the cannula with more rapid removal of fat and the aspirated tissue showed less blood content with intact viable fat cells. Patients report less pain and discomfort on the ultrasound-treated sides and the examiner found less swelling and bruising, with superior skin shrinkage. Clinical recovery was also enhanced by the external ultrasound. This has been confirmed by other authors [16].

On the other hand, a double-blind study of Lawrence and Cox [17] comes to the conclusion that no differences can be found between patients treated with ultrasound (1 MHz, 3 W/cm²) and control. The authors suggest that

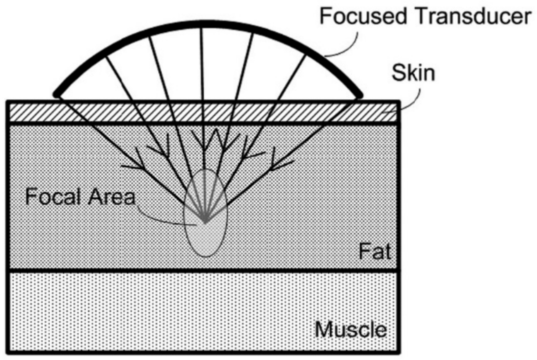

Fig. 2: HIFU beam passing through the skin and superficial tissues to fat tissue [8].

external ultrasound leads to placebo effects.

High-intensity focused ultrasound (HIFU)

More recently, HIFU has been used for body sculpting. The ultrasound exposures are similar to those used in therapeutic HIFU for other applications, such as e. g. treatment of cancer. The mechanism of action is based essentially on the temperature increase in the focal area (Fig. 2). The temperature in the adipose tissue rises rapidly above 55 °C, producing coagulative necrosis. Studies have shown that the lipids contained in adipocytes ablated by HIFU and residual cellular debris, are safely ingested by tissue macrophages. The debris does not become liberated systemically, i.e. serum lipid levels are not raised, the lipid profile altered, or diffuse inflammation induced. There are some authors who believe, on the basis of histological examination, that fat cells can be destroyed by cavitation [8]. However, these findings have not been confirmed [18]. Kyriakou et al. [19] exposed excised porcine fat to HIFU and they found inertial cavitation using passive cavitation detector only at 0.5 MHz and an acoustic pressure amplitude p_- > 1.6 MPa but not if f > 1 MHz for p_- up to 3MPa.

Frank and Saedi [20] have summarized the results of five clinical studies involving 604 volunteers. A rough estimate gives an average waist reduction of (2.9 ± 1.1) cm when treated with an ultrasound energy flux of (158 ± 16) J/cm². All tests were performed using the same ultrasonic device at 2 MHz (focus: depth 13 mm, length 10 mm, diameter 1 mm) described by Jewell et al. [3].

Jewell et al. [21] treated three groups of about 60 volunteers with 3 different energy fluxes and after 12 weeks observed the following waist circumference reductions: 1.21 cm (0 J/cm², sham control), 2.1 cm (144 J/cm²) and 2.5 (177 J/cm²), i.e. there could occur a be a not insignificant placebo effect.

Shek et al. [22] conducted HIFU treatments in 53 Asian subjects under conditions that were comparable to other studies. They found no significant changes in waist circumference. The authors conclude that there were fundamentally different chances of success in Asian and Caucasian human women.

In summary it can be said that the use of HIFU for fat reduction is a new, relatively non-invasive, method. It is primarily used on patients with BMI ≤30 kg/m², and it can be better used to treat very limited targets locally in non-obese patients than to reduce on a larger scale. A reduction in the BMI is often not achieved.

Other results are summarized by Sklar et al. [12].

Shock waves

Increasing numbers of studies about the use of shock waves in dermatology are being published. So-called radial shock waves are often used. These are generated in a pneumatic system by colliding an accelerated pin with an applicator (Fig. 3). Compressed air is used to fire a projectile within a guiding tube that strikes a metal applicator placed on the patient's skin. The projectile generates stress waves in the applicator that transmit pressure waves non-invasively into tissue. The maximum pressure amplitude may be as high as 28 MPa (Electro Medical Systems SA, Nyon, Switzerland). Császár et al. [13] studied commercial shockwave devices and measured a maximum positive pressure amplitude of ~ 10

