Selective Lipolysis by Novel Ultrasound and Radiofrequency for Body Contouring

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ABSTRACT

Introduction Recently, the use of ultrasound (ULS) and radiofrequency (RF) technology has become a common modality in the aesthetic market for non-invasive lipolysis and body contouring. Available focused and non focused, ULS technologies are non-selective, produce high temperature, and can cause epidermal injury. There is a need for a ULS technology that will selectively disrupt/destroy adipocyte membrane integrity without causing damage to the overlying epidermis or to nearby cells in the adipose tissue, such as blood vessels or nerves.
Objectives To assess the efficacy and safety of the Accent® Ultra workstation (Alma Lasers Ltd. Caesarea, Israel) in reducing localized fat deposits and tightening the overlying skin for non-invasive body contouring in non-obese patients.
Material & Methods Twenty-four patients (22 female/2 male) ranging in age from 19 to 60 (average 34) with body mass index ranging from 23 to 30 (average 26.3 kg/m^2) underwent 4 treatments spaced 2 weeks apart. Treatment protocol comprised alternate ULS shear wave ("cold") mode and compression wave ("hot") mode for deep heating (ULS module) followed by RF module. The treatment was applied to 2 areas of 150cm^2 during the same session. Photographs and circumference measurements were made at fixed reference points on the upper ("B"), middle ("A"), and lower ("C") abdomen before and 2 weeks after the final treatment. Since the procedure is painless, no pretreatment anesthesia was required for either the ULS or the RF applications.
Results Average reduction in abdomen circumference at 3 reference points were -4.37cm (upper abdomen); -5.88cm (middle abdomen) and -5.32cm (lower abdomen) measured 2 weeks after the 4th treatment. Individual patient weights were similar to weight measurment at baseline. No adverse side effects were recorded during or after any of the treatments.
Conclusion Lipolysis ULS and RF technologies are safe and effective modalities for non-invasive body contouring in non-obese patients.

INTRODUCTION

Existing non-invasive and minimally-invasive technologies for improving the appearance of skin and subcutaneous fat appearance, such as deep body massage, radiofrequency (RF), and light-based treatments, have gained popularity due to minimal downtime, relative safety, and temporary cosmetic benefit. Recently, the use of ultrasound (ULS) technology has became a common modality in the aesthetic market for non-invasive treatment of adiposis and for body contouring. Available focused and non focused (cavitation-based) ULS technologies are non-selective, produce high temperature and can cause epidermal injury. While clinicians attest to ULS effectiveness for heating deep tissue, there is widespread belief that heating alone cannot achieve significant results, especially when delivered at non-thermal settings. There is a need for a ULS technology that will non-thermally & selectively disrupt/destroy adipocyte membrane integrity without causing significant damage to the epidermis or to nearby cells in the adipose layer, such as blood vessels or nerves.

ACCENT® ULTRA

The Accent Ultra workstation (Alma Lasers Ltd. Caesarea, Israel) provides two state-of-the-art modules for the treatment of adiposis (Figure 1). The Ultra module includes an ultrasound-powered sonotrode applicator (Figure 1). The Ultra module targets fat reduction and body contouring while the UniForm module treats skin laxity, and body contouring.

Figure 1. *Accent-Ultra (left) with Ultra (ULS) module (middle) and UniForm (RF + massage) module (right)*

The UniForm module includes an RF applicator surrounded by a rotating massage applicator, which enhances deep lymphatic drainage.
The Ultra module provides both a "hot" mode and a "cold" mode. For example, 20 second cycles comprise alternating hot (up to 5 sec.) and cold (at least 15 sec.) ULS. For example, if the operator sets 5 seconds of hot, the module will continuously generate alternating blocks of 5 seconds hot ULS followed by 15 seconds cold ULS. The hot mode provides compressive ultrasonic waves, producing a high level of cavitation, whereas the cold mode provides transverse acoustic waves, producing selective disruption of adipocyte membranes. The UniForm can be used for massage only or for combined Unipolar RF with massage. In combination, the RF progressively increases subcutaneous heat, inducing thermal effects and increasing local metabolism while in parallel, the adjacent massage ring enhances micro-circulation and facilitates drainage of trapped intercellular fluid to lymphatics and breakdown of erythrocytic adhesions.

