ERCHONIA® Scanner device (GLS)

Green Diode
Body Contouring
Clinical Study Results

Erchonia Corporation

July 23, 2012

(Study based on the ERCHONIA CORPORATION Erchonia GLS: **A double-blind, placebo-controlled, randomized evaluation of the effect of the Erchonia® Scanner Device (GLS) Green Diode on body contouring of the waist, hips and thighs clinical study protocol*: Version 2.0, March 24, 2011)***

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STUDY INFORMATION

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PRINCIPAL CLINICAL INVESTIGATORS

Two Principal Investigators participated in this clinical study at two separate test sites. Each Principal Investigator, as listed below, was determined suitable and qualified to participate by the National Institutional Review Board listed below.

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INSTITUTIONAL REVIEW BOARD

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PURPOSE OF STUDY

The purpose of this clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) manufactured by ERCHONIA CORPORATION (the Company) for non-invasive body contouring of the waist, hips and thighs by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks.

DEVICE DESCRIPTION

The Erchonia® GLS device used in this study comprises six independent diodes, 532 nanometer (green diodes) variable frequency device. The variable frequency feature of the GLS is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® GLS has the following specifications:

- ✓ Configuration: 6 Class 2 Line Generated Laser Diode Modules
- ✓ Wavelength: 532nm
- ✓ Power Output (Mean): 17mw
- ✓ Modulation: Constant Wave (CW)
- ✓ Display: Full Color TFT Touch Screen Control Center
- ✓ Adjustments:
    - 44” Vertical Arm Height Adjustment.
    - Four Independent Adjustable Arms for Desired Laser Concentration
- ✓ Power Source: 100-240VAC 50-60Hz
- ✓ Chassis:
    - Metal Frame Powder Coated for Ease of Cleaning
    - 4 Anti-Static Casters (4 Locking)
- ✓ Housing: Black Carbon Fiber Finish Thermoformed from Non-Allergen Material/Plastic
- ✓ Weight: 70lbs.

The Erchonia® GLS utilizes internal mechanics that collects the light emitted from the each of the laser diodes and processes each through a proprietary patented lens which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. These patterns overlap each other to guarantee total coverage within the target area. The target area is approximately 8” x 10” inches or 80 square inches, approximately 516 square centimeters.

The Erchonia® GLS contains 6 independent diodes, 4 of which are mounted in scanner devices, positioned 120 degrees apart from the next with each titled at a 30 degree angle. The fifth and sixth diodes are 4” from center, each tilted at a 15 degree angle. Each scanner emits 17mW, 532nm of green laser light.

The Erchonia® GLS is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure no possible instance of residual effect, a pair of specialty glasses was provided for use during procedure applications with the Erchonia® Scanner device (GLS). These safety glasses, manufactured by Laser Safety Industries, sufficiently and effectively block the laser light spectrum at OD6+ @ 190-532nm.

STUDY DESIGN

This study was a placebo-controlled, randomized, double-blind parallel group two-center design.

STUDY SUBJECT POPULATION

RECRUITMENT AND COMPENSATION

All qualifying study subjects were recruited from among the investigators' normal pool of patients who voluntarily came to their offices for evaluation for a body contouring procedure.

Qualifying subjects were neither charged nor compensated for their participation in the clinical study, including the cost of the laser procedures.

SAMPLE SIZE

Sixty-seven (67) individuals were enrolled in the study. All 67 enrolled subjects completed study participation according to protocol through to the study end point evaluation visit. Thirteen (13) subjects did not return for the 2-week post-procedure follow-up evaluation visit.

Of the 67 participating subjects, 35 were randomized to the active treatment group and 32 were randomized to the placebo group.

ELIGIBILITY CRITERIA

All subjects who qualified as eligible for participation in this clinical study satisfied each of the following inclusion criteria and none of the following exclusion criteria.

Inclusion Criteria

- Signed informed consent form
- Body Mass Index (BMI) is less than 30 kg/m².
- Subject 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; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs. (As per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by *A joint Ad Hoc Committee of the American Society of Lipo-Suction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS))*
- Subject is willing and able to abstain from partaking in <u>any treatment other than the study procedure (existing or new)</u> to promote body contouring and/or weight loss during the course of study participation. Such treatments include, but are not limited to:
  - ✓ over-the-counter and/or prescription medications indicated to promote body sculpting/weight loss, including dietary/herbal supplements/minerals and appetite suppressants such as Xenical (orlistat), Meridia (sibutramine), Alli, etc.
  - ✓ weight loss programs/diet plans such Weight Watchers, LA Weight Loss, SlimFast, Atkin's, etc.
  - ✓ surgical procedures to promote body sculpting/weight loss, such as liposuction, abdominoplasty, stomach stapling, lap bands, etc.
  - ✓ alternative therapies such as acupuncture, body wraps, hypnotherapy, etc.
- Subject is willing and able to maintain his or her regular (typical pre-study) diet and exercise regimen without effecting significant change in either direction during study participation.
- 18 years to 65 years of age, inclusive.
- Male or female.

Exclusion Criteria

- Body Mass Index (BMI) of 30 kg/m² or greater (body weight in 'obese' category according to the current standard definitions of the Center for Disease Control (**CDC**) and World Health Organization (**WHO**) for individuals over 18 years of age.
- Diabetic dependent on insulin or oral hypoglycemic medications.
- Known cardiovascular disease such as cardiac arrhythmias, congestive heart failure.
- Cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.
- Prior surgical intervention for body sculpting/weight loss, such as liposuction, abdominoplasty, stomach stapling, lap band surgery, etc.
- Medical, physical, or other contraindications for body sculpting/weight loss.
- Current use of medication(s) known to affect weight levels and/or to cause bloating or swelling and for which abstinence during the course of study participation is not safe or medically prudent.
- Any medical condition known to affect weight levels and/or to cause bloating or swelling.
- Diagnosis of, and/or taking medication for, irritable bowel syndrome.
- Active infection, wound or other external trauma to the areas to be treated with the laser.
- Photosensitivity disorder.
- Current cancer or recording treatment for cancer.
- Pregnant, breast feeding, or planning pregnancy prior to the end of study participation.
- Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in past two years.
- Developmental disability or cognitive impairment that would preclude adequate comprehension of the informed consent form and/or ability to record the necessary study measurements.
- Involvement in litigation and/or a worker's compensation claim and/or receiving disability benefits related to weight-related and/or body shape issues.
- Participation in a clinical study or other type of research in the past 30 days.

SAMPLE DEMOGRAPHICS

GENDER

Of the 55 subjects for whom gender was recorded, 46 subjects were female (84%) and 9 subjects (16%) were male:

- ✓ Test subjects (n=25): 22 females (88%); 3 males (12%)
- ✓ Placebo subjects (n=30): 24 females (80%); 6 males (20%)

AGE

Of the 49 subjects for whom age was recorded, subject age ranged from 20 to 63 years. The mean and standard deviation age in years for test, placebo subjects and all subjects combined, are shown in Table 1 below.

Table 1: Mean and standard deviation of age by treatment group

Age (years)	Test (n=20)	Placebo (n=29)	All (n=49)
Mean	36.60	39.03	38.04
Standard deviation	10.05	10.16	10.08

A **t-test for independent samples** revealed no statistically significant difference in age between test and placebo group subjects: μa-μb=-2.43; t=-0.83; df=47; p(two-tailed)=0.41 (p>0.05).

ETHNICITY

For the 61 subjects for whom ethnicity was recorded, subject ethnicity breakdown for test, placebo and all subjects combined, is shown in Table 2 below.

Table 2: Subject ethnicity by treatment group

Ethnicity	Test (n=29)	Placebo (n=32)	All (n=61)
Caucasian	26 (90%)	30 (94%)	56 (92%)
African American	1 (3%)	1 (3%)	2 (3%)
Middle Eastern	2 (7%)	1 (3%)	3 (5%)

POTENTIAL CONFOUNDING STUDY FACTORS

There were no potential confounding factors identified throughout the duration of the study, as follows:

- Diet, exercise and concomitant medication use: As part of the study qualification criteria, subjects were required to agree to maintain their pre-study enrollment pattern of diet, exercise and medication use. Details of these variables were recorded at the pre-procedure phase and subjects were required to record a daily diary during the procedure administration and post-procedure administration phases, listing any deviations from reported baseline diet, exercise and concomitant medication use. No subject reported any deviation from baseline diet, exercise or concomitant medication use that was notable enough to impact recorded study measurements.

- Skin markers: The investigator recorded the following skin markers for each subject pre-procedure:

  - ✓ notation of hernias, scars, asymmetries, cellulite, stretch marks, discoloration, etc.
  - ✓ presence of stria and dimpling
  - ✓ underlying abdominal musculofacial system and presence/absence of flaccidity and diastasis recti
  - ✓ quality of the skin and its elasticity

  These skin markers were re-evaluated following completion of the 2-week procedure administration phase. No changes from baseline were noted for any subject.

- Adverse events/reactions: There were no adverse events and/or reactions recorded for, or reported by, any subject - test or placebo - throughout the duration of this clinical study.

PRE-PROCEDURE VARIABLES

The following variables were recorded pre-procedure for each subject prior to commencement of administration of the study procedure phase.

- Body Weight (lbs.): The mean and standard deviation pre-procedure Body Weight for test subjects and placebo subjects are shown in Table 3 below.

  Table 3: Mean and standard deviation pre-procedure body weight by treatment group

Body Weight (lbs)	Test (n=35)	Placebo (n=32)
Mean	154.33	154.18
Standard deviation	28.83	26.19

  A **t-test for independent samples** was conducted to evaluate the significance of the difference in subject pre-procedure Body Weight recordings between treatment groups. The difference was found to be not statistically significant: μa-μb=-0.15; t=-0.02; df=65; p(two-tailed)=0.98 (p>0.05).

- Body Mass Index (BMI): The mean and standard deviation pre-procedure BMIs for test subjects and placebo subjects are shown in Table 4 below.

  Table 4: Mean and standard deviation pre-procedure BMI by treatment group

Body Mass Index (BMI)	Test (n=35)	Placebo (n=32)
Mean	25.83	24.77
Standard deviation	2.93	3.27

  A **t-test for independent samples** was conducted to evaluate the significance of the difference in subject pre-procedure BMI recordings between treatment groups. The difference was found to be not statistically significant: μa-μb=-1.05; t=+1.39; df=65; p(two-tailed)=0.17 (p>0.05).

- Circumference Measurements: The circumference in inches (ins) was measured for each subject's waist, hips and each of the left and right thighs, and the combined measurement also calculated by summing these individual area measurements.

  The mean and standard deviation pre-procedure circumference measurements for test subjects and placebo subjects are shown in Table 5 below.

Table 5: Pre-procedure circumference measurements by treatment group

Circumference in inches		Test (n=35)	Placebo (n=32)
Waist	Mean	33.45	32.58
	SD	3.89	5.03
Hip	Mean	39.76	39.27
	SD	3.27	3.89
Right thigh	Mean	23.41	22.69
	SD	1.77	2.25
Left thigh	Mean	23.35	22.50
	SD	1.63	2.11
Total inches	**Mean**	119.97	117.04
	SD	8.52	11.03

A **t-test for independent samples** was conducted to evaluate the significance of the difference in subject pre-procedure body circumference measurements between treatment groups. The circumference difference was not statistically significant for the waist, hips, right thigh and for all body areas combined, but it was statistically significantly different between treatment groups for baseline left thigh circumference measurements, as shown in Table 6 below.

Table 6: Significance of the differences in pre-procedure circumference measurements between treatment groups

Body area	μa-μb	t	df	p(two-tailed)	p
Waist	0.872	+0.80	65	0.43	p>0.05
Hip	0.484	+0.55	65	0.58	p>0.05
Right thigh	0.727	+1.48	65	0.14	p>0.05
Left thigh	0.845	+1.85	65	0.07	p>0.05
Total of all areas	2.93	+1.20	65	0.23	p>0.05

In conclusion, prior to commencement of the study procedure administration phase, there was no statistically significant difference found between subjects randomized to the two treatment groups (test and placebo) for the recorded baseline measures of body weight; body mass index (BMI); waist, hips, right thigh, left thigh and combined circumference measurements.

PROCEDURE ADMINISTRATION

Each subject received six total procedure administrations with the Erchonia® GLS (active or sham) across a consecutive two-week period: three procedures per week, each procedure at least two days but no more than three days apart. Exposure time to the Erchonia® GLS laser was 15 minutes across the frontal region and 15 minutes across the lateral region for each procedure administration. Each procedure administration took place at the investigator's test site.

STUDY OUTCOME MEASURES

Study outcome **assessment time points** were:

- Mid-point evaluation: End of Week One of the procedure administration phase (after the 1st 3 procedure administrations)
- Endpoint evaluation: End of Week Two of the procedure administration phase (after the 6th and final procedure administration)
- Post-procedure Follow-up evaluation: Two weeks following the final procedure administration.