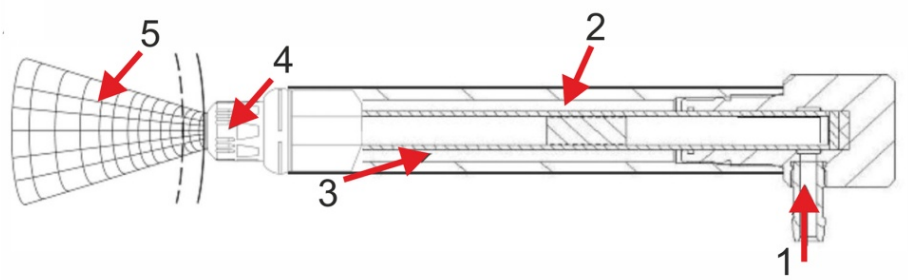

Fig. 3: Schematic representation of a radial extracorporeal shock wave therapy device [13]
(1) compressed air, (2) projectile, (3) guiding tube, (4) metal applicator, (5) shock wave field

MPa.

Apart from the destruction of fat cells the investigators sought to achieve effective and long-lasting improvement of age-related connective tissue weakness in the extremities, in particular, the treatment of cellulite is of interest [23][24].

Safety considerations

Invasive Ultrasound Procedures

The application of internal ultrasound to liposuction (iUAL) is based on a surgical procedure similar to tumescent liposuction without the use of ultrasound (SAL). It also includes specific medications (e.g. anaesthetic substances). Surgical liposuction is still considered the gold standard for sculpting the body, however, these invasive approaches come with inherent risks including hospitalization and morbidity [25]. Compared with these risks, the additional burden posed by application of ultrasound is generally assessed as low. Reported complications of iUAL have included seroma formation, contact dermatitis [26], skin pigmentation changes, reversible nerve injuries and thermal injuries to the skin. More frequent is the occurrence of contour irregularities such as skin wrinkles, dents, or failures of the skin to redrape ideally which, however, are not dissimilar to standard SAL procedures. Many of these effects seem to be technique dependent and should be minimized as surgeons gain more experience.

The mechanism as to how iUAL liquefies fat is not yet fully understood and more research is needed to provide greater clarity here. However, many researchers agree that the desired emulsification of fat requires the presence of cavitation in the tissue. The instrumentation used in iUAL uses high intensities, in close contact with the suction sonotrode. Intensities between 50 and 1000 W/cm² near the tip of the probe are assumed [27]. Consequently, chemical effects in addition to the mechanical also may occur, in particular the formation of free radicals by the generation of sonoluminescence in the collapsing cavitation bubbles [28]. Specific dosimetry for these cases does not yet exist, but is recommended [27].

The use of ultrasound in non-surgical procedures

The influence of **physio**therapeutic ultrasound when used with plane waves in liposuction is controversial, but side effects are also not expected.

The use of HIFU is described in numerous studies as being harmless. Potential slight changes are of a temporary nature. Thus, in a randomized, sham-controlled study of noninvasive sculpting of the abdomen, the 24-week safety profile of HIFU was similar to that of sham treatment [29]. The procedure was generally well tolerated for total energies of 141 J/cm² and 177 J/cm². The most common treatment-related adverse events were pain, ecchymosis, and swelling. No burns or scarring occurred, and there were no clinically meaningful changes in lipid findings or inflammation. In 2011, the first- and second-generation of HIFU devices were approved by the FDA for use on the waist with a focal depth of 1.3 cm [30].

Kiessling et al. [31] warn against the use of shock waves in pregnant women. They have performed in vivo experiments with radial extracorporeal shockwaves on chicken embryos. 3/240 showed severe congenital defects (missing eyes, missing coat or malformed pelvis).

Concluding remarks

There is, in general, a lack of basic research in the field of ultrasound assisted lipolysis. The mechanisms of fat cell destruction have not yet been sufficiently researched in detail. The vast majority of published studies come from clinical researchers in the fields of plastic or esthetic surgery whose focus naturally is on the visual treatment successes. There is a lack of controlled prospective studies which are specifically directed towards ultrasonic safety issues.

A further constraint in assessing the safety of ultrasound in lipolysis is a lack of reliable data on the ultrasonic output parameters for the equipment used. Information from authors is usually limited to imprecise manufacturer's instructions. The manufacturers themselves also publish very little quantitative and reliable output data. The devices on the market are often declared as being cosmetic rather than medical devices, and are therefore exempt from the rigorous standards in force for diagnostic ultrasound devices.

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