Body Shaping Treatments: A Comparison of Laser Lipolysis, Non-Invasive Low Level Laser Therapy and Ultrasound Methods

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Introduction

This report is intended to describe and compare three of the current widely used technologies within the medical and aesthetic communities to achieve body shaping or fat reduction treatments: invasive laser lipolysis, non-invasive low level laser therapy and ultrasound. The key outcome of all of these treatments is the reduction in size or destruction of adipose (fat) cells in targeted anatomical locations to moderate the amount of body fat stored there. This report will focus on the mechanism of action, effects on the body's tissues, operator dependency and the risks of complications from the treatments and in particular highlight the safety of treatment for the patient and operator of one particular low level laser device; the ilipo, manufactured by Chromogenex Technologies Ltd, UK.

While the surgical technique of Tumescent Lipoplasty (liposuction) is still the preferred option for body-sculpting procedures, the number of procedures performed annually in many countries has decreased dramatically over the last few years as clients look for less invasive procedures with fewer risks of complications and down time from normal everyday life. In the United States for instance, the number of lipoplasty procedures declined to 198,000 in 2009 from 245,000 in 2008 (-19%) and from 350,000 in 2000 (-44%)[(1)]. This decline is significant, despite its obvious continuing popularity, and is due to the high potential for significant complications, morbidity and mortality associated with the actual practical procedure and anaesthesia requirements [(2)(3)]. The development of adjuncts to support traditional lipoplasty procedures while attempting to moderate the risks of treatment saw the introduction of ultrasound assisted liposuction (UAL) and laser assisted liposuction (LAL), which have demonstrated some success in this matter although not eliminated the risk, and in some cases have introduced their own additional hazards. Non-invasive treatment options have since been developed, using low[(4)(5)] and high intensity[(6)(7)] focused ultrasound, low level lasers[(8)(9)], radio-frequency[(10)], injection lipolysis[(11)] and cryolipoliysis[(12)]. Some of these methods are not without their treatment risks and limitations, but despite this have been incorporated into many aesthetic and therapeutic spas/clinics globally.

Ultrasound Treatments

Ultrasound used for body shaping can be divided into two broad categories: low-frequency non-thermal ultrasound and high-intensity focused ultrasound (HIFU).

Non-thermal devices use low frequency ultrasound to increase the likelihood of causing a cavitation effect (with some minor heat generation through absorption). Cavitation is where bubbles are created inside the cell, which swell and rupture, creating mechanical stress that disrupts the adipose cell membrane and releases the stored triglyceride contents. The treatment is performed by applying a transducer to the skin surface above the target fat pocket and applying the ultrasound in pulses to create repeated compressions and rarefactions in the tissue. These rarefactions generate cavitation events, causing cell death through mechanical disruption[13]. Operator manipulation of the transducer probe is the limiting factor for controlling the boundaries of the treatment zone and prevent targeting of unwanted tissues.

HIFU devices focus high intensity ultrasonic energy to deep subcutaneous tissue, generating a thermal effect capable of ablating adipose tissue[14]. Exposure of adipocytes to a temperature of 56^{o}C or higher for 1s is adequate to cause rapid cell death by coagulative necrosis. Similar to the non-thermal devices, the ultrasound energy is applied to the skin surface above the target fat pocket by an internally focused transducer, which focuses the Ultrasound waves so that they converge at a specified depth and location. This focused point provides some protection to skin, nerves, blood vessels or organs encountered before or beyond the focal point, as the ultrasound waves will not have enough energy here to create too much thermal damage. Heat, sufficient to create the ablative effect on adipose tissue, is only generated at the point where the focused beams converge to ensure tissue lysis is confined to the treatment zone.

The cell debris of both methods of ultrasound treatment are then expected to be safely ingested by tissue macrophages initiated by the local inflammatory response[15] although further clinical study needs to be done to confirm that there are no significant changes to serum lipid levels or undue stress to the liver and kidneys.

Most devices limit the treatment areas to stomach, flanks, back, outer thighs and the buttocks to prevent the use of ultrasound directly over bone unprotected by sufficient tissue layers. Sensations during treatment are explained to be mild and transient pain due to secondary vibrations felt in nearby bones and heating and oral analgesics may be recommended. Side effects of treatment can be prolonged erythema, bruising, oedema and surface burns/blisters.

Laser Lipolysis

Laser lipolysis uses fibre-optic delivery of high powered infra red laser energy (either diode or Nd:YAG lasers) to ablate target adipose tissues followed by cannula extraction of the debris of treatment. The risks of this treatment are reduced over conventional dry or tumescent liposuction surgery, since mechanical force to disrupt tissues is replaced by laser disruption, reducing trauma to the area and thus anaesthesia can be reduced to local only. Recovery after treatment is also more rapid than conventional liposuction surgery.

