NEAR LASER ASSISTED LIPOLYSIS (NLAL™) LIPOSISE EXERCISE MODEL 777

Clinical Study Results Report for:

A double-blind, placebo-controlled, randomized evaluation of the effect of the Epiderma, Inc NLAL™ Liposise Exercise Model 777 on the reduction of the circumference of the waist:
Version 1.0, February 20, 2013

EPIDERMA, INC.

January 30, 2017

TABLE OF CONTENTS

STUDY INFORMATION

SPONSOR
Epiderma Inc.
3196 N. Federal Highway
Boca Raton, FL 33431
Contact: Sasson Moulavi, MD
Telephone: 561-362-5818
E-mail: DrSass@smartforlife.com
www.nlalipo.com

MONITORS

- Epiderma Inc.
  3196 N. Federal Highway
  Boca Raton, FL 33431
  Contact: Sasson Moulavi, MD
  Telephone: 561-362-5818
  E-mail: DrSass@smartforlife.com
  www.nlalipo.com

- Regulatory Insight, Inc.
  Nashville Office
  1503 Red Oak Drive
  Brentwood, TN 37027
  Contact: Elvira Walls, Clinical Consultant
  Telephone: 615-712-9743
  Fax: 615-712-9852
  e-mail: Elvira@reginsight.com

CLINICAL CONSULTANT
Regulatory Insight, Inc.
Nashville Office
1503 Red Oak Drive
Brentwood, TN 37027
Contact: Elvira Walls, Clinical Consultant
Telephone: 615-712-9743
Fax: 615-712-9852
e-mail: Elvira@reginsight.com

REGULATORY CONSULTANT
Regulatory Insight, Inc.
Denver Office
33 Golden Eagle Lane
Littleton, CO 80127
Contact: Kevin Walls, Principal Consultant
Telephone: 720-962-5412
Fax: 720-962-5413
e-mail: kevin@reginsight.com

PRINCIPAL INVESTIGATORS AND TEST SITES

- Ariel Soffer, M.D., FACC
  21500 Biscayne Boulevard
  Suite 133
  Aventura, FL 33180
  Phone: 305-792-0555
  STUDY NUM: 1161352

- Brenda Borton, ARNP
  190 Glades Road
  Suite E
  Boca Raton, FL 33432
  Phone: 561-338-3999
  STUDY NUM: 1161574

INSTITUTIONAL REVIEW BOARD

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789
www.wirb.com
WIRB PRO. NUM: 20152883

PURPOSE OF STUDY

The purpose of this clinical study is to determine the effectiveness of the NLAL™ Liposise Exercise Model 777, manufactured by Epiderma, Inc. (the Company), for use as a non-invasive aesthetic treatment for the temporary reduction in circumference of the waist, by applying red diode (635 nm) LED energy around the waist for 20 minutes combined with 30 minutes of simultaneous cardiovascular exercise, four (4) times across two (2) weeks.

DEVICE INFORMATION: EPIDERMA NLAL™ LIPOSISE EXERCISE MODEL 777

NLAL™ Liposise is a portable low level laser system that consists of a control unit, connection leads up to 12 paddles, and Velcro attachment straps.

Each paddle is a multi-diode device containing thirty (30) cold red laser 635nm scatter and dominant light emitting diodes (LEDs) that is designed to be placed directly on the skin of the treatment area and secured in place with the use of a Velcro attachment strap. The system operates using between 8 and 12 paddles depending on the size of the circumference area that is to be treated. The paddles are connected to the control unit via connection leads. The control unit is an electrically powered unit. The output of each diode (30 per paddle) is 2.16 mW/cm^2. When the laser paddles are placed on the skin and activated, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat to effect the formation of pores on the cells causing them to spill out water, Glycerol and fatty acids into the interstitial space beneath the fatty layer in the skin, thus reducing the adipocyte cells in size. The NLAL™ Liposise system has an average LED absorption rate of 70%.

Treatment is activated for 20 minutes in combination with a simple simultaneous 20 minute cardiovascular exercise routine immediately followed by an additional 10 minutes of cardiovascular exercise.

The Epiderma, Inc. NLAL™ Liposise Laser Light System 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 there was no possible instance of residual effect, LaserPair 635nm Goggles Laser Safety Glasses were provided for use during procedure administrations with the Epiderma NLAL™ for both the administration investigator and the subject.

Additional device details are contained on pages 3 to 14 of the accompanying clinical study protocol document.

STUDY DESIGN

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

Additional details of the study design are contained on page 3 of the accompanying clinical study protocol document.

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 and/or those responding to an ad for the study.

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

SAMPLE SIZE

Fifty-four (54) individuals were enrolled in the study. All 54 enrolled subjects completed study participation according to protocol as per the study visit schedule through to the study endpoint evaluation visit (final study evaluation visit) at 4 weeks post-procedure.

Of the 54 participating subjects, 27 were randomized to the active treatment group and 27 were randomized to the placebo group.

ELIGIBILITY CRITERIA

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

Inclusion Criteria

- Body Mass Index (BMI) is greater than 30 kg/m².
- Subject is willing and able to abstain from partaking in any treatment other than the study procedure (existing or new) to promote body contouring/circumference reduction/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, mesotherapy
- Subject is willing and able to comply with the study specified diet and fluid guidelines throughout the entire duration of his or her study participation.
- Subject agrees to maintain consistency of any pre-study exercise regimen throughout the entire duration of his or her study participation.
- 18 years to 70 years of age, inclusive.
- Male or female.

Exclusion Criteria

- Known cardiovascular disease such as cardiac arrhythmias, congestive heart failure.
- Uncontrolled hypertension
- Diabetes Type I or uncontrolled Diabetes Type 2
- Epilepsy
- Thyroid Gland dysfunction
- 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.
- Medical, physical, or other contraindications for the diet requirements of the study.
- Medical, physical, or other contraindications for the exercise requirements of the study.
- Current use of medication(s) known to affect weight levels/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 study device
- Known photosensitivity disorder
- Immunosuppressive disorder
- Current active cancer or currently receiving treatment for cancer (surgery, chemotherapy, radiation, experimental, etc.)
- Kidney or liver disease
- Pregnant 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 in the opinion of the investigator 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.

STUDY PROCEDURE ADMINISTRATION

Each subject received four (4) total procedure administrations with the Epiderma NLAL® Liposise Laser System (active or placebo) across a consecutive two-week period: two procedures per week, each procedure approximately evenly spaced. Treatment with the Epiderma NLAL® Liposise Laser System (active or placebo) was activated for 20 minutes in combination with a simple simultaneous 20 minute cardiovascular exercise routine immediately followed by an additional 10 minutes of cardiovascular exercise. Each procedure administration took place at the investigator's test site.

Additional details of the study procedure administration process are contained on page 5 of the accompanying clinical study protocol document.

STUDY OUTCOME EVALUATION

STUDY OUTCOME MEASURES

The study outcome measures were:

Body Weight: measured in pounds (lbs.) using a standardized digital scale.

Body Mass Index (BMI): calculated as the ratio of weight to height.

Waist Circumference: measured in inches (ins.) for the subject's waist at the height of the iliac crest using a flexible retractable tape measure.

Subject Satisfaction with Overall Outcome Rating: The subject responded to the following question using the 5-point Likert scale below:

"How satisfied or dissatisfied are you with any change you may have noticed in the appearance of your waist area after having received the procedures with the Epiderma NLAL™ Liposise?"

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

Subject Perceived Group Allocation and Rationale: The subject recorded whether he or she believed that he or she had received the study procedures with the true or fake Epiderma NLAL™ Liposise System and recorded his or her or rationale for this participation.

