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.

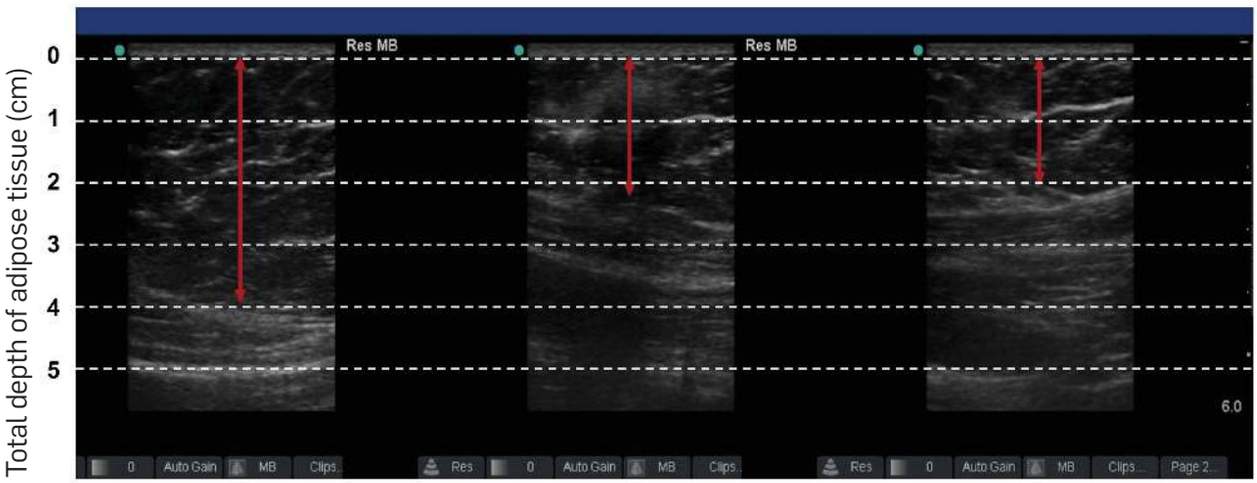
Results:

- 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



Baseline | 3 Month Post Tx | 6 Month Post Tx

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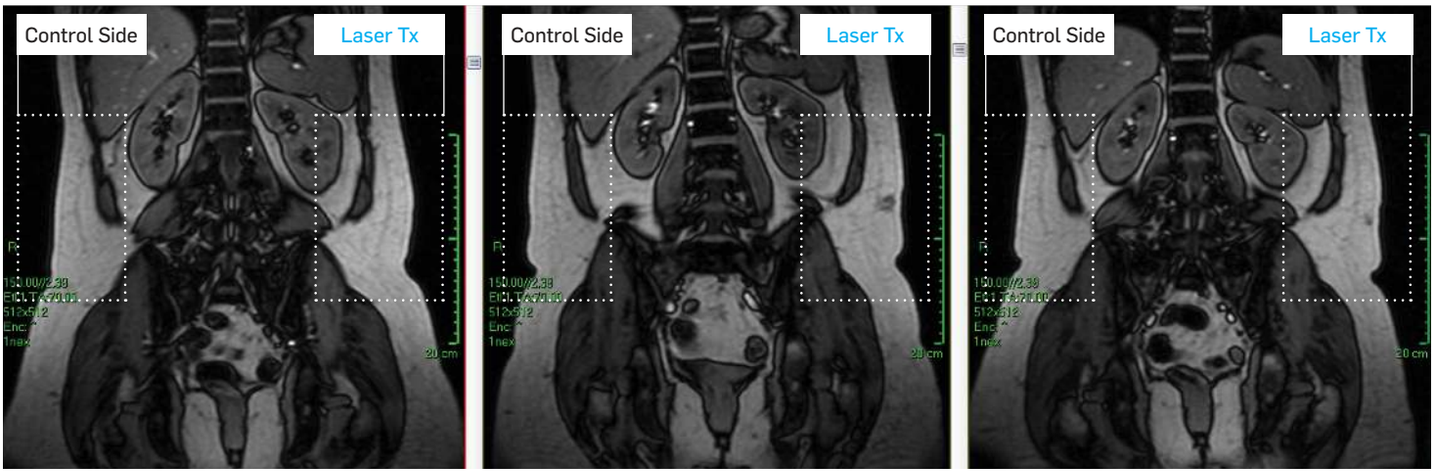
Results-MRI Measurements

Average reduction in fat volume as compared to cryolipolysis:

	3 MONTH POST TX		6 MONTH POST TX	
Fat Volume Reduction	**Laser Side**	**Cryo Side**	**Laser Side**	**Cryo Side**
Average Reduction	**24% (±9%)**	**22% (±13%)**	**21% (±10%)**	**19% (±9%)**

Example of fat thickness changes demonstrated by MRI:



Baseline | 3 Month Post Tx | 6 Month Post Tx

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