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Treatment Outcomes recorded in Low Level Laser Diode Treatments for Fat Reduction and Body Reshaping – A Retrospective Review

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Abstract

Despite low level lasers being presented as a possible adjunct to liposuction procedures in 2001, scientific studies of the exact mechanism are still lacking in conclusive evidence. Initial research report the benefits of low level laser therapy (LLLT) to stimulate the release of fatty acids from the cell, facilitating the extraction of the adipose tissue during lipoplasty, shortening operating times, reducing post treatment effects and the need for analgesia for the patient. Several years later this effect of stimulating the release of the stored contents of adipose cells has been applied to non-invasive fat reduction or body shaping treatments with a variety of devices offered on the market. Clinical research for this non-invasive option is lacking, with minimal studies currently published using controlled and large population groups to demonstrate effect. Despite this, these cold laser devices still prove to be a popular treatment opportunity within the global aesthetic market.

The purpose of this paper is to review the ability of one of these LLLT devices, the ilipo, to provide a safe and effective non-invasive opportunity for patients to specifically target and reduce unwanted fat deposits.

A review of 82 patients having completed 3 treatment sessions indicated a mean circumference reduction of -2.9% (SD 1.68) compared to their pre-treatment size.
An additional group of 20 patients having completed 8 treatment sessions indicated a continued cumulative mean circumference reduction with successive treatments up to -8.2% (SD 2.9). These results indicate a 95% confidence that 8 laser sessions will result in an average reduction of a patient's pre treatment circumference of -8.2% +/- 1.26.

Exclusion criteria allow for the conclusion that diet and exercise habits would have minimal impact on results achieved, other than the exercise sessions immediately post treatment which provides the sustained and cumulative reduction trend.

There were no recorded instances of discomfort of side effects from treatment.

The conclusion of this review is that ilipo offers a safe and effective opportunity for targeted fat reduction in a short timescale. Data suggests that a trend of -1% reduction in circumference is typically achieved with each ilipo treatment.

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Introduction

The history of low levels lasers in the fat reduction market began in 2000 with the documented research by Neira *et al* identifying the application of per-cutaneous low level 635nm laser light to emulsify fat and accelerate wound healing after liposuction procedures [(1)]. This treatment method was proposed based on previous understanding of the direct action of 630-660nm low intensity laser radiation on the mitochondria within cells, accelerating the electron transport cascade and increasing H^+ and Ca^{2+} diffusion across the mitochondrial membrane into the main cell structure [(2)(3)]. These ion concentration changes trigger the opening of pores within the cell wall and the release of a lipase enzyme which breaks down the stored triglycerides into free fatty acids and glycerol. These smaller sized molecules being able to be transported through the cell pores. Neira and his colleagues research continued through 2001 and 2002 with the use of MRI and electron microscopy to confirm the mechanism of action of fat liquefaction without damage to the integrity of the cell structure or surrounding tissues [(4)(5)]. Microscopic investigations highlighted the extrusion of the contents from the cells, reducing cell size until after an average of 8 minutes; the globular cell structure has collapsed. Higher magnification transmission electron microscopy even directly visualised the channels or pores in the individual cell walls.

While Neira's research presented the benefits of this technique as an adjunct to tumescent lipoplasty procedures it was perhaps a natural progression for the laser industry to investigate the possibilities of this bio-stimulation effect without the need for invasive procedures. Without the physical extraction of the released cell contents via cannula as in liposuction it is presumed, although not demonstrated, that the fatty acids and glycerol are mobilised via the lymphatic and then circulatory systems for re-esterification in other available subcutaneous storage space. The human body is not designed to excrete fat; rather it is programmed to store any excess dietary calories on a day to day basis for future periods of reduced calorie intake or fasting. If fatty acids are stimulated to be released from adipose cells without an actual energy requirement in the bodies tissues, they would simply circulate the body until re-stored unless they are metabolised to meet increased energy demands.