The following **study measures** were evaluated at each of the assessment time points:

- Mid-point evaluation:
  - ✓ Body Weight
  - ✓ BMI
  - ✓ Circumference measurements (waist, hips, right thigh, left thigh)

- Endpoint evaluation:
  - ✓ Body Weight
  - ✓ BMI
  - ✓ Circumference measurements (waist, hips, right thigh, left thigh)
  - ✓ Subject satisfaction with procedure outcome

- Post-procedure evaluation:
  - ✓ Body Weight
  - ✓ BMI
  - ✓ Circumference measurements (waist, hips, right thigh, left thigh)

STATISTICAL ANALYSIS

PRIMARY EFFICACY OUTCOME ANALYSIS

The primary efficacy outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from baseline (pre-procedure) to following completion of the two-week procedure administration phase (study endpoint: end of week 2).

Individual subject success criteria
The individual subject success criteria was defined as at least a 3.0 inch reduction in combined circumference measurements for the waist, hips and bilateral thighs from baseline to study endpoint.

Overall study success criteria.
Overall study success criteria was defined as at least a 35% difference between treatment groups, comparing the proportion of individual successes in each group.

Evaluation Time Point
The evaluation time point at which study success will be analyzed is following completion of the sixth and final study procedure administration, two weeks after treatment phase onset.

Populations Examined
It was intended that the primary outcome measure be evaluated for the following two subject populations:

a) *Intent-to-Treat (ITT) Population*
For the ITT analysis, all subjects who had been randomized to treatment group were included, provided they had circumference measurements recorded at baseline. Dropouts, terminated subjects, and so forth were included by carrying forward the last observation for all time points following dropout (Last Observation Carried Forward – LOCF – method). If a subject was not a dropout, but had no data in a relative day range, the last observation prior to the time point being analyzed was used in the ITT analysis.

b) Per-Protocol Population
Analysis based on the per-protocol population was intended to corroborate the conclusions drawn from the analysis of data based on the ITT population. The per-protocol analysis excluded subjects with major protocol deviations and incompletes (drop-outs, non-compliant subjects, disqualified subjects, etc.).

Every enrolled randomized subject in this clinical study had recorded circumference measurements at both baseline and at the end of week two study end evaluation time point. Therefore, only the ITT analysis was performed for primary outcome study success evaluation, with no need to employ last observation carried forward (LOCF) methodology.

Primary Outcome Measure Analyses

Proportion of successes

Table 7 below shows the number and percentage of test and placebo group subjects who met the study **individual subject success criteria**

Table 7: Individual Success Criteria met by treatment group

	Test subjects	**Placebo subjects**
n	35	32
n meeting success criteria	24	6
% meeting success criteria	**68.57%**	**18.75%**

There is a **difference of 49.82% between procedure groups**, such that 49.82% more test group than placebo group subjects showed a total decrease in combined circumference measurements from pre-procedure to study end point of 3 inches or greater, exceeding the pre-established target of a 35% difference between treatment groups by 14.82%.

A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of successes between treatment groups.

The results are as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	24	11	35
Placebo Group	6	26	32
	30	37	67

- p(two-tailed)=0.000063; p<0.0001

The difference was found to be **statistically significant at p(two-tailed<0.0001),** meaning that the two treatment groups gave significantly different results, such that the greater treatment effect observed for subjects in the test group relative to subjects in the placebo group is statistically significant and can be attributed to the efficacy of the application of the Erchonia® GLS over a placebo device.

Change scores

Table 8 below shows the mean and standard deviation of the magnitude of the change in combined circumference measurements (in inches) from pre-procedure to study endpoint for test versus placebo subjects.

Table 8: Mean and standard deviation of the change in total circumference measurements (inches) by treatment group

	Test subjects (n=35)	Placebo subjects (n=32)
Mean	-3.895	-1.136
SD	3.03	2.27

A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in combined circumference (total number of inches) from study baseline to endpoint. The difference was found to be **statistically significant at p<0.0001:** μa-μb=-2.76*;* t=-4.18; df=65; p(two-tailed)<0.0001, such that the mean decrease in number of total inches from baseline to study endpoint for test group subjects was significantly greater than that for placebo group subjects.

Primary Outcome Measure Covariate Analyses

A series of **one-way ANCOVAs for two independent samples** were performed on the primary outcome measure of change in combined circumference measurements from baseline to study endpoint to adjust for the covariates of pre-procedure body weight (lbs), body mass index (BMI), and combined body circumference (inches).

a) Pre-Procedure Body Weight (lbs)

Adjusted Means:

- ✓ Test group: -3.894 inches
- ✓ Placebo group: -1.137 inches

F=17.57; p=0.000087 (p<0.0001)

In consideration of pre-procedure body weight as a covariate, F=17.57 is statistically significant at p<0.0001 such that if the individual differences in pre-procedure body weight are removed, then the two adjusted means significantly differ to the degree of p<0.0001. **This indicates that the actual Erchonia® GLS laser is more effective than the placebo device, and this treatment effect is independent of subjects' baseline body weight.**

- r^2 = 0.02; Baseline body weight accounted for 2% of the variance in the change in total body circumference measurements from baseline to study endpoint assessment.
- r = -0.15: Very low correlation between baseline body weight and change in body circumference measurements from baseline to study endpoint assessment.

b) Pre-Procedure Body Mass Index (BMI)

Adjusted Means:
- ✓ Test group: -3.817 inches
- ✓ Placebo group: -1.221 inches

F=15.29; p=0.00023 (p<0.0005)

In consideration of pre-procedure BMI as a covariate, F=15.29 is statistically significant at p<0.0005, such that if the individual differences in pre-procedure BMI are removed, then the two adjusted means significantly differ to the degree of p<0.0005. **This indicates that the actual Erchonia® GLS laser is more effective than the placebo device, and this treatment effect is independent of subjects' baseline BMI.**

- r^2 = 0.03; Baseline BMI accounted for 3% of the variance in the change in total body circumference measurements from baseline to study endpoint assessment.
- r = -0.18: very low correlation between baseline BMI and change in body circumference measurements from baseline to study endpoint assessment.

c) Pre-procedure Total circumference (inches)

Adjusted Means:
- ✓ Test group: -3.833 inches
- ✓ Placebo group: -1.204 inches

F=15.72; p=0.00019 (p<0.0005)

In consideration of pre-procedure total circumference measurement as a covariate, F=15.72 is statistically significant at p<0.0005, such that if the individual differences in pre-procedure total circumference measurements are removed, then the two adjusted means significantly differ to the degree of p<0.0005. **This indicates that the actual Erchonia® GLS laser is more effective than the placebo device, and this treatment effect is independent of subjects' baseline total body circumference measurement.**

- r^2 = 0.03; Baseline total body circumference measurements accounted for 3% of the variance in the change in total body circumference measurements from baseline to study endpoint assessment.
- r = -0.16: very low correlation between baseline total body circumference measurements and change in body circumference measurements from baseline to study endpoint assessment.

Baseline to Endpoint Total Body Circumference Measurements

Table 9 below shows the mean and standard deviation of the baseline and study endpoint total body circumference measurements (inches) and the change between the 2 assessment points for test and placebo subjects.

Table 9: Mean and standard deviation of the baseline and study endpoint total body circumference measurements and the change between the two points by treatment group

	Test (n=35) mean (st. dev.)	**Placebo (n=32) mean (st. dev.)**
Baseline	119.97 (8.52)	117.04 (11.30)
End point	116.08 (8.10)	115.91 (11.50)
Change	-3.895 (3.03)	-1.136 (2.27)

A **t-test for correlated samples** was conducted to evaluate the mean change in total combined body circumference measurements (total number of inches) from study baseline to endpoint for test group and placebo group subjects.

- *Test Group*

For test group subjects, the mean change from baseline to study endpoint in total body circumference measurement was found to be **statistically significant, at p<0.0001:** μa-μb=-3.895; t=+7.60; df=34; p(two-tailed)<0.0001.

- *Placebo Group*

For placebo group subjects, the mean change from baseline to study endpoint in total body circumference measurement was found to be **statistically significant, at p<0.01:** μa-μb=-1.136; t=+2.83; df=31; p(two-tailed)=0.0081 (p<0.01).

Although a statistically significant mean change in total body circumference measurement from baseline to study endpoint evaluation was found for both test and placebo subject groups, both the magnitude and the significance of that change occurred to a notably lesser degree for placebo group subjects. The mean change in total body circumference for placebo group subjects was less than one-third the magnitude of the change for test subjects (-1.136 inches versus -3.895 inches), and the statistical significance of the change was lesser for placebo group subjects at p<0.01 compared with p<0.0001 for test group subjects.

In addition, the change in body circumference measurement for placebo subjects was not clinically meaningful. Clinically meaningful change for combined waist-hips-thighs circumference measurements across an evaluation period is determined as a decrease of 3.0 inches or greater. This was exceeded for the test group as a whole (mean combined change of -3.895 inches), but the -1.135 inches mean decrease for the placebo group did not even approach the 3.0+ inches established level of clinically meaningful change.

Further support for the statistical significance and clinical meaningfulness of the change in total body circumference measurements for the test subject group compared with the placebo subject group over the study treatment evaluation period is provided by **Linear Regression Analysis** that was performed to evaluate the contribution of changes in **body weight** measurements between the Baseline and Week 2 (study endpoint) evaluations to the changes

in the primary measure of combined body circumference measurements between Baseline and Week 2 (study endpoint) evaluations, for both treatment groups.

Y = a + bX
Y = change in body circumference (inches)
X = change in weight (lbs.)
a = Y-intercept: estimated average value of Y when X=0
b = slope: estimated average change in Y when X increases by one unit
r = correlation co-efficient: strength of the association between the changes in X and Y
r^2 = measure of the shared variance between the 2 variables

The results are as follows:

Test Subject Group (n=35)

Y=-3.80+0.105X

- *Y-intercept*: -3.80: When there is no change in body weight, the estimated average change in body circumference measurement is -3.80 inches.
- *Slope:* 0.105: The estimated average change in body circumference (inches) is 0.105 inches per each 1 lb change in body weight.
- t=0.32, df=33, p(2-tailed)=0.75; p>0.05
- r^2 = 0.003; Change in body weight accounted for 0.3% of the variance in the change in body circumference measurement.
- *r* = -0.056: There is no association between change in body weight and change in body circumference measurements

Placebo Group Subjects (n=32)

Y=-1.107+0.515X

- *Y-intercept*: -1.107: When there is no change in body weight, the estimated average change in body circumference measurement is -1.107 inches.
- *Slope:* 0.515: The estimated average change in body circumference (inches) is 0.515 inches per each 1 lb change in body weight.
- t=-2.24, df=30, p(2-tailed)=0.033; p<0.05
- r^2 = 0.144; Change in body weight accounted for 14.4% of the variance in the change in body circumference measurement.
- *r* = 0.38: There is a moderate association between change in body weight and change in body circumference measurements.

Therefore, for **test group subjects**, mean change in body weight had no significant impact on the statistically significant mean change (decrease) that occurred in the primary study measure of combined circumference measurements from baseline to study endpoint evaluation. **This indicates that the treatment effect of the Erchonia® GLS laser accounted for the change in body circumference measurements, and weight loss was not a significantly contributing factor**.

For **placebo group subjects**; however, mean change in body weight did have a statistically significant impact on the mean change that occurred in the primary study measure of combined circumference measurements from baseline to study endpoint evaluation.

In summary, the above findings combined indicate that the sizable, statistically significant and clinically meaningful decreases in total body circumference measurements that occurred for the test subject group over the study treatment evaluation period is independent of changes in body weight for those subjects over that same period and can be attributed solely to the positive treatment effect of the Erchonia® GLS laser over placebo. Conversely, even though there was a statistically significant decrease in body circumference measurements for the placebo subject group over the same evaluation period, it occurred to a notably lesser degree, did not approach the level of a clinically meaningful change, and the change that did occur can be largely attributed to a change in body weight over that treatment period.

SECONDARY EFFICACY OUTCOME ANALYSIS

Change in inches in combined waist-hips-thighs circumference across all study measurement points

Circumference measurements were recorded at baseline, end of procedure administration week 1, end of procedure administration week 2 (study end point) and 2 weeks post-procedure.

(i) Intent-to-Treat (ITT) Analysis
ITT analysis for change in total circumference measurements across the four study measurement time points was conducted for all randomized subjects who had a measurement recorded at baseline. All 67 randomized subjects had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Thirteen (13) of the 67 subjects did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 8 subjects who had been randomized to the test group and 5 subjects who had been randomized to the placebo group. For these 13 subjects, the last observation carried forward (LOCF) procedure was employed, such that the subject's week 2 circumference measurement was carried forward as the week 2 post-procedure measurement.

