Non-invasive Circumference Reduction with Low Level Laser Therapy: A double blind, randomised, controlled study

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ABSTRACT

Background   The ability of low-intensity Diode Lasers to reduce the contents of adipocytes and hence their volumes, without causing damage to the cells of neighbouring tissues has been investigated for several years with a focus on opportunity to provide non-invasive body contouring options.

Objective   Following initial FDA clearance for the study device for the temporary improvement for the appearance of cellulite in 2010, the intention of this study was to provide evidence for submission to the FDA on the safety and efficacy of this skin contact low level laser therapy for selective abdominal circumference reduction compared to results achievable by a patient with exercise alone.

Study Design   Double-blind, randomised, placebo-controlled trial of 8 twenty-minute treatment interventions delivered 3 times weekly for 2-3 weeks at a single private practice site in the United Kingdom. Thirty-four volunteers between the ages of 18-65 years with a body mass index (BMI) of 20 and 40 kg/m^2 and who satisfied the set inclusion criteria participated. Participants were randomly allocated to receive low-level laser treatments or sham irradiation from devices identical in appearance. Both groups followed maintained similar dietary patterns and completed identical exercise sessions immediately post treatment. Reduction in the waist circumference from baseline to completion of the treatment administration phase was assessed with individual study success criterion being a participant achieving a mean circumference reduction of 4.0cm (1.5 in) or more, and overall study success criteria of a difference of at least 35% in the two groups.

Results   79% of the treatment group achieved the individual study success criteria of achieving a mean circumference reduction of 4.0cm (1.5in) from the waist anatomy, while only <7% of the control group achieved this target reduction using exercise alone. Participants in the treatment group demonstrated a mean circumference reduction of -4.7cm compared to a mean reduction of -0.88cm for the control group. The mean difference of -3.8cm between the two groups was found to be statistically significant (t=6.4052; P<0.0001)

Conclusion The results of this study suggest that low level laser therapy can reduce circumference measurements of specifically treated anatomical areas and offer a significant increase in net reduction than diet and exercise alone. FDA clearance for circumference reduction was subsequently given in March 2012.

INTRODUCTION

Body shaping/fat targeting treatments continue to dominate the surgical and nonsurgical industry. Despite a dramatic dip in demand during the last decade, Lipoplasty continues to be a leading procedure, regaining its crown as the most popular cosmetic surgical procedure in the US in 2011 for the first time in three years over breast augmentation [1][2], and experiencing a 13% increase in procedures in 2011 compared to 2010. Despite this growth, the public demand for non-surgical options to manage focal adiposities continues to grow. This is driven by the desire for safer procedures, minimal

side effects and discomfort, rapid recovery time but also with the requirement for rapid results. This market has been filled with a variety of non-invasive body contouring technologies including vacuum massage, radio frequency, ultrasound, fat freezing [3][4] and low-level laser technology (LLLT).

The biological effects of LLLT in a wide range of medical, surgical and therapeutic treatments have been well documented for more than 20 years, with the focus in recent years as an adjunct treatment to lipoplasty to facilitate fat retrieval and improve recovery time for the patient [5][6]. Microscopic and magnetic resonance studies demonstrated how the contents of adipocytes could be freed through pores in the cell membrane, without destroying the cell following in vivo irradiation with 635nm laser light [7]. Eighty percent of the cell content was released from the cells after 4 minutes of laser exposure increasing to 99% released after 6 minutes. Transmission electron microscopy of the excised cells after laser dosing visualised pores in the fat cells through which it was presumed that the contents of the cell made their egress, to be taken up by the lymphatic system for re-esterification in other tissues or use within the metabolic pathways for energy production.

A natural evolution from this surgical adjunct procedure has seen the development of devices specifically for skin contact delivery of the laser light for targeted body shaping without the requirement for the surgical extraction. Treatment with the laser combined with a healthy balanced diet and period of exercise post treatment, provide a demand for energy use within the body that can balance the metabolite release from the fat cells.