A randomised controlled study into the effect of a non-invasive device for body contouring was published in 2010 by Caruso-Davis *et al* [(6)] using a 1:1 grouping of 40 persons receiving either 8 laser or sham treatments over a 4 week interval to the abdominal area. Criteria for inclusion in the study were to have had a stable weight prior to commencement of the study and no change to diet or exercise habits for the duration of the treatments. This device utilised 2 paddles which were placed directly onto three separate placements on the surface of the abdominal area for approximately 10 minutes each - a 30 minute procedure in total. Each paddle housed four lasers emitting visible red light of wavelength 635-680nm. Additionally, 2 separate enhancement probes were placed bilaterally in the inguinal region. Results demonstrated a mean girth loss of 0.4-0.5cm per treatment (Laser -0.59 +/-

0.71cm vs. placebo -0.19 +/- 0.47 cm) and a cumulative girth loss after 4 weeks of -2.15 cm (-0.78 +/- 2.82 vs. 1.35 +/- 2.64cm for the control group). Blinded evaluation of standardized photographs also showed statistically significant cosmetic improvement after the 8 treatments. No adverse effects were reported during the study.

One of the discussion points of this particular study observed that while this treatment offered statistically viable reduction of waist circumference, the mobilised fat would either be burned for food or be distributed into the fat depots typical of that person's fat distribution and without periodic treatments, the body would redistribute fat to its original patterns.

This potential risk of relapse to the body's original shape after LLLT treatments have ceased theoretically can be avoided by increasing the body's demand for energy after each treatment and using up the freed fatty acids via normal metabolic pathways with a period of cardio-vascular exercise.

The ilipo low level laser diode device was launched onto the world market in early 2008, incorporating the procedure of laser irradiation into a treatment program which included a period of post treatment exercise and guidelines for lifestyle re-education. Until a miracle fat reduction/weight loss treatment option without effort on the part of the person is discovered, adjustment of an unhealthy diet and activity lifestyle should be adopted, although ilipo treatment offers speed and motivation to achieve a patient's desired results.

The primary aim of this review was to evaluate the outcome of treatments from aesthetic patients electing to undergo ilipo treatment as a method of rapid and targeted fat reduction for the abdominal region. This was undertaken in two stages; first evaluating the effect of the first 3 treatments on circumference measurement, followed by an additional review of patients who had completed a course of 8 sessions over 4 weeks (standard suggested treatment course)

The secondary aim was to confirm the safety of this treatment option with investigation of patient records for notation of any instances of adverse effects experienced by the patients during the treatment period.

Method

All patients assessed for inclusion in this review had voluntarily attended and paid for treatment at the clinics and given written consent for their procedures.

Stage 1:

Initially a review of patient records from a single clinic (The West London Dermatology Clinic, London, UK) was undertaken to identify a male and female population for review who met the following criteria:

- Treatments had been undertaken in the time period from the 1st October 2010 to 28th February 2011 on the abdominal region.

- Prior to treatment commencing, patients had been identified during consultation as currently consuming an average diet which meets UK nutritional guidelines for calories and ratios of fat, carbohydrate (including sugars) and fibre [(7)]. This diet pattern would be continued during the time period of the treatments reviewed.

- Prior to treatment commencing, patients had been identified during consultation as already undertaking an average exercise regimen of 3x30 minute exercise sessions per week for a minimum of 3 months prior to treatment beginning.

- Prior to treatment commencing, patients had been identified during consultation as having a stable weight, gaining or losing no more than 2.5 kg in the 3 months prior to commencing treatment.

- The first 3 treatment sessions were undertaken within a 9 day time period from first treatment.

- Patients had undertaken only the exercise session after each treatment session without additional sessions on non-treatment days.

Only the data from the first 3 treatment sessions would be analysed since these sessions would be completed within a 9 day period from the commencement of treatment allowing us to minimise influence of unexpected calorie controlled dieting and/or increased exercise levels.

