

Low Level Laser for Fat Reduction and Body Reshaping – Case Studies with the I-lipo laser diode system.

D Freeman M.Sc. Ph.D., E Beynon-Williams
August 2009

The authors would also like to thank Dr Christopher Griffin and the Midlands Ultrasound and Medical Services for their research contributions.

Abstract

The ability of low level lasers to cause photomodulation of individual adipose cells so that they release their contents without damage to the cell or surrounding tissues provided has been successfully and safely used for several years, first as an adjunct treatment to reduce the post treatment swelling and discomfort of liposuction procedures and more recently on their own as a non-invasive body reshaping treatment option.

The purpose of this study was to report the ability of the I-lipo laser diode system to be used as a fat reduction and body reshaping system, offering patients immediate and long term changes to specific problem fatty areas. Single treatment observations on circumference measurement changes of the abdomen were reported for 20 patients and a single case study was presented of a female patient middle-abdominal region during a course of eight treatment sessions over four weeks. Interim results from pilot study using real-time ultrasound to make direct observations and measurements of the subcutaneous adipose layer were also presented.

Observations and measurements confirm the I-lipo laser diode device as an effective, safe and pain free option for immediate and long-term body reshaping.

Introduction

Light therapy is one of the oldest therapeutic methods used by the human race, from Hippocrates noting the favourable effects of the sun's rays in late 5th Century BC, UV-therapy in the medical environment to today, when nearly every high street has a clinic or salon providing light based treatment options⁽¹⁾⁽²⁾. In particular history records the use of visible red light for curing various medical conditions since the middle ages, such as when those suffering from small pox were cured by being placed in rooms illuminated only by dim red light which filtered through thick red curtains from the sunlight outside.

The biological and physiological effects of low level lasers on tissues was first evaluated in the 1960's and 1970's in Eastern Europe, in particular in Hungary and the

Soviet Union ⁽³⁾. During its early stages laser bio-stimulation was viewed with a great deal of scepticism, the credibility of these early studies showing the direct action of low intensity visible laser light on an organism at the molecular level in doubt. Since then, low level laser therapy (LLLT) has passed through various development phases and matured into a viable treatment option with much of the early controversies no longer topical, and is now considered an everyday part of light therapy, from use in the physiotherapy world for pain relief and tissue repair⁽⁴⁾⁽⁵⁾⁽⁶⁾⁽⁷⁾ thorough to needle-less acupuncture point stimulation⁽⁸⁾.

The use of LLLT for as an effective treatment modality for pain relief was taken one step further in the early part of the 21st century. Neira et al documented the ability of LLLT to emulsify fat and accelerate wound healing after liposuction procedures using scanning electron microscopy (SEM) and magnetic resonance imaging (MRI)⁽⁹⁾⁽¹⁰⁾. This work highlighted the mechanism of adipose cell liquefaction with the cell contents being evacuated through the pores in the cell membrane into the interstitial space. This procedure of releasing the fat prior to the actual surgical intervention facilitated the fat extraction by eliminating the need for prolonged tunnelling and reduced post treatment discomfort, swelling and bruising.

Following the successful development of a combination LLLT and vacuum massage system for body reshaping and cellulite treatment in 2004 ⁽¹¹⁾⁽¹²⁾⁽¹³⁾, Chromogenex Ltd. then produced the I-lipo low level laser system for reduction and body shaping, which was launched in early 2008. This system builds on the low level laser assisted liposuction procedure developed by Neira, offering the patient fat reduction and inch loss without the requirement for actual surgical intervention.

The I-lipo uses 650nm visible red laser diodes, a wavelength which has been demonstrated in the early LLLT work to target the mitochondria of the adipose cells ⁽¹⁴⁾. Light of 630-660nm absorbs into the Cytochrome-c-oxidase unit of the proton transport chain within the mitochondria, intensifying the biological processes to increase hydrogen and calcium ions (H⁺ and Ca²⁺) output. This increased product output temporarily changes the chemical balance within the cells. Increases in pH inside the cell causes charge distribution changes in the cell walls opening pores in through which cellular contents can pass. Changes in Ca²⁺ ion in the cell stimulates the production of a lipase enzyme, which breaks down the enclosed triglycerides into glycerol and fatty acids ⁽¹⁵⁾. Compared to the large bulky structure of the stable triglyceride molecule that the body stores its surplus dietary energy as, the smaller glycerol and free fatty acids are now able to be mobilised through the pores in the cell wall via transport proteins.