A 1-2mm incision is made, into which a 1mm cannula and optical fibre can be inserted into the tissue. High intensity infra red energy is then delivered (up to 30W in some devices) and the cannula is manipulated by the operator back and forth in 'sweeps' through the tissue with one hand while maintaining the other hand in contact with the treatment area to assess temperature. Speed of cannula movement is operator dependant and can have a huge impact on treatment outcome or instances of side effects[16]. Energy absorption creates heat in the tissue, eventually reaching a temperature where the cell membrane is completely disrupted and the cell destroyed. Clinical endpoint for treatment on a specific zone is estimated by the operator by temperature testing of the skin surface by hand. Optimal dosage is reached when the skin feels warm to the touch (approximately $40^{o}C$). Liquefied fat debris from treatment is then removed by aspiration with a larger cannula (3mm) and the area is strapped with surgical tape to enforce contouring/shape which remains in place for several days. Additional to this, compression garments are required for up to 4 weeks. The patient can be expected to return to work in 1-2 days, and back to light exercise in several days.

Additional to the local anaesthesia, strong analgesia is provided during the initial recovery period, reduced to oral analgesia for the following few days as required. Some patients may require sedation during the procedure to support the local anaesthesia and reduce discomfort. Finally, a short course of antibiotics are also prescribed.

Post treatment effects include discomfort, oedema, ecchymoses (bruising) lasting typically 1 week (but up to 3 weeks) and localised tenderness. Significant complications such as bleeding, infection and surface and deep tissue burns are also a consideration.

Since clinical endpoint is determined only by surface skin temperature, it is not an accurate method for determining the actual heat generated in the deeper tissues. Some research has indicated deep tissue temperatures as high as $55^{o}C$ being reached, which is high enough to cause tissue necrosis and inflammation to the bulk tissue and increase the potential for significant burns[17].

This technique is suitable for small volumes or pockets of fat removal rather than entire anatomical regions such as the abdomen.

Low Level Laser Therapy

Low level laser therapy has a long history of safe and effective use in the bio-stimulation of human tissues since its first scientific evaluation in the 1960's[18], with its primary use in the physiotherapy and alternative medicines industries for facilitating the repair of soft tissue injuries[19][20][21][22] and laser acupuncture[23]. The mechanism of bio-stimulation of the tissue cells is widely researched and understood [24][25].

At the start of the 21st century this cellular bio-stimulation effect of low level visible red light was suggested as an adjunct treatment to traditional tumescent lipoplasty procedures, to free up the stored fat from its adipose cells and make the cannula extraction of the fat contents faster, with less manual force that would mean less post operative side effects and discomfort for the patient [26][27].

The natural progression of this technology, in response to patient requirements of non-invasive treatment options, was to remove the surgical element. Trans-cutaneous application of low level laser light (630nm-660nm) results in stimulation of the adipose mitochondria and a temporary acceleration of the electron transport cascade which produces cellular energy (ATP). This temporary acceleration of normal chemical reactions inside the cell briefly changes the cell pH resulting in the break down of the stored triglycerides into free fatty acids and glycerol and their movement across the intact cell membrane into the interstitial space. From here the lymphatic system automatically transport the free fatty acids around the body to the tissues for metabolism during exercise to provide ATP leaving empty adipose cells which take up less volume, thus reducing dress size in that area. It is important to remember that this change of cell chemistry, break down of triglycerides into free fatty acids and glycerol and their subsequent transport around the body is experienced as a natural response in the body every time the day to day calorie needs of the body are not met due to diet restrictions or increased exercise. The fatty acids and glycerol released from the cells during treatment are managed by the body via normal metabolic pathways. There is no damage to the cell integrity or that of surrounding tissues.

Low level laser treatments are carried out by positioning pads containing the laser diodes directly onto the surface of the intended treatment area and securing in place, usually with elasticated strapping. The strapping provides additional eye safety by preventing accidental exposure to any light. Some devices, such as the ilipo, also incorporate skin sensor technology to prevent diode activation if the pad is not fully in contact with the skin surface. The lasers are then activated to deliver a pre-set energy level for a pre-set time duration to the area, eliminating the need for operator selection of parameters, decision on clinical end-point or risk of overdose of therapy.

