
In-Vivo Selective Lipolysis with Novel Ultrasound Technology- Case Report

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Introduction

Non-invasive external ultrasound (ULS) energy is a high growth area in dermatology and plastic surgery with several devices under development and other equipment already in use. The focused ULS biological effect is based on cavitation phenomena. Since cavitation has no tissue selectivity, it may produce in addition to fat lysis damage to blood vessels as well as to nerves. Thus, there is a need to develop ULS technology which will enable a selective effect on the fat layer with minimal as possible effect on the epidermal-dermal layers.

Objective

To histologically assess and characterize the acute and sub-acute effect of a novel, noninvasive ULS technology on human skin and specifically on the fat layer.

Materials & Methods

The Accent Ultra (Alma Lasers Ltd. Caesarea, Israel) combines two technologies for the treatment of adiposis: ULS (Ultra module) for selective lipolysis, and radiofrequency (UniForm™ module) for the purpose of tissue temperature elevation. In the current case, the patient was treated only with the ULS module. The tip of the sonotrode is 6 cm² in area and is positioned perpendicular to the skin. The Ultra module operates in 20 second cycles of alternating "Hot" (up to 5 sec) and "Cold" (at least 15 sec) of ultrasound energy. The "Hot" mode provides compressive ultrasonic waves, producing a high level of cavitation, while the "Cold" mode provides transverse shear waves for selective disruption of adipocyte membranes.

Treatment protocol: The abdomen treatment area was cleaned then marked with a 15 x 10 cm grid to the right and left of the umbilicus. Each grid was further divided into 4 quadrants of 7.5 x 5 cm each. A coat of Vaseline® (~1-2 mm) was spread evenly over the entire grid area, serving as a coupling medium. Each quadrant received alternately ULS compressive waves ("Hot") and shear waves ("Cold") at a ratio of 1:3 (5:15 seconds, respectively) for 8 minutes/each.

Biopsies: A 35 year-old woman (skin type=III; BMI =23.5kg/m²) underwent three 3mm punch biopsies: (i) before;at baseline (Control); (ii) 7-days after and (iii) 15-days after a single Accent Ultra treatment (Ultra module).

Biopsies were taken in the right and left lower abdomen area.

The specimens were soaked in Formalin 10%, prior to being fixed in paraffin, cut by the microtome and stained with both Hematoxyline and Eosin (H&E) and PAS for adipocytes. Structural changes were defined as repeated deviation from the normal structure of the tissue.

Results

Fat layer effect: 1) **Cellular level:** a) Membrane shape alteration; b) Disruption of cellular membranes; c) Necrotic cells 2) **Tissue level:** large areas of empty bullae which may indicate a) lysis of many fat cells in the same space or b) disruption between the fat tissue and its neighboring septa (Figures 1 & 2).

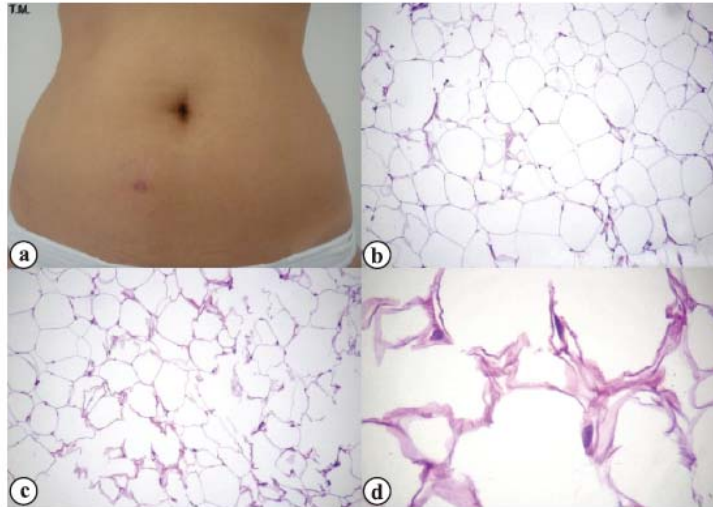
Discussion

The histology results demonstrate that the new acoustic wave physical parameters enable to acutely and selectively disrupt the adipocytes with no clinical or histological evidence of any damage in the epidermis-dermis layers. In brief, since size and content of adipocytes differ significantly from all other cells in the epidermal dermal and sub-cutis layers, they should differ in their self-resonance. Therefore, applying the appropriate combination of – longitudinal and transverse acoustic waves, may selectively affect the adipocytes with minimal or no effect on neighboring tissues.

Summary

Fat tissue modulation by noninvasive selective lipolysis is a feasible modality as it reduces pre-procedural morbidity such as infection, scarring, anesthesia-related complications, and other risks associated with surgical procedures.

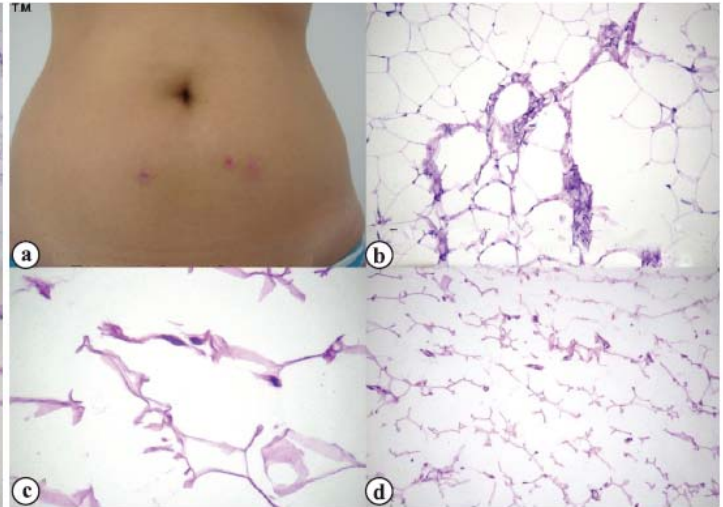
Figure 1. 7-days after treatment



Legends

- (1a) Accent Ultra - 7 days after treatment
- (1b) Normal (original magnification X 100)
- (1c) Rupture of adipocytes which are rolled and mimic thick septa (original magnification X 100)
- (1d) Rupture of adipocytes (which are rolled and mimic thick septa (original magnification X 400)

Figure 2. 15-days after treatment



Legends

- (2a) Accent Ultra - 15 days after treatment
- (2b) There are large cavities, apparently as a result of the breakdown of membranes of adipocytes and some small adipocytes (ruptured), rolled, forming thicker septa (original magnification X 100)
- (2c) Most of the cells are without nuclei (original magnification X 400)
- (2d) An area with adipocytes membranes' breakage (original magnification X 100)