Assessment Investigator Perceived Group Allocation and Rationale: The Assessment Investigator recorded whether he or she believed the subject to have received the study procedures with the true or fake Epiderma NLAL™ Liposise System and recorded his or her or rationale for this participation.

Additional details of the study outcome measures are contained on page 6 of the accompanying clinical study protocol document.

STUDY OUTCOME ASSESSMENT TIME POINTS AND EVALUATIONS

The study outcome assessment time points and associated evaluations were:

Pre-Procedure (Baseline)
- ✓ Weight, Body Mass Index (BMI)
- ✓ Waist Circumference measurement

Procedure Administration Phase: Week 1 End
- ✓ Weight, Body Mass Index (BMI)
- ✓ Waist Circumference measurement

Procedure Administration Phase: Week 2 End
- ✓ Weight, Body Mass Index (BMI)
- ✓ Waist Circumference measurement

Post-Procedure: Study Endpoint Evaluation (two weeks after study procedure administration end):
- ✓ Weight, Body Mass Index (BMI)
- ✓ Waist Circumference Measurement
- ✓ Subject Satisfaction With Overall Outcome Rating
- ✓ Subject Perceived Group Allocation and Rationale
- ✓ Assessment Investigator Perceived Group Allocation and Rationale

Additional details of the study assessment time points and associated evaluations are contained on page 7 of the accompanying clinical study protocol document.

POTENTIAL CONFOUNDING STUDY FACTORS

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

STUDY DIET, FLUID AND EXERCISE REQUIREMENTS

In order to participate in this clinical study, a subject was required to agree to adhere to the following study diet and fluid intake, and exercise, requirements throughout the duration of his or her participation in the trial, as follows:

- No food was to be consumed in the two hour period preceding (before) each scheduled procedure administration with the Epiderma NLAL™ Liposise System.
- No food was to be consumed in the two hour period following (after) each completed procedure administration with the Epiderma NLAL™ Liposise System.
- Water was to be consumed before and after each procedure administration.
- A minimum of 64 oz. of water was to be consumed daily.
- An approximate 1,200 calorie per day food plan was to be followed daily. It was recommended that meal replacement products be consumed for breakfast and/or lunch and/or snacks. It was recommended that lunch and/or evening meals consist of lean proteins and an assortment of greens and non-starchy vegetables. It was requested that the following foods should be avoided: dairy, fruits, alcohol, simple carbohydrates, and fatty and sugary foods.
- There was to be no major deviation in type, duration and frequency of exercise engaged in throughout the duration of the clinical trial.

Subject compliance with the study diet and fluid intake and exercise requirements was confirmed at each procedure administration and post-procedure administration visit as well as recorded daily throughout the procedure administration and post-procedure administration study phases by the subject in the Subject Daily Diary, as applicable.

All subjects reported/confirmed compliance with the study diet and fluid intake, and exercise requirements at each procedure administration and post-procedure administration visit. No subject reported or recorded any notable deviation in any of the study requirements in the Subject Daily Diary.

CONCOMITANT MEDICATION AND THERAPY USE

Medications (OTC and prescription) routinely taken by the subject and other therapies or treatments routinely engaged in by the subject (non-study excluded) at the time of baseline assessment were recorded. As part of the study qualification criteria, subjects were required to agree to maintain their pre-study enrollment pattern of medication use throughout duration of participation in the clinical study.

Subjects were required to record any use of over-the-counter and prescription medication and any therapy engaged in that was different than that reported as typical during the pre-procedure phase daily throughout the procedure administration phase and the post-procedure administration phase in the Subject Daily Diary.

Based on the information recorded in the Subject Daily Diary, no subject reported any deviation from baseline concomitant medication use notable enough to impact study outcome.

SKIN MARKERS NOTATION

At baseline evaluation, at each of the two procedure administration visits (end of weeks 1 and 2) and at the 2 weeks post-procedure administration visit, the Assessment Investigator recorded the presence and location of any existing skin markers on the subject's waist area, as follows:

- Notation of hernias, scars, asymmetries, cellulite, stretch marks, varicose veins, discoloration, etc.
- Presence of stria and dimpling
- Underlying abdominal musculofacial system and presence/absence of flaccidity and diastasis recti; excess weight; loose skin
- Notation of the quality of the subject's skin and its elasticity

No new skin markers were identified at any of the three evaluation visits relative to notations recorded at baseline evaluation. No worsening of any skin markers occurred at any of the three evaluation visits relative to notations recorded at baseline evaluation. However, there were a few instances (2 to 4 subjects) wherein positive changes were recorded; that is, slight improvements in the appearance of some scars, stretch marks, cellulite, flaccidity and loose skin from baseline were noted at a subsequent evaluation point. This is not a surprising finding, as several laser light devices have received clearance for various skin improvement applications such as reduction in the appearance of scars, acne scars, wrinkles and cellulite.

ADVERSE EVENTS

Evaluation for observed and/or reported Adverse Events was made by the Assessment Investigator at each test site visit (4 procedure administration visits and one post-procedure evaluation visit) and assessed and recorded daily throughout the study duration as present/ absent by the subject in the Subject Daily Diary. There were no adverse events reported, observed or recorded by either the Assessment Investigator or the subject for any study subject, whether assigned to the test or to the placebo group, throughout the duration of this study.

PROCEDURE ADMINISTRATION PROTOCOL

The Administration Investigator recorded on the Procedure Administration Record sheet the date on which each procedure administration was administered to a subject and whether or not the procedure administration was completed according to the specified protocol. Evaluation of the Procedure Administration Record sheets shows that each subject received the requisite 4 procedure administrations without deviation of timing (spacing of individual procedure administrations) or procedural methodology.

MAXIMUM HEARTRATE

During each individual procedure administration, simultaneously with the activation of the 20-minute NLAL™ Liposise System procedure, the subject commenced exercise on the cardiovascular machine that endured 30 minutes. In order to optimize and standardize the effect of the cardiovascular exercise as combined with the NLAL™ Liposise System, the target was for the subject to reach 65% of maximum heartrate during exercise on the cardiovascular machine.

Percent of maximum heartrate reached by each subject was recorded at each of the four procedure administration visits. All subjects reached the minimum required 65% of maximum heartrate at all four procedure administration visits with the exception of one test group subject who reached a lesser 45% of maximum heartrate during the first two procedure administration visits, but did reach the required minimum 65% of maximum heartrate during each of the final two procedure administrations. The range of percent (%) of maximum heartrate reached by subjects overall during procedure administration visits (excluding the one test group subject reported above) was 65% to 100%.

RESULTS SUMMARY, CONCLUSION AND SUPPORT OF SUBSTANTIAL EQUIVALENCE

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Epiderma NLAL™ Liposise Exercise Model 777 for use as a non-invasive aesthetic treatment for the temporary reduction in circumference of the waist, by applying red diode (635 nm) LED energy around the waist for 20 minutes, four (4) times across two (2) weeks with simultaneous cardiovascular exercise.

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

SUBJECTS: Fifty-four (54) subjects completed the study, 27 of whom were randomized to the active procedure group and 27 who were randomized to the placebo group.

Subjects were 18 to 70 year old males and females with Body Mass Index (BMI) greater than 30 kg/m² who were seeking to reduce their waist circumference.

Subject age averaged 42.57 years. The majority of subjects were females (89%) of Caucasian (43%), Hispanic (28%) and African American (20%) descent.

STUDY MEASURES: The study primary efficacy outcome measure of waist circumference was measured at baseline, at the end of week 1 of the procedure administration phase (after the first two procedure administrations), at the end of week 2 of the procedure administration phase (after the final two procedure administrations), and at two weeks post-procedure administration (study endpoint). Body weight and body mass index (BMI) were also measured at these same assessment points. Subject satisfaction with procedure outcome, and subject and assessment investigator perceived subject group assignment, were recorded at study endpoint evaluation.

