The use of ultrasound for cosmetic or aesthetic body shaping

Introduction

Cosmetic or aesthetic body shaping or body contouring is a rapidly growing field in cosmetic dermatology. The devices used can be invasive or non-invasive, which aim to reshape an area of the body through the removal of excess adipose tissue [1].

For invasive procedures (surgical, chemical, laser-, radiofrequency- & ultrasonic-assisted liposuction) the effect of liposuction and safety issues mainly depend on the handling experience of the surgeon [2]–[6].

Non-invasive procedures (radiofrequency-assisted lipolysis, cryolipolysis, high-intensity focused electromagnetic field (HIFEM), physiotherapeutic and high-intensity focused ultrasound) have the advantage of less trauma and faster recovery [4], [7]–[11].

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

General principles

Ultrasound devices can be classified in two categories: high- and low-intensity devices that are applied internally (invasive) or from external (non-invasive). All devices deliver sound waves across the skin to the subcutaneous fat and depending on the ultrasound energy (intensity) used either rapidly increase the temperature (high-intensity ultrasound) and induce focal coagulative necrosis [12] or generate cavitation combined with streaming (low-intensity ultrasound) in the target area. Both effects destroy the fat tissue matrix to varying degrees by dislodging the cell compartments which causes single cells or small lipocyte packets to be released into the extracellular space, triggering the innate immune response.

With non-invasive methods the loose lipid cells are slowly absorbed over the course of several weeks or more by the macrophages [13], [14], while invasive methods aspirate the fat cells mixed with the needed tumescent fluid by acoustic streaming (Fig. 1) [15]. The adipose cells themselves contain no gas, so the ultrasound energy does not cavitate adipose cells.

Some parameters like focal depth and energy output need to be adjusted based on the thickness of the patient´s skin (e.g. facial or body), which ultimately determines the treatment outcome and to balance between heating or cavitational effects. Each procedure lasts in general around 30-90 min depending on the treatment location on the body and needs to be repeated sometimes a second time after an interval of 3-4 weeks [14].

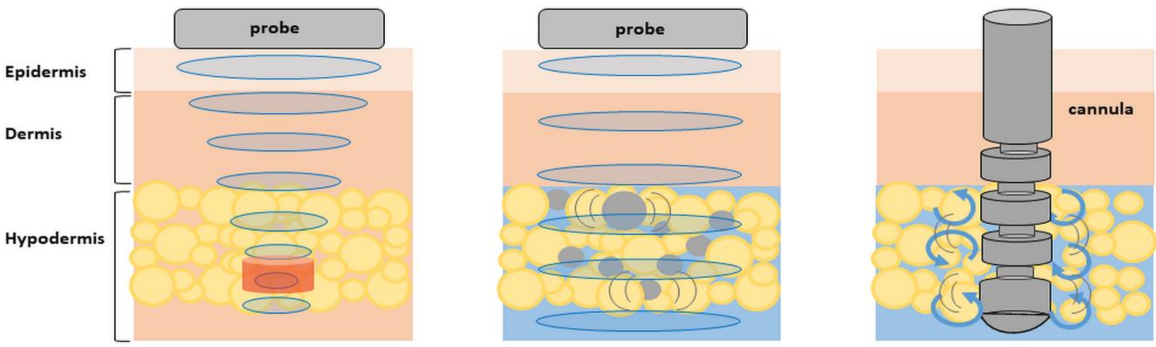

Fig.1: Mechanisms to dislocate fat tissue: from external by heating with high intensity and/or focusing (left), by cavitational effects with low-frequency (middle) o by cavitation and streaming effects using an internal cannula (right).

Invasive Ultrasound-assisted methods

Ultrasound-assisted liposuction (UAL) is designed to work in conjunction with traditional tumescent liposuction. In this method a saline solution, which also contains specific pharmaceutical additives and naturally small gas bubbles, 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 [16], [17].
In the case of UAL the cannula used is part of an ultrasound system, which oscillates at 20-30 kHz. An emulsion of the fat with the wetting liquid caused by cavitation and direct mechanical mechanisms is produced by the application of ultrasound [17].
Data published on the acoustic output parameters of the devices in use are extremely sparse. Jewell et al. [18] quote a maximum acoustic power of 13 W continuous wave, corresponding to a maximum energy density of 175 mJ/mm^3 and a maximum amplitude of the cannula of 100 µm, for the VASER system of Sound Surgical Technologies LLC (Louisville, USA).