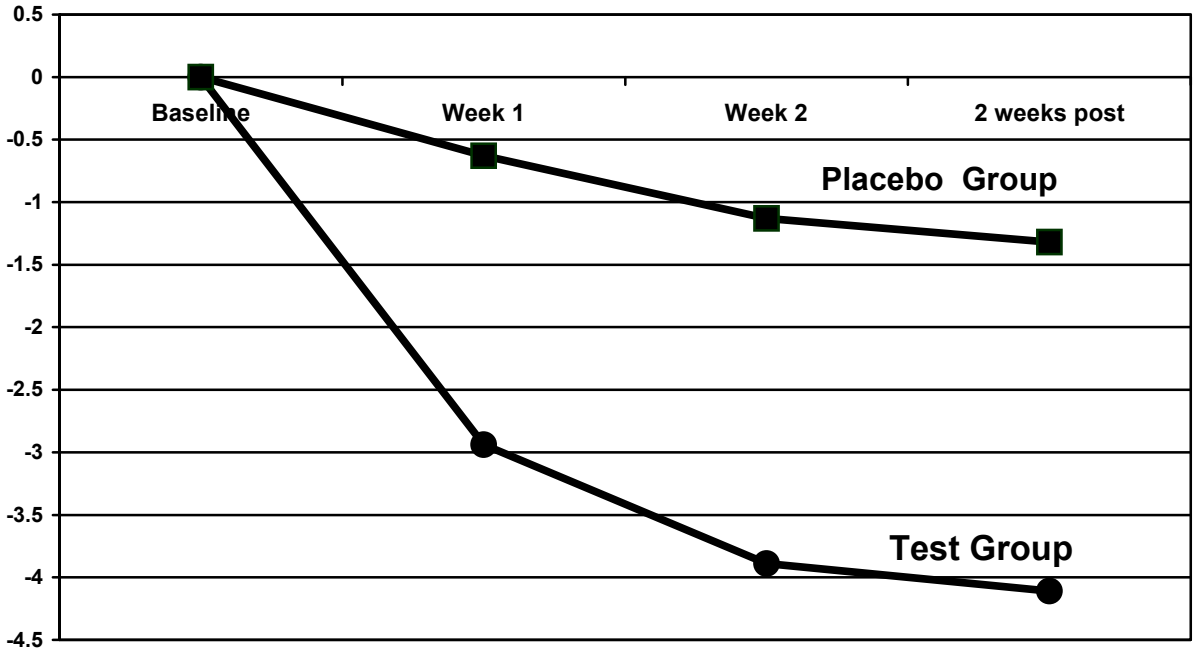
Table 10 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points for the ITT subject population.

Table 10: Total circumference measurements across study duration by treatment group for the ITT population.

	Test Group (n=35)		Placebo Group (n=32)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	119.97	8.52	117.04	11.30
Week 1 (Mid)	117.03	9.02	116.41	11.75
Week 2 (End)	116.08	8.10	115.91	11.50
2 weeks post	115.86	8.85	115.72	11.20

Chart 1 below shows the change from baseline in mean total circumference measurements across the subsequent three study measurement time points by treatment group for the ITT population.

Chart 1: Change from baseline in mean total circumference measurements by subsequent measurement time point by treatment group for the ITT population



One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group for the ITT sample.

- *Test Subjects*

For the ITT population, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=28.83$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

➢ *Placebo Subjects*

For the ITT populations, for subjects assigned to the placebo device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=3.64$, $p=0.016$; $p<0.05$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment point, at the $p<0.05$ level:

✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population, for placebo subjects, there was no statistically significant change in total circumference measurements across the procedure administration phase through study endpoint, but a statistically significant change was detected from baseline to 2-weeks post-procedure assessment, although the magnitude of that change (-1.32 inches) was less than one-third of the magnitude of that change for test group subjects (-4.11 inches) across the same assessment period.

(i) Per Protocol Analysis

Analyses based on the per-protocol population were also performed for the change in total circumference measurements across the four study measurement time points to corroborate the conclusions drawn from the ITT analyses. This analysis excluded subjects with major protocol deviations and incompletes (drop-outs, non-compliant subjects, disqualified subjects, etc.). The per-protocol analysis does not carry data forward.

Thirteen (13) of the 67 enrolled subjects did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 8 subjects who had been randomized to the test group and 5 subjects who had been randomized to the placebo group. Therefore, the per-protocol analysis for change in total body circumference is based on a total of 54 subjects: 27 subjects in the test group and 27 subjects in the placebo group.

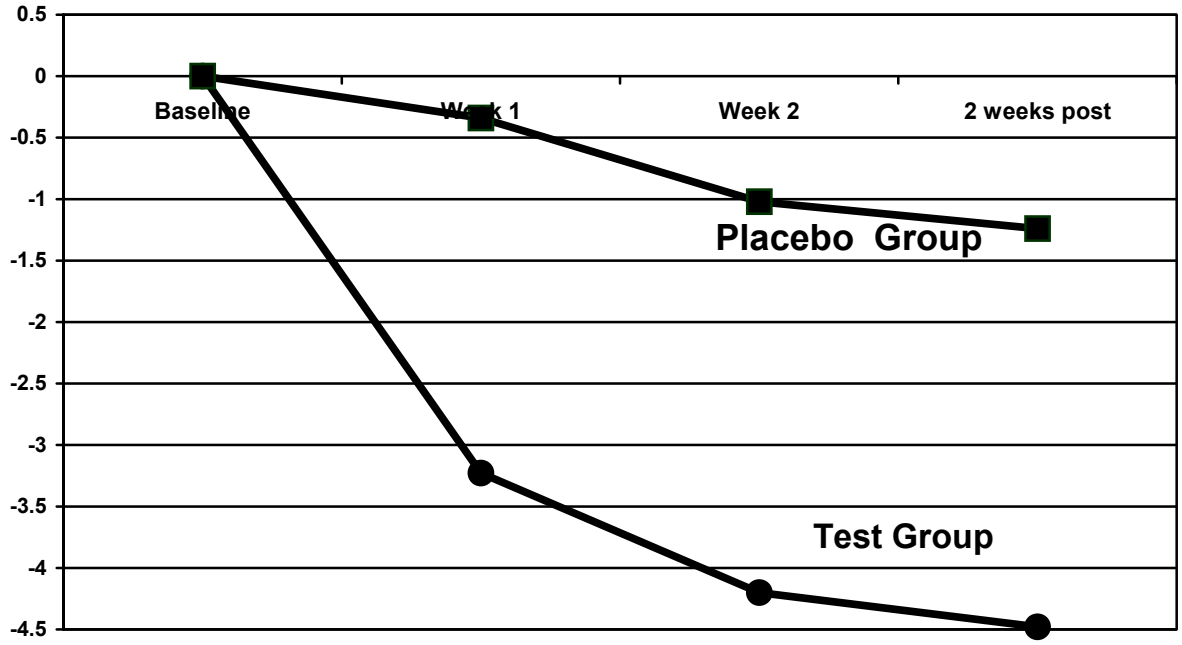
Table 11 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points for the per-protocol subject population.

Table 11: Total circumference measurements across study duration by treatment group for the per-protocol population.

	Test Group (n=27)		**Placebo Group (n=27)**	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	120.37	8.98	117.47	11.65
Week 1 (Mid)	117.14	9.76	117.13	12.13
Week 2 (End)	116.17	8.74	116.45	11.77
2 weeks post	115.89	9.64	116.23	11.43

Chart 2 below shows the change from baseline in subjects' mean total circumference measurements across the subsequent three study measurement time points by treatment group for the per-protocol population.

Chart 2: Change from baseline in mean total circumference measurements by subsequent measurement time point by treatment group for the per-protocol population



One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group in the per-protocol sample.

- *Test Subjects*

For the per protocol population, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=26.59$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per-protocol population, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per-protocol population, for subjects assigned to the placebo device group, the changes in total combined circumference measurement across measurement points were <u>not statistically significant</u> for any interval ($F=2.68$, $p=0.053$ $p>0.05$).

Change in inches in individual area circumference measurements across all study measurement points

Circumference measurements were recorded at baseline, end of procedure administration week 1 (midpoint), end of procedure administration week 2 (study end point) and 2 weeks post-procedure for each of the waist, hips and right and left thighs.

(i) Intent-to-Treat (ITT) Analysis

Table 12 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the ITT subject population.

Table 12: Individual treatment area circumference measurements across study duration by treatment group for the ITT population.

	Test Group (n=35)		Placebo Group (n=32)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	33.45	3.89	32.58	5.03
Week 1 (Mid)	32.77	3.79	32.48	5.14
Week 2 (End)	32.48	3.55	32.61	5.20
2 weeks post	32.41	3.58	32.45	5.18
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	39.76	3.27	39.27	3.89
Week 1 (Mid)	38.90	2.97	38.98	3.88
Week 2 (End)	38.64	2.91	38.77	3.80
2 weeks post	38.60	3.23	38.68	3.80
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.41	1.77	22.69	2.25
Week 1 (Mid)	22.70	1.96	22.60	2.35
Week 2 (End)	22.58	1.89	22.32	2.12
2 weeks post	22.56	2.00	22.35	2.10
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.35	1.63	22.50	2.11
Week 1 (Mid)	22.66	1.94	22.35	2.25
Week 2 (End)	22.39	1.79	22.20	2.06
2 weeks post	22.29	1.92	22.24	2.02

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the ITT population.

Waist Circumference

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=9.54$ $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 1 (study midpoint): $p<0.05$
- ✓ Baseline and week 2 (study endpoint): $p<0.01$
- ✓ Baseline and 2 weeks post-procedure follow-up: $p<0.01$

Therefore, based on the ITT population, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval ($F=0.47$, $p=0.70$; $p>0.05$).

Hip Circumference

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected ($F=9.23$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population, for test subjects**,** compared with baseline, hip circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval ($F=2.17$, $p=0.097$; $p>0.05$).

Right Thigh Circumference

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected ($F=17.18$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population, for test subjects**,** compared with baseline, right thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in right thigh circumference measurement across measurement points were not statistically significant for any interval ($F=2.51$, $p=0.06$; $p>0.05$).

Left Thigh Circumference

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected ($F=17.74$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in left thigh circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population, for test subjects**,** compared with baseline, left thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval ($F=1.43$, $p=0.23$; $p>0.05$).

(ii) Per Protocol Analysis

Table 13 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the per protocol subject population.

Table 13: Individual treatment area circumference measurements across study duration by treatment group for the per protocol population.

	Test Group (n=27)		Placebo Group (n=27)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	33.88	4.02	32.58	5.25
Week 1 (Mid)	33.07	4.02	32.56	5.40
Week 2 (End)	32.68	3.71	32.67	5.40
2 weeks post	32.59	3.75	32.47	5.38
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	39.84	3.47	39.49	3.99
Week 1 (Mid)	38.83	3.12	39.16	4.07
Week 2 (End)	38.71	2.99	39.03	3.94
2 weeks post	38.67	3.40	38.92	3.96
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.38	1.86	22.81	2.28
Week 1 (Mid)	22.67	2.18	22.83	2.35
Week 2 (End)	22.45	2.08	22.47	2.03
2 weeks post	22.43	2.21	22.51	1.99
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.28	1.72	22.59	2.10
Week 1 (Mid)	22.56	2.09	22.58	2.26
Week 2 (End)	22.32	1.94	22.29	2.07
2 weeks post	22.20	2.09	22.33	2.01

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the per protocol population.

Waist Circumference

- *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=10.11$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 1 (study midpoint): $p<0.05$
- ✓ Baseline and week 2 (study endpoint): $p<0.01$
- ✓ Baseline and 2 weeks post-procedure follow-up: $p<0.01$

Therefore, based on the per protocol population, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval ($F=0.42$, $p=0.74$; $p>0.05$).

Hip Circumference

- ➢ *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected ($F=7.99$, $p=0.0001$; $p<0.005$).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per protocol population, for test subjects**,** compared with baseline, hip circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval ($F=1.55$, $p=0.21$; $p>0.05$).

Right Thigh Circumference

- ➢ *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected ($F=16.60$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per protocol population, for test subjects**,** compared with baseline, right thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in right thigh circumference measurement across measurement points were not statistically significant for any interval (F=2.8, p=0.054; p>0.05).

Left Thigh Circumference

- *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected (F=15.08, p<0.0001).

A subsequent Tukey HSD test revealed that significant decreases in left thigh circumference measurements occurred between the following assessment points, at the p<0.01 level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per protocol population, for test subjects**,** compared with baseline, left thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval (F=1.87, p=0.14; p>0.05).

Change in body weight in pounds between study measurement points: A comparison between test and placebo procedure groups

Body weight measurements were recorded at baseline, end of procedure administration week 1, end of procedure administration week 2 (study end point) and 2 weeks post-procedure.