The ilipo™ laser diode device, developed and manufactured in the UK by Chromogenex Ltd, was launched onto the European market in March 2008 for the cosmetic treatments of targeted fat reduction, body shaping and cellulite. Following initial clearance by the FDA in 2010 for improvement of cellulite and based on the 4 years of in-field experience of over 1000 devices globally, the intention of this study is to provide data on safety and efficacy for the device to provide circumferential reduction via fat volume reduction.

MATERIAL AND METHODS

Participants

Thirty-four were recruited for participation from the usual patient population at the study site who had voluntarily inquired at the clinic of possible routes of cosmetic treatment with the goal of circumferential reduction/body shaping of the waist or abdominal regions.

Eligible subjects were both male and female; between the ages of 18-65 years; willing and able to abstain from partaking in any treatment other than the study procedure that may enhance body contouring and/or weight loss throughout the duration of the study (such as significant diet restrictions, diet supplements, treatments or therapies); have not undergone significant weight gain or loss (+/- 2.5kg) in the 6 months previous to inclusion on the study; and are willing and able to complete the required post treatment exercise program.

No subject recruited had any of the following exclusionary conditions: Pregnancy, within 3 months post partum (or still lactating) or planning pregnancy before the conclusion of the study; diabetes mellitus (on insulin or oral hypoglycemic medications); known cardiovascular disease, history of cardiac surgery, implantable cardiac devices; unstable hypertension; kidney or liver related complications or diseases or thyroid disorders; excessive alcohol consumption (greater than 21 units per week); prior history of surgical intervention for body sculpting/fat reduction on the waist/abdominal anatomy; active infection or trauma to the intended treatment site; diagnosis of, and/or taking medication for irritable bowel syndrome; auto-immune or immune related disorders; use of medications known to cause weight gain or bloating for which it is not medically prudent to cease during the study duration; serious mental illness or cognitive impairment that may prevent ability to understand informed consent procedure; and participation in other clinical study or research program within 3 months prior to inclusion on this study.

All subjects underwent consultation with full explanation of study procedures and requirements before written informed consent was obtained. The subjects were not charged for any aspect of treatment or related evaluations, nor any form of compensation given to the subject. Subjects were informed that those subsequently revealed to be allocated to the control group would have access to a similar course of actual treatment interventions once the study had been completed.

Randomisation and Blinding

The study was a prospective, placebo controlled, double-blind design carried out at a single private practice site. Thirty-four participants were recruited; 19 were randomised to the test group and 15 to the control, sham-irradiation, group. Randomisation was performed by an external source and was computer generated.

The investigator responsible for collecting measurement data was blind to participant group allocations and all data was secured immediately after collection to prevent access during subsequent measurement points.

Device

The test group subjects were treated with a multi-diode low-level laser delivering 658nm visible red laser light. The device (the ilipo™, manufactured by Chromogenex Ltd) consists of four independent treatment pads, each containing 9 (40mW) diodes each evenly distributed across the 130mm X 84mm surface area, controlled by a base interface unit. The laser pads are located in direct contact with the skin surface and retained in place with an elasticated strap during treatment.

The control group subjects received sham irradiation from a device, which was identical in physical appearance to the actual treatment device but with laser output power limited to <1mW per laser diode to maintain the perception of visible light output for the subjects during treatment.

Treatment

The treatment schedule consisted of a treatment phase of 8 individual 20 minute treatment interventions, delivered 3 times weekly over a 2-3 week period.

After baseline measurement data had been collected the participant was made comfortable on a treatment couch laying face up in a semi-recumbent position. Treatment was performed by placing the four treatment pads, first on the left side of the abdomen with the first pad lying adjacent to the umbilicus and subsequent pads adjacent to one another along the medio-lateral axis of the abdomen. The pads are secured in contact with the skin surface with a strap around the abdomen to prevent pad movement. The device then delivers a continuous emission of 658nm visible red laser-light for a programmed 10-minute interval. On completion of this, the device automatically returns to standby and the pads are manually relocated to the right side of the abdomen beginning again, adjacent to the umbilicus and extending around the right side of the abdomen and the procedure is repeated.