BIOLOGICAL INTERACTION OF ACCENT-ULTRA

In solids, several types of sound waves are possible, according to the way the molecules propagating the sound oscillate. Compression and shear waves are the two modes of propagation most widely found in ultrasonic medical applications.

In compression waves, the oscillations occur longitudinally, along the direction of wave propagation (Figure 2). Compression waves can be generated in liquids, as well as solids, because the energy travels through the tissue structure by a series of compression and expansion movements.

In the shear waves, the particles oscillate at a right angle or transverse to the direction of propagation (figure 2). Shear waves do not pass through liquids, do not produce cavitation, and penetrate deeply without strong absorption and dispersion. Shear waves require an acoustically solid material for effective propagation and are relatively weak in comparison with compression waves.
Cavitation is defined as the physical force of the compression waves on gases within fluid. As the waves propagate through tissue, the characteristic compression and expansion causes microscopic gas bubbles in the tissue fluid to contract and expand. Substantial injury to the cell can occur when microscopic gas bubbles expand and then collapse rapidly, causing a ‘‘microexplosion.’ Although true microexplosions, referred to as unstable cavitation, are not thought to commonly occur at therapeutic levels of ultrasound, pulsation of gas bubbles may disrupt cellular activity, altering the function of the cell.
If the acoustic and medium conditions are conducive, the bubbles can expand and collapse causing cavitation, which forms shock waves and focused ultrasound local high pressure and raises the temperature leading to non-selective damage in the interaction zone. Focused ultrasound focuses the ULS energy intensity to a target region but does not solve the problem of collateral damage within that region.

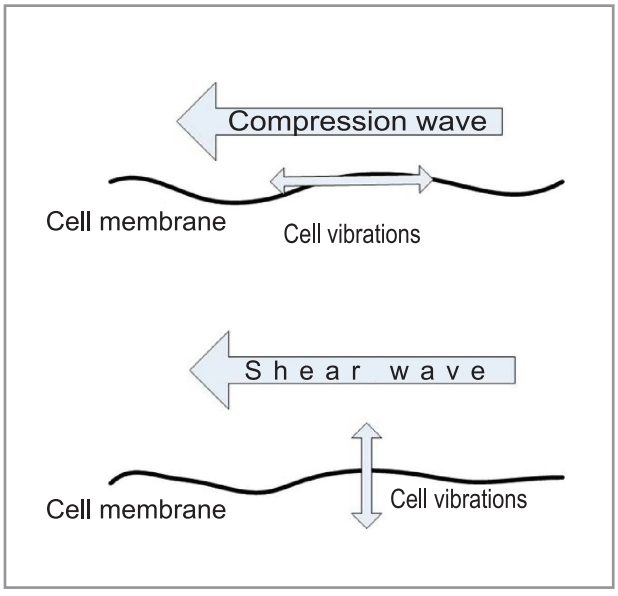


Figure 2. *Compression and transverse shear wave directions of vibration and propagation*

ACCENT ULTRA SELECTIVE LIPOLYSIS – MECHANISM OF ACTION

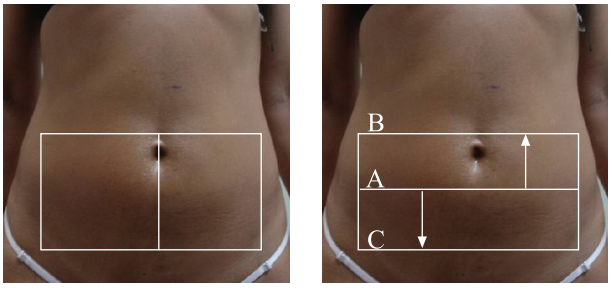
The Ultra sonotrode behaves as a resonator, naturally resorating with greater at certain. The Ultra provides a “cold” mode where primarily shear ULS waves are delivered to the patient and a “hot” mode where primarily compression waves are delivered. The compression waves may be useful for ‘pre-heating’ the tissue before delivering the shear waves.
The shear waves propagate to the adipose tissue to: (i) repeatedly stretch and relax the adipocyte membranes, deforming and damaging the adipocytes and triggering delayed cell death and (ii), causing substantially no collateral damage to adjacent cells, which are structurally more robust.
The shear wave produces cell membrane vibrations in a direction perpendicular to the wave propagation in contrast with the commonly used compression wave where the directions of membrane vibration and wave propagation coincide (Figure 2).