(i) Intent-to-Treat (ITT) Analysis

Table 14 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the ITT subject population

Table 14: Body weight measurements across study duration by treatment group for the ITT population

	Test Group (n=35)		Placebo Group (n=32)	
Body weight	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	154.33	28.83	154.18	26.19
Week 1 (Mid)	154.17	29.28	154.28	26.36
Week 2 (End)	153.43	28.96	154.09	26.05
2 weeks post	153.67	28.94	154.05	25.89

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the ITT population.

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change in body weight measurement across assessment points was detected ($F=6.18$, $p=0.0067$; $p<0.01$).

A subsequent Tukey HSD test revealed that significant decreases in body weight measurements occurred between the following assessment points:

- ✓ Baseline and week 2 (study endpoint): $p<0.01$
- ✓ Baseline and 2 weeks post-procedure: $p<0.05$
- ✓ Week 1 (midpoint) and week 2 (study endpoint): $p<0.05$

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.19$, $p=0.9$; $p>0.05$).

(i) Per Protocol Analysis

Table 15 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the per protocol subject population

Table 15: Body weight measurements across study duration by treatment group for the per protocol population

	Test Group (n=25)		Placebo Group (n=26)	
Body weight	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	154.09	30.35	156.40	27.57
Week 1 (Mid)	153.82	31.03	156.54	27.73
Week 2 (End)	153.15	30.52	156.32	27.45
2 weeks post	153.50	30.49	156.27	27.27

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the per protocol population.

- *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, a significant change in body weight measurement across assessment points was detected ($F=3.52$, $p=0.019$; $p<0.05$).

A subsequent Tukey HSD test revealed that a significant decrease in body weight measurements occurred between the following assessment point:

- ✓ Baseline and week 2 (study endpoint): $p<0.05$

- *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.19$, $p=0.9$; $p>0.05$).

Change in body mass index (BMI) between study measurement points: A comparison between test and placebo procedure groups

Body mass index (BMI) was recorded at baseline, end of procedure administration week 1, end of procedure administration week 2 (study end point) and 2 weeks post-procedure.

(i) Intent-to-Treat (ITT) Analysis

Table 16 below shows the mean and standard deviation BMI measurements, by treatment group, at each of the four time points, for the ITT subject population

Table 16: BMI measurements across study duration by treatment group for the ITT population

	Test Group (n=35)		Placebo Group (n=32)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	25.83	2.93	24.77	3.27
Week 1 (Mid)	25.85	2.94	24.78	3.27
Week 2 (End)	25.71	2.90	24.75	3.25
2 weeks post	25.76	2.93	24.74	3.23

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the ITT population.

- *Test Subjects*

Based on the ITT population, for subjects assigned to the test device group, a significant change in BMI measurement across assessment points was detected ($F=3.4$, $p=0.021$; $p<0.05$).

A subsequent Tukey HSD test revealed that a significant decrease in BMI measurements occurred between the following assessment point:

- ✓ Week 1 (study midpoint) and week 2 (study endpoint): $p<0.05$

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.2$, $p=0.90$; $p>0.05$).

(i) Per Protocol Analysis

Table 17 below shows the mean and standard deviation BMI, by treatment group, at each of the four time points, for the per protocol subject population

Table 17: BMI across study duration by treatment group for the per protocol population

	Test Group (n=25)		Placebo Group (n=26)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	26.13	3.08	25.02	3.42
Week 1 (Mid)	26.14	3.12	25.03	3.43
Week 2 (End)	26.01	3.04	25.00	3.41
2 weeks post	26.08	3.07	25.00	3.38

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the per protocol population.

- *Test Subjects*

Based on the per protocol population, for subjects assigned to the test device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=1.85$, $p=0.15$; $p>0.05$).

- *Placebo Subjects*

Based on the per protocol population, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.17$, $p=0.92$; $p>0.05$).

Study outcome satisfaction ratings: A comparison between test and placebo procedure groups

At the completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in body shape attained following the procedure administration with the Erchonia® GLS using the following five-point scale:

- ✓ Very Satisfied
- ✓ Somewhat Satisfied
- ✓ Neither Satisfied nor Dissatisfied
- ✓ Not Very Satisfied
- ✓ Not at All Satisfied

Thirty-one (31) of the 35 test subjects (89%) and 31 of the 32 placebo subjects (97%) responded to this question.

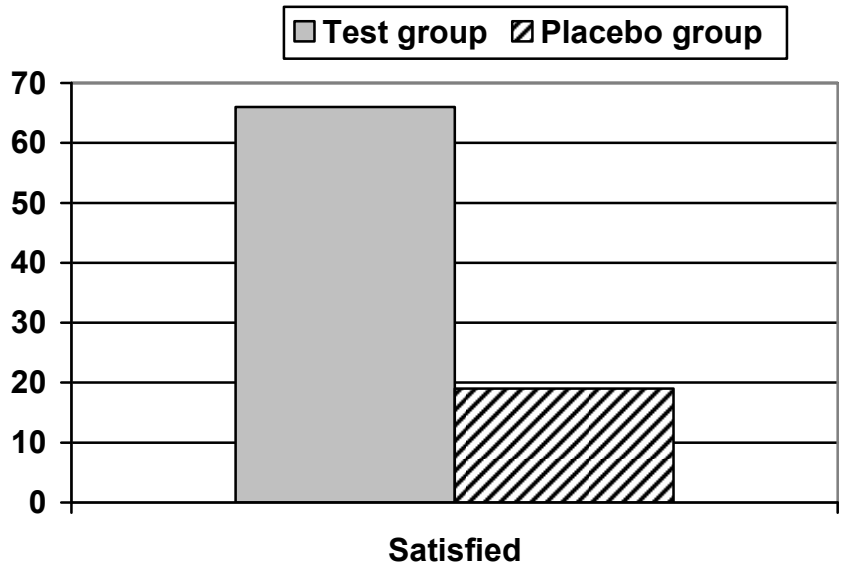
Table 18 below shows the number/percent of subjects who reported each level of satisfaction/ dissatisfaction by treatment group.

Table 18: Number/percent of subjects by study outcome satisfaction level by treatment group

	Test group (n=31)		**Placebo group (n=31)**	
	n	**%**	**n**	**%**
Very satisfied	13	42%	2	6%
Somewhat satisfied	7	23%	4	13%
Neither satisfied nor dissatisfied	5	16%	20	65%
Not very satisfied	4	13%	5	16%
Not at all satisfied	2	6%	-	-

Chart 3 below shows the percentage of subjects who were “Satisfied” (‘Very Satisfied’ +’Somewhat Satisfied’) with the study outcome by treatment group.

Chart 3: Percentage of test and placebo group subjects who were “Satisfied”



Clinical Study Results
By Individual Test Site

Test Site #1: Gregory C. Roche, M.D. F.A.C.S.
Bloomfield Hills, MI

Test Site #2: Robert F. Jackson, M.D. F.A.C.S
Marion, IN

STUDY SUBJECT POPULATION

SAMPLE SIZE

Test Site #1: Thirty-five (35) individuals were qualified and enrolled in the study and subsequently completed the clinical study protocol through to the 2-week Study Endpoint evaluation visit at Test Site #1. Four (4) subjects did not return for the 2-week follow-up evaluation visit at Test site #1.

Of the 35 enrolled subjects at Test Site #1, 17 subjects were randomized to the active treatment group and 18 subjects were randomized to the placebo group.

Test Site #2: Thirty-two (32) individuals were qualified and enrolled in the study and subsequently completed the clinical study protocol through to the 2-week Study Endpoint evaluation visit at Test Site #2. Nine (9) subjects did not return for the 2-week follow-up evaluation visit at Test Site #2.

Of the 22 enrolled subjects at Test Site #2, 18 subjects were randomized to the active treatment group and 14 subjects were randomized to the placebo group.

SAMPLE DEMOGRAPHICS

GENDER

Test Site #1: Of the 33 subjects for whom gender was recorded at Test Site #1, 24 subjects were female (73%) and 9 subjects (27%) were male:

- ✓ Test subjects (n=16): 13 females (81%); 3 males (19%)
- ✓ Placebo subjects (n=17): 11 females (65%); 6 males (35%)

Test Site #2: Of the 22 subjects for whom gender was recorded at Test Site #2, all 22 subjects were female (100%):

AGE

Test Site #1: The age range for the 33 subjects at Test Site #1 for whom age was recorded was 20 to 63 years.
Test Site #2: The age range for the 16 subjects at Test Site #2 for whom age was recorded was 21 to 62 years.

The mean and standard deviation age in years for test, placebo subjects and all subjects combined, for each of Test Sites #1 and #2, are shown in Table 19 below.

Table 19: Mean and standard deviation of age by treatment group by test site

Age (years)	Test (n=16)	Placebo (n=17)	All (n=33)
Test Site #1			
Mean	37.25	42.00	39.70
Standard deviation	10.14	11.49	10.96
	Test (n=4)	**Placebo (n=12)**	**All (n=16)**
Test Site #2			
Mean	34.00	34.83	34.63
Standard deviation	10.68	6.16	7.13

ETHNICITY

Ethnicity was recorded for 33 subjects at **Test Site #1** and for 26 subjects at **Test Site #2.**

Subject ethnicity breakdown for test, placebo and all subjects combined, for each test site, is shown in Table 20 below.

Table 20: Subject ethnicity by treatment group by test site

Ethnicity	Test (n=16)	Placebo (n=17)	All (n=33)
Test Site #1			
Caucasian	13	16	29
African American	1	1	2
Middle Eastern	1	-	1
Caucasian & Middle Eastern	1	-	1
Ethnicity	**Test (n=12)**	**Placebo (n=14)**	**All (n=26)**
Test Site #2			
Caucasian	12	13	25
African American	-	-	-
Middle Eastern	-	-	-
Caucasian & Middle Eastern	-	1	1

PRE-PROCEDURE VARIABLES

- Body Weight (lbs.): The mean and standard deviation pre-procedure Body Weight for test subjects and placebo subjects at each test site are shown in Table 21 below.

Table 21: Mean & std. deviation pre-procedure body weight by treatment group by test site

Body Weight (lbs)	Test (n=17)	Placebo (n=18)
Test Site #1		
Mean	156.41	161.22
Standard deviation	22.37	26.51
	Test (n= 18)	**Placebo (n=14)**
Test Site #2		
Mean	152.37	145.12
Standard deviation	34.39	23.66

- Body Mass Index (BMI): The mean and standard deviation pre-procedure BMIs for test subjects and placebo subjects at each test site are shown in Table 22 below.

Table 22 Mean & std. deviation pre-procedure BMI by treatment group by test site

Body Mass Index (BMI)	Test (n=17)	Placebo (n=18)
Test Site #1		
Mean	27.22	25.31
Standard deviation	2.05	3.21

	Test (n=18)	Placebo (n=14)
Test Site #2		
Mean	24.51	24.09
Standard deviation	3.07	3.32

- Circumference Measurements: The mean and standard deviation pre-procedure circumference measurements for test subjects and placebo subjects at each test site are shown in Tables 23 & 24 below.

Table 23: Pre-procedure circumference measurements by treatment group for **Test Site #1**

Circumference in inches		**Test (n=17)**	**Placebo (n=18)**
Waist	Mean	33.31	32.35
	SD	3.96	5.20
Hip	Mean	38.91	38.65
	SD	3.06	3.53
Right thigh	Mean	23.07	22.31
	SD	1.69	1.70
Left thigh	Mean	22.97	22.10
	SD	1.55	1.82
Total inches	**Mean**	118.26	115.40
	SD	7.01	9.70

Table 24: Pre-procedure circumference measurements by treatment group for **Test Site #2**

Circumference in inches		**Test (n=18)**	**Placebo (n=14)**
Waist	Mean	33.59	32.88
	SD	3.93	4.99
Hip	Mean	40.56	40.07
	SD	3.33	4.31
Right thigh	Mean	23.74	23.18
	SD	1.83	2.79
Left thigh	Mean	23.70	23.02
	SD	1.66	2.40
Total inches	**Mean**	121.58	119.15
	SD	9.65	13.16

STATISTICAL ANALYSIS

PRIMARY EFFICACY OUTCOME ANALYSIS

Every enrolled randomized subject in this clinical study had recorded circumference measurements at both baseline and at the end of week two study end evaluation time point. Therefore, only the ITT analysis was performed for primary outcome study success evaluation, with no need to employ last observation carried forward (LOCF) methodology.

Primary Outcome Measure Analyses

Proportion of successes

Test Site #1: Table 25 below shows the number and percentage of test and placebo group subjects at Test Site #1 who met the study **individual subject success criteria**.

