High-Intensity Focused Ultrasound for the Reduction of Subcutaneous Adipose Tissue Using Multiple Treatment Techniques

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BACKGROUND

• Increasing demand for noninvasive alternatives to traditional body sculpting procedures

• Non-invasive options include: cryolipolysis, radiofrequency ablation, laser therapies, injection lipolysis, low-intensity nonthermal ultrasound, and high-intensity focused ultrasound (HIFU)
BACKGROUND

• High-Intensity Focused Ultrasound (HIFU)
  • Relies on same principles as conventional ultrasound
  • Is a non-invasive alternative to liposuction for localized reduction of subcutaneous adipose tissue (SAT)
  • Allows focused ultrasound energy to be delivered at specific depths in SAT, preventing exposure and damage to tissues outside of focal zone
  • Has intensity brought to a sharp focus in the subcutaneous fat to necrose adipocytes
  • Results in lesion healing and lipid reabsorption with the gradual metabolism of free lipids
OBJECTIVES

1. To evaluate the efficacy of treatment with HIFU using two treatment techniques and two fluence settings per treatment cycle for circumferential waist reduction through two IRB-approved clinical studies

2. To compare adipose injury and resolution with two fluence settings through histology
## STUDY DESIGN

- Two IRB-approved clinical studies
- Eight investigational sites in the U.S. and Canada
- Device used: Liposonix® System (Model 2)
- Single treatment with 1 of 5 treatment protocols
- Total fluence delivered → 150-180 J/cm² with either 30 J/cm² or 60 J/cm² per treatment pass

<table>
<thead>
<tr>
<th>Treatment Protocol</th>
<th>Fluence per Pass (J/cm²)</th>
<th>Site Time (secs)</th>
<th>Treatment Technique</th>
<th># of Passes</th>
<th>Total Fluence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>46</td>
<td>Grid Repeat*</td>
<td>5</td>
<td>150 J/cm²</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>46</td>
<td>Grid Repeat*</td>
<td>6</td>
<td>180 J/cm²</td>
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<tr>
<td>3</td>
<td>30</td>
<td>46</td>
<td>Site Repeat**</td>
<td>5</td>
<td>150 J/cm²</td>
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<tr>
<td>4</td>
<td>60</td>
<td>66</td>
<td>Grid Repeat*</td>
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<td>180 J/cm²</td>
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<tr>
<td>5</td>
<td>60</td>
<td>66</td>
<td>Site Repeat**</td>
<td>3</td>
<td>180 J/cm²</td>
</tr>
</tbody>
</table>

* Grid repeat (GR): passes completed sequentially at all treatment sites (site 1, site 2, site 3, etc.)
** Site repeat (SR): All passes at one treatment site completed before moving to the next treatment site
GRID VS SITE REPEAT

GRID

Site 1 pulse
Site 2 pulse
Site 3 pulse

SITE

Site 1 3-6 pulses
Site 2 3-6 pulses
Site 3 3-6 pulses
METHODS

• Efficacy Evaluations:
  • Change in waist circumference 12 weeks after treatment
    • Measured in a standardized and consistent method
  • Investigator-assessed clinical improvement at 12 weeks
  • Subject satisfaction scores at 12 weeks

• Histology Evaluations:
  • Comparisons of adipose injury and resolution with treatment at 30 J/cm² and 60 J/cm²
STUDY POPULATION

- 116 subjects received a single HIFU treatment
- 106 subjects currently complete with 12 week follow-up

<table>
<thead>
<tr>
<th>Treatment Protocol</th>
<th>Treatment Parameters</th>
<th>Number of Subjects</th>
<th>Gender (F/M)</th>
<th>Age (Years)</th>
<th>BMI (kg/m²)</th>
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<tbody>
<tr>
<td>1</td>
<td>30J GR (5 passes)</td>
<td>26</td>
<td>24/2</td>
<td>49.5±8.6</td>
<td>24.3±3.3</td>
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<tr>
<td>2</td>
<td>30J GR (6 passes)</td>
<td>26</td>
<td>21/5</td>
<td>43.3±11.3</td>
<td>23.6±2.0</td>
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<tr>
<td>3</td>
<td>30J SR (5 passes)</td>
<td>25</td>
<td>22/3</td>
<td>43.6±11.4</td>
<td>25.7±2.9</td>
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<tr>
<td>4</td>
<td>60J GR (3 passes)</td>
<td>14</td>
<td>12/2</td>
<td>46.1±8.9</td>
<td>24.7±2.7</td>
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<tr>
<td>5</td>
<td>60J SR (3 passes)</td>
<td>15</td>
<td>11/4</td>
<td>44.6±10.3</td>
<td>25.8±2.2</td>
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</tbody>
</table>

