

The Use and Mechanism of Action of High Intensity Focused Ultrasound for Adipose Tissue Removal and Non-Invasive Body Sculpting

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PURPOSE

To document the feasibility of use and mechanism of action of High Intensity Focused Ultrasound (HIFU) for adipose tissue removal and body sculpting.

HIFU has been used extensively in the clinical setting to treat different types of tumors, however, there is no published literature on its use for adipose tissue removal.

MATERIALS AND METHODS

Pre-clinical study:

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

Clinical study:

Twenty-four patients underwent HIFU treatment to their lower abdominal adipose tissue followed by abdominoplasty at different time points.

The clinical study was performed between July, 2003 and February, 2004 at Hospital Santa Monica in Mexico City after Ethics Committee & Ministry of Health approval was obtained.

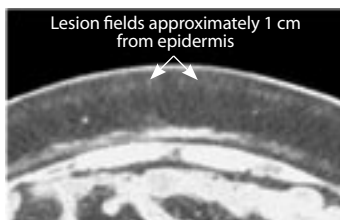
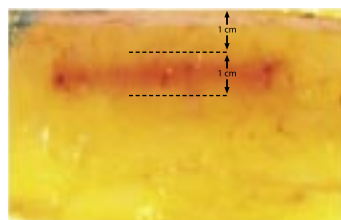
Lesion fields (swine & human) were examined for gross and histological HIFU induced pathophysiological changes at various times after therapy, from several hours to eight weeks.

RESULTS

The depth from skin to lesion field, as well as the depth of the HIFU treatment site, was determined by the transducer focal length. (A)

Histology with computer-aided mapping of damaged adipocytes demonstrated control of therapy within the target area. (B)

Gross pathology and CT imaging revealed discrete lesion fields within the adipose tissue that did not extend into the dermis, the rectus muscle or fascia. (C, D)



C Abdominoplasty specimen

D

Peri-acute (hours) and acute (7 days) phase histology revealed a well demarcated zone of adipocyte disruption with minimal inflammatory response, consisting predominantly of macrophages. (E)

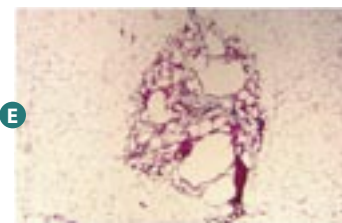
Four-week chronic histology revealed scavenger macrophages with abundant foamy cytoplasm within treatment zones. (F)

Eight-week chronic histology demonstrated 75% resolution of the treated adipose tissue with collapse of the surrounding fibrovascular stroma. (G)

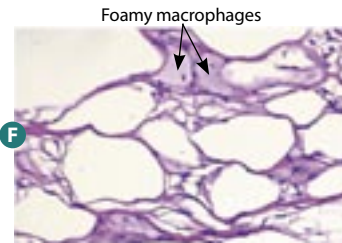
Eight-week gross pathology from both pre-clinical and clinical studies demonstrated excellent resorption of damaged adipose tissue. (H)

Lipid panels drawn from human patients throughout the trial did not reveal any new clinical changes from baseline.

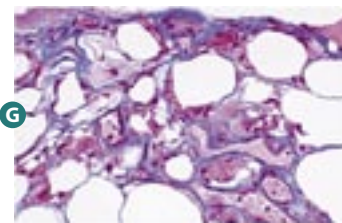
One-week and six-week full-body necropsy studies on swine revealed no fatty liver changes or other systemic abnormalities.



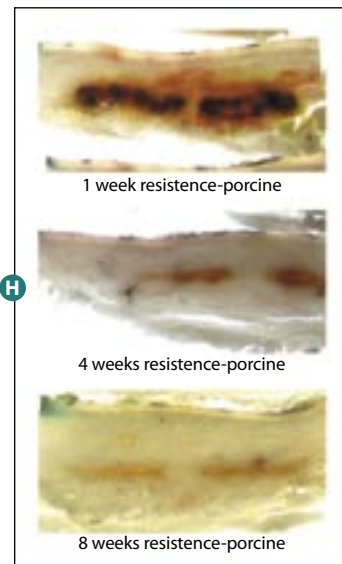
E



F



G



H

CONCLUSIONS

The use and mechanism of action of HIFU therapy for fat removal has been proven in both pre-clinical and human clinical trials and provides a non-invasive method for body sculpting.