Treatments were performed using the ilipo low level laser device, where 4 treatment pads are placed starting at the umbilicus and extending around one side of the abdomen for a laser irradiation time of 10 minutes. This procedure was then repeated on the opposite side of the abdomen. Total irradiation time was 20 minutes. Circumference measurements were taken before and immediately after treatment on three separate placements within the area to be treated, each 4cm apart. A 30 minute post treatment exercise session was then undertaken within the clinic facilities, under the instruction of a personal fitness instructor, using a combination of vibration plate, cross trainer and rowing machine to provide a cardio workout to metabolise the fatty acids freed from the adipose cells during treatment.

Stage 2:

Next a review of patient records from two separate clinics was undertaken (The West London Dermatology Clinic, London, UK and Essentials Laser Skin Clinic, Cardiff, UK) to identify a population of male and female patients who met the following criteria:

- Treatments had been undertaken in the time period from the 1st July 2010 to 30th November 2010 on the abdominal region.

- Patients were 18 years of age or older at the start of treatment.

- Prior to treatment commencing, patients had been identified during consultation as currently consuming an average diet which meets UK nutritional guidelines for calories and ratios of fat, carbohydrate (including sugars) and fibre. This diet pattern would be continued during the time period of the treatments reviewed.

- Prior to treatment commencing, patients had been identified during consultation as already undertaking an average exercise regimen of up to 3x30 minute exercise sessions per week for a minimum of 3 months prior to treatment beginning.

- All 8 Treatments were completed within a four week timescale from commencement.

- Patients had undertaken only the exercise session after each treatment session without additional sessions on other days.

- Patients would not be included if their data had previously been included in the Stage 1 review.

Treatment, measurement and post treatment exercise procedure was as discussed in the Stage 1 review.

Results

Stage 1:

A total of 82 patients during the specified period met the criteria guidelines and were included within the data review of which 9 were male and 71 were female between the ages of 22 and 68 years.

For each patient the mean value of their 3 circumference measurements after the 3rd treatment session were calculated and then converted to a % loss/gain compared to their pre-treatment circumference measurement average. The data for the total population showed a Normal Distribution (see Fig. 1) with a mean *reduction* in circumference measurement of -2.8cm and standard deviation of 1.68 and a mean reduction in % loss compared to starting circumference of -2.9% over the three treatments with a standard deviation of 1.76.