Once in the interstitial space they are taken up by the body's lymphatic system and transported to the appropriate tissues to be turned into energy during exercise. The I-lipo also employs separate single laser diode probes, which are placed on the nearest Lymphatic nodes to the treatment site during the procedure to optimise the lymphatic stimulation and movement of the cell contents away from the treatment location. Once treatment is over and the laser irradiation ceases, the stimulus to the biological processes in the mitochondria is removed and they return to their natural reaction rate.

This mechanism of mobilisation of adipose cell contents is exactly what the body undertakes as and when energy demands need to be met. In these instances, hormones initiate the mitochondrial stimulation and enzymes released from the brain in response to reduced daily calorie intake or instances of exercise. The I-lipo mobilises the energy before the body realises it needs it, with subsequent post treatment exercise using these freed metabolites. This mechanism allows the patient to choose the area of body reshaping or target stubborn fatty deposits that previous diet and exercise has been unable to shift.

1. Multi-participant study of the effects of single treatments with I-lipo

Previous research has demonstrated almost 100% evacuation of the adipose cell contents into the interstitial space during 6-8 minutes of per-cutaneous laser irradiation⁽¹⁰⁾. Due to the rapid movement of the lymphatic system, these contents can be removed from the treatment site within a few minutes leaving behind collapsed cellular structures which will now take up less subcutaneous volume. Hence, circumference measurements of the patient before and immediately after treatment will typically demonstrate a reduction.

This reduction can then be maintained if an appropriate energy demand is placed on the body, such as exercise, that will burn off these freed metabolites and remove them from the body permanently. If these metabolites are not burned off during exercise they are likely to be restored into adipose tissue by the body's natural mechanisms and thus it would be expected for the patient to regain the loss in measurements seen after treatment.

This section presents the data from 20 separate patients who underwent a single I-lipo laser procedure on the middle abdominal region. Prior to undergoing treatment all patients completed a full medical history and gave written consent to treatment.

• Treatment Method

The dimensions of the I-lipo treatment pads are 130mm by 84mm giving a working surface coverage area of 109.2cm². Each pad contains 9 40mW 650nm laser diodes which are distributed to cover an area of 72cm² (assuming that the laser light retains suitable strength for molecular activity with a spread of 10mm into tissue as previous studies have demonstrated⁽⁸⁾⁽¹⁶⁾⁽¹⁷⁾).

Circumference measurement points were determined within the patients chosen area of most concern. Three separate measurements were made each 4cm apart to cover the span of the I-lipo treatment pads and the exact level of each of these three measurements was recorded as height from the floor at four separate guide points on the anterior and posterior of the abdomen. Marks at these four guide points would then provide a standard placement for the tape measure for pre and post treatment measurements.

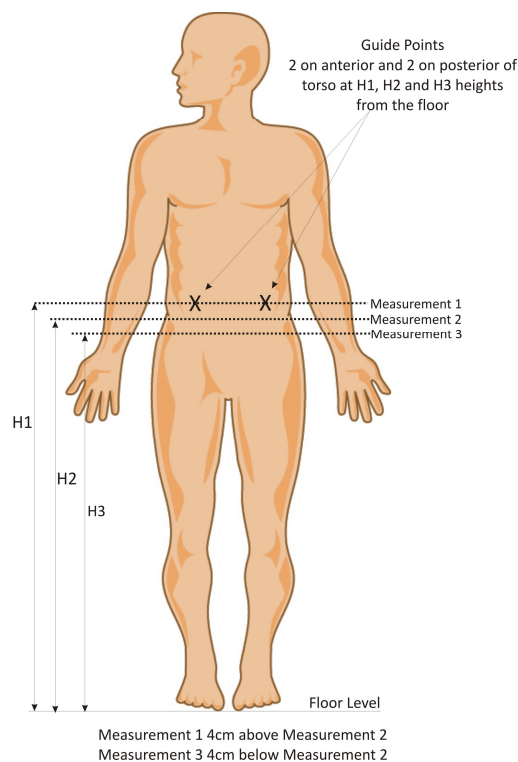


Fig. 1. Schematic of Measurements made pre and post treatment