Non-invasive Ultrasound-assisted methods

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

Low-intensity, low-frequency ultrasound

In this method, frequencies between 100 kHz and 1 MHz are used. A focused ultrasound system (e.g. 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 [19].

Studies in gel phantoms and animal preparations have shown that thermal effects can be excluded for low-intensity, low-frequency methods. Based on microscopic images of ultrasonically exposed fatty tissue, it is concluded that cavitation must be the primary mechanism of the fat cell disintegration [19]. 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 micro-vascular, 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 [20].
Milanese et al. [21] reported on the application of external US at 150 kHz and 1.65 W/cm^2. 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. [22] 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. [23] .

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. [24] sonicated for 10-20 minutes at 3 MHz and 3 W/cm^2 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 [25] found less resistance to the canulla with more rapid removal of fat and the aspirated tissue showed less blood content with intact viable fat cells. In this study patients report about 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 [26].
On the other hand, a double-blind study of Lawrence and Cox [27] comes to the conclusion that no differences can be found between patients treated with ultrasound (1 MHz, 3 W/cm^2) and control. The authors suggest that external ultrasound leads to a placebo effect.

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 small area (Fig. 1).
The temperature in the adipose tissue rises rapidly to 65-70 °C [10], 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 [19]. However, these findings have not been confirmed [28]. Kyriakou et al. [29] 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 3 MPa.
Frank and Saedi [12] 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/cm^2. 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. [30]
Jewell et al. [31] 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/cm^2, sham control), 2.1 cm (144 J/cm^2) and 2.5 (177 J/cm^2), i.e. a statistically significantly greater least squares mean change from baseline waist circumference. Shek et al. [32] 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 women.
In summary it can be said that the use of HIFU for fat reduction is a new, relatively noninvasive, method. It is primarily used on patients with BMI <30 kg/m^2, and it can be better used to treat very limited targets locally in non-obese patients than to reduce fat on a larger scale. A reduction in the BMI is often not achieved. Other results are summarized by Sklar et al. [23].

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. 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). Császär et al. [33] studied commercial shockwave devices and measured a maximum positive pressure amplitude of ~ 10 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 [33], [34].

Safety considerations

Invasive ultrasound procedures

The application of internal ultrasound to liposuction (UAL) 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). This invasive approach comes with inherent potential risks of anesthesia, intraoperative fluid balance and the technical aspects [17], [35], [36]. Reported complications of UAL

have included seroma formation, contact dermatitis [37], 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 suction-assisted lipolysis procedures. Many of these effects seem to be technique dependent and should be minimized as surgeons gain more experience.
The mechanism as to how UAL fragments fat is attributed to the generation of cavitation and its effect to dislocate the fat matrix. The newer instrumentation in UAL uses continuous mode with 11 to 13 W applied with a 3-5 mm thin cannula and an efficiency range of 155 to 175 mJ/mm^3 near the tip of the probe [18], [38].

Non-invasive ultrasound procedures

Liposuction with equipment comparable with physiotherapeutic ultrasound outcome is rare because of less satisfied results and seems not be to be continued [5], [27].
The use of HIFU is described in numerous studies as having limited and mild adverse events. 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 [39]. The procedure was generally well tolerated for total energies of 141 J/cm^2 and 177 J/cm^2. 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 [40]–[42].
Kiessling et al. [43] 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, still 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 and well-designed studies which are specifically directed towards ultrasonic safety issues [13].
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.

Basic Terminology [14], [15], [44]
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.

technical methods:
surgical – fat reduction or body contouring by using surgical procedures
chemical – introducing special fat busters into small areas of the body in combination with other methods.
radiofrequency-assisted – these devices cause skin tightening and mild fat reduction based on the principle of volumetric heating caused by the various impedances of different skin layers and denaturation of collagen fibers.
cryolipolysis – controlled cooling to specifically target areas of adipose tissue whilst preserving surrounding structures.
laser-assisted – low-level laser therapy to create temporary microscopic openings within the cell membrane of adipocytes, allowing lipids to leak out.
ultrasonic-assisted – removing fat cells by using ultrasound effects (e.g. HIFU, physiotherapeutic, shockwave).
HIFEM – Magnetic resonance contouring with High-intensity focused electromagnetic technology uses the stimulation of muscle contractions that trigger intensive lipolysis within fat cells.
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

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