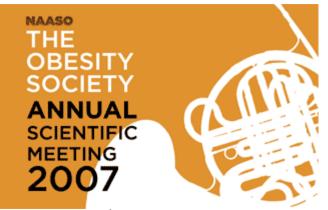
Peer Review Publications From Meridian Medical Inc.



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The Efficacy of the Lapex 2000 Lipo Laser in Body Contouring and Fat Reduction

Caruso-Davis M, Guillot T, Yu Y, Bissoon L, Greenway F Published in Obesity Journal 15:A99, 2007, 2007 Presented at NAASO Annual Scientific Meeting, New Orleans, LA. October 20-24, 2007.

INTRODUCTION

The Meridian LAPEX Lipo Laser System is a semi-conductor based low energy laser device that emits light at 632 nm, is non-thermal and non-invasive. This Lipo Laser System was originally developed to treat carpel tunnel syndrome, but was modified for use in body contouring and spot fat reduction. In this study we explored the efficacy of the Lipo Laser in body contouring and fat reduction on subjects' waistlines as evidence by girth measurements and photographs.

OBJECTIVES

The 2 primary objectives are: (a)To improve the body contour as evidenced by girth measurement reduction of the waistline. (b)To improve body contour as evidenced by photographs showing a better and more defined body contour.

STATISTICAL METHODS

The difference in average reduction between the LAPEX 2000 Lipo Laser treatment / active arm, and the control / placebo for subjects in the modified intent to treat group was compared using a two-sided two sample t-test with an alpha of 0.05.

METHODS

Forty healthy men and women ages 18-65 with a BMI <30 kg/m2 were randomized in a 1:1 ratio to either an experimental or control treatment. Each subject was treated with the Lipo Laser on their waistlines 30 minutes twice a week for four weeks. Standardized waist circumference measurements and photographs were taken before and after treatment 1, 3 and 8. Subjects were asked not to change their diet or exercise habits.

RESULTS

Each treatment with the Lipo Laser gave a loss of 0.4 - 0.5 cm in waist girth. On the third treatment, this difference, 0.405 cm (-0.059 ± 0.708 vs. -0.19 ± 0.47 cm (mean ± SD)), was significant (p<0.05). The cumulative girth loss at treatment three was 1.74 cm (-1.895 ± 2.967 vs. -0.16 ± 2.458 cm) (p<0.05). Cumulative girth loss at 4 weeks of treatment was 2.15 cm (-0.781 ± 2.817 vs. 1.353 ± 2.644 cm) in those who maintained their weight within 1.5 kg of their baseline weight (p<0.05). The standardized pictures showed $1.21 (1.21 \pm 0.419 \text{ vs. } 0 \pm 0)$ difference between the Lipo Laser and the placebo treatment in appearance on a 0-3 scale favoring the Lipo Laser comparing the baseline to the week 4 pictures (p<0.001).

SUMMARY and CONCLUSIONS

The Lipo Laser gives significant girth loss that is maintained over repeated treatments and is cumulative over 4 weeks of 8 treatments. This girth loss of approximately one inch from the waist was accompanied by a clinically and statistically significant improvement in appearance.

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Mechanistic Studies for Local Fat Reduction

Caruso-Davis M, Guillot T, Yu Y, Mashtalir N, Bissoon L, Dhurandhar N, Greenway F Published in Obesity Journal 16(suppl. 1):S161, 2008. Presented at NAASO Annual Scientific Meeting, Phoenix, Arizona. October 3-7, 2008.

Background

Local fat reduction for cosmetic purposes utilizes two different mechanisms. One is an ablative mechanism in which the fat cells are destroyed, exemplifi ed by the combination of phosphatidylcholine (PC) and deoxycholate (DC). PC with DC is felt to cause local fat reduction secondary to the detergent action of DC, and it is also believed that PC acts only as an emulsifi er. The other mechanism of local fat reduction is non-ablative in which fat cells release their fat, exemplifi ed by LipoLaser (LL) which emits low energy laser light. The LL has been shown by electron microscopy to open pores in fat cells allowing the triglyceride to leak out into the interstitial space. We performed studies to elucidate the mechanism of the two types of local fat reduction.