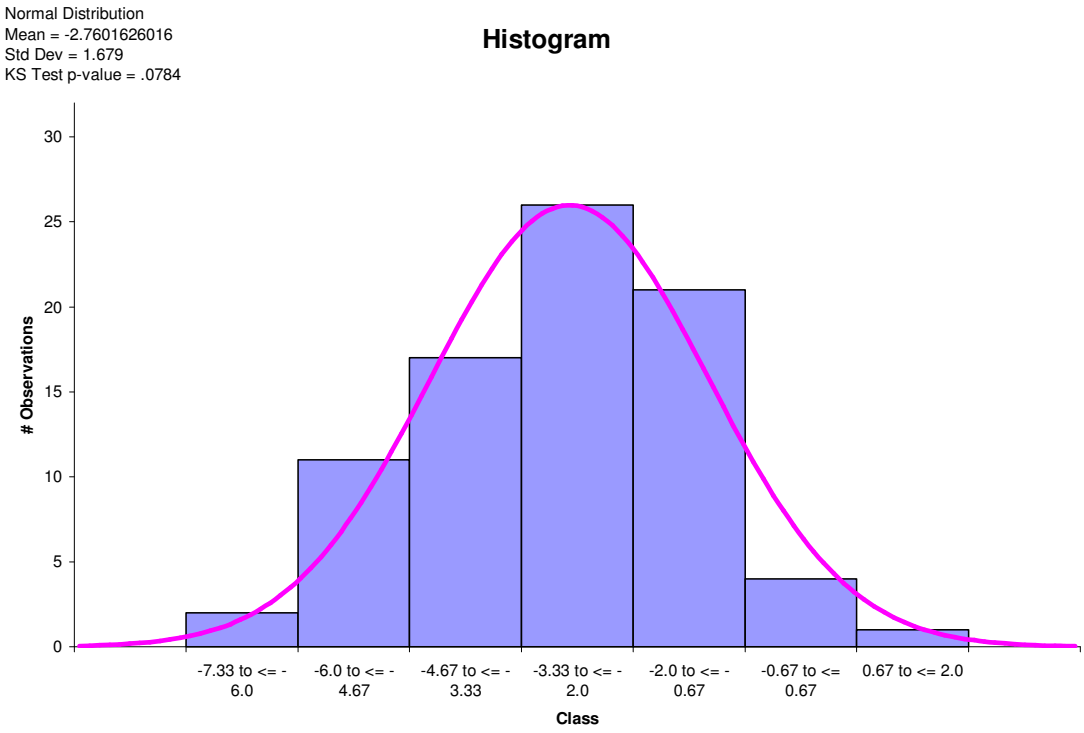

Fig 1. Normal distribution of reduction in mean circumference data of 82 patients having undertaken 3 treatments

Stage 2:

A total of 20 patients were identified as meeting the criteria guidelines, 11 from the London clinic and 9 from the Cardiff clinic. Of these, 18 were female and 2 male and the age ranged from 26 to 76 years.

All 20 patients experienced reductions in the 3 separate circumference measurements after 8 treatments with the minimum response being 12.3cm and a maximum response of 45.4cm over the 3 measurements.

The average value of each patient's 3 separate measurements was then calculated and converted to a % reduction compared to circumference measurement prior to commencing treatment. The mean reduction of the total group was -8.24cm (SD 3.39) and mean % reduction equalled -8.2% (SD 2.94). These results indicate a confidence that 95% of treatments (of 8 laser sessions) will result in an average reduction of the patient's pre treatment circumference of -8.2 +/- 1.26%.

No adverse effects were reported in any patient records at either stage of the review nor where there any reports of patient dissatisfaction with treatment outcome.

From this group of 20, 10 patients were selected at random for further data analysis. In Fig 2. We can see the trend of % reduction of mean circumference after each treatment for each of these 10 patients compared to their pre-treatment mean circumference.

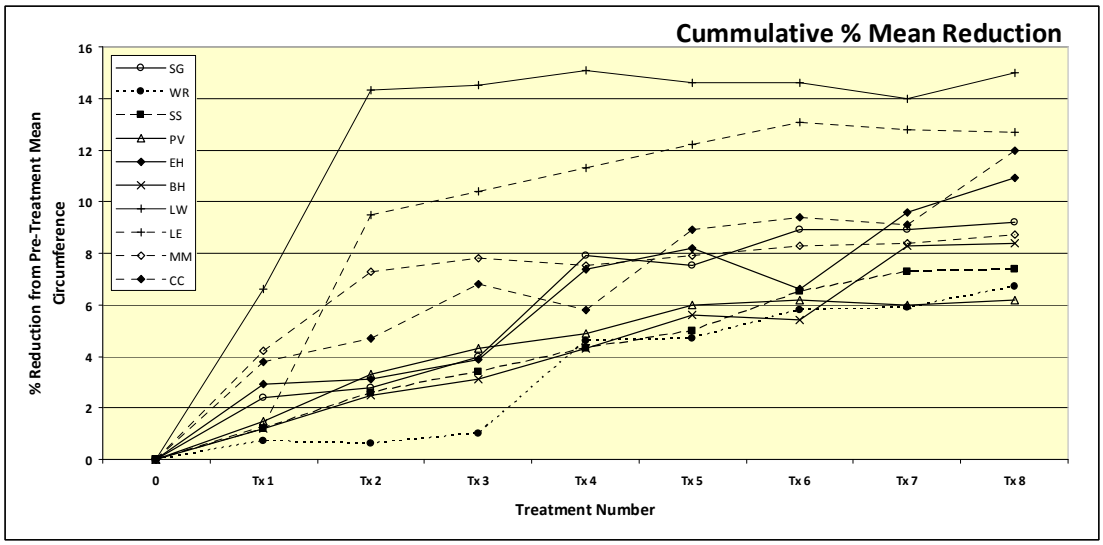

Fig 2. Percentage Reduction Trend of Mean Circumference Measurement with each Treatment for 10 Patients