CLINICAL STUDY

Material & Methods

Twenty-four patients (22 females/2 males) age range between 19-60 years (average 34 year- old) with body mass index between 23-30 (average 26.3 kg/m2) underwent 4 treatments of ULS and RF spaced 2 weeks apart. Exclusion criteria included: Patient has existing or history of cancer, including skin malignancy; Patient has existing skin diseases; multi-systemic diseases (diabetes, hypertension, coronary artery disease, renal insufficiency); Patient has history of collagen or vascular disease; Patient has implantable pacemaker, or automatic implantable defibrillator/ cardioversor (AICD) or any other implantable electric device; Patient has any large metallic implant, i.e. artificial hip joint; Patient has history of hypertrophic scar or keloid formations; Patient had prior aesthetic surgery or treatment in the area to be treated within 3 months of study enrolment; Patient has had body contouring procedure (surgical or non-surgical) within 30 days of study enrollment; Patient has used any medication that can cause dermal hypersensitivity or affect skin characteristics within 30 days of study enrollment; Patient has used Acutane (isotretinoin) within the past 6 months; Patient is female who is pregnant, lactating, or plans to become pregnant during the study period. All Fitzpatrick's skin types can be included for the treatment. At baseline patient's weight and height was measured using standard equipment.

Body (standing) circumference measurements were taken in 3 distinct anatomical areas – at the naval level and at 5 cm above and below the naval (Fig. 3) using a standard anthropometric measuring tape. Patients were photographed for baseline, before each treatment, and 2 weeks after the last treatment using a high resolution digital camera (Nikon D-70).



(a) (b)

Figure 3. *Bilateral grids of 15 x 10 cm each (a); Three circumference reference areas (b)*

Each patient abdomen treatment area was cleaned and marked with bilateral 15 x 10 cm grid using a surgical marker. Each grid was further divided into 4 small quadrants of 7.5 x 5 cm each. A coat of Vaseline was spread evenly over the entire grid area to serve as coupling medium. Each quadrant received alternately ULS compression waves ("hot") and ULS shear waves ("cold") at a ratio of 1:3 (5:15 seconds, respectively) for a period of 8 minutes. The tip (sonotrode) of the Ultra handpiece was maintained perpendicular to the skin and maneuvered with a semi-rotational movement within the quadrant. Skin reaction during the treatment is slight erythema and transient warmth. After completion of the Ultra treatment on the two 150 cm2 grids, the area was cleaned with alcohol and dried with soft cloth in preparation for treatment with the UniForm module treatment which commenced immediately. The entire (bilateral) 300 cm2 area was defined as the treatment area. Mineral oil was spread evenly over the area. Applied UniForm RF energy levels ranged between 150-180 W and accumulated energy ranged between 60-80 kJ. The energy levels were adjusted depending on the subject's sensitivity, skin response and fat layer thickness The temperature was monitored with a laser thermometer and the total energy counter was seen on the screen of the platform. The end criterion was reaching the recommended total energy (kJ) and maintaining skin temperature between 40-43^{o}C. During treatment heat sensation was felt and erythema was noticeable. Treatment session lasted approximately 35-40 min. No post treatment care was needed. Post treatment, patients were instructed to drink plenty of water for the next 2-3 days. Thus, Ultra treatment followed by UniForm treatment were applied to two areas of 150cm2 (15 x 10 cm) in the same session.

Results

Baseline average body circumference measurements at for the 3 different reference abdomen points (B =upper; A= middle; C= lower) were 78.5cm (range 62-107cm; upper), 83.9cm (range 67-108.4cm; middle) and 89.6cm (range 73.2-116cm; lower). Two weeks after the last treatment the average body circumference measurements for the 3 reference abdomen points (A, B, C) were reduced by average of -4.37cm; (upper abdomen, figure 4); -5.88cm (middle abdomen) and -5.32cm (lower abdomen, figure 4). No significant patients body weight change occured during the course of the study. No adverse side effects were recorded during or after each treatment in the study group.

