Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA® OBESITY LASER ON THE REDUCTION OF THE CIRCUMFERENCE OF THE HIPS, WAIST AND UPPER ABDOMEN FOR INDIVIDUALS WITH BODY MASS INDEX (BMI) OF 30 TO 40 KG/M²: Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® Obesity Laser in reducing circumference of the hips, waist and upper abdomen when applied to individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m², by applying the laser to the treatment area 12 times across 4 consecutive weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites.

SUBJECTS: Fifty-three (53) subjects completed the study, 28 of whom were randomized to the active procedure group and 25 who were randomized to the placebo group.

Subjects were 18 to 65 year old males and females with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² who were indicated for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise.

Subject age averaged 47.09 years. The majority of subjects were Caucasian and there were more female than male subjects, as shown in Table 1 below.

Table 1: Baseline demographics

Gender	**Female**				**Male**			
n=53	*number*		*%*		*number*		*%*	
	45		85%		8		15%	
Ethnicity	**Caucasian**		**African American**		**Hispanic**		**Caucasian/Hispanic**	
n=53	*number*	*%*	*number*	*%*	*number*	*%*	*number*	*%*
	41	77%	9	17%	2	4%	1	2%

STUDY MEASURES: The study primary outcome measure of combined hips-waist-upper abdomen circumference was measured at baseline, mid-point (two weeks) of the procedure administration phase, at completion of the four-week procedure administration phase (endpoint) and two weeks after completion of the procedure administration phase. Body Mass Index (BMI) was also measured at these same assessment points. Subject satisfaction with procedure outcome and subject and assessment investigator perceived subject group assignment were recorded at endpoint.

BASELINE MEASUREMENTS: Table 2 below contains the mean (average) baseline circumference measurements (inches) and body mass index (BMI) by procedure group.

Table 2: Mean (Average) baseline measurements by procedure group

Circumference Measurements (inches)	**Test Group (n=28)**	**Placebo Group (n=25)**
Hips	44.53	43.11
Waist	39.60	40.43
Upper Abdomen	39.22	39.27
Total Body Circumference	***123.35***	***122.81***
Body Mass Index (BMI: kg/m²)	34.58	33.60

A series of t-tests for independent samples found there was no statistically significant difference in any of the above baseline measurements between subject procedure groups ($p>0.05$).

STUDY PROCEDURE: Subjects received twelve thirty-minute procedure administrations with the Erchonia® Obesity Laser across the frontal and dorsal aspects of the hips-waist-upper abdomen treatment region across a consecutive four-week period: three procedures per week, each procedure two or three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was defined as the change in total combined inches in circumference measurements (hips, waist and upper abdomen) from baseline (pre-procedure) to following completion of the four-week procedure administration phase (study endpoint). It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total combined circumference across this primary evaluation period. It was also pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 40% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

71.43% of subjects who received the active study procedures with the Erchonia® Obesity Laser attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 12% of subjects who received the 'fake' (placebo) laser procedures. A Fischer's Exact Test for two independent proportions found this difference of 59.43% between subject procedure groups to be statistically significant at $p<0.00005$.

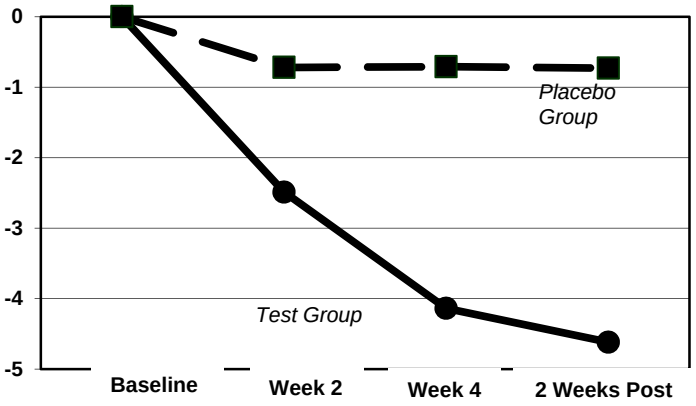
The mean change in combined circumference measurement for subjects who received the active study procedures with the Erchonia® Obesity Laser was a decrease of 4.14 inches, while the mean change in combined circumference measurements for subjects who received the 'fake' (placebo) laser procedures was a decrease of 0.71 inches. A t-test for two independent samples found the mean change in combined circumference measurements from baseline to study endpoint for test (active procedure) group subjects to be significantly greater than that for placebo (sham procedure) group subjects, at $p<0.0001$.