BASELINE MEASUREMENTS: Table 1 shows the mean (average) baseline waist circumference (inches), body weight (lbs.) and body mass index (BMI in kg/m²) by subject procedure group.

Table 1: Mean baseline measurements by procedure group

Baseline Measure	**Test Group (n=27)**	**Placebo Group (n=27)**
Waist Circumference (inches)	45.01	43.70
Body Weight (pounds)	210.67	205.24
Body Mass Index (BMI: kg/m²)	34.77	35.27

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

STUDY PROCEDURE: Subjects received four twenty-minute procedure administrations with the Epiderma NLAL® Liposise Laser System (active or placebo) across a consecutive two-week period, two procedures per week. Each procedure administration with the NLAL® occurred simultaneously with 30 minutes of simple cardiovascular exercise.

STUDY RESULTS

Waist Circumference: Primary efficacy outcome measure for this clinical study was the change in waist circumference measurement (measured in inches at the height of the iliac crest) from baseline (pre-procedure) to endpoint (two weeks following completion of the two-week study procedure administration phase with the Epiderma NLAL™ Liposise System) evaluation. It was pre-determined that a subject would be considered a study success if he or she attained a 2.0 inch or greater reduction in waist circumference across the primary evaluation period. It was also pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 45% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

70.4% of subjects who received the active study procedures with the Epiderma NLAL™ Liposise System attained a decrease in waist circumference measurements of 2.0 inches or greater compared with 14.8% of subjects who received the 'fake' (placebo) laser procedures. A Fischer's Exact Test for two independent proportions found this difference of 55.6% between subject procedure groups to be statistically significant at $p<0.0001$.

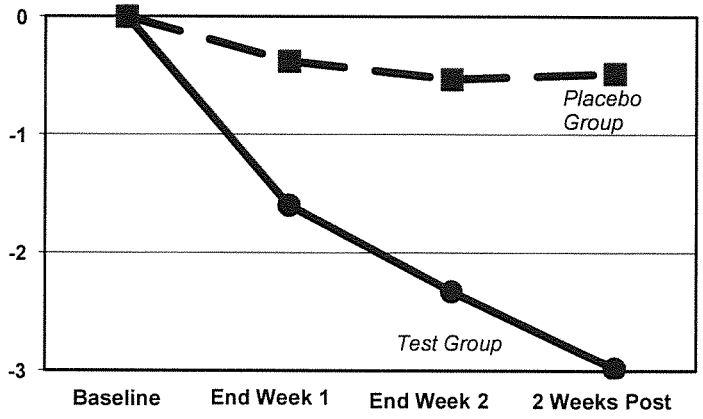
The mean change in waist circumference measurement for subjects who received the active study procedures with the Epiderma NLAL™ Liposise System was a decrease of 2.98 inches, while the mean change in waist circumference measurements for subjects who received the 'fake' (placebo) laser procedures was a decrease of 0.48 inches, a difference of -2.50 inches. A t-test for two independent samples found the mean change in waist circumference from baseline to study endpoint for test group subjects to be significantly greater than that for placebo group subjects, at $p<0.0001$ ($t=-5.54$).

Table 2 and Chart 1 below show the mean change in waist circumference measurements across the four study evaluation points for test and placebo group subjects.

Table 2: Mean waist circumference across evaluation points

Waist Circumference (inches)	**Test Group**	**Placebo Group**
Baseline	45.01	43.70
End of Week 1	43.51	43.32
End of Week 2	42.68	43.18
2 Weeks Post (Endpoint)	42.03	43.22

Chart 1: Mean change in waist circumference at each study evaluation point relative to baseline



For test subjects, waist circumference measurements decreased progressively across study duration culminating in a mean decrease of 2.98 inches by 2 weeks post-procedure evaluation. In contrast, for placebo subjects, the magnitude of change in waist circumference across study duration was not notable. Considered together, these findings support the progressive effectiveness of the Epiderma NLAL™ Liposise System over time compared with placebo.

Body Weight: For test subjects, body weight measurements decreased progressively and notably across study duration culminating in a mean decrease of 11.36 pounds from baseline to 2 weeks post-procedure (endpoint) evaluation, over a 5% decrease, a clinically relevant change. In contrast, the magnitude of change in body weight reached a mean decrease of 2.62 pounds at study endpoint, a non-clinically relevant decrease of about 1%.

Body Mass Index (BMI): For both test and placebo subjects, body mass index (BMI) decreased progressively but negligibly from baseline at each of the three subsequent evaluation points; although the mean decrease in BMI was greater for test than for placebo group subjects.

Body weight and BMI findings support the progressive effectiveness of the Epiderma NLAL™ Liposise System over time compared with placebo.

Study Outcome Satisfaction Ratings: At study endpoint, the subject was asked to rate his or her satisfaction or dissatisfaction with any perceived change in the appearance of the waist area using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. More test group than placebo group subjects were 'Very Satisfied' with the study outcome (17 versus 11 subjects, respectively); and only one test group subject reported dissatisfaction with the study outcome compared with five placebo group subjects.

ADVERSE EVENTS: No adverse events were reported, observed or recorded by either the Assessment Investigator or the subject for any study subject, whether assigned to the test or to the placebo group, throughout the duration of this study. There were no negative changes in skin markers in the waist area, and no notable deviations from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION: The Epiderma NLAL™ Liposise System is an effective tool for reducing waist circumference in individuals with Body Mass Index (BMI) greater than 30 kg/m² over a 4-week period.

SAMPLE DEMOGRAPHICS

Tables 1 through 3 below show subject demographics by procedure group.

GENDER

Table 1 shows subject gender breakdown for test subjects and placebo subjects.

Table 1: Gender breakdown by procedure group

Gender	Test (n=27)	Placebo (n=27)
Female	22	26
Male	5	1

In both procedure groups, the majority of subjects enrolled were females.

AGE

Table 2 shows the mean and standard deviation age in years for test subjects and placebo subjects.

Table 2: Age by procedure group

Age (years)	Test (n=27)	Placebo (n=27)
Mean	43.52	41.63
Standard deviation	13.76	13.50

A **t-test for independent samples** revealed no statistically significant difference in age between test and placebo group subjects: μa-μb=1.89; t=+0.51; df=52; p(two-tailed)=0.61 (p>0.05).

ETHNICITY

Table 3 shows ethnicity breakdown for test subjects and placebo subjects.

Table 3: Subject ethnicity by procedure group

Ethnicity	Test (n=27)	Placebo (n=27)
Caucasian	14	9
Hispanic	8	7
African American	2	9
American Indian	1	-
African American/Hispanic	1	2
Caucasian/Hispanic	1	-

PRE-PROCEDURE (BASELINE) VARIABLES

Tables 4 through 6 below show the mean and standard deviation pre-procedure (baseline) measures recorded prior to the study procedure administration phase, by procedure group.

BODY WEIGHT

Table 4 shows the mean and standard deviation pre-procedure body weight in pounds for test subjects and placebo subjects.

Table 4: Baseline body weight by procedure group

Body Weight (lbs)	Test (n=27)	Placebo (n=27)
Mean	210.67	205.24
Standard deviation	33.48	31.88

A **t-test for independent samples** conducted to evaluate pre-procedure body weight between procedure groups found the difference to be not statistically significant: μa-μb=5.429; t=+0.61; df=52; p(two-tailed)=0.54 (p>0.05).

BODY MASS INDEX (BMI)

Table 5 shows the mean and standard deviation pre-procedure BMI in kg/m² for test subjects and placebo subjects.