Methods

We measured the lipolytic response and appearance of human fat cells in culture to PC and DC exposure. We exposed human fat cells in culture to laser light or an ambient light condition in the presence of serum, heat inactivated serum, or no serum. We also evaluated human fat cells in culture for metabolic activity and cell viability when exposed to LL or ambient light.

Results

PC stimulated lipolysis 2.3 fold compared to assay buffer (p<0.001). DC, a detergent destroyed all the human fat cells at 10-1 M, destroyed half the cells at 10-2 M, at 10-3 M, the fat cells were not destroyed. Exposure to serum and heat inactivated serum both destroyed the human fat cells in response to either LL or ambient light, confi rming that the creation of pores in the fat cells was by a non-complement mediated mechanism. Human fat cells in culture exposed to LL and to ambient light had the same number of non-viable cells, but cells exposed to LL had lower metabolism, consistent with the stress of having pores in the cell membrane (p<0.0001).

Conclusions

The combination of PC and DC destroys fat cells by a detergent action based on the DC content. At low concentrations of DC, PC can act as a lipolytic stimulator to reduce fat by a non-ablative mechanism. LL opens pores in fat cells and allows egress of the triglycerides contained within them. LL open pores in the fat cells by a non-complement dependent mechanism, but does decrease fat cell metabolism without affecting the viability of the fat cells.



30th ASLMS Annual Conference April 14-18, 2010



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Effects of Low-level Laser Therapy in Subcutaneous Fat Reduction and

Improvement in Body Contour

Vinod Podichetty MD, Daniel Bourassa, DC Presented at ASLMS 30th Annual Conference Phoenix, Arizona, April 14-18, 2010

BACKGROUND AND OBJECTIVE

Low-level laser therapy (LLLT) has evolved as an efficient tool to provide therapeutic outcomes for a variety of medical indications. Currently, this is a U.S. Food and Drug Administration–approved technology for improving pain alleviation. However, recent studies on LLLT indicate "liquefaction" or release of stored fat in adipocytes by opening of the cell membrane after a short treatment. Nonetheless, clinical data is limited. The aim of the study was to assess the clinical effects of low-level laser therapy on subcutaneous fat reduction and improvement in body contouring.

STUDY DESIGN /MATERIALS and METHODS

Retrospective data review of patients (n=311) treated with Low-level laser therapy (658nm, 150 mW array/40 mW+/-20% diode laser radiation source) for a period of 26 months. All patients were meticulously screened and advocated on proper diet and exercise before treatment initiation. The LLLT was applied topically to skin of the abdomen and torso to areas where undesired fat was present.

RESULTS

272 females, 39 males (age range: 18-81 yrs) underwent from 1 to 24 laser treatments to the abdominal and torso areas. 54.6% (n=170) patients had 6 or more treatment sessions. Measured loss from a single first session treatment in 81% of the sample (n=253) averaged 2.79 cm (range: 0-9 cm) or 1.4cm in girth reduction covering all application times. Overall, 130 patients who completed all 6 and 12 sessions achieved an average sustained losses of 6.55 cm and 11.04 cm corresponding to an average girth reduction of 0.48 -0.55 cm per session. With weight loss of a minimum of 0.68 kg per week results averaged 9.0 cm for the 6 session group and 16.1 cm for the 12 session group corresponding to an average girth reduction 0.67-0.75 cm per session. 75.2% were able to sustain at least 4 cm or more loss in 6 or more sessions. Patient satisfaction and photographic assessment demonstrated significant higher score in all patients. Only 6 patients (<3%) of the 253 patients measured for their first session experienced no loss from the treatment. No significant complications were encountered in the patient population.

CONCLUSION

While there is a high demand for body shaping procedures, effective non-invasive body contouring alternatives for non-surgical candidates are very few. Cosmetic surgery patients are reluctant to undergo procedures that require general anesthesia and pose a multitude of potentially serious risks and complications with a possibility of several weeks of recovery time. Low level laser therapy appears to be safe and an efficacious method for reducing subcutaneous fat in the abdominal and torso areas where undesired fat is present.