Guided Acoustic Waves Technology for Selective Non-Invasive Lipolysis and Circumference Reduction– A Preliminary Report

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Abstract

Background: UltraSpeed™ (Alma Lasers) integrates a novel, non-invasive, non-focused, acoustic-guided wave's technology to target the subcutaneous adipose tissue for the purpose of selective lipolysis and subsequent body contouring.
Methods: Subjects (25 females, 1 male), of a mean age of 43.7 years (Min 22, Max 61 years), 18.5 > BMI < 35, were treated once a week or once in two weeks, in a total of 2-7 sessions. Skin temperature was maintained between 41-43°C. Subjects were weighed, circumferences were measured using a fixed measuring tape at three points and photos were taken before and after treatments.
Results: A significant reduction in abdomen circumferences was measured. No adverse events, aside from moderate transient erythema.
Conclusion: The UltraSpeed handpiece is a safe and effective applicator for circumference reduction and body contouring.
Key words: Guided acoustic waves, Body contouring, Lipolysis

Introdution

Focused and non-focused ultrasound devices intended for aesthetic applications deliver ultrasound energy and are claimed to target the underlying subcutaneous adipose tissue, leading to triglyceride efflux from fat cells, and consequentially to reduced size, necrosis or apoptosis of targeted adipocytes. A growing body of evidence from both ex-vivo and in-vivo studies, has established the effectiveness of low frequency, non-focused ultrasound technology on subcutaneous adipose tissue and body contouring.[1-5] Indeed, in an earlier preclinical animal study with the UltraSpeed handpiece (Internal communication, Alma Lasers), we observed disruption of subcutaneous adipocyte integrity and rupture of adipocyte cell membranes (Data not shown). Herein, we report our first clinical experience of this novel acoustic-guided wave handpiece in a heterogeneous population with excessive adiposis in the abdomen area.

Technology

The UltraSpeed handpiece combines a novel mode of non-focused ultrasound technology, delivered via an extra-large applicator plate for high-speed body contouring ***(Fig. 1a)***. The device features a plate-type sonotrode, which emits acoustic-guided vibration waves through concentric profiles ***(Fig. 1b)***, to heat the target tissue. The complex vibrational waves are comprised of two modes of vibration: flexural-asymmetrical and longitudinal. The device is available with the Alma Accent Prime™ platform.

(a) (b)

Fig. 1. The UltraSpeed handpiece (a); large plate spot (60cm^2) with guided waves pond-ripple-like expression (b).

Methods

After signing informed consent, subjects were asked about their medical history. Subjects with a body mass index (BMI) below 35 were eligible to participate in the study. Subjects with a clinically significant disease such as cancer, active tuberculosis, reproductive organs disease, heart disease, abdominal wall hernias and diabetes, were excluded from the study. Pregnant or lactating women were also excluded. Body circumferences at the level of the belly button BB), 5 cm above BB and 5 cm below the BB and the corresponding

landmarks on the back, were measured at the same distance from the floor, using a metal pole with a fixed metric measuring tape. Subjects were instructed to maintain their standard caloric intake and lifestyle during the course of the study.

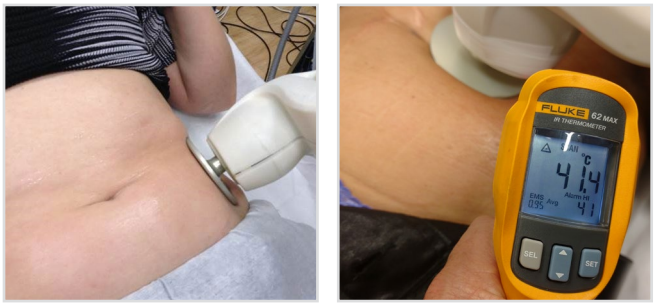
TABLE 1

Subjects Body Mass Index and number of treatments (n=26)

Character		No of Subjects	(%)
BMI (m^2/Kg)	Normal (>18.5)	10	38
	Overweight	10	39
	Obese (<35)	6	23
Number of Treatments	2	4	15
	3	3	12
	4	6	23
	5	9	35
	6	3	12
	7	1	4

Treatment

Each subject was placed in a supine position on a medical bed. The borders of the treatment area were marked with an erasable surgical pen. As the treatment is practically pain-free, local anesthetic was not used. Treatment parameters were selected from the Accent Prime platform. The UltraSpeed round shape sonotrode was then coated with a thin layer of white petroleum jelly (Vaseline), placed on the subject's abdomen and moved in slow-to-moderate semi-rotational movements across the treatment area (~600cm^2). The large spot/plate of the UltraSpeed handpiece (~60cm^2) allows for high coverage and for efficient increases in skin temperature from pre-therapeutic (~32°C) to a therapeutic level (~41-43°C), which is then monitored by a hand-held IR thermometer, for the short duration of the treatment ***(Figure 2)***. A high-resolution digital camera (Nikon, Japan) was used to photograph the treated area before and after treatment in a standard photography conditions.



(a) (b)

Fig. 2. UltraSpeed with its round thermal profile (a) and skin temperature IR monitoring end-point (b).

Statistical analysis

Results were statistically analyzed using a one-tailed paired t-test in Excel (Microsoft Office 2010). Differences were considered statistically significant when p value was < 0.05.

Results

A total of 26 patients underwent 2-7 treatment sessions, conducted at 1-2 week intervals. Baseline BMI and the distribution of treatments (visits) per patient are presented in Table 1. Patients were followed-up one-or two weeks after the last treatment session. Treatment time for the full abdominal area ranged between 20-24 minutes. Skin temperature at the end of the treatment sessions was ~42°C and erythematous and radiant skin was noted on the entire treatment area. Subjects reported minimal discomfort during the procedure. Significant circumference reduction, averaging between 1.2-1.4 cm, was achieved in all measured areas (N=26; Table 2, Fig. 3). A maximal circumferential reduction of 10 cm was obtained at 5 cm below BB in one of the subjects after four treatments only. Only 8 out of 26 subjects attended the follow up (FU) visits and showed a mean circumferential reduction of 2.5-3.5 cm, with median reduction of 3 cm (data not shown), which could not be ascribed to patient weight loss. No adverse events apart from moderate erythema, were observed or reported.

Fig. 3. Multiple views of a 57 year-old female subject with normal BMI before (top row) and after six (bottom row) UltraSpeed treatments. Reduction of 5.5cm, 4.5cm and 3.5cm were obtained 5 cm above BB, at the BB and 5cm below the BB, respectively.

TABLE 2

Change in abdominal circumference following treatments with UltraSpeed

	Circumferential Reduction (cm)			Weight Reduction (Kg)
	5cm Above BB	BB	5cm below BB	
Mean	1.2	1.4	1.3	1.05
SD	2.3	1.9	2.6	
P*	<0.005	<0.001	<0.01	N.S**
Max	5.5	6	10	

* Compared to baseline

** Not Significant

Conclusion Remarks

Significant circumferential reductions were observed following UltraSpeed treatments despite major differences in age, BMI of the treated subjects. Taken together with its safety profile, UltraSpeed is a promising technology in non-invasive body contouring that need further clinical investigation.

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