Table 5: Pre-procedure BMI by procedure group

Body Mass Index (BMI)	Test (n=27)	Placebo (n=27)
Mean	34.77	35.27
Standard deviation	4.29	5.17

A **t-test for independent samples** conducted to evaluate pre-procedure BMI recordings between procedure groups found the difference to be not statistically significant: μa-μb=-0.5; t=-0.39; df=52; p(two-tailed)=0.7 (p>0.05).

WAIST CIRCUMFERENCE

Table 6 shows the mean and standard deviation pre-procedure waist circumference measurements in inches for test subjects and placebo subjects.

Table 6: Pre-procedure waist circumference measurements by procedure group

Waist Circumference	Test (n=27)	Placebo (n=27)
Mean	45.01	43.70
Standard deviation	4.44	5.87

A **t-test for independent samples** conducted to evaluate pre-procedure waist circumference measurements between procedure groups found the difference to be not statistically significant: μa-μb=1.31; t=+0.93; df=52; p(two-tailed)=0.36 (p>0.05).

In conclusion, there was no statistically significant difference found between subjects randomized to the two procedure groups (test and placebo) for the recorded pre-procedure (baseline) measures and variables.

STATISTICAL ANALYSIS

PRIMARY EFFICACY OUTCOME ANALYSIS

Primary efficacy outcome measure for this clinical study was pre-defined as a statistically significant and clinically meaningful difference in the proportion of test subjects and placebo subjects demonstrating a reduction of at least 2.0 inches in waist circumference (measured at the height of the iliac crest) at two weeks following completion of the two-week study procedure administration phase with the Epiderma NLAL™ Liposise System.

Individual Subject Success Criteria
Individual subject success criteria was pre-defined as at least a 2.0 inch reduction in waist circumference measured at the height of the iliac crest from baseline to two weeks following completion of the two-week study procedure administration protocol with the Epiderma NLAL™ Liposise System.

Overall Study Success Criteria.
Overall study success criteria was pre-defined as at least a 50% difference between procedure groups, comparing the proportion of individual subject successes in each procedure group.

Evaluation Time Point
The evaluation time point for primary success was pre-established as two weeks following completion of the two-week study procedure administration phase (study endpoint) relative to baseline.

Populations Examined
For the primary outcome measure, it was intended that the two following analyses be performed:

- Intent-to-treat analysis: including all randomized subjects with measures recorded at baseline, and
- Per-protocol analysis: excluding subjects with major protocol deviations, incompletes, etc.

As every enrolled randomized subject in this clinical study had recorded circumference measurements at all evaluation points through to and inclusive of the study two-week post-procedure follow-up evaluation, only the ITT analysis was performed for primary outcome study success evaluation.

Primary Outcome Measure Analyses

Proportion of successes
Table 7 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 procedure group

	Test subjects	**Placebo subjects**
n	27	27
n meeting success criteria	19	4
% meeting success criteria	**70.40%**	**14.80%**

There is a **difference of 55.60% between procedure groups**, such that 55.60% more test group than placebo group subjects attained a decrease in waist circumference measurement from pre-procedure to study end point evaluation of 2.0 inches or greater, exceeding the pre-established target of a 50% difference between procedure groups by 5.60%.

A Fischer's Exact Test for two independent proportions was conducted to compare the proportion of successes between procedure groups, with results as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	19	8	27
Placebo Group	4	23	27
	23	31	54

- p(two-tailed)=0.00008; p<0.0001

The difference was found to be **statistically significant at p(two-tailed)<0.0001,** meaning that the two procedure 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 Epiderma NLAL™ Liposise System over a placebo device.

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

Table 8: Change in waist circumference measurements (inches) by procedure group

	Test subjects (n=27)	**Placebo subjects (n=27)**	**Change**
Mean	-2.98	-0.48	-2.50
SD	2.12	1.01	2.50

A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in waist circumference (inches) from study baseline to endpoint. The difference was found to be **statistically significant at p<0.0001:** μa-μb=-2.50; t=-5.54; df=52, such that the mean decrease in inches of waist circumference from baseline to study endpoint for test group subjects was statistically 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 waist circumference measurements from baseline to study endpoint to adjust for the covariates of pre-procedure waist circumference, body weight and body mass index (BMI) measurements, with results as follows:

(i) Waist Circumference

	Test subjects (n=27)	Placebo subjects (n=27)
Observed Mean	-2.98	-0.48
Adjusted mean	-2.93	-0.53

F=28.92; p<0.00005.

(ii) Body Weight

	Test subjects (n=27)	Placebo subjects (n=27)
Observed Mean	-2.98	-0.48
Adjusted mean	-2.99	-0.46

F=30.94; p=0.000001; p<0.00005.

(iii) Body Mass Index (BMI)

	Test subjects (n=27)	Placebo subjects (n=27)
Observed Mean	-2.98	-0.48
Adjusted mean	-2.98	-0.48

F=30.03; p=0.000001; p<0.00005.

In consideration of each of pre-procedure waist circumference, body weight and BMI measurements as covariates, all calculated F values are statistically significant at p<0.00005, such that if the individual differences in pre-procedure waist circumference, body weight and BMI measurements are removed, the two adjusted means would significantly differ to the degree of p<0.00005. **This indicates that the actual Epiderma NLAL™ Liposise System is more effective than the placebo device, and that this treatment effect is independent of subjects' baseline waist circumference, body weight or body mass index (BMI).**

SECONDARY EFFICACY OUTCOME ANALYSES

Secondary efficacy outcome analyses evaluate the change across and between all study evaluation points (pre-procedure (baseline); end of procedure administration week 1; end of procedure administration week 2; and post-procedure administration week 2 (study endpoint)) with respect to the study outcome measures of waist circumference, body weight and body mass index (BMI). As all subjects completed all evaluations and had all measures recorded through to the final study post-procedure evaluation, only the intent-to-treat (ITT) analysis was performed. As no claims are intended to be made based on the evaluation of secondary efficacy outcomes, the respective data is being presented in descriptive format only.

Waist Circumference Measurements Across Study Duration

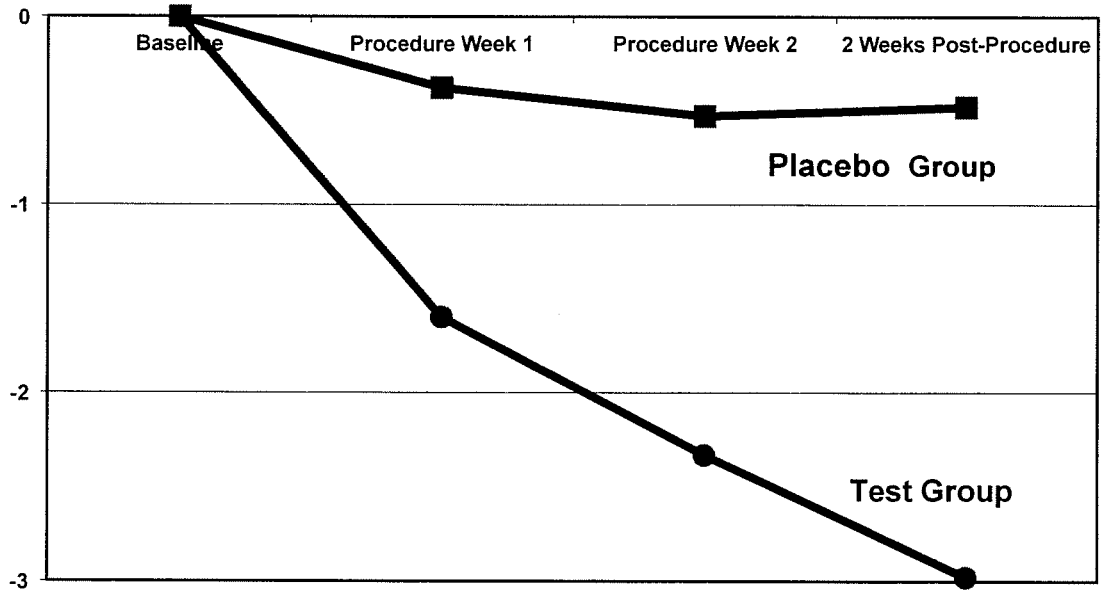
Table 9 shows the mean and standard deviation waist circumference measurements across the four study evaluation points from baseline to 2 weeks post-procedure evaluation by procedure group.