Table 3 and Chart 1 below show the mean change in combined circumference measurements across the four study evaluation points for test and placebo group subjects.

Table 3: Mean total circumference measurements (ins.) across evaluation points

	Test Group	Placebo Group
Baseline	123.35	122.81
Midpoint (week 2)	120.86	122.09
Endpoint (week 4)	119.21	122.10
2 Weeks Follow-up	118.73	122.08

Chart 1: Mean change in total circumference measurements (ins.) at each study evaluation point relative to baseline



For test subjects**,** total circumference measurements decreased progressively from baseline at each of the three subsequent evaluation points culminating in a mean decrease of 4.62 inches by 2 weeks post-procedure evaluation. For placebo subjects, the magnitude of the change was constant for all three subsequent evaluation points relative to baseline, indicating lack of any change in total circumference measurements beyond week 2 evaluation. Additionally, the magnitude of the changes relative to baseline for placebo group subjects were notably less that the respective changes for test group subjects. Considered together, these findings support progressive effectiveness of the Erchonia® Obesity Laser over time compared with placebo.

(ii) <u>Individual Body Area Circumference Measurements</u>: Table 4 below shows the mean (average) circumference measurements for each of the hips, waist and upper abdomen by procedure group across study evaluation.

Table 4: Individual circumference measurements across study duration by procedure group

Hips	**Test (n=28)**	**Placebo (n=25)**
Baseline	33.45	32.58
Midpoint	32.77	32.48
Endpoint	32.48	32.61
Follow-up	32.41	32.45

Waist	**Test (n=28)**	**Placebo (n=25)**
Baseline	39.76	39.27
Midpoint	38.90	38.98
Endpoint	38.64	38.77
Follow-up	38.60	38.68

Upper Abdomen	**Test (n=28)**	**Placebo (n=25)**
Baseline	39.76	39.27
Midpoint	38.90	38.98
Endpoint	38.64	38.77
Follow-up	38.60	38.68

Individual area circumference measurements decreased progressively from baseline at each of the three subsequent evaluation points culminating in a mean decrease of -1.86 inches for the hips, -1.24 inches for the waist and -1.51 inches for the upper abdomen from baseline to 2 weeks post-procedure evaluation. For placebo subjects, the magnitude of the respective changes were small to negligible, culminating in a mean decrease of -0.47 inches for the hips, -0.22 inches for the waist and -0.04 inches for the upper abdomen from baseline to 2 weeks post-procedure evaluation. Additionally, the magnitude of the changes relative to baseline for placebo group subjects were notably less than the respective changes for test group subjects relative to baseline. Considered together, these findings support progressive effectiveness of the Erchonia® Obesity Laser procedures over time compared with placebo.

(iii) Study outcome satisfaction ratings: At completion of study procedure administration, the subject was asked to rate how satisfied he or she was with any overall perceived change in the appearance of the hips-waist-upper abdomen area using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. 79% of test group subjects reported being ‘Satisfied’ (‘Very Satisfied’ or ‘Somewhat Satisfied’) with the study outcome compared with 16% of placebo subjects.

(v) Adverse events: No adverse event occurred for any subject throughout duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION: The Erchonia® Obesity Laser is an effective tool for reducing circumference measurements of the hips-waist-upper abdomen in individuals with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² over a 4-week period.