Clinical and Histological Evaluations of a 1060nm Laser Device for Non-Invasive Fat Reduction

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Study Design:
- 17 subjects in total were treated; 11 treatments being in the abdomen and 6 in the flank.
- Pre- and post-treatment, a thermocouple needle was placed into the treatment area to measure tissue temp at interval depths (5, 10, 15, 20, 25, 30mm).
- 1060nm diode laser with contact cooling for skin protection to cause injury to subcutaneous adipose tissue (SAT) by establishing a controlled hyperthermic temperature of 42-47°C.

Evaluation:
- Ultrasound measurements of fat thickness were performed at baseline, 6 and 12 weeks post-treatment.
- High resolution photographs were taken at baseline and 12 weeks post-treatment.

Results:
- Laser treatments were well-tolerated by all subjects with no damage to the skin.
- Side effects included mild pain, stinging and numbness, all resolved by 2 weeks.

Conclusion:
- Ultrasound, MRI, and photographic evaluations show similar level of fat reduction by laser hyperthermic treatment as compared to cryolipolysis (24%).
- The in vivo tissue response demonstrated that a prolonged hyperthermic exposure can cause adipocyte injury.

Fat thickness changes demonstrated by ultrasound
Results-MRI Measurements

Average reduction in fat volume as compared to cryolipolysis:

<table>
<thead>
<tr>
<th>Fat Volume Reduction</th>
<th>3 MONTH POST TX</th>
<th>6 MONTH POST TX</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Laser Side</td>
<td>Cryo Side</td>
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<tr>
<td>Average Reduction</td>
<td>24% (±9%)</td>
<td>22% (±13%)</td>
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</tbody>
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Example of fat thickness changes demonstrated by MRI:

Baseline | 3 Month Post Tx | 6 Month Post Tx