Table 25: Individual Success Criteria met by treatment group for Test Site #1

	Test subjects	**Placebo subjects**
n	17	18
n meeting success criteria	13	4
% meeting success criteria	**76.47%**	**22.22%**

There is a **difference of 54.25% between procedure groups**, such that 54.25% more test group than placebo group subjects at Test Site #1 showed a total decrease in combined circumference measurements from pre-procedure to study end point of 3 inches or greater, exceeding the pre-established target of a 35% difference between treatment groups by 19.25%.

A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of successes between treatment groups at Test Site #1.

The results are as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	13	4	17
Placebo Group	4	14	18
	17	18	35

- p(two-tailed)=0.0022; p<0.005

The difference was found to be **statistically significant at p(two-tailed<0.005),** meaning that the two treatment groups gave significantly different results, such that the greater treatment effect observed for subjects in the test group relative to subjects in the placebo group at Test Site #1 is statistically significant and can be attributed to the efficacy of the application of the Erchonia® GLS over a placebo device.

Test Site #2: Table 26 below shows the number and percentage of test and placebo group subjects at Test Site #2 who met the study **individual subject success criteria**.

Table 26: Individual Success Criteria met by treatment group for Test Site #2

	Test subjects	Placebo subjects
n	18	14
n meeting success criteria	11	2
% meeting success criteria	**61.11%**	**14.29%**

There is a **difference of 46.82% between procedure groups**, such that 46.82% more test group than placebo group subjects at Test Site #2 showed a total decrease in combined circumference measurements from pre-procedure to study end point of 3 inches or greater, exceeding the pre-established target of a 35% difference between treatment groups by 11.82%.

A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of successes between treatment groups at Test Site #2.

The results are as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	11	7	18
Placebo Group	2	12	14
	13	19	32

- p(two-tailed)=0.012; p<0.05

The difference was found to be **statistically significant at p(two-tailed)<0.05,** meaning that the two treatment groups gave significantly different results, such that the greater treatment effect observed for subjects in the test group relative to subjects in the placebo group at Test Site #2 is statistically significant and can be attributed to the efficacy of the application of the Erchonia® GLS over a placebo device.

Change scores

Test Site #1: Table 27 below shows the mean and standard deviation of the magnitude of the change in combined circumference measurements (in inches) from pre-procedure to study endpoint for test versus placebo subjects at Test Site #1.

Table 27: Mean and standard deviation of the change in total circumference measurements (inches) by treatment group for Test Site #1

	Test subjects (n=17)	Placebo subjects (n=18)
Mean	-4.60	-1.33
SD	2.44	2.68

A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in combined circumference (total number of inches) from study baseline to endpoint. The difference was found to be **statistically**

significant at p<0.001: μa-μb=-3.27*;* t=-3.77; df=33; p(two-tailed)=0.00064; p<0.001, such that the mean decrease in number of total inches from baseline to study endpoint for test group subjects was significantly greater than that for placebo group subjects at Test Site #1.

Test Site #2: Table 28 below shows the mean and standard deviation of the magnitude of the change in combined circumference measurements (in inches) from pre-procedure to study endpoint for test versus placebo subjects at Test Site #2.

Table 28: Mean and standard deviation of the change in total circumference measurements (inches) by treatment group for Test Site #2

	Test subjects (n=18)	Placebo subjects (n=14)
Mean	-3.23	-0.88
SD	3.44	1.67

A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in combined circumference (total number of inches) from study baseline to endpoint. The difference was found to be **statistically significant at p<0.05:** μa-μb=-2.35*;* t=-2.34; df=30; p(two-tailed)=0.026; p<0.05, such that the mean decrease in number of total inches from baseline to study endpoint for test group subjects was significantly greater than that for placebo group subjects at Test Site #2.

Baseline to Endpoint Total Body Circumference Measurements

Test Site #1: Table 29 below shows the mean and standard deviation of the baseline and study endpoint total body circumference measurements (inches) and the change between the 2 assessment points for test and placebo subjects for Test Site #1.

Table 29: Mean and standard deviation of the baseline and study endpoint total body circumference and the change between the two points by treatment group for Test Site #1

	Test (n=17) mean (st. dev.)	Placebo (n=18) mean (st. dev.)
Baseline	118.26 (7.01)	115.40 (9.70)
End point	113.66 (7.21)	114.07 (10.14)
Change	-4.60 (2.44)	-1.33 (2.68)

A **t-test for correlated samples** was conducted to evaluate the mean change in total combined body circumference measurements (total number of inches) from study baseline to endpoint for test group and placebo group subjects for Test Site #1.

- *Test Group*

For test group subjects at Test Site #1, the mean change from baseline to study endpoint in total body circumference measurement was found to be **statistically significant at p<0.0001:** μa-μb=4.60*;* t=+7.79; df=16; p(two-tailed)<0.0001.

➢ *Placebo Group*

For placebo group subjects at Test Site #1, the mean change from baseline to study endpoint in total body circumference measurement was found to be **just statistically significant at p<0.05:** μa-μb=1.33*;* t=+2.11; df=17; p(two-tailed)=0.0499 (p<0.05).

Test Site #2: Table 30 below shows the mean and standard deviation of the baseline and study endpoint total body circumference measurements (inches) and the change between the 2 assessment points for test and placebo subjects for Test Site #2.

Table 30: Mean and standard deviation of the baseline and study endpoint total body circumference and the change between the two points by treatment group for Test Site #2

	Test (n=18) mean (st. dev.)	**Placebo (n=14) mean (st. dev.)**
Baseline	121.58 (9.65)	119.15 (13.16)
End point	118.35 (8.42)	118.27 (13.04)
Change	-3.23 (3.44)	-0.88 (1.67)

A **t-test for correlated samples** was conducted to evaluate the mean change in total combined body circumference measurements (total number of inches) from study baseline to endpoint for test group and placebo group subjects for Test Site #2.

➢ *Test Group*

For test group subjects at Test Site #2, the mean change from baseline to study endpoint in total body circumference measurement was found to be **statistically significant at p<0.001:** μa-μb=3.23*;* t=+3.98; df=17; p(two-tailed)=0.00097; p<0.001.

➢ *Placebo Group*

For placebo group subjects at Test Site #2, the mean change from baseline to study endpoint in total body circumference measurement was also found to be not statistically significant: μa-μb=0.88*;* t=+1.98; df=13; p(two-tailed)=0.069 (p>0.05).

SECONDARY EFFICACY OUTCOME ANALYSIS

Change in inches in combined waist-hips-thighs circumference across all study measurement points

(i) Intent-to-Treat (ITT) Analysis
ITT analysis for change in total circumference measurements across the four study measurement time points was conducted for all randomized subjects who had a measurement recorded at baseline, as follows:

- **Test Site #1:** All 35 randomized subjects at Test Site #1 had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Four (44) of the 35 subjects at Test Site #1 did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 1 subject who had been randomized to the test group and 3 subjects who had been randomized to the placebo group.

- **Test Site #2:** All 32 randomized subjects at Test Site #2 had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Nine (9) of the 32 subjects at Test Site #2 did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 7 subjects who had been randomized to the test group and 2 subjects who had been randomized to the placebo group.

For subjects at both test sites with missing observations at the 2 weeks post-procedure assessment point, the last observation carried forward (LOCF) procedure was employed, such that the subject's week 2 circumference measurement was carried forward as the week 2 post-procedure measurement.

Test Site #1: Table 31 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points for the ITT subject population at Test Site #1.

Table 31: Total circumference measurements across study duration by treatment group for the ITT population at Test Site #1.

	Test Group (n=17)		Placebo Group (n=18)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	118.26	7.01	115.40	9.70
Week 1 (Mid)	114.63	7.65	114.88	10.60
Week 2 (End)	113.66	7.21	114.07	10.14
2 weeks post	113.16	7.45	108.44	26.12

One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group for the ITT sample at Test Site #1.

- *Test Subjects*

For the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=23.91$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #1, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

For the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in total circumference measurement across assessment points were not statistically significant ($F=1.27$, $p=0.29$; $p>0.05$).

Test Site #2: Table 32 below shows the mean and standard deviation total circumference by treatment group at each of the four time points for the ITT subject population at Test Site #2.

Table 32: Total circumference measurements across study duration by treatment group for the ITT population at Test Site #2.

	Test Group (n=18)		Placebo Group (n=14)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	121.58	9.65	119.15	13.16
Week 1 (Mid)	119.30	9.82	118.39	13.22
Week 2 (End)	118.35	8.42	118.27	13.04
2 weeks post	118.41	9.49	117.86	12.93

One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group for the ITT sample at Test Site #2.

- *Test Subjects*

For the ITT population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=8.55$, $p=0.000107$; $p<0.0005$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 1: $p<0.05$
- ✓ Baseline and week 2 (study endpoint): $p<0.01$
- ✓ Baseline and 2 weeks post-procedure follow-up: $p<0.01$

Therefore, based on the ITT population at Test Site #2, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

For the ITT population at Test Site #2, for subjects assigned to the placebo device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=4.15$, $p=0.012$; $p<0.05$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment point, at the $p<0.01$ level:

- ✓ Baseline and 2 weeks post-procedure follow-up

(i) <u>Per Protocol Analysis</u>

- **Test Site #1:** Four (4) of the 35 enrolled subjects at Test Site #1 did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 1 subject who had been randomized to the test group and 3 subjects who had been randomized to the placebo group. Therefore, the per-protocol analysis for change in total body circumference at Test Site #1 is based on a total of 31 subjects: 16 subjects in the test group and 15 subjects in the placebo group.

- **Test Site #2:** Nine (9) of the 32 enrolled subjects at Test Site #2 did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 7 subjects who had been randomized to the test group and 2 subjects who had been randomized to the placebo group. Therefore, the per-protocol analysis for change in total body circumference at Test Site #2 is based on a total of 23 subjects: 11 subjects in the test group and 12 subjects in the placebo group.

Test Site #1: Table 33 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points for the per-protocol subject population at Test Site #1.

Table 33: Total circumference measurements across study duration by treatment group for the per-protocol population at Test Site #1.

	Test Group (n=16)		Placebo Group (n=15)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	118.19	7.23	116.32	9.69
Week 1 (Mid)	114.64	7.90	116.15	10.72
Week 2 (End)	113.31	7.30	114.98	10.05
2 weeks post	112.78	7.52	114.97	9.52

One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group in the per-protocol sample at Test Site #1.

- *Test Subjects*

For the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=28.32$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 1
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per-protocol population at Test Site #1, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per-protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in total combined circumference measurement across measurement points were not statistically significant for any interval ($F=1.45$, $p=0.24$ $p>0.05$).

Test Site #2: Table 34 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points for the per-protocol subject population at Test Site #2.

Table 34: Total circumference measurements across study duration by treatment group for the per-protocol population at Test Site #2.

	Test Group (n=11)		Placebo Group (n=12)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	123.55	10.60	118.90	14.05
Week 1 (Mid)	120.77	11.38	118.42	14.09
Week 2 (End)	120.32	9.31	118.29	13.87
2 weeks post	120.41	10.90	117.81	13.74

One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group in the per-protocol sample at Test Site #2.

- *Test Subjects*

For the per protocol population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in total circumference measurement across assessment points was detected ($F=4.71$, $p=0.0082$, $p<0.01$).

A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements occurred between the following assessment points, at the $p<0.05$ level:

- ✓ Baseline and week 1
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per-protocol population at Test Site #2, for test subjects**,** compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per-protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in total combined circumference measurement across measurement points were not statistically significant for any interval ($F=2.38$, $p=0.087$ $p>0.05$).

Change in inches in individual area circumference measurements across all study measurement points

(i) Intent-to-Treat (ITT) Analysis

Test Site #1: Table 35 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the ITT subject population at Test Site #1.

Table 35: Individual treatment area circumference measurements across study duration by treatment group for the ITT population at Test Site #1.

	Test Group (n=17)		Placebo Group (n=18)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	33.31	3.96	32.35	5.20
Week 1 (Mid)	32.72	3.63	32.26	5.41
Week 2 (End)	32.31	3.35	32.21	5.36
2 weeks post	32.04	3.39	32.13	5.29
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	38.91	3.06	38.64	3.52
Week 1 (Mid)	37.91	2.33	38.65	4.09
Week 2 (End)	37.71	2.48	38.31	3.84
2 weeks post	37.50	3.52	38.19	3.86
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.07	1.69	22.32	1.72
Week 1 (Mid)	22.10	2.15	22.04	1.81
Week 2 (End)	21.88	2.03	21.89	1.56
2 weeks post	21.96	2.18	21.97	1.47
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	22.97	1.55	22.10	1.82
Week 1 (Mid)	21.90	1.96	21.92	1.91
Week 2 (End)	21.76	1.89	21.67	1.62
2 weeks post	21.66	1.88	21.76	1.57

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the ITT population at Test Site #1.