The data suggests two distinct groups of response to treatment: patients that experience a large % reduction very quickly, after treatment session 1 or 2, and then maintain this % reduction over the subsequent treatments until the end of the course (Patients LE, MM, LW) (see Fig 3.);

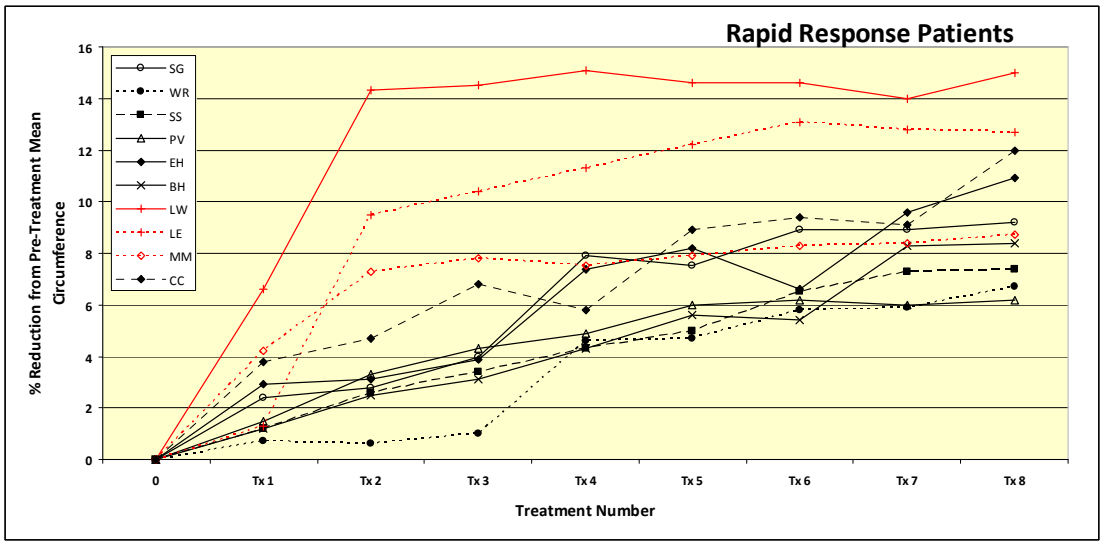

Fig 3. Patients Demonstrating Initial Rapid % Reduction Response During Early Treatment Sessions, With Maintenance of This Reduction During Latter Treatments

and patients that experience a linear trend of % reduction for the duration of the course of treatments (Patients SG, CC, BH, EH, SS, WR, PV) (see Fig 4.).