* Grid repeat (GR): passes completed sequentially at all treatment sites (site 1, site 2, site 3, etc.)

** Site repeat (SR): All passes at one treatment site completed before moving to the next treatment site
RESULTS – PAIN EVALUATION

Subject-Reported Pain During Treatment (0=no pain, 10=intolerable pain)

- No differences in pain between Site Repeat and Grid Repeat groups within each fluence level
- Less discomfort with 30J/cm² versus 60J/cm² (P<0.05)
RESULTS – CLINICAL EFFICACY

2.4 cm average reduction over all treatment methods

* Significant difference seen at 12 weeks vs. baseline (P<0.01) for all groups

* Body weight remained stable (mean change, <1.4% per group) throughout the study
RESULTS – CLINICAL EFFICACY

- Investigator-Rated Improvement 12 Weeks Post-Treatment
- Average improvement score over all treatment groups of 3.8±0.6

(1=much worse, 2=worse, 3=no improvement, 4=improved, 5=much improved)
RESULTS – SAFETY AND SATISFACTION

• Similar satisfaction results (Likert Satisfaction Scale) between all groups

• More than 60% of subjects reported scores of “satisfied” or “very satisfied”
RESULTS – SAFETY AND SATISFACTION

• Most common responses immediately post-treatment were mild-to-moderate erythema (58%), mild edema (13%), and mild-to-moderate tenderness (38%)

• 7% of patients presented with mild bruising and 33% with mild tenderness at 4 week follow-up

• Above responses were transient
  • Resolved by 12 week follow-up
  • 3 patients presented with mild tenderness at the 12 week follow-up and resolved shortly thereafter

• No treatment-related SAEs were observed
PATIENT PHOTOS (BEFORE AND AFTER)

Photos courtesy of: Solta Medical Aesthetic Center
60 J/cm² Grid Repeat
Waist Circumference Change: -2.4 cm

Photos courtesy of: Mark Lupin, MD
60 J/cm² Site Repeat
Waist Circumference Change: -3.4 cm
RESULTS – HISTOLOGY

Histology results (A) 1 week and (B) 12 weeks post-treatment

- Comparable adipose injury with 30J/cm² and 60J/cm² per pass treatments seen 1 week post-treatment (Top, Figure A)
- Comparable injury resolution seen 12 weeks post-treatment (Bottom, Figure B)

Legend:
- Focal areas of reactive adipocytes
- Minimal infiltrate of inflammatory cells
- Spilling of blood or serum
- Presence of fibrosis
- Coagulative necrosis
SUMMARY

• HIFU is an effective single treatment modality for reduction of circumferential waist SAT with minimal downtime and adverse events

• HIFU treatment at total doses of 150 J/cm² to 180 J/cm² was associated with average reductions in waist circumference of more than 2.4 cm

• All treatment groups had significant reductions in waist circumference and similar investigator improvement/subject satisfaction scores 12 weeks post-treatment
  • No statistical difference in patient discomfort between grid repeat and site repeat treatments
  • Less patient discomfort reported with 30 J/cm² vs. 60 J/cm² treatments
SUMMARY

- Site repeat treatment at 60J/cm² displayed a trend towards more consistent circumferential reductions across all subjects
  - 73% of subjects in the 60J/cm² site repeat group had a treatment response of more than 1 inch 12 weeks post-treatment
  - First description that both 30 J/cm² and 60 J/cm² HIFU treatments produce statistically significant SAT reduction, allowing increased user latitude in treatment regimen options