Waist Circumference

- *Test Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=9.84$ $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment points, at the p0.01 level:

- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #1, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval (F=0.56, p=0.64; p>0.05).

Hip Circumference

- ➢ *Test Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected (F=5.18,p=0.0035 p<0.005).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 2 (study endpoint): p<0.05
- ✓ Baseline and 2 weeks post-procedure follow-up: p<0.01

Therefore, based on the ITT population at Test Site #1, for test subjects**,** compared with baseline, hip circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval (F=0.90, p=0.45; p>0.05).

Right Thigh Circumference

- ➢ *Test Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected (F=12.22, p<0.0001).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points, at the p<0.01 level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)

✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #1, for test subjects**,** compared with baseline, right thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

➢ *Placebo Subjects*
Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in right thigh circumference measurement across measurement points were not statistically significant for any interval (F=2.51, p=0.42; p>0.05).

Left Thigh Circumference

➢ *Test Subjects*
Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected (F=14.19, p<0.0001).

A subsequent Tukey HSD test revealed that significant decreases in left thigh circumference measurements occurred between the following assessment points, at the p<0.01 level:

✓ Baseline and week 1 (midpoint)
✓ Baseline and week 2 (study endpoint)
✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #1, for test subjects**,** compared with baseline, left thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

➢ *Placebo Subjects*
Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval (F=1.06, p=0.37; p>0.05).

Test Site #2: Table 36 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the ITT subject population at Test Site #2.

Table 36: Individual treatment area circumference measurements across study duration by treatment group for the ITT population at Test Site #2.

	Test Group (n=18)		Placebo Group (n=14)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	33.59	3.93	32.88	4.99
Week 1 (Mid)	32.2	4.03	32.75	4.98
Week 2 (End)	32.63	3.83	33.13	5.13
2 weeks post	32.76	3.82	32.86	5.20
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	40.56	3.33	40.07	4.31
Week 1 (Mid)	39.83	3.27	39.39	3.69
Week 2 (End)	39.51	3.07	39.36	3.78
2 weeks post	39.64	3.54	39.29	3.77
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.74	1.83	23.18	2.79
Week 1 (Mid)	23.26	1.63	23.32	2.80
Week 2 (End)	23.24	1.53	22.89	2.64
2 weeks post	23.13	1.69	22.84	2.69
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.70	1.66	23.02	2.40
Week 1 (Mid)	23.38	1.67	22.93	2.58
Week 2 (End)	22.97	1.50	22.91	2.42
2 weeks post	22.89	1.80	22.88	2.41

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the ITT population at Test Site #2.

Waist Circumference

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=2.97$, $p=0.04$, $p<0.05$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment point:

✓ Baseline and week 2 (study endpoint): $p<0.05$

Therefore, based on the ITT population at Test Site #2, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint, demonstrating effectiveness of the laser procedures.

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval (F=0.59, p=0.63; p>0.05).

Hip Circumference

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected (F=4.01, p=0.012, p<0.05).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment points, at the p<0.05 level:

- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #2, for test subjects**,** compared with baseline, hip circumference measurements were statistically significantly lower at, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval (F=1.95, p=0.14; p>0.05).

Right Thigh Circumference

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected (F=5.87, p=0.0016, p<0.005).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 1 (midpoint): p<0.05
- ✓ Baseline and week 2 (study endpoint): p<0.05
- ✓ Baseline and 2 weeks post-procedure follow-up: p<0.01

Therefore, based on the ITT population at Test Site #2, for test subjects**,** compared with baseline, right thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected ($F=5.76$, $p=0.0023$, $p<0.005$).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points:

- ✓ Week 1 (midpoint) and week 2 (endpoint): $p<0.05$
- ✓ Week 1 (midpoint) and 2 weeks post-procedure follow-up: $p<0.01$

Left Thigh Circumference

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected ($F=5.96$, $p=0.0015$, $p<0.005$).

A subsequent Tukey HSD test revealed that significant decreases in left thigh circumference measurements occurred between the following assessment points, at the $p<0.01$ level:

- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the ITT population at Test Site #2, for test subjects**,** compared with baseline, left thigh circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval ($F=0.39$, $p=0.76$; $p>0.05$).

(ii) Per Protocol Analysis

Test Site #1: Table 37 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the per protocol subject population, at Test Site #1.

Table 37: Individual treatment area circumference measurements across study duration by treatment group for the per protocol population for Test Site #1

	Test Group (n=16)		Placebo Group (n=15)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	33.52	4.00	32.75	5.46
Week 1 (Mid)	32.86	3.70	32.67	5.67
Week 2 (End)	32.44	3.42	32.72	5.62
2 weeks post	32.16	3.47	32.62	5.55
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	38.81	3.13	38.92	3.48
Week 1 (Mid)	37.78	2.34	38.88	4.27
Week 2 (End)	37.50	2.40	38.55	3.98
2 weeks post	37.28	2.43	38.42	4.01
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.02	1.72	22.47	1.64
Week 1 (Mid)	22.11	2.22	22.37	1.72
Week 2 (End)	21.75	2.02	22.00	1.24
2 weeks post	21.83	2.19	22.10	1.09
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	22.84	1.59	22.18	2.76
Week 1 (Mid)	21.89	2.03	22.18	3.66
Week 2 (End)	21.63	1.86	22.72	2.19
2 weeks post	21.52	1.84	21.83	1.94

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the per protocol population at Test Site #1.

Waist Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=10.59$, $p<0.0001$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 2 (study endpoint): p<0.01
- ✓ Baseline and 2 weeks post-procedure follow-up: p<0.01
- ✓ Week 1 (midpoint) and 2 weeks post-procedure follow-up: p<0.05

Therefore, based on the per protocol population at Test Site #1, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, and between study midpoint and 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval (F=0.18, p=0.91; p>0.05).

Hip Circumference

- ➢ *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected (F=5.60, p=0.0024; p<0.005).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment points:

- ✓ Baseline and week 2 (study endpoint): p<0.05
- ✓ Baseline and 2 weeks post-procedure follow-up: p<0.01

Therefore, based on the per protocol population at Test Site #1, for test subjects**,** compared with baseline, hip circumference measurements were statistically significantly lower at study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- ➢ *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval (F=0.82, p=0.49; p>0.05).

Right Thigh Circumference

- ➢ *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected (F=14.30, p<0.0001).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment points, at the p<0.01 level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per protocol population at Test Site #1, for test subjects**,** compared with baseline, right thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in right thigh circumference measurement across measurement points were not statistically significant for any interval (F=1.3, p=0.29; p>0.05).

Left Thigh Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected (F=14.98, p<0.0001).

A subsequent Tukey HSD test revealed that significant decreases in left thigh circumference measurements occurred between the following assessment points, at the p<0.01 level:

- ✓ Baseline and week 1 (midpoint)
- ✓ Baseline and week 2 (study endpoint)
- ✓ Baseline and 2 weeks post-procedure follow-up

Therefore, based on the per protocol population at Test Site #1, for test subjects**,** compared with baseline, left thigh circumference measurements were statistically significantly lower at study midpoint, study endpoint and at 2 weeks post-procedure assessment, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval (F=1.51, p=0.23; p>0.05).

Test Site #2: Table 38 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points, for the per protocol subject population, at Test Site #2.

Table 38: Individual treatment area circumference measurements across study duration by treatment group for the per protocol population for Test Site #2

	Test Group (n=11)		Placebo Group (n=12)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	34.40	4.20	32.36	5.21
Week 1 (Mid)	33.39	4.63	32.42	5.28
Week 2 (End)	33.02	4.25	32.60	5.36
2 weeks post	33.23	4.22	32.29	5.40
Hip	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	41.34	3.52	40.21	4.61
Week 1 (Mid)	40.36	3.57	39.50	3.97
Week 2 (End)	40.48	2.98	39.63	3.98
2 weeks post	40.68	3.70	39.54	3.97
Right thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.91	2.01	23.23	2.92
Week 1 (Mid)	23.48	1.94	23.42	2.94
Week 2 (End)	23.48	1.78	23.06	2.66
2 weeks post	23.30	2.02	23.02	2.72
Left thigh	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	23.90	1.88	23.10	2.52
Week 1 (Mid)	23.55	1.84	23.08	2.64
Week 2 (End)	23.34	1.63	23.00	2.52
2 weeks post	23.20	2.10	22.96	2.52

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group for the per protocol population at Test Site #2.

Waist Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in waist circumference measurement across assessment points was detected ($F=2.65$, $p=0.047$, $p<0.05$).

A subsequent Tukey HSD test revealed that significant decreases in waist circumference measurements occurred between the following assessment point:

✓ Baseline and week 2 (study endpoint): $p<0.05$

Therefore, based on the per protocol population at Test Site #2, for test subjects**,** compared with baseline, waist circumference measurements were statistically significantly lower at study endpoint.

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were not statistically significant for any interval (F=0.46, p=0.79; p>0.05).

Hip Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in hip circumference measurement across assessment points was detected (F=3.22, p=0.037; p<0.05).

A subsequent Tukey HSD test revealed that significant decreases in hip circumference measurements occurred between the following assessment point, at the p<0.05 level:

- ✓ Baseline and week 1 (midpoint)

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were not statistically significant for any interval (F=1.22, p=0.32; p>0.05).

Right Thigh Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected (F=3.86, p=0.019, p<0.05).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment point, at the p<0.05 level:

- ✓ Baseline and 2 weeks post-procedure follow-up

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, a significant change (decrease) in right thigh circumference measurement across assessment points was detected (F=3.49, p=0.026, p<0.05).

A subsequent Tukey HSD test revealed that significant decreases in right thigh circumference measurements occurred between the following assessment point, at the p<0.05 level:

- ✓ Week 1 (midpoint) and 2 weeks post-procedure follow-up

Left Thigh Circumference

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, a significant change (decrease) in left thigh circumference measurement across assessment points was detected ($F=2.41$, $p=0.09$, $p>0.05$).

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were not statistically significant for any interval ($F=0.41$, $p=0.75$; $p>0.05$).

Change in body weight in pounds between study measurement points: A comparison between test and placebo procedure groups

(i) Intent-to-Treat (ITT) Analysis

Test Site #1: Table 39 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the ITT subject population at Test Site #1

Table 39: Body weight measurements across study duration by treatment group for the ITT population for Test Site #1

	Test Group (n=17)		Placebo Group (n=18)	
Body weight	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	156.41	22.37	161.22	26.51
Week 1 (Mid)	155.94	22.79	160.97	26.71
Week 2 (End)	155.05	22.56	160.78	26.35
2 weeks post	155.62	22.30	160.78	25.98

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the ITT population at Test Site #1.

- *Test Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change in body weight measurement across assessment points was detected ($F=5.64$, $p=0.0022$; $p<0.005$).

A subsequent Tukey HSD test revealed that significant decreases in body weight measurements occurred between the following assessment point, at the $p<0.01$ level:

- ✓ Baseline and 2 weeks post-procedure

- *Placebo Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.35$, $p=0.79$; $p>0.05$).

Test Site #2: Table 40 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the ITT subject population at Test Site #2

Table 40: Body weight measurements across study duration by treatment group for the ITT population for Test Site #2

	Test Group (n=18)		Placebo Group (n=14)	
Body weight	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	152.37	34.39	145.12	23.66
Week 1 (Mid)	152.49	34.93	145.68	24.13
Week 2 (End)	151.89	34.54	145.56	23.87
2 weeks post	151.83	34.63	145.47	23.97

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the ITT population at Test Site #2.

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=1.97$, $p=0.13$; $p>0.05$).

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.71$, $p=0.55$; $p>0.05$).

(i) Per Protocol Analysis

Test Site #1: Table 41 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the per protocol subject population at Test Site #1

Table 41: Body weight measurements across study duration by treatment group for the per protocol population at Test Site #1

	Test Group (n=14)		Placebo Group (n=14)	
Body Weight	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	152.14	20.82	166.00	26.39
Week 1 (Mid)	151.57	21.20	165.86	26.61
Week 2 (End)	150.66	20.87	165.43	26.35
2 weeks post	151.36	20.69	165.43	25.89

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the per protocol population at Test Site #1.

- *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, a significant change in body weight measurement across assessment points was detected ($F=4.67$, $p=0.007$; $p<0.01$).

A subsequent Tukey HSD test revealed that a significant decrease in body weight measurements occurred between the following assessment point, at the $p<0.01$ level:

- ✓ Baseline and week 2 (study endpoint)

- *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.44$, $p=0.73$; $p>0.05$).

Test Site #2: Table 42 below shows the mean and standard deviation body weight measurements (lbs), by treatment group, at each of the four time points, for the per protocol subject population at Test Site #2

Table 42: Body weight measurements across study duration by treatment group for the per protocol population at Test Site #2

	Test Group (n=11)		Placebo Group (n=12)	
Waist	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	156.57	40.44	145.20	25.50
Week 1 (Mid)	156.68	41.35	145.68	25.91
Week 2 (End)	156.33	40.61	145.69	25.74
2 weeks post	156.22	40.75	145.58	25.85

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in body weight measurements across the four time points for each treatment group for the per protocol population at Test Site #2.