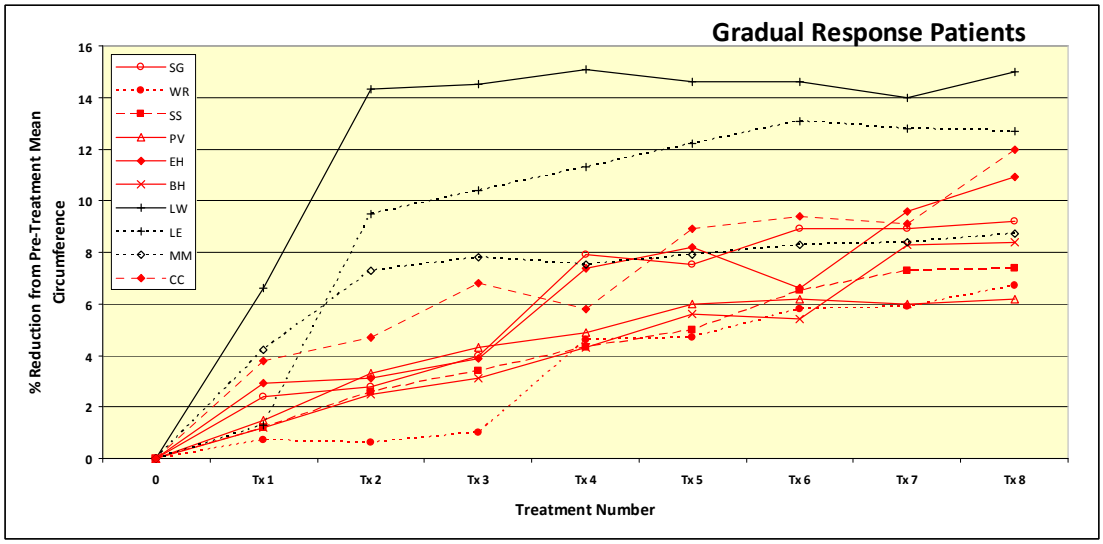

Fig 4. Patients Demonstrating Gradual Linear % Reduction Response with Successive Treatments

If we consider the group with a steady response (Patients SG, CC, BH, EH, SS, WR, PV) only for the moment, linear regression of their data demonstrates the following trend line gradients (see Fig 4.):

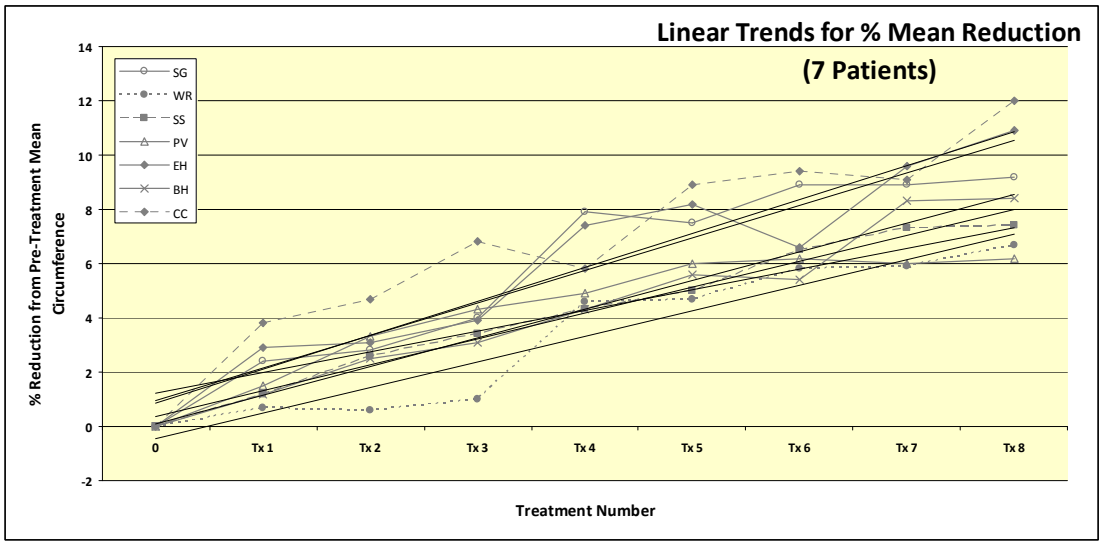

Fig 4. Data Trend for 7 Linear % Reduction Patients

Gradients and R^2 correlation values are detailed in Table 1. below.

Patient Reference	Gradient of Linear Regression Line	R^2 Value
SG	1.20	0.9049
CC	1.26	0.9102
BH	1.05	0.9720
EH	1.25	0.9160
SS	0.955	0.9837
WR	0.94	0.9104
PV	0.76	0.8600

Table 1. R^2 Correlation and Gradient of Linear Regression Trend Lines of 7 Patients

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Discussion

The results from the review of the results of the first 3 ilipo treatments indicate an effective mean reduction effect on circumference measurement of almost -3% for each patient. Since these 3 sessions were completed within a period of 9 days, along with the patient histories of stable weight, diet and exercise prior to and during treatment we are able to reason that these results are unlikely to be as a result of diet and exercise and the measurement changes can be directly correlated to the effect of the ilipo device.