After each treatment session a 30-40 minute cardio vascular exercise program was completed based on the participants existing exercise regimen. The aim of this exercise session is to provide a demand for energy on the body to balance the metabolites released from the fat cells during laser treatment. This would support their utilisation rather than re-esterification back into available adipose cells. Both the treatment and the control group completed this exercise program mentored by a personal fitness trainer who monitored heart rate and recorded total calories used for each session.

Data Collection

Subject weight and height were measured prior to the first treatment intervention. Weight was re-measured after the fourth intervention and again after the final treatment intervention.

The precise circumferential measurements of the treatment area were taken on a standing subject immediately before and after the first, fourth and last treatment session. The measurement were made by identifying and marking the point midway between the top of the iliac crest and the lowest point of the ribcage on each side of the anatomy and applying the tape measure to cover these two points, keeping the line of the tape measure parallel to the floor. Additional measurements were taken 4.0cm (1.5 inches) above and again 4.0cm below this central point. From these three circumference measurements the mean value was used in subsequent statistical analysis. The same tape measure used for all measurements throughout the study. The tape measure used was a Myotape from Accufitness, which uses a torsion system to retract the tape around the area to be measured and minimises investigator error from tension irregularities. A single individual was responsible for taking all subject measurements to further minimise inter-investigatory variability.

Data Analysis

The primary efficacy outcome measure was defined as the change in circumference measurement (cm) of the waist from baseline (pre procedure) to following completion of the intervention delivery phase (end of week 3)

The individual subject success criteria was defined as a mean reduction of a minimum of 4.0cm (1.5 inches) averaged from 3 separate measurements within the treated area from baseline to after completion of the procedure administration phase (3 weeks). The overall study success criterion, established by the Food and Drug Administration (FDA) is defined as at least a 35% difference between treatment groups as seen in previous similar technology trials.

Statistical analysis of the two treatment groups was completed using the unpaired student t-test comparing changes in weight, BMI and mean circumference data.

Subject satisfaction with treatment outcome on their target zone was assessed after their final treatment intervention, using a 5 point grading system: 1 – Not at all satisfied; 2 – Not very satisfied; 3 – Neither satisfied or dissatisfied; 4 – Some what satisfied; and 5 – Very satisfied.

Table 1. Subject Enrolment Summary

Subject Status	*n*	Notes
Enrolled	34	
Discontinued – Subject Withdrawal Prior to end of intervention delivery phase	2	Automobile accident Influenza
Discontinued – Subject Withdrawal After Intervention delivery but prior to follow-up	2	Un-contactable, unknown reason
Discontinued – Investigator Withdrawal	0	

Data was analysed according to the intention-to-treat principle. Withdrawals were included by carrying forward the last measurement observation following Last Observation Carried Forward (LOCF) method. Two participants did not complete all scheduled treatment observations but had completed their fourth treatment intervention at which data was collected; this data being carried forward for the final treatment analysis. Both these participants were from the Test Group.

Four of the 34 participants did not have circumference measurements recorded at the 2-week post procedure measurement point: three of these subjects had been randomised into the Test Group and one into the sham Control Group. For these four subjects, the LOCF method was again employed.

RESULTS

At baseline, the differences in subject pre-procedure weight measurements between experimental groups were not found to be statistically significant (t= 0.6710; df= 32; P= 0.5070). Similarly the differences in subject pre-procedure BMI recordings between

experimental groups were not found to be statistically significant (t= 0.7677; df= 32; P= 0.4483).