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.43$, $p=0.73$; $p>0.05$).

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in body weight measurements across measurement points were not statistically significant for any interval ($F=0.55$, $p=0.65$; $p>0.05$).

Change in body mass index (BMI) between study measurement points: A comparison between test and placebo procedure groups

(i) Intent-to-Treat (ITT) Analysis

Test Site #1: Table 43 below shows the mean and standard deviation BMI measurements, by treatment group, at each of the four time points, for the ITT subject population at Test Site #1.

Table 43: Body weight measurements across study duration by treatment group for the ITT population at Test Site #1

	Test Group (n=17)		Placebo Group (n=18)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	27.22	2.05	25.31	3.22
Week 1 (Mid)	27.18	2.12	25.24	3.16
Week 2 (End)	26.99	2.12	25.22	3.18
2 weeks post	27.09	2.09	25.22	3.08

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the ITT population at Test Site #1.

- *Test Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the test device group, a significant change in body weight measurement across assessment points was detected ($F=4.01$, $p=0.013$; $p<0.05$).

A subsequent Tukey HSD test revealed that a significant decrease in body weight measurements occurred between the following assessment point, at the $p<0.05$ level:

- ✓ Baseline and week 2 (study endpoint)

- *Placebo Subjects*

Based on the ITT population at Test Site #1, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.52$, $p=0.67$; $p>0.05$).

Test Site #2: Table 44 below shows the mean and standard deviation BMI measurements, by treatment group, at each of the four time points, for the ITT subject population at Test Site #2.

Table 44: Body weight measurements across study duration by treatment group for the ITT population at Test Site #2

	Test Group (n=18)		Placebo Group (n=14)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	24.51	3.07	24.09	3.32
Week 1 (Mid)	24.59	3.11	24.18	3.42
Week 2 (End)	24.50	3.07	24.14	3.36
2 weeks post	24.50	3.10	24.14	3.42

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the ITT population at Test Site #2.

- *Test Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the test device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.92$, $p=0.44$; $p>0.05$).

- *Placebo Subjects*

Based on the ITT population at Test Site #2, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.76$, $p=0.52$; $p>0.05$).

(i) Per Protocol Analysis

Test Site #1: Table 45 below shows the mean and standard deviation BMI, by treatment group, at each of the four time points, for the per protocol subject population at Test Site #1.

Table 45: BMI across study duration by treatment group for the per protocol population at Test Site #1

	Test Group (n=14)		Placebo Group (n=14)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	27.26	2.26	25.72	3.26
Week 1 (Mid)	27.21	2.33	25.68	3.22
Week 2 (End)	27.00	2.34	25.63	3.23
2 weeks post	27.13	2.30	25.62	3.11

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the per protocol population at Test Site #1.

- *Test Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the test device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=2.44$, $p=0.056$; $p>0.05$).

- *Placebo Subjects*

Based on the per protocol population at Test Site #1, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.46$, $p=0.71$; $p>0.05$).

Test Site #2: Table 46 below shows the mean and standard deviation BMI, by treatment group, at each of the four time points, for the per protocol subject population at Test Site #2.

Table 46: BMI across study duration by treatment group for the per protocol population at Test Site #2

	Test Group (n=11)		Placebo Group (n=12)	
BMI	**Mean**	**St. Dev.**	**Mean**	**St. Dev.**
Baseline	24.69	3.47	24.21	3.56
Week 1 (Mid)	24.79	3.56	24.28	3.64
Week 2 (End)	24.75	3.46	24.28	3.60
2 weeks post	24.75	3.51	24.27	3.68

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in BMI measurements across the four time points for each treatment group for the per protocol population at Test Site #2.

- *Test Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the test device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.42$, $p=0.74$; $p>0.05$).

- *Placebo Subjects*

Based on the per protocol population at Test Site #2, for subjects assigned to the placebo device group, the changes in BMI measurements across measurement points were not statistically significant for any interval ($F=0.52$, $p=0.67$; $p>0.05$).

Study outcome satisfaction ratings: A comparison between test and placebo procedure groups

- **Test Site #1:** All seventeen (17) of the test subjects (100%) and 17 of the 18 placebo subjects (94%) responded to this question at Test Site #1.

- **Test Site #2:** Fourteen (14) of the 18 test subjects (78%) and all 14 placebo subjects (100%) responded to this question at Test Site #2.

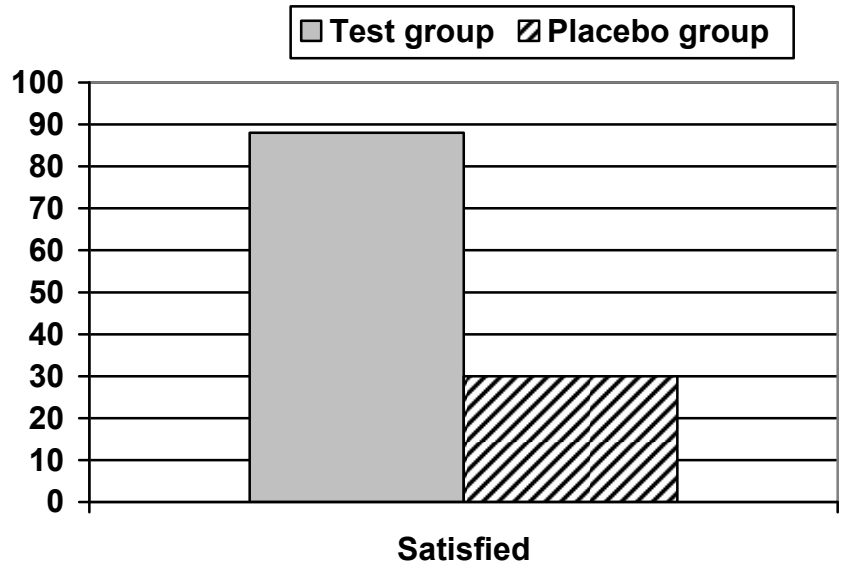
Test Site #1: Table 47 below shows the number/percent of subjects who reported each level of satisfaction/dissatisfaction by treatment group for Test Site #1.

Table 47: #/% subjects by study outcome satisfaction level by treatment group at **Test Site #1**

	Test group (n=17)		**Placebo group (n=17)**	
	n	**%**	**n**	**%**
Very satisfied	11	65%	2	12%
Somewhat satisfied	4	23%	3	18%
Neither satisfied nor dissatisfied	2	12%	12	70%
Not very satisfied	-	-	-	-
Not at all satisfied	-	-	-	-

Chart 4 below shows the percentage of subjects who were "Satisfied" ('Very Satisfied' +'Somewhat Satisfied') with the study outcome by treatment group at **Test Site #1.**

Chart 4: Percentage of test and placebo group subjects who were "Satisfied" at Test Site #1



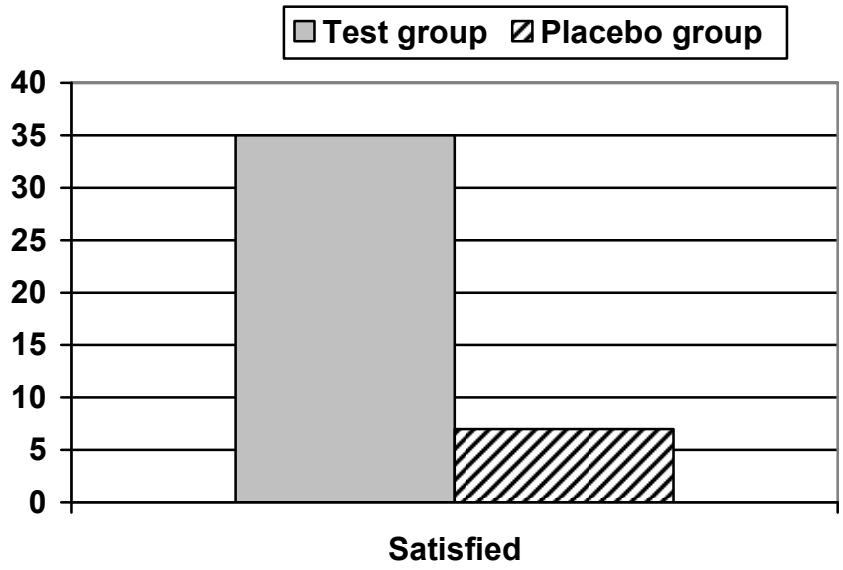
Test Site #2: Table 48 below shows the number/percent of subjects who reported each level of satisfaction/dissatisfaction by treatment group for Test Site #2.

Table 48: #/% subjects by study outcome satisfaction level by treatment group at **Test Site #2**

	Test group (n=14)		**Placebo group (n=14)**	
	n	**%**	**n**	**%**
Very satisfied	2	14%	-	-
Somewhat satisfied	3	21%	1	7%
Neither satisfied nor dissatisfied	3	21%	8	57%
Not very satisfied	4	30%	5	36%
Not at all satisfied	2	14%	-	-

Chart 5 below shows the percentage of subjects who were “Satisfied” (‘Very Satisfied’ +’Somewhat Satisfied’) with the study outcome by treatment group at **Test Site #2.**

Chart 4: Percentage of test and placebo group subjects who were “Satisfied” at Test Site #2



Individual Subject Results

INDIVIDUAL SUBJECT DATA THROUGH FOLLOW-UP

The following tables contain the individual subject data for circumference measurements recorded at baseline, 1 week (study midpoint), 2 weeks (study endpoint) and 2 weeks post-treatment (study follow-up) evaluations.

Combined Waist, Hips and Bilateral Thighs Circumference: The table below shows the **combined waist, hips and bilateral thighs circumference** measurements in inches by treatment group across the four evaluation points.

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR001	A	99.5	98.25	97	999
GR002	A	119.5	114.5	119.25	999
GR004	A	113.5	113.5	112.25	999
GR007	A	120	128.25	118	118
GR008	A	116.75	116.75	116.75	116.75
GR011	A	133.75	132	133.75	131
GR012	A	134	139	139	139
GR014	A	113.5	110	109.25	109.75
GR016	A	122.5	115	118.25	113
GR019	A	114.5	115.25	114	114
GR020	A	126.75	126.75	119	120
GR022	A	101.5	101.5	101.5	101.5
GR023	A	117.5	113.25	113.25	112.5
GR024	A	106.75	105.5	106.75	106.75
GR030	A	112.75	114	111	114
GR028	A	109	109	109	112.5
GR026	A	107.5	107.25	107.25	108.5
RJ008	A	119.25	119.25	119.25	117.75
RJ028	A	114.5	111.5	111.25	999
RJ013	A	126.75	125	125	999
RJ003	A	121.35	116.5	116	115.25
RJ005	A	122.25	119.75	120.75	117.5
RJ001	A	112.5	113.75	113.75	114
GR034	A	108	108	108	107.25
RJ038	A	103	103	103	103
RJ039	A	106	106	106	106
RJ040	A	109.75	109.75	109.75	109.75
RJ042	A	154.5	155	154	153.5
RJ043	A	121	122	120.75	121
RJ044	A	134	133.5	133.75	133.75
RJ046	A	110.25	109.5	109.5	109.5
RJ047	A	113	113	113	112.75

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR003	B	109.75	108.75	109	107
GR005	B	116	112.5	111.25	111
GR006	B	129.5	126	123.25	126.5
GR009	B	119.5	114.5	119.25	999
GR010	B	100.75	93.75	93.75	93.75
GR013	B	115.75	109	109	109
GR015	B	114.75	110.75	111.25	112.75
GR017	B	118.5	118.5	116	115.5
GR018	B	126.5	122.25	123.5	122.25
GR021	B	114.5	110.5	107.5	107.5
GR025	B	119	118.5	114	112
RJ035	B	110.375	110.375	107.125	3996
RJ024	B	129.75	126.5	119.25	3996
RJ023	B	117.25	112.25	112.75	3996
RJ006	B	126.5	117	117.5	118
RJ004	B	122.5	123	123.25	999
RJ007	B	124	125	126.5	128.5
RJ010	B	116.75	111	112.5	111.5
RJ012	B	114.5	112.25	113.25	111.75
RJ015	B	141.2	138.25	135	137.25
RJ017	B	108	108.5	108.5	999
RJ018	B	130.875	128	124.75	119
RJ032	B	117	117	116.75	114.25
RJ002	B	141.75	142.5	136.75	142
RJ030	B	117.5	117.25	115	999
RJ009	B	121.25	117.75	118	119
RJ029	B	124	121	121	999
RJ036	B	111.5	108.25	108	108.75
RJ037	B	113.75	111.5	114.5	114.5
GR027	B	127.5	126	121.75	120.75
GR045	B	116.75	111	110.25	109.5
GR046	B	118.75	115	113.5	113.75
GR031	B	122	120.5	119	118.5
GR029	B	115	115	113	115
GR047	B	126	116.25	117	109.75

Waist Circumference: The table below shows the **waist circumference** measurements in inches by treatment group across the four evaluation points.