Table 9: Waist circumference measurements across study duration by procedure group

	Test (n=27)		Placebo (n=27)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Pre-Procedure	45.01	4.44	43.70	5.87
Procedure Administration Week 1 End	43.41	4.48	43.32	5.85
Procedure Administration Week 2 End	42.68	4.18	43.18	5.70
Post-Procedure Week 2	42.03	4.14	43.22	5.86

Chart 1 below illustrates the changes in mean waist circumference measurements across study evaluation points relative to baseline by procedure group.

Chart 1: Change in mean waist circumference measurements across study duration relative to baseline, by procedure group



For test subjects, waist circumference measurements decreased progressively and notably from baseline at each of the three subsequent evaluation points, culminating in a mean decrease of 2.98 inches from baseline to 2 weeks post-procedure (endpoint) evaluation.

In contrast, for placebo subjects, the magnitude of the change was fairly constant and minimal for all three subsequent evaluation points relative to baseline, at -0.38 inches, -0.52 inches and -0.48 inches, respectively, indicating lack of any change in notable waist circumference measurements across study duration.

Considered together, these findings are supportive of the progressive effectiveness of the Epiderma NLAL™ Liposise System over time compared with placebo.

Body Weight Measurements Across Study Duration

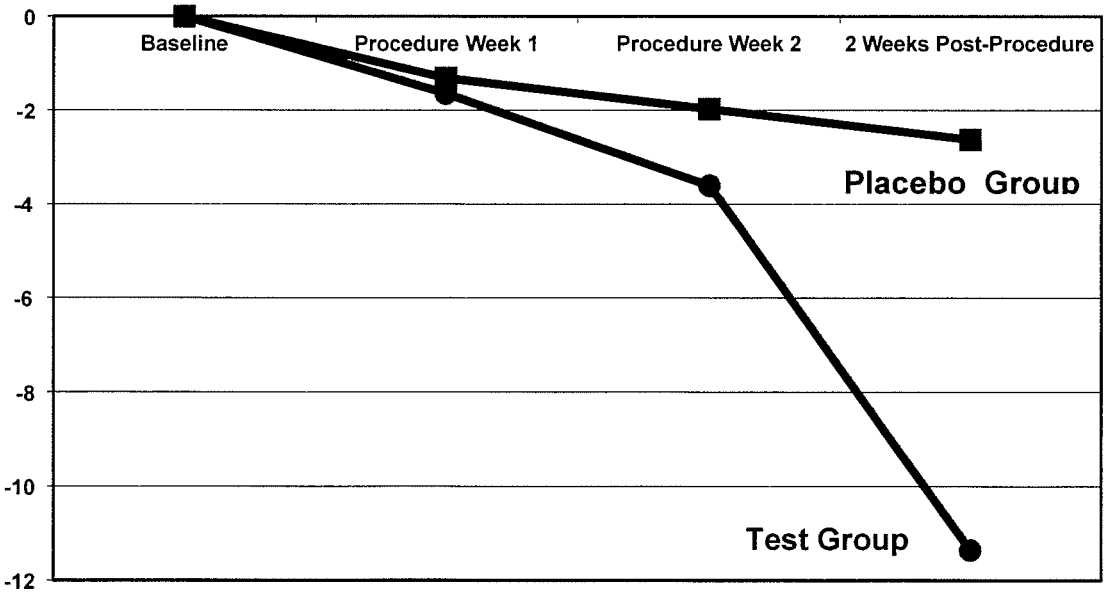
Table 10 shows the mean and standard deviation body weight measurements in pounds across the four study evaluation points from baseline to 2 weeks post-procedure evaluation by procedure group.

Table 10: Body weight measurements across study duration by procedure group

	Test (n=27)		Placebo (n=27)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Pre-Procedure	210.67	33.48	205.24	31.88
Procedure Administration Week 1 End	209.03	32.79	203.93	32.38
Procedure Administration Week 2 End	207.06	32.47	203.28	32.38
Post-Procedure Week 2	199.31	25.73	202.62	32.70

Chart 2 below illustrates the change in mean body weight measurements across study evaluation points relative to baseline, by procedure group.

Chart 2: Change in mean body weight measurements across study duration relative to baseline by procedure group



For test subjects, body weight measurements decreased progressively and notably from baseline at each of the three subsequent evaluation points, culminating in a mean decrease of 11.36 pounds from baseline to 2 weeks post-procedure (endpoint) evaluation, over a 5% decrease which is a clinically relevant change.

In contrast, for placebo subjects, the magnitude of the change was negligible for all three subsequent evaluation points relative to baseline, culminating in a mean decrease of 2.62 pounds from baseline to 2 weeks post-procedure (endpoint) evaluation, about a 1% decrease, which is a not a clinically relevant change.

Considered together, these findings are supportive of the progressive effectiveness of the Epiderma NLAL™ Liposise System over time compared with placebo.

Body Weight Measurements Across Study Duration

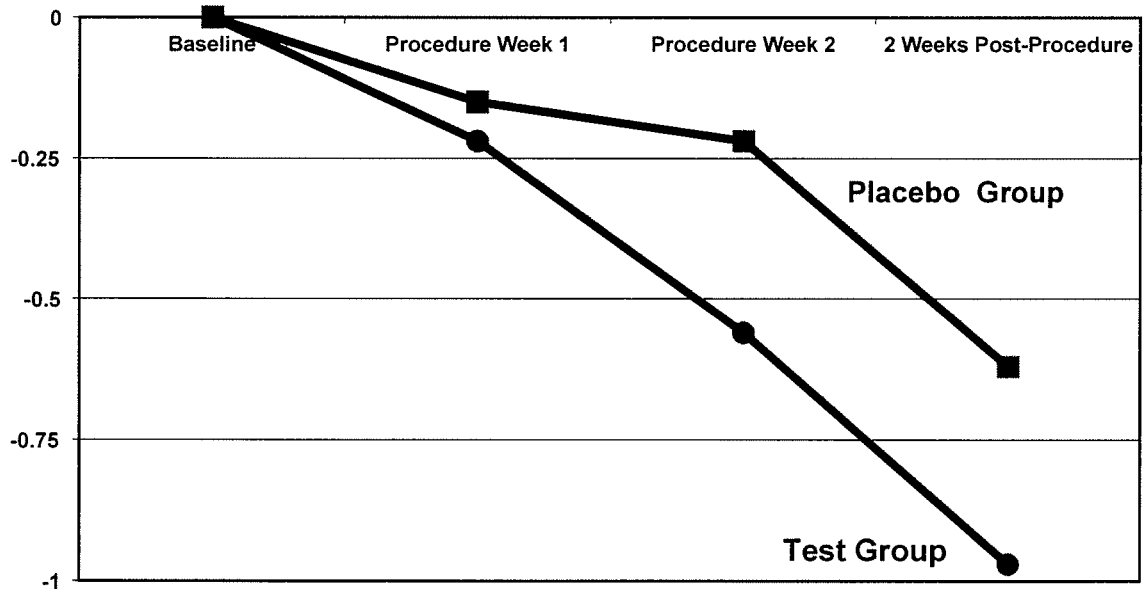
Table 11 shows the mean and standard deviation body mass index (BMI) measurements across the four study evaluation points from baseline to 2 weeks post-procedure evaluation by procedure group.