TABLE 2. Pre-Procedure Weight Measurements for Treatment Groups (n= 34)

Weight (kg)	Test Group (n=19)	Control Group (n=15)
Mean	76.995	73.500

kg, kilograms

TABLE 3. Pre-Procedure Body Mass Index Measurements for Treatment Groups (n=34)

BMI (kg/m^2)	Test Group (n=19)	Control Group (n=15)
Mean	27.400	26.247

BMI, Body Mass Index

In addition, the baseline measurements for mean abdominal circumference (mean of three individual circumference measurements spanning the treatment area) were not found to be statistically significant between the two groups (t= 0.6190; df= 32; P= 0.5403).

TABLE 4. Pre-Procedure Circumference Measurements for Treatment Groups (n=34)

Circumference (cm)	Test Group (n=19)	Control Group (n=15)
Mean	99.068	96.680

cm, centimetres

Of the 15 Control Group of participants receiving sham light irradiation, 6.7% (1 participant) demonstrated a decrease in mean circumference measurement from baseline pre-procedure to the end of the intervention delivery phase of -4.0 cm (-1.5 inches) or greater, while 79% (15 participants) of the 19 enrolled Test Group participants demonstrated a reduction of -4.0 cm or greater, a significant difference between both groups (P<0.0001).

Comparison of the Test Group and Control Group mean circumference reduction from baseline measurements to the end of the intervention delivery phase demonstrated a mean difference of -3.809 cm between the two groups.

TABLE 5. Total Number and Percentage of Treatment Group Participants Meeting the Individual Success Criteria (n=34)

	Test Group (n=19)	Control Group (n=15)
Number of Participants Meeting success criteria	15	1
% Meeting success criteria	78.95%	6.66%

The difference was found to be extremely statistically significant (t= 6.4052; df=32; P<0.0001). Thus we have a >99.99% confidence that the mean reduction of circumference demonstrated by a participant in the Test Group will be greater than the circumference reduction achieved by a participant in the Control Group.

TABLE 6. Mean Change in Circumference Measurements (Mean of 3 separate measurements spanning treatment area) From Baseline to End of Intervention Delivery Phase (n=34)

	Test Group (n=19)	Control Group (n=15)
Mean reduction in circumference (cm)	-4.689	-0.880

cm, centimetres

Analysis of the mean number of calories metabolised for each participant in the post treatment exercise session demonstrated a mean of 383 kcals for the Test Group compared to 394.5 kcals for the Control Group (t=-0.5225; df=32; P=0.6050), a difference, which by conventional criteria, is not considered statistically significant.

TABLE 7. Mean Calories Metabolised per Post-Intervention Exercise Session (n=34)

	Test Group (n=19)	Control Group (n=15)
Mean calories, kcals	383.16	394.47

Comparison of the mean weight trends of both Test and Control groups at each measurement sample point (Baseline, Treatment 4 & Treatment 8) demonstrates a progressive reduction in both groups between subsequent sampling time points; with the mean total weight reduction for the Test Group (Baseline to Treatment 8) equalling -1.11kg or -1.4% from baseline compared to -0.87kg or -1.2% from baseline weight for the Control Group.

TABLE 8. Mean Weights at each Measurement Sampling Time Point During the Treatment Delivery Phase (*n*=34)

Mean Weight (Kg)	Test Group (*n*=19)	Control Group (*n*=15)
Baseline	76.99	73.50
Treatment 4	76.29	72.86
Treatment 8	75.88	72.63

Kg, Kilograms

It would be expected for the participants of both Test and Control Groups to demonstrate some weight reduction due to the increased activity undertaken after each treatment intervention, which was in addition to their baseline activity levels prior to enrolment on the study.

Patient satisfaction of the result and improvement of their waist shaping was assessed with an electronic survey emailed to each participant immediately subsequent to the treatment intervention delivery phase being completed. 28 surveys were returned, 16 from the Test Group and 12 from the Control Group. Of the 6 patients who did not complete a Patient Satisfaction Form, 3 were in the Test Group while 3 were in the Control Group. For these participants, a score of 3 (neither satisfied or dissatisfied) was used during analysis. A comparison of participant scoring for each group found a mean score for the Test Group of 3.7, while the Control Group scored just 2.9 (*t*=2.2821; df=32; *P*=0.0293) which is statistically significant.