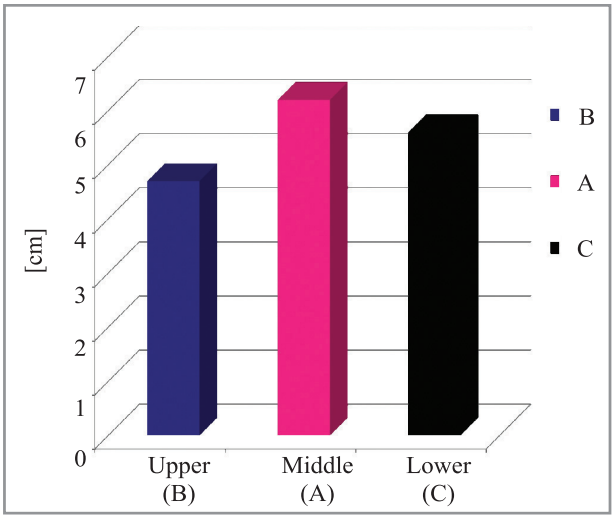


Figure 4. *Circumference reduction (cm) for abdomen areas*

Discussion

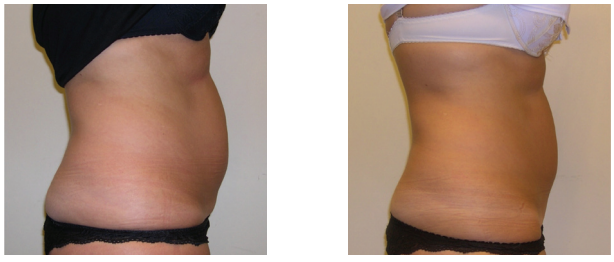
Therapeutic ultrasound (ULS) for body contouring is a fast growing area, with several devices under development and others already in use. Available average power focused (cavitation-based) ULS technologies are non-selective, produce high temperature and can cause epidermal injury. Fat tissue modulation by selective lipolysis is feasible through the use of ULS energy transmitted transcutaneously. The Accent Ultra represents a novel modality of fat tissue modulation. The delivered ULS shear waves travel to the adipocytes of adipose tissue via epidermis and dermis, causing no, or relatively minimal, collateral damage to the layers of tissue above and adjacent non-adipocyte cells. The Accent Ultra concept is based on an inherent property of the ULS wave called self resonance. Adipocytes are composed of 90% triglycerides and free fatty acids, their size is 50-150m compared to 5-15m for neighboring cells in the treated region. Since size and content of adipocytes differ significantly from the other cells in the epidermal, dermal, and sub-cutis layers, they also differ in their resonance.shear forces. Ideally, selective lipolysis should be non-invasive; preserve epidermis, dermis, blood vessels, nerves etc. while destroying the fat cells; generate minimal heat and pain; and be fast and easy to operate. The Accent Ultra acoustic meets these criteria.

The significant circumference reduction can be explained by the combination of the ULS and the RF and the synergistic effect of the UniForm handpiece following ULS treatment. The UniForm handpiece with its deep heating unipolar radiofrequency technology can facilitate contraction of collagen fibers; firming and improving laxity and its deep heat reaches the hypodermis and the adipocytes; the increase in subcutenous fat heating induces hypermetabolism which together with the massage roller improves blood and lymphatic circulation and metabolic wastes drainage, smoother skin appearance, shrinkage of the subcutenous layer and overall skin contouring.

In summary: The use of combined ULS and RF technology for fat modulation is safe and effective modality for the purpose of non-invasive body contouring.

Before		***After 4 Tx.***	
B	*105.5 cm*	*101.5 cm*	*(-4)*
A	*114.0 cm*	*107.0 cm*	*(-7)*
C	*120.5 cm*	*113.0 cm*	*(-7.5)*

Before		***After 4 Tx.***	
B	*100.0 cm*	*92.5 cm*	*(-7.5)*
A	*106.5 cm*	*95.5 cm*	*(-11)*
C	*107.0 cm*	*98.0 cm*	*(-9)*



Before		***After 4 Tx.***	
B	*86 cm*	*92 cm*	*(-6)*
A	*94.5 cm*	*98 cm*	*(-3.5)*
C	*102 cm*	*103 cm*	*(-1)*

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