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR001	A	26.75	26.25	26	999
GR002	A	30	30.25	30.25	999
GR004	A	34.25	34.25	32.75	999
GR007	A	32	31.25	31	31
GR008	A	30.5	30.5	30.5	30.5
GR011	A	46	46.5	46	45.5
GR012	A	41.25	42.5	42.5	42.5
GR014	A	29	28.5	28.5	27.25
GR016	A	37.5	35	36.75	35
GR019	A	31	30	31	31
GR020	A	34	34	34	34
GR022	A	26.5	26.5	26.5	26.5
GR023	A	31	31	31	31
GR024	A	26	26.25	26	26
GR030	A	34.5	36	35	36
GR028	A	30	30	30	31
GR026	A	34	34	34	34
RJ008	A	33.25	34	34	34
RJ028	A	35	33	35	999
RJ013	A	37	36.5	37.5	999
RJ003	A	27.35	30.5	28	27.5
RJ005	A	32.25	29	33	29.5
RJ001	A	31	31.75	31.75	32
GR034	A	28	28	28	28
RJ038	A	27	27	27	27
RJ039	A	30	30	30	30
RJ040	A	28	28	28	28
RJ042	A	44.5	45.5	45.5	45
RJ043	A	34.75	34	34.5	34.75
RJ044	A	39.75	39.25	39.5	39.75
RJ046	A	29.5	29	29	29
RJ047	A	31	31	31	31

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR003	B	29	30.5	30.5	30
GR005	B	30.5	30	30	30
GR006	B	35	35	34.75	35.5
GR009	B	30	30.5	30.25	999
GR010	B	25.75	25.75	25.75	25.75
GR013	B	27.25	26.5	26.5	26.5
GR015	B	36.5	35.5	35.75	36
GR017	B	37.5	37.5	37	36.5
GR018	B	33.5	32.75	33.5	32.75
GR021	B	33	32.25	31.5	31.5
GR025	B	34	34	32	32
RJ035	B	27.5	27.5	26.875	999
RJ024	B	37	36.5	35.75	999
RJ023	B	33.25	31.75	32.5	999
RJ006	B	35	32.25	29	30
RJ004	B	35.25	34.5	35.5	999
RJ007	B	34	35	36.5	36.5
RJ010	B	32	29.5	29.5	30.25
RJ012	B	29	28.5	28.25	28.25
RJ015	B	44	42.5	42	41.75
RJ017	B	31	30.5	32.75	999
RJ018	B	36.375	35	34.5	32
RJ032	B	34.5	34.5	34	35
RJ002	B	38.75	40	36.75	38
RJ030	B	29	30	28.75	999
RJ009	B	31	31	30.75	32.5
RJ029	B	33.25	32.75	32	999
RJ036	B	31	28	29.25	28.5
RJ037	B	32.75	31	32.75	32.75
GR027	B	39.5	39	37.25	37
GR045	B	36.5	35	34.5	34
GR046	B	39.5	37	36	36
GR031	B	33.5	32.5	32.5	30
GR029	B	32	32	30.5	30
GR047	B	33.25	30.5	31	31

Hip Circumference: The table below shows the **hip circumference** measurements in inches by treatment group across the four evaluation points.

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR001	A	32.5	33.5	34	999
GR002	A	40.25	40	40.75	999
GR004	A	39	39	36.5	999
GR007	A	43.5	45.5	43.5	43.5
GR008	A	39.5	39.5	39.5	39.5
GR011	A	44.5	43.25	44.5	43.5
GR012	A	43.5	47.5	47.5	47.5
GR014	A	38	36.5	36	36.5
GR016	A	38	37	37.5	34
GR019	A	39.25	38.5	39	39
GR020	A	43	43	38	40
GR022	A	32.5	32.5	32.5	32.5
GR023	A	38.5	38.75	38.75	38
GR024	A	35.25	34	35.25	35.25
GR030	A	37.75	37	36	37
GR028	A	38	38	38	37.5
GR026	A	34.5	34.25	34.25	34.5
RJ008	A	39.5	39.5	39.5	39.5
RJ028	A	37.5	37.5	36	999
RJ013	A	41	40	39.5	999
RJ003	A	46.75	39	40	40.75
RJ005	A	41.25	40.5	41	39.25
RJ001	A	37	37.5	37.5	37.5
GR034	A	38	38	38	38
RJ038	A	38	38	38	38
RJ039	A	34	34	34	34
RJ040	A	39	39	39	39
RJ042	A	50	49.5	49.5	49.5
RJ043	A	39	39	39	39
RJ044	A	44	44	44	44
RJ046	A	36	36	36	36
RJ047	A	38	38	38	38

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR003	B	37	37.25	37.5	37
GR005	B	39.5	39.5	38.25	38
GR006	B	43.5	40.75	40.5	41
GR009	B	40.5	40	41	999
GR010	B	31.25	31	31	31
GR013	B	42.5	38.5	38.5	38.5
GR015	B	36	35	34.5	34.75
GR017	B	38	38	37	37
GR018	B	41	38	39.25	38
GR021	B	37	38.25	36	36
GR025	B	39.5	39	41	39
RJ035	B	36	36	36.75	999
RJ024	B	43	41	37	999
RJ023	B	38.25	37.5	36	999
RJ006	B	43	39.75	41	42
RJ004	B	40.5	41	40.75	999
RJ007	B	41	41	42	42
RJ010	B	39	37	38.5	37.25
RJ012	B	40	38	38.5	38.5
RJ015	B	46.5	45.5	44.75	45.25
RJ017	B	35.5	35	34	999
RJ018	B	44	43	41.75	41.25
RJ032	B	38.5	38.5	38.5	37
RJ002	B	46.5	47	45.25	48
RJ030	B	41.5	41.75	40.25	999
RJ009	B	42.75	41	41.75	42
RJ029	B	40.5	40.75	41.25	999
RJ036	B	37.5	37.25	37	38
RJ037	B	36	36	36.25	36.25
GR027	B	41	40.5	39.25	39
GR045	B	37	36	35.75	35.5
GR046	B	38.25	38	37.5	37.75
GR031	B	39	38.5	38	40
GR029	B	37	37	38	39
GR047	B	43.5	39.25	38	35

Right Thigh Circumference: The table below shows the **right thigh circumference** measurements in inches by treatment group across the four evaluation points.

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR001	A	20.25	19	18	999
GR002	A	24.25	22	24	999
GR004	A	20.25	20.25	22	999
GR007	A	22.25	26	22	22
GR008	A	23.5	23.5	23.5	23.5
GR011	A	22.25	21	22.25	22
GR012	A	24.75	24	24	24
GR014	A	23.5	22.5	22.75	23
GR016	A	23.5	22	22	22
GR019	A	22	23.25	22	22
GR020	A	24.75	24.75	23.5	23
GR022	A	21.5	21.5	21.5	21.5
GR023	A	24.5	22	22	22
GR024	A	23	23	23	23
GR030	A	20	20.5	20	20.5
GR028	A	20.5	20.5	20.5	22
GR026	A	20	20	20	20
RJ008	A	23.5	23	23	22
RJ028	A	21	21	19.5	999
RJ013	A	24.75	24.5	24	999
RJ003	A	23.25	24	23.5	23
RJ005	A	24.25	24.75	23.25	24.5
RJ001	A	22	22.5	22.5	22.5
GR034	A	21	21	21	21
RJ038	A	19	19	19	19
RJ039	A	21	21	21	21
RJ040	A	21.75	21.75	21.75	21.75
RJ042	A	31	31	30	30
RJ043	A	23.75	24.5	23.75	23.75
RJ044	A	25	25	25	25
RJ046	A	22.25	22.5	22	22
RJ047	A	22	22	22	21.75

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR003	B	21.5	20	20	20
GR005	B	23	22	22	22
GR006	B	25.5	25.5	24.5	25.75
GR009	B	24	22	24	999
GR010	B	21.5	18.5	18.5	18.5
GR013	B	23	22.5	22.5	22.5
GR015	B	21	20.5	20.25	21
GR017	B	21.5	21.5	21	21
GR018	B	26.5	26.25	25.25	26.25
GR021	B	22.5	20	20	20
GR025	B	23	23	20.5	20.5
RJ035	B	23	23	22.5	999
RJ024	B	25	24	23.5	999
RJ023	B	23.25	21.75	22.25	999
RJ006	B	24	22.5	23.5	22.5
RJ004	B	23.5	24	23.75	999
RJ007	B	24.5	25	25	25
RJ010	B	22.75	22	22	22
RJ012	B	23	23.25	23.25	22.75
RJ015	B	25.5	25.25	24.5	25
RJ017	B	20.5	22	21	999
RJ018	B	25.5	25	24.5	23.5
RJ032	B	21.75	21.75	22	21
RJ002	B	28.25	27.5	27.25	28
RJ030	B	23.5	22	23	999
RJ009	B	23.75	22.75	22.75	22.5
RJ029	B	25.5	23.75	24	999
RJ036	B	21	21.25	20.75	21.25
RJ037	B	23	22	22.75	22.75
GR027	B	23.5	23	22.5	22.25
GR045	B	22.25	20	20	20
GR046	B	20.5	20	20	20
GR031	B	25	25	24.5	24.5
GR029	B	23	23	22.5	23
GR047	B	25	23	24	22

Left Thigh Circumference: The table below shows the **left thigh circumference** measurements in inches by treatment group across the four evaluation points.

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR001	A	20	19.5	19	999
GR002	A	25	22.25	24.25	999
GR004	A	20	20	21	999
GR007	A	22.25	25.5	21.5	21.5
GR008	A	23.25	23.25	23.25	23.25
GR011	A	21	21.25	21	20
GR012	A	24.5	25	25	25
GR014	A	23	22.5	22	23
GR016	A	23.5	21	22	22
GR019	A	22.25	23.5	22	22
GR020	A	25	25	23.5	23
GR022	A	21	21	21	21
GR023	A	23.5	21.5	21.5	21.5
GR024	A	22.5	22.25	22.5	22.5
GR030	A	20.5	20.5	20	20.5
GR028	A	20.5	20.5	20.5	22
GR026	A	19	19	19	20
RJ008	A	23	22.75	22.75	22.25
RJ028	A	21	20	20.75	999
RJ013	A	24	24	24	999
RJ003	A	24	23	24.5	24
RJ005	A	24.5	25.5	23.5	24.25
RJ001	A	22.5	22	22	22
GR034	A	21	21	21	20.25
RJ038	A	19	19	19	19
RJ039	A	21	21	21	21
RJ040	A	21	21	21	21
RJ042	A	29	29	29	29
RJ043	A	23.5	24.5	23.5	23.5
RJ044	A	25.25	25.25	25.25	25
RJ046	A	22.5	22	22.5	22.5
RJ047	A	22	22	22	22

Subject ID	Group	Baseline	Week 1	Week 2	2 Weeks Post
GR003	B	22.25	21	21	20
GR005	B	23	21	21	21
GR006	B	25.5	24.75	23.5	24.25
GR009	B	25	22	24	999
GR010	B	22.25	18.5	18.5	18.5
GR013	B	23	21.5	21.5	21.5
GR015	B	21.25	19.75	20.75	21
GR017	B	21.5	21.5	21	21
GR018	B	25.5	25.25	25.5	25.25
GR021	B	22	20	20	20
GR025	B	22.5	22.5	20.5	20.5
RJ035	B	23.875	23.875	21	999
RJ024	B	24.75	25	23	999
RJ023	B	22.5	21.25	22	999
RJ006	B	24.5	22.5	24	23.5
RJ004	B	23.25	23.5	23.25	999
RJ007	B	24.5	24	23	25
RJ010	B	23	22.5	22.5	22
RJ012	B	22.5	22.5	23.25	22.25
RJ015	B	25.2	25	23.75	25.25
RJ017	B	21	21	20.75	999
RJ018	B	25	25	24	22.25
RJ032	B	22.25	22.25	22.25	21.25
RJ002	B	28.25	28	27.5	28
RJ030	B	23.5	23.5	23	999
RJ009	B	23.75	23	22.75	22
RJ029	B	24.75	23.75	23.75	999
RJ036	B	22	21.75	21	21
RJ037	B	22	22.5	22.75	22.75
GR027	B	23.5	23.5	22.75	22.5
GR045	B	21	20	20	20
GR046	B	20.5	20	20	20
GR031	B	24.5	24.5	24	24
GR029	B	23	23	22	23
GR047	B	24.25	23.5	24	21.75