10 of the 16 Test Group participants recorded a 'satisfied' score (6 scoring 'somewhat' satisfied [4] and 4 scoring 'very' satisfied [5]) compared to 4 of the 12 Control Group (3 scoring 'somewhat' satisfied [4] and 1 scoring 'very' satisfied [5]). Only 1 participant in the Test Group scored a 'dissatisfied' score ('not very' satisfied [2]) compared to 5 of the Control Group (4 scoring 'not very' satisfied [2] and 1 scoring 'not at all' satisfied [1]).

TABLE 13. Participant Satisfaction Scoring (*n*=34)

	Test Group (*n*=16)		Control Group (*n*=12)	
Score 5	4	}53%	1	}26.5%
Score 4	5		3	
Score 3	8	42%	6	40%
Score 2	1	}5%	4	}33.5%
Score 1	0		1	

[5] Very Satisfied; [4] Somewhat Satisfied; [3] Neither Satisfied or Dissatisfied; [2] Not Very Satisfied; [1] Not At All Satisfied

Over all 53% of the Test Group were 'satisfied' with treatment outcome compared to 5% being 'dissatisfied'. Only 26.5% of the Control Group was similarly 'satisfied' with treatment outcome compared to 33.5% of the same group being 'dissatisfied' with their results.
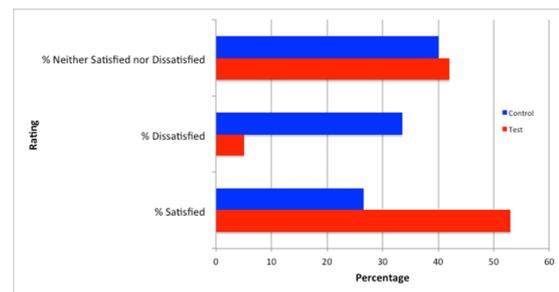

Fig. 4.
Percentage of Test and Control Participants who were Satisfied and Dissatisfied (*n*=34)
'Satisfied' included (very + Somewhat) and "Dissatisfied" included (not very + not at all satisfied) for each treatment group

The percentage satisfaction from this Participant survey is considerably lower than the percentage of participants that actually achieved the individual study success criteria (53% of test group satisfied, where 79% had actually achieved the success criteria of a mean reduction of at least 4cm (1.5 inches). Patient perceived satisfaction of success for elective cosmetic procedures is subjective – a participant may have expectations and goals prior to intervention that the intervention cannot deliver or meet the defined success criteria for the study despite clear explanations at the consultation stage.

However if we analyse the participants mean percentage circumference reduction results (mean reduction at Treatment 8 compared to Baseline) we actually find a reasonable correlation of increasing satisfaction score with increasing result [Table 14]. Mean percentage reduction would be expected to be a better reflection of a participant's overall perceived success relative to baseline measurements.

TABLE 14. Mean % Reduction from Baseline after Intervention number 8 of each Scoring Group

	Test Group (n=19)	Control Group (n=15)
5 (Very Satisfied)	-6.2% (n=4)	-4.7% (n=1)
4 (Somewhat Satisfied)	-4.9% (n=6)	-2.6% (n=3)
3 (Neither Satisfied or Dissatisfied)	-4.2% (n=8)	-1.0% (n=6)
2 (Not Very Satisfied)	-2.1% (n=1)	0.3% (n=4)
1 (Not At All Satisfied)	None (n=0)	4.6% (n=1)

DISCUSSION

The first law of photobiology states that for low-power visible light to be able to have any effect on a living biological system, the photons must be absorbed by the electron absorption bands belonging to some molecular or chromophoric photoreceptors [8]. Chromophores almost always occur in the following way: the conjugated systems of pi electrons and metal complexes. Examples of these chromophores can be seen in chlorophyll, haemoglobin, cytochrome and oxidase, myoglobin, flavins, flavoproteins and porphyrins. Absorption of the photon energy electronically promotes excited states and the primary molecular processes will give rise to a biological effect in the cell, which we can measure.