Table 11: BMI measurements across study duration by procedure group

	Test (n=27)		Placebo (n=27)	
	Mean	**St. Dev.**	**Mean**	**St. Dev.**
Pre-Procedure	34.77	4.29	35.27	5.17
Procedure Administration Week 1 End	34.55	4.19	35.12	5.30
Procedure Administration Week 2 End	34.21	4.20	35.05	5.30
Post-Procedure Week 2	33.80	4.06	34.65	5.61

Chart 3 below illustrates the change in mean BMI across study evaluation points relative to baseline. by procedure group.

Chart 3: Change in mean BMI across study duration relative to baseline by procedure group



For both test and placebo subjects, body mass index (BMI) decreased progressively but negligibly from baseline at each of the three subsequent evaluation points; although the mean decrease in BMI was greater for test group subjects than for placebo group subjects.

ADDITIONAL OUTCOME MEASURES

Subject Satisfaction With Study Outcome

At two weeks post-procedure evaluation (study endpoint), the subject was asked to rate their response to the following question on a five-point scale Likert scale:

"How satisfied or dissatisfied are you with any change you may have noticed in the appearance of your waist area after having received the procedures with the NLAL™ Liposise?"

- ✓ Very satisfied
- ✓ Somewhat satisfied
- ✓ Neither satisfied nor dissatisfied
- ✓ Not very satisfied
- ✓ Not at all satisfied

Table 12 shows the number of subjects who reported each level of satisfaction/dissatisfaction by procedure group.

Table 12: Subject satisfaction with study outcome by procedure group

	Test group (n=27)	Placebo group (n=27)
Satisfaction Level	**n**	**n**
Very satisfied	17	11
Somewhat satisfied	4	7
Neither satisfied nor dissatisfied	5	4
Not very satisfied	1	4
Not at all satisfied	-	1

It can be seen from Table 12 that more test group subjects than placebo group subjects were 'Very Satisfied' with the study outcome. Conversely, only one test group subject reported dissatisfaction with the study outcome compared with five placebo group subjects.

STUDY BLINDING EFFICACY EVALUATION

At study endpoint evaluation (2 weeks post-procedure), an assessment of perceived group allocation by both the subject and the Assessment Investigator was conducted. The subject and the Assessment Investigator, separately, were asked whether he or she believed the subject had received the study procedures with the true or the fake Epiderma NLAL™ Liposise System, and the reason for that belief.

An '**accurate determination'** of group allocation occurred when the subject or the Assessment Investigator correctly guessed the subject's procedure group assignment, as follows:

- A subject who received the true (active) study procedures records that he or she believes to have received the true (active) study procedures
- A subject who received the 'fake' (placebo) study procedures records that he or she believes to have received the 'fake' (placebo) study procedures
- An Assessment Investigator records that he or she believes a subject to have received the true (active) study procedures when in fact that subject did receive the true (active) study procedures
- An Assessment Investigator records that he or she believes a subject to have received the 'fake' (placebo) study procedures when in fact that subject did receive the 'fake' (placebo) study procedures

(i) Subject Perceived Group Allocation: Accurate determination of subject group allocation, as defined above, as recorded by subjects, is as follows:

- ✓ 24 of the 27 test group subjects (88%); and
- ✓ 5 of the 27 placebo group subjects (19%)

The **Fischer's Exact categorical analysis** technique for comparison of proportion of successes (accurate procedure group allocation determination) with respect to subject perceived group allocation recordings, between test and placebo subject groups was performed, with results as follows:

2 X 2 Table	**Accurate Determination**	**Inaccurate Determination**	
Test Device	24	3	27
Placebo Device	5	22	27
	29	25	54

- ➢ p(two-tailed)<0.000001

(ii) Assessment Investigator Perceived Group Allocation: Accurate determination of subject group allocation, as recorded by the Assessment Investigator, is as follows:

- ✓ 20 of the 27 test group subjects (74%); and
- ✓ 16 of the 27 placebo group subjects (59%)

The **Fischer's Exact categorical analysis** technique for comparison of proportion of successes (accurate procedure group allocation determination) with respect to Assessment Investigator perceived subject group allocation recordings, between test and placebo subject groups, was performed, with results as follows:

2 X 2 Table	**Accurate Determination**	**Inaccurate Determination**	
Test Device	20	7	27
Placebo Device	16	11	27
	36	18	54

- p(two-tailed)=0.39; p>0.05

The results of the Fischer's Exact analyses indicates that the Assessment Investigators were better able to accurately determine a subject's procedure group assignment than the subject themselves, which is not necessarily unexpected, as subjects are typically less objective (more subjective) in their determinations, stemming from initial expectations of attaining improvement following study completion, while Assessment Investigators who do not have the emotional investment of the subject tend to more objective and base their perceived group allocations on objective factual information of actual outcomes.

Regardless of perceived procedure group assignment determination and/or accuracy /inaccuracy of that determination as made by both the subject and the Assessment Investigator, with respect to supporting blinding maintenance throughout study duration, the supportive comments (rationales/reasoning) for perceived procedure group assignment provide confirmation of successful maintenance of study blinding during study duration, as supportive rationales provided indicated that procedure group allocation perceptions by both subjects and Assessment Investigators were based on perception of change or lack thereof in weight, circumference measurements, appearance, fit of clothes, etc., rather than allusion to clues arising from the device itself (such as noise, heat, light, sensation output, etc.). Therefore, these results combined indicate that **study blinding was successfully executed and maintained throughout the study duration**.

Subject and Assessment Investigator Rationales for Perceived Group Allocation Determination

The written rationales provided by subjects and Assessment Investigators to support perceived procedure group allocation determinations are provided below.

(i) Subject Rationales For Perceived Group Allocation Determinations:

- *Test Subject Group Allocation Determinations*: Rationales provided by test group subjects in support of a 'test/active' device group allocation determination:

  - ✓ Lost weight
  - ✓ Feel smaller and happy waist is coming down
  - ✓ Felt a difference - clothes were much looser
  - ✓ Felt like I was losing weight and clothes fit better
  - ✓ I lost inches

- ✓ I lost inches from my waist
- ✓ Losing weight; pants are looser
- ✓ Lost a lot of weight and my waist is smaller
- ✓ Lost some inches
- ✓ Lost weight and waist got smaller
- ✓ My waist and stomach has gotten smaller
- ✓ Very happy with weight loss
- ✓ Waist feels smaller and feel smaller in pants
- ✓ Waist is smaller
- ✓ Felt stomach movement while doing treatment

- *Test Subject Group Allocation Determinations*: Rationales provided by test group subjects in support of a 'fake/placebo' device group allocation determination:

  - ✓ I don't feel that loss of weight is due to the laser

- *Placebo Subject Group Allocation Determinations*: Rationales provided by placebo group subjects in support of a 'fake/placebo' device group allocation determination:

  - ✓ Felt better, but did not feel a difference in my clothes fitting
  - ✓ I was not losing inches quickly
  - ✓ It did not work for me

- *Placebo Subject Group Allocation Determinations*: Rationales provided by placebo group subjects in support of a 'test/active' device group allocation determination:

  - ✓ Clothes are fitting better especially around waist
  - ✓ Feel the difference with clothes on and feel skinnier
  - ✓ Feeling better, friends say waist is shrinking
  - ✓ Felt like it was working
  - ✓ I felt a difference
  - ✓ I can see the difference
  - ✓ I did lose some weight
  - ✓ I feel smaller than when I started
  - ✓ It's amazing how much movement I have now that I lost weight and inches off my waist
  - ✓ Lost weight
  - ✓ Lost weight, clothes feel looser
  - ✓ My stomach is going down in size
  - ✓ Waist has shrunk

