# Investigation of the Effects of Direct Target Fat Cell and Lymphatic Stimulation with Laser Irradiation During ilipo LLLT Treatment for Body Shaping

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## Introduction

This report investigates the effects on circumference measurements of various combinations of active or inactive treatment pad and LS probe diodes. The treatment outcome on circumference measurement is compared to effects of a normal typical ilipo treatment procedure on the abdominal area of the body.

As an additional investigation, comparison is also made to 'Placebo pads' intended for use in blinded placebo controlled studies to investigate the effectiveness of ilipo treatments.

## Method

10 patients were recruited for treatment in each of the following groups:

**Group 1:**

- Ilipo treatment pads (INACTIVE), secured in place with elastic strapping, LS probes (INACTIVE)

**Group 2:**

- Ilipo Treatment pads (INACTIVE), secured in place with elastic strapping, LS Probes (ACTIVE)

**Group 3:**

- Placebo (Diode output <1mW) Treatment pads (ACTIVE), secured in place with elastic strapping, LS PROBES (ACTIVE)

**Group 4:**

- Ilipo Treatment pads (ACTIVE), secured in place with elastic strapping, LS PROBES (ACTIVE)

Evaluation of the data collected from these groups should allow the following:

- Confirmation of previous investigational data which demonstrates that a single ilipo treatment with direct laser irradiation of the target fat cells and lymphatic stimulation cause measureable circumference reduction immediately after treatment
- Confirmation whether lymphatic stimulation alone, without direct irradiation of the target fat cells, will have an effect
- Confirmation whether the presence of the pads and elastic strapping around the abdomen is causing an effect rather than or enhancing the effect of the ilipo treatment
- Confirmation whether the placebo pads are suitable for sham irradiation in controlled studies where the patient is blinded to the group they are recruited into

The treatment procedure used for all patients in all groups is detailed below with just the ACTIVE/INACTIVE status of the pads or probes or use of Placebo pads differing between each group.

Prior to treatment, 3 separate circumference measurements within the intended treatment area were made using a MyoTape measuring tape, from Accufitness. This tape measure uses a torsion system to retract the tape around the area to be measured and minimises measurement error from the operator.

The first of the 3 measurements was made at the level of the umbilicus with the second and third measurements being made 4cm above and then 4cm below this first measurement level. At each measurement point, the tape measure was positioned and self secured around the abdomen circumference, parallel to the floor and four marks were made on the skin around the abdomen with a surgical skin marking pen to allow accurate repositioning of the tape measure for the post treatment data collection.

The patients were then positioned face up, in a semi-recumbent position on a treatment couch and the device pads/probes were attached. Treatment was performed by placing the four treatment pads first on the left side of the abdomen with the first treatment pad lying lengthways, adjacent to the umbilicus and with subsequent pads adjacent to one another along the mediolateral axis of the abdomen. Care was taken to ensure that the position of the pads covered the points from which measurements had been made. The pads were secured in contact with the abdomen surface with an elasticated strap. The LS single laser diode probes were secured to the skin surface directly over the superficial inguinal lymphatic nodes using adhesive rings. Treatment commenced with laser irradiation of the left side of the body for 10 minutes. After the 10 minutes the pads were repositioned to the right side of the abdomen using the same arrangement as previously, beginning with the first pad lying lengthways and adjacent to the umbilicus and the other 3 pads extending around the right side of the abdomen to cover the positions from which measurements had been made. As with standard ilipo treatment practice the LS probes were also repositioned approximately 2-3cm inwards along the inguinal crease to further maximise coverage of the inguinal node clusters. Treatment then

recommenced on this side of the body with a 10 minute dose of laser irradiation. Once completed, the pads and LS probes were removed and the 3 separate circumference measurement points were once again assessed using the tape measure.

When the pads were required to be INACTIVE, the pressure sensors on the surface of the pad were disabled to prevent the pad diodes illuminating during activation of the device. This would not prevent LS probes from being ACTIVE where required.

When both pads and LS probes are required to be INACTIVE, the device itself was not activated.

The intended Placebo pads use identical laser diodes as in the standard ilipo treatment pads, but with the power output of <1mW, which was expected to be a sub-therapeutic dose.

## Results

Fig 1 below displays the mean circumference measurement of each of the 3 measurement taken from each patient and compares the trend across each of the groups evaluated.

Data above the x axis (+ve) indicates a gain in mean circumference measurement, data below the x-axis (-ve) indicates a reduction in mean circumference measurement.