In the case of low-intensity laser treatment in the adipose cell, the chromophore is accepted as a component in the reactions of the mitochondrial respiratory chain [9]. It has been found that the absorption spectra obtained for cytochrome and oxidase (COX) in different states of oxidation are very similar to the spectra of action for the biological responses to light, and so it was suggested that this is the main photoreceptor of the red area – NIR in the mammiferous cells. Absorption of light by these photoreceptors causes a short-term activation of the respiratory chain and oxidation of the NAD pool, changing the redox state both of the mitochondria and of the cytoplasm [10][11].

Thus, activation of the electron transport chain results in an increase in the force of the protons, an electrical potential of the mitochondrial membrane, an increase in the pH of the cell cytoplasm by the movement of the hydrogen ions through the mitochondrial membrane into the cell cytoplasm and a net result of increase in phosphorylation of the ADP to increase the reserve of ATP. These are the normal chemi-osmotic effects that are seen during cell respiration [12] [11]. The inference that the light absorption of certain wavelengths can create this temporary acceleration of the normal cell respiratory rate has been confirmed in experiments. The force of the protons improves the electrical potential and ATP synthesis using a He-Ne laser in the mitochondria [14], as well as greater activity of the ATPs synthesised with the visible broadband light [15].

The osmotic pressure, in turn, moves the hydrogen ions from high to low concentrations and is also applied to the individual cells. The increase in the cytoplasm concentration of hydrogen ions which create changes in the cell membrane makes it possible for the cell content to circulate to the extracellular space in order to restore the pH balance through the cell membrane. In Neira's work [16] it was shown that the cell content can exit through transitory pores in the irradiated adipose cells.

The changes in the activity of the respiratory chain also alter the flow of calcium ions between the mitochondria and the cytoplasm, which results in a change in the balance of the

Ca^+/Ca^{2+} ions towards an increase in Ca^{2+} ions. The increase in the local concentration of Ca^{2+} ions starts a migration of the calcium ions through the calcium channels into the cell membrane, a process regulated by cyclic adenosine monophosphate (cAMP). The cAMP has also shown that it is involved in the regulation of lipid metabolism since changes in concentration of the cAMPs on the inner surface of the adipose membrane activate the lipase cytoplasmic enzymes in order to convert the stored triglycerides into fatty acids and glycerol, both elements that can easily pass through the cell membrane by the transitory pores.

Once in the extracellular space, the free fatty acids and the glycerol are transported through the lymphatic system with the normal excess fluid of residues, to be drained into the subclavian circulatory system through the thoracic duct.

In this double-blind, controlled, randomised study we observed that the circumference of the waist/abdomen could be rapidly and selectively reduced due to a decrease in the adipose layer volume by application of low-level laser of 658nm. This treatment method offers a completely non-invasive option for body shaping/fat reduction that provides a targeted action on selective areas vastly superior to results that can be demonstrated with the same time period of diet management and exercise alone.

The individual study success criterion for this study was set as a participant achieving a mean reduction of 4cm (1.5 inches) from the waist anatomy. 15 of the 19 Test Group participants achieved this measurement reduction, representing 79%. Only 1 of the 15 participants in the Control Group receiving sham laser irradiation achieved this target reduction, representing <7%. This difference in the two groups of >72% is greater than the defined overall study success criteria of a difference of at least 35%.

These results, despite being a small population size, demonstrate good effect on the measured circumference of the waist

anatomy when the active laser treatment intervention is given compared to sham irradiation. During the study, diet and exercise factors remained statistically equivalent, such that measured effect on the waist can be concluded to be as a result of the ilipo™ treatment to that area.