The mean circumference measurement reduction in cm after the 3 sessions was 2.76cm which is approximately 60% greater than the result all ready demonstrated with 3 treatments in the research by Caruso-Davies discussed earlier also using another LLLT device (mean reduction for that study of 1.74cm).

The results from the review of patients who underwent 8 treatment sessions indicate a continued cumulative circumference reduction trend as indicated from the Stage 1 review of the results after 3 treatment interventions, with mean measurement reduction compared to their pre-treatment circumference after the eight treatment of -8.2% (SD 2.9).

From random sampling of 10 of the 20 patient population who underwent 8 treatments, two distinct groups of response to treatment seem to occur, those that respond with large % reduction in circumference measurement within the first 1-2 treatments and then tend to maintain this % reduction during the remaining treatment course, and those that respond gradually, with a linear trend.

R^2 values for these 7 patients with the linear response trend vary from 0.86 to 0.98 which indicates very good correlation of each patient's data with the linear regression trend line. Gradients of these lines vary from 0.76 to 1.26 with a mean value of 1.06.

This data would therefore suggest that each treatment could offer a sustained average -1% reduction trend which allows a prospective patient to consider their desired outcome and have a realistic idea of how many treatments would be required to reach it. Inclusion criteria regarding pre-treatment diet and exercise habits and the maintenance of the habits during treatment reduce the likelihood of excessive contribution to effect on circumference measurements over and above the effect of targeted fat reduction with ilipo and the subsequent exercise to ensure use of the freed fatty acids.

The normal distribution of the population data allows us to calculate the probability values that 86% of any patient treated with ilipo will expect a % reduction of their circumference measurement of a minimum of -5% and 53% achieving a minimum of -8% reduction after a course of 8 treatments in 4 weeks.

Further analysis of larger population groups is necessary to investigate if the 2 different response groups continue to be a trend across all patients treated and to try to identify clinical or patient demographics that might be a reason for these differences.

Conclusion

Other non-invasive body shaping options for patient's today range from the basic water reducing body wrap to more specific fat targeting options such as high frequency ultrasound cavitation techniques. Each is not without its drawbacks; wraps and simple vacuum massage techniques require frequent, multiple treatment interventions to achieve measurable effect which are most often not sustained once treatment ceases. Ultrasound treatments have relatively long appointment times (compared to ilipo LLLT) and are not without discomfort or risk of side effects from the destruction of fat cells and release of stored triglycerides into the body as opposed to the natural metabolites expelled by ilipo.

The data from this review indicates that ilipo treatment offers patients the opportunity for non-invasive, safe and effective reduction of targeted fat deposits in a relatively short timescale without the need for dramatic and unhealthy diet restrictions. This is achieved by stimulation of the body's normal biological pathways rather than by tissue destruction and with the simplest of treatment regimen for both the operating clinic and patient.

This review data demonstrates a good representation of the expected population response with typically treatment trend towards an average of -1% reduction in pre-treatment circumference size after each successive treatment. This reduction can be cumulative and sustained with inclusion of a suitable exercise session post treatment.

Study data due for publication in the Spanish Society of Aesthetic Medicine Magazine - Medicina Estetica, in April 2011 by Prof. Dr Raul Pinto and Dr Ricardo Hoogstra investigates the effect of 8 ilipo treatment sessions on a group of normal or below normal weight with specific abdominal fat accumulation and will demonstrate significant reduction in mean circumference even in these patient types.

Further work is currently being carried out in several sites, including a blinded, placebo controlled study of efficacy and investigations into effects on blood chemistry and cellular structure which will be released later in 2011.

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