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#LB15

A MULTICENTER STUDY OF THE SAFETY AND EFFICACY OF A NON-INVASIVE 1060nm DIODE LASER FOR FAT REDUCTION OF THE FLANKS **Bruce Katz, Sean Doherty**

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Background: A previous study has demonstrated that a non-invasive hyperthermic treatment maybe an effective method for fat reduction. This is a prospective, controlled (treatment versus no-treatment) study to evaluate a non-invasive 1060nm laser treatment of the flank to achieve disruption of adipocyte cells intended for non-invasive aesthetic use.

Study: 10 males and 39 females between 20 and 55 years were consented and enrolled this IRB approved study. Subjects were enrolled if they were healthy volunteers with a BMI of 30 or under. Subjects received laser treatment to one side of the body (flank) and the other side severed as a control. Follow up visits were conducted 6 weeks and 12 weeks post treatment. 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. At the end of the study the subjects were asked to complete a satisfaction questionnaire. Adverse events were recorded at all visits.

Results: 3 blinded board certified dermatologists were trained and conducted an evaluation of before and after photographs. On average, reviewers were able to identify the post treatment photograph 90.3% of the time (93%, 90%, 88% respectively). At 6 weeks post a single treatment, a 1.9mm (+/-1.2mm) fat reduction was calculated from ultrasound images. The control side exhibited a 0.1mm (+/-0.9mm) fat reduction. At 12 weeks post a single treatment, a 2.6mm (+/-1.3mm) fat reduction was seen and the control side exhibited a -0.1mm (+/-0.9mm) fat reduction. Statistically significant reductions were achieved based on paired t-test (p-value <.001) comparing treated and control sides at 6 and 12 weeks. At the 12 week follow up visit 96% (41/43) of the subjects rated that they were satisfied (slightly satisfied, satisfied, and extremely satisfied). No serious adverse events were reported. The common transient side effects were mild to moderate tenderness which subsided within 1-4 weeks post treatment.

Conclusion: The non-invasive 1060nm diode laser used in this study was a successful and safe means of fat reduction of the flanks.

NON-INVASIVE FAT REDUCTION OF THE ABDOMEN: A MULTICENTER STUDY WITH A 1060nm DIODE LASER

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Background: Non-invasive fat reduction is growing in popularity for body contouring. According to published data, body temperature alterations as minimal as 6°C can affect adipocytes. In this study we examine a non-invasive laser treatment for fat reduction in the abdomen.

Study: Thirty-five subjects received a single treatment session of multiple applications of 1060nm laser on different portions of the abdomen for fat reduction. Objective and subjective evaluations included ultrasound imaging and high resolution 2D photography at baseline, 6 and 12 weeks post treatment. Subjects were requested to maintain their standard diet and exercise routine throughout the study. Weight was recorded at baseline and at each follow up visit. Patient satisfaction was recorded at 12 weeks.

Three blinded evaluators were asked to choose the baseline photo from randomized pre and post treatment sets. Fat thickness change was measured using ultrasound imaging at the same location at 6 and 12 weeks post treatment compared to baseline.

Results: At twelve weeks, reviewers were able to identify the post treatment photograph 95% of the time (94%, 94%, and 97% respectively). Fat thickness reduction based on ultrasound images was 1.8mm (+/- 1.4mm) at 6 weeks and 3.1mm (+/- 1.7mm) at 12 weeks post a single treatment (n = 33 subjects). Statistically significant reductions were achieved based on paired t-test (p-value < .001) comparing 6 and 12 weeks to baseline. 91% (29/32) of subjects were satisfied (slightly satisfied, satisfied, and extremely satisfied). The most common side effect was mild to moderate tenderness which subsided within 1-3 weeks post treatment. No serious adverse events were reported.

Conclusion: The data demonstrates that light based non-invasive body contouring is an efficacious modality. Subjects tolerated the treatment well. Side effects were mild and resolved without intervention. Consistent reduction in the thickness of the subcutaneous fat layer was demonstrated based on ultrasound measurements and blinded photographic assessment.