While this study has been conducted at a single site, the results collected are indicative of results seen in practice in clinics utilising this device. A pilot study published in the Cosmetic Medicine, SEME magazine (Scientific Journal of the Spanish Cosmetic Medicine Society) by Prof Dr Raul Pinto & Dr Ricardo Hoogstra in Argentina in July 2010 [17], measured similar data samples using identical treatment procedures on a group of 15 females. These females were specifically selected to be of normal to low bodyweight but with unwanted fat deposits around the waist that have failed to reduce as a result of previous controlled diet and exercise regimens alone. The practical treatment intervention procedure was as per the standard protocol used by the ilipo™ device and identical to the protocol used in the double-blinded placebo controlled study completed at the West London Dermatology Clinic, with each participant undertaking 8 treatment interventions of 20 minute laser irradiation to encompass the waist anatomy followed by a standardised 45 minute cardio-vascular exercise session. The mean circumference reduction (of the three separate measurements within the scope of the treatment area) was 5.28cm (±1.2).

Another pilot study, completed by the Groupe de Recherche et d'Evaluation en Dermtologie et Cosmetologie in Paris, France (Principle investigator: S Boisnic MD, Associate Professor at the University of Paris Pitie Salpetriere Hospital) also completed 8 treatments using the ilipo™ device on the waist anatomy of 8 participants (and also 7 participants having had their thighs treated in a similar manor). Again, maintaining a standardised diet and exercise regimen throughout the study as per the participants pre-study routine with the addition of a 30-40minute additional exercise session immediately post treatment the reported mean circumference reduction of

the waist of the 8 participants was -4.16cm. In this study additional measurements using echography were made of the adipose thickness at each sampling time point that demonstrated a mean reduction in thickness of the subcutaneous fat layer of -11.5%.

Assessment of participant satisfaction with the treatment for providing improved shaping to the waist anatomy found that 53% of the Test Group were 'satisfied' with the treatment outcome, compared to just 5% being dissatisfied. This compares to only 26.5% of the Control Group indicating a similar 'satisfied' score whereas 33.5% of the same group were 'dissatisfied' with their results. A similar percentage of both groups described themselves as neither satisfied or dissatisfied with the results.

Further study work needs to be conducted to evaluate the long-term maintenance of the circumferential loss in the specific targeted area. While the first law of thermodynamics would suggest that:

$$Energy\ intake\ into\ a\ body = Energy\ Expenditure + \Delta Energy\ Stores$$

That is if Energy Intake (calories from diet) < Energy Expenditure then there will be a degradation of the body's energy stores (Glycogen, fat and protein) while if Energy Intake > Energy Expenditure then there will be an increase in the body's energy stores (primarily as fat). Thus after reduction of

Conclusion

Non-invasive LLLT using diode laser at 658nm was significantly more effective at reduction of waist circumference than sham treatment.

subcutaneous adipose layer stores from ilipo™ treatment, if calorie intake from diet roughly equals daily requirements placed upon the body there should be no net increase in fat storage in the body and no reason to expect a regaining of adipose deposition at the treatment site while this homeostasis remains so. Whether there may be some redistribution of the body's fat reserves back to its normal pattern that might include the treatment area is a factor that needs to be investigated further to be able to fully evaluate long-term maintenance of results.

Early indications from this study suggest that the female subject might benefit greater treatment on this particular anatomical area than the male subject, explained perhaps by the greater female tendency for subcutaneous fat storage in this area although further population data does need to be collected to allow for a robust conclusion on this although this would correlate with the general experience of over 1000 devices globally.

The measurement data and patient satisfaction with the treatment outcome support the use if the ilipo™ low level-laser treatment to specifically target the waist anatomy for circumference reduction and body shaping. A healthy lifestyle of diet and exercise would be required to maintain energy homostatis in the fat cells after their treatment.

Subjective assessment was significantly positive for the treatment group. No adverse effects were reported by any subject and treatment was delivered without pain or discomfort or down-time form normal activities.

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