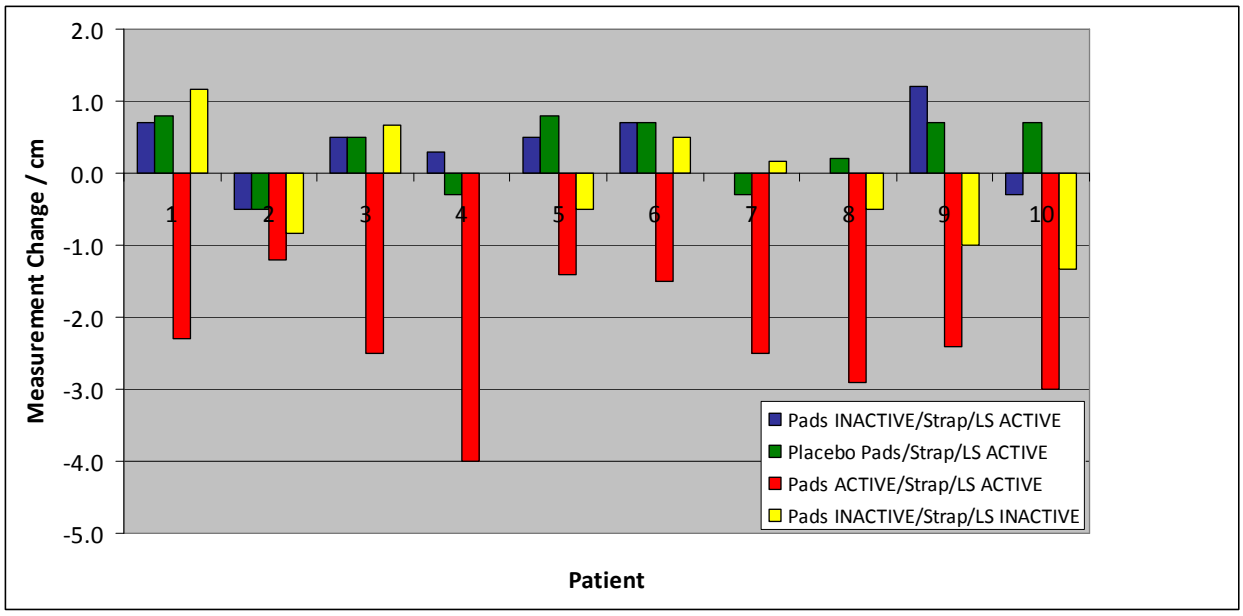


*Fig 1. Mean circumference measurement of individual patients in each treatment group*

- Group 1 (Pads INACTIVE/LS INACTIVE) indicated on the graph above with the yellow bars has a mean circumference effect across the entire group population of a ***gain*** of 0.2cm (SD 0.8)
- Group 2 (Pads INACTIVE/LS ACTIVE) indicated on the graph above with the blue bars has a mean circumference effect across the entire group population of a ***gain*** of 0.3cm (SD 0.51)
- Group 3 (Placebo pads/LS ACTIVE) indicated on the graph above with the green bars has a mean circumference effect across the entire group population of a ***gain*** of 0.3cm (SD 0.52)
- Group 4 (Pads ACTIVE/LS ACTIVE) indicated on the graph above with the red bars has a mean circumference effect across the entire group population of a ***reduction*** of 2.4cm (SD 0.85)

*p*-values from 2 sample *t*-test comparison of the data from all of the groups is given in Table 1 below

| t Test Analysis (Mean) | INACTIVE ILIPO | PLACEBO ILIPO | ACTIVE ILIPO | INACTIVE ILIPO/INACTIVE LS |
|---|---|---|---|---|
| INACTIVE ILIPO | 1.0 | 0.943214 | **0.0** | 0.662019 |
| PLACEBO ILIPO | | 1.0 | **0.0** | 0.62623 |
| ACTIVE ILIPO | | | 1.0 | **0.000002** |
| INACTIVE ILIPO/INACTIVE LS | | | | 1.0 |

*Table 1. 2-sample, 2-tailed t-test comparison of data groups*

These *p*-values indicate:

- no statistical difference on the effect on circumference reduction of groups 1, 2 and 3
- a confidence level of 99.9998% that the standard ilipo treatment with ACTIVE pads and ACTIVE LS probes (Group 4) has a measureable effect on circumference reduction when compared to groups 1,2 and 3.

## Discussion

The results of this investigation indicate that:

1. there is an immediate and measurable circumference reduction effect of patients circumference measurement after a single 20 minute ilipo treatment session,
2. the effect of ilipo requires a combination of direct laser irradiation of the target fat cells in conjunction with direct laser stimulation of the nearest lymphatic nodes to the treatment area,
3. direct laser stimulation of the lymphatic system alone does not produce a measurable reduction in circumference,

4. the positioning of the device pads and the securing of these pads on the intended treatment area with elastic strapping does not have an compression effect that might effect the reduction of the circumference measurement over and above the effect of the ilipo treatment itself,
5. the intended placebo pads for use in any future blinded placebo controlled studies do not have any effect of fat cell bio-stimulation and will not cause any effect on circumference reduction.