(ii) Assessment Investigator Rationales For Perceived Group Allocation Determinations:

- *Test Subject Group Allocation Determinations*: Rationales provided by the Assessment Investigator in support of a 'test/active' device group allocation determination for a subject who had been assigned to the test subject group:

  - ✓ He lost inches from his waist`
  - ✓ Patient lost inches around waist
  - ✓ She lost inches off her waist
  - ✓ She lost inches off waist
  - ✓ Subject lost more than 2 inches from waist
  - ✓ Waist has gotten smaller and reduced in inches
  - ✓ Waist has reduced and stomach has shrunk
  - ✓ Waist reduction is visible, had to tighten his belt
  - ✓ Waist has reduced

- *Test Subject Group Allocation Determinations*: Rationales provided by the Assessment Investigator in support of a 'fake/placebo' device group allocation determination for a subject who had been assigned to the test subject group:

  - ✓ Lost weight but difficult to see results
  - ✓ Patient lost weight but not inches off the waist
  - ✓ No big reduction in waist
  - ✓ Not much weight loss

- *Placebo Subject Group Allocation Determinations*: Rationales provided by the Assessment Investigator in support of a 'fake/placebo' device group allocation determination for a subject who had been assigned to the placebo subject group:

  - ✓ Difficult to see change in loss of inches
  - ✓ Difficult to see reduction in waist
  - ✓ Hard to see the waist reducing in size
  - ✓ I cannot see much change in her waist
  - ✓ Patient lost some weight but difficult to see results
  - ✓ Not much reduction in waist
  - ✓ She has lost some weight and inches around her waist but it is hard to see
  - ✓ Subject did reduce a little around the waist but it wasn't all that noticeable
  - ✓ Waist change did not occur
  - ✓ No weight loss

- *Placebo Subject Group Allocation Determinations*: Rationales provided by the Assessment Investigator in support of a 'fake/placebo' device group allocation determination for a subject who had been assigned to the test subject group:

  - ✓ Patient has lost weight and inches from waist; looks smaller after treatments
  - ✓ She has gone down in inches around her waist
  - ✓ Smaller waist
  - ✓ Stomach does not poke out the way it did before treatments
  - ✓ Waist has come down in size

PRIMARY OUTCOME MEASURE RESULTS BY INDIVIDUAL TEST SITE

- **Test Site #1: Brenda Borton, ARNP**
  Boca Raton, FL

- **Test Site #2: Ariel Soffer, M.D. F.A.C.C.**
  Aventura, FL

STUDY SUBJECT POPULATION

STUDY TEST SITES

There were two study test sites in this clinical study:

- **Test Site #1**: Brenda Borton, ARNP; Boca Raton, FL
- **Test Site #2**: Ariel Soffer, M.D., F.A.C.C.; Aventura, FL

SAMPLE SIZE

Table 1 below shows sample size breakdown by procedure group at each of the two test sites.

Table 1: Sample size breakdown by procedure group by test site

Test Site	Test (n=27)	Placebo (n=27)
Test Site #1	4	5
Test Site #2	23	22

Although fewer subjects were enrolled at Test Site #1, the proportion of test and placebo subjects enrolled at the two sites is comparable.

PRIMARY EFFICACY OUTCOME ANALYSIS

As 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, only the ITT population was evaluated for primary outcome study success evaluation by test site.

Primary Outcome Measure Analyses

(i) Proportion of successes

Test Site #1: Table 2 shows the number of test and placebo group subjects at Test Site #1 who met the study **individual subject success criteria**.

Table 2: Individual Success Criteria met by procedure group for Test Site #1

	Test subjects	Placebo subjects
n	23	22
n meeting success criteria	15	3
% meeting success criteria	**65%**	**14%**

Test Site #2: Table 3 below shows the number of test and placebo group subjects at Test Site #2 who met the study **individual subject success criteria**.

Table 3: Individual Success Criteria met by procedure group for Test Site #2

	Test subjects	Placebo subjects
n	4	5
n meeting success criteria	4	1
% meeting success criteria	**100%**	**20%**

Given the discrepancy in sample size between the two test sites, the consistency in the trend of proportion of study successes between procedure groups at each test site is notable, and supportive of overall study success.

(ii) Change scores

Test Site #1: Table 4 shows the mean and standard deviation of the baseline and study endpoint waist circumference measurements (inches) and the change between the two assessment points for test and placebo subjects for Test Site #1.

Table 4: Baseline and endpoint waist circumference by procedure group for Test Site #1

	Baseline		Endpoint		Change	
	Mean	St. Dev.	Mean	St. Dev.	Mean	St. Dev.
Test (n=23)	45.47	4.46	42.46	4.12	-3.01	2.31
Placebo (n=22)	43.81	6.38	43.36	6.37	-0.45	0.94

Test Site #2: Table 5 shows the mean and standard deviation of the baseline and study endpoint waist circumference measurements (inches) and the change between the two assessment points for test and placebo subjects for Test Site #2.

Table 5: Baseline and endpoint waist circumference by procedure group for Test Site #2

	Baseline		Endpoint		Change	
	Mean	St. Dev.	Mean	St. Dev.	Mean	St. Dev.
Test (n=4)	42.38	3.71	39.56	3.83	-2.81	0.24
Placebo (n=5)	43.20	3.19	42.60	3.07	-0.60	1.39

Table 6 compares the mean change from baseline to endpoint evaluation in the primary outcome measure of waist circumference between test and placebo group subjects at Test Site #1, Test Site #2 and all study subjects combined.

Table 6: Mean change in waist circumference by procedure group by test site and subjects overall

	Test Group	Placebo Group
All Subjects Combined (n=27)	-2.98	-0.48
Test Site #1 (n=45)	-3.01	-0.45
Test Site #2 (n=9)	-2.81	-0.60

The mean change in waist circumference measurements from study baseline (pre-procedure) evaluation to study endpoint (2 weeks post-procedure) evaluation is highly consistent and comparable for both test group and placebo group subjects across test sites and when compared to the mean change for all study subjects combined.

These findings support overall study success, as overall study results with respect to the primary efficacy outcome measure were replicable across two different test sites, with two different device and two different device operators.

Individual Subject Results

INDIVIDUAL SUBJECT DATA THROUGH POST-PROCEDURE (STUDY ENDPOINT) EVALUATION

WAIST CIRCUMFERENCE: Individual subject data for waist circumference measurements (inches) recorded at each study procedure evaluation point of pre-procedure (baseline), end of procedure administration week 1, end of procedure administration week 2 and 2 weeks post-procedure (study endpoint) are presented in Table 1 below, by procedure group.