Energy levels used are low level, typically around 40mW. This level of laser energy is also referred to as cold laser as there is insufficient laser energy to have a thermal effect on the tissue, eliminating the risk of surface or deep tissue burns. The

majority of patients have no sensation at all during treatment, while a few may feel a mild warming from the presence of the pads close to the skin surface for the treatment duration. Post treatment signs or symptoms are nil. No instances of post treatment complications have been recorded in studies conducted[8][9]. Scientific research has confirmed that serum lipid levels and profiles remain unaltered and in a significant majority of treated patients in one study, can actually be reduced as a result of low level laser treatments[28] so no long term implications are expected to cardiac or circulatory health.

Patients can return to normal activity, including exercise immediately post treatment.

Conclusion

Table 1. below, compares the certain aspects of the three technologies related to safety and post treatment effects and complications. Of the three technologies discussed in this report low level laser devices, such as the ilipo device, offer the non-invasive treatment with the least biological impact on the body, lowest risk of side effects or margin for operator influence or error.

Its use of laser diodes has led to some worries regarding the safety of the technology and treatment both on behalf of the patient and the operator performing treatment. No instances of side effects have been reported from over 600 ilipo devices used globally since its introduction in March 2008. The power output of the device is low level thus will not have a thermal effect on tissues being treated. As a Class 3b device there are some associated eye risks if exposed to the beam within the Nominal Ocular Hazard Distance (NOHD) which is within 32cm of source. Practically, this exposure is unlikely to happen; since the laser diodes are only and can only be illuminated when the treatment pad is placed (light source downwards) onto the skin surface. This is controlled by the skin sensor safety switches in the pads. The pads are then also secured in place with circumferential strapping to prevent movement. Were a pad to be lifted off of the skins surface during treatment, the diodes would be instantly deactivated.

The laser light used in low level laser therapy is orders of magnitude different to the laser light used in the ablative and surgical technique of laser lipolysis; milli Watts in low level laser compared to Watts of power in laser lipolysis. Hence, why low level laser ‘stimulates’ tissue while laser lipolysis ‘ablates’ tissue that is exposed to the laser.

The treatment mechanism for low level laser therapy is by stimulation of existing biochemical/metabolic pathways as opposed to tissue destruction which is seen in Ultrasound and laser lipolysis techniques. By only emptying the cell contents rather than destroying the cell to release stored contents the ability for future fat storage in that area remains. In procedures where fat cells are surgically removed or destroyed, any future fat storage (from mismanaged diet and exercise lifestyle) will

have to be distributed for storage in other anatomical locations, which could include around the internal organs and within the visceral cavity, one of the contributory factors to developing type II non insulin dependant diabetes. Low level laser therapy leaves the cells intact and able to store future fat in the original area, reducing this risk.

Finally, the ilipo device has pre-set treatment parameters which remove the risk of accidental ineffective dosing or overdosing of the patient, nor does treatment require manual skill by the operator to ensure treatment success or minimise side effects, making it one of the simplest devices to operate practically.

	ULTRASOUND	LASER LIPOLYSIS	LOW LEVEL LASER THERAPY
Invasive/Non-invasive	Non-invasive	Invasive, surgical procedure	Non-invasive
Mechanism	Mechanical/thermal destruction of soft tissue	Surgical incision, thermal destruction by ablation & coagulation of soft tissue	Stimulation of existing metabolic pathways, no tissue destruction
Energy Type/Dose	Ultrasound waves Increasing tissue temp in excess of 40^{o}C	High powered Class 4 infra red laser light (Nd:YAG or diode) Up to 30W	Low level Class 3b visible red laser diodes 40mW
Restrictions of Treatment Areas	Most devices cite abdomen, flanks and out thigh/hip areas, specify minimum of 2cm fat layer over bone to prevent accidental damage to bone	All devices specify treatment is only suitable for SMALL localised pockets of fat	None
Requires Anaesthesia/Analgesia	Oral analgesia and/or skin cooling may be necessary	Local Anaesthesia, sedation and analgesia required	None
Discomfort during treatment	Mild and transient pain,	Sensations of probe movement within tissue	None
Side effects	Erythema for several hours, bruising, oedema, skin burns, deeper tissue burns Risks of accidental exposure of focused ultrasound energy on unwanted organs/tissues/bone	Pain, tenderness, bleeding, bruising, oedema, infection, nerve damage, scarring, persistent symptoms, burns	None
Downtime after treatment	Minimal, mainly visual appearance, some sensation discomfort	1-2 days until resumption of gentle routine, several days before exercise Compression garments for up to 4 weeks	None
Operator dependant parameter selection/treatment delivery	Yes Treatment head must be kept in motion to prevent burns	Yes Manual manipulation of laser through tissue layers Endpoint decided by operator judgement of temperature to touch of surface skin above treatment area	No, pre-programmed fixed treatment parameters

Table 1. Comparison of ultrasound, laser lipolysis and low level laser therapy

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