

Evaluation of the Acute and Chronic Systemic and Metabolic Effects from the Use of High Intensity Focused Ultrasound for Adipose Tissue Removal and Non-Invasive Body Sculpting

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PURPOSE

To evaluate the acute and chronic systemic and metabolic effects from the use of High Intensity Focused Ultrasound (HIFU) for adipose tissue removal.

HIFU provides a non-invasive method for adipose tissue removal.

Damaged and disrupted adipocytes along with released triglyceride content are resorbed through normal physiological pathways via inflammatory cells.

MATERIALS AND METHODS

Pre-clinical study:

Transcutaneous HIFU* was administered to subcutaneous abdominal adipose tissue in swine to establish safety.

Clinical study:

From June, 2003 to February, 2004, twenty-four patients were treated with HIFU in the lower abdomen at Hospital Santa Monica in Mexico City, followed by abdominoplasty at different time points. Ethics Committee and Ministry of Health approvals were obtained.

Treated adipose tissue volumes ranged from 25 cc to 225 cc.

HIFU-treated tissue residence times ranged from:

- peri-acute (hours) in 4 patients
- 4-7 days in 7 patients
- 4 weeks in 1 patient
- 56-59 days in 6 patients
- 84-86 days in 6 patients

Each abdominoplasty flap was examined for gross and histologic HIFU induced tissue changes.

Each patient had blood drawn at the following time intervals:

- Baseline
- 24 hours
- 48 hours
- 72 hours
- 1 week – 4 weeks
- 1-3 months

(Dependent on the treated tissue residence time)

Blood was analyzed for changes in lipid panels, free fatty acids, and end organ function.

RESULTS

There were no clinically significant changes from baseline in any of the 24 patient lipid panels including:

- free fatty acids
- total cholesterol
- very low density lipoprotein (VLDL)
- high density lipoprotein (HDL)
- low density lipoprotein (LDL)
- triglyceride levels

In addition, when examined at the varying time intervals post HIFU therapy, none of the 24 patients had clinically significant changes from baseline in:

- comprehensive metabolic panel
- amylase
- lipase
- complete blood count with differential values

CONCLUSIONS

The use of HIFU for non-invasive adipose tissue removal does not induce any clinically significant acute or chronic changes in lipid metabolism, free fatty acids, glucose metabolism, kidney and liver function and provides a safe method for body sculpting.