Table 1: Individual subject waist circumference measurements across study duration by procedure group

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB102	A	41	38	37	35
BB104	A	46	46	46	44.5
BB105	A	43.5	42.5	41	40.25
BB107	A	48	47	46.5	46.5
AS002	A	39.5	38.5	37.5	36.75
BB108	A	46	44.5	44.5	45
BB117	A	52	52	44.5	42.75
BB125	A	42	41.5	41	40
BB128	A	43.5	42	41.5	41
AS003	A	44.5	41.5	41.5	41.5
BB111	A	43.25	42.9	42.5	42.5
BB122	A	40	40.25	39.5	39
BB133	A	59.5	55.5	54.25	53
BB103	A	49.5	49	48.5	47
BB139	A	43.5	43.5	42.5	41
AS008	A	46.5	41.5	44.5	44
BB124	A	46.5	46	45	43.75
BB126	A	41.5	39	38	38
BB113	A	52	51	50	50
BB136	A	46	38	38	38.5
BB137	A	45	44	44	44
BB138	A	45.5	45	45	44.5
BB140	A	44	43	42	39.5
AS006	A	39	38.5	36.5	36
BB144	A	42.5	42.5	42	41.75
BB145	A	40.5	39	38	38
BB143	A	44.5	40	41	41

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB101	B	39.5	39.5	39.5	39.5
BB106	B	35.5	32.5	34.25	32.5
BB121	B	55.5	53.5	53	55
BB116	B	37.5	37	36.5	36
BB120	B	44.25	43.5	43	42.5
BB109	B	50.5	50.5	50	50
BB110	B	41.5	41.5	40	41.5
BB118	B	50	50	49.5	50
BB114	B	42.5	42.25	42.25	42.25
BB132	B	39	39	38.5	39
BB129	B	56	56.5	56.5	55
BB130	B	56	55.25	55	55
BB135	B	47	47	47	46
BB127	B	42.25	41	40.5	41
BB141	B	39.5	39	38.5	38
AS007	B	39	39.5	39	38
BB125	B	43.1	43	43	43
BB112	B	34.5	34.5	34.5	34.5
AS001	B	41	41	42	42
BB115	B	40.02	40	41	41
BB123	B	37.5	39.1	38.7	40
BB131	B	42	41	41.75	40.5
BB134	B	45.25	45	44	44
BB142	B	45	44.5	44.5	44.5
AS005	B	44	44	44	44
AS009	B	47	45	44.5	44
AS004	B	45	45	45	45

BODY WEIGHT: Individual subject data for body weight measurements (pounds) recorded at each study procedure evaluation point of pre-procedure (baseline), end of procedure administration week 1, end of procedure administration week 2 and 2 weeks post-procedure (study endpoint) are presented in Table 2 below, by procedure group.

Table 2: Individual subject body weight measurements across study duration by procedure group

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB102	A	191	189	185.8	179.4
BB104	A	240.3	240	238.3	231.7
BB105	A	223.33	220.4	219.8	219.7
BB107	A	262.51	258.6	252.2	252.2
AS002	A	153.4	153.4	152.1	155.6
BB108	A	218.4	215.6	213.4	216.2
BB117	A	186.89	185.6	177.6	170.5
BB125	A	217.49	217.8	220.8	214.5
BB128	A	239.8	234.7	230.6	222.2
AS003	A	176	175.6	175.4	178.6
BB111	A	185.6	185.3	183.6	180.1
BB122	A	182.5	183.6	184.5	185
BB133	A	227.9	234.7	229.4	229.8
BB103	A	219.1	214.8	215.3	206.8
BB139	A	202.58	202.3	200.8	195.4
AS008	A	227.58	224.6	216	215.6
BB124	A	279.99	280	278.6	238.9
BB126	A	180	180	180	180
BB113	A	288	280.6	280.8	172.45
BB136	A	207.59	205	205	204
BB137	A	204.81	198	198	197
BB138	A	240.08	238	238	235
BB140	A	210.78	214.1	209.8	201.8
AS006	A	201.3	195	188	183
BB144	A	180.69	177.4	177.2	176.2
BB145	A	169.98	169.7	169.7	169.7
BB143	A	170.42	170	170	170

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB101	B	190.3	190.3	190	189
BB106	B	165.8	161.4	164.9	161.8
BB121	B	275.8	273.3	272.2	268
BB116	B	159.59	156.9	153.8	151
BB120	B	182.9	180.3	177.4	167.7
BB109	B	222.18	224.7	22.2	224.4
BB110	B	202.3	197	194.3	191.3
BB118	B	253.31	253.9	251.9	256.6
BB114	B	171.6	170.6	170.6	169.2
BB132	B	177.89	176.5	175.2	176.8
BB129	B	272.2	272.2	272	268.5
BB130	B	255.2	256.8	254.8	254.9
BB135	B	238.54	238.4	238.7	239.4
BB127	B	219.8	213.5	214.7	214.4
BB141	B	169.29	169.4	166.4	168
AS007	B	195.7	191.7	190.2	188.7
BB125	B	196.6	195.3	195.5	193.6
BB112	B	207	205	205	205
AS001	B	198.6	196.8	197.4	198.6
BB115	B	228.47	227.2	227.2	227.2
BB123	B	164	164.4	162.3	165.5
BB131	B	207.4	203.2	205.6	206.1
BB134	B	200.2	200.4	200.4	200.4
BB142	B	198.99	202.1	200.4	200.7
AS005	B	203.2	203.2	203.2	203.4
AS009	B	200.6	200	198.8	198.2
AS004	B	184	181.5	183.5	182.4

BODY MASS INDEX (BMI): Individual subject data for body mass index (BMI) measurements (kg/m^2) recorded at each study procedure evaluation point of pre-procedure (baseline), end of procedure administration week 1, end of procedure administration week 2 and 2 weeks post-procedure (study endpoint) are presented in Table 3 below, by procedure group.

Table 3: Individual subject BMI measurements across study duration by procedure group

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB102	A	36.1	35.7	35.1	33.9
BB104	A	33.5	33.5	33.2	32.3
BB105	A	34	33.5	33.4	33.4
BB107	A	32.8	32.3	31.5	31.5
AS002	A	30	30	29.7	30.4
BB108	A	36.3	35.9	35.5	36
BB117	A	33.47	33.95	32.5	31.18
BB125	A	30.3	30.4	30.8	29.9
BB128	A	35.4	34.7	34	32.8
AS003	A	34.3	33.2	33.1	33.7
BB111	A	32.9	33.9	33.6	32.9
BB122	A	31.3	31.5	31.5	31.7
BB133	A	41.7	42.9	42	42
BB103	A	35.9	35.2	35.3	34.4
BB139	A	32.7	32.7	32.4	31.54
AS008	A	35.6	35.18	33.83	33.77
BB124	A	39	39	38.9	38.7
BB126	A	31.9	31.9	31.9	31.9
BB113	A	51	49.7	49.7	48.1
BB136	A	36.8	36.3	36.3	36.1
BB137	A	36.3	35.1	35.1	34.9
BB138	A	37.6	37.3	37.3	36.8
BB140	A	34	34.6	33.9	32.6
AS006	A	30.6	29.6	28.6	27.8
BB144	A	33	32.5	32.4	32.2
BB145	A	32.1	32.1	32.1	32.1
BB143	A	30.2	30.1	30.1	30.1

Subject ID	Group	Baseline	End Week 1	End Week 2	2 Weeks Post
BB101	B	32.6	32.6	32.6	32.4
BB106	B	30.3	29.5	30.2	29.6
BB121	B	47.3	46.9	46.7	46
BB116	B	30.1	29.7	29.1	28.53
BB120	B	33.5	33	32.5	30.7
BB109	B	37	37.4	37	37.3
BB110	B	37	36	35.5	35
BB118	B	42.1	42.9	42.6	43.82
BB114	B	32.4	32.2	32.2	32
BB132	B	32.5	32.3	32	32.2
BB129	B	49.8	49.8	49.8	49.1
BB130	B	41.2	41.5	41.2	41.2
BB135	B	39.7	39.7	39.7	39.8
BB127	B	30.2	29.4	29.5	24.4
BB141	B	30	30	29.5	29.8
AS007	B	31.6	31	30.7	30.5
BB125	B	30.8	31.5	31.6	31.2
BB112	B	33.4	33.1	33.1	33.1
AS001	B	37.5	37.2	38.5	37.5
BB115	B	38	37.8	37.8	37.8
BB123	B	31	31.1	30.7	31.3
BB131	B	33.5	32.8	33.2	31.9
BB134	B	36.6	36.6	36.6	36.6
BB142	B	36.4	37	36.6	36.7
AS005	B	31.8	31.8	31.8	31.9
AS009	B	34.4	34.3	34.1	34
AS004	B	31.6	31.2	31.5	31.3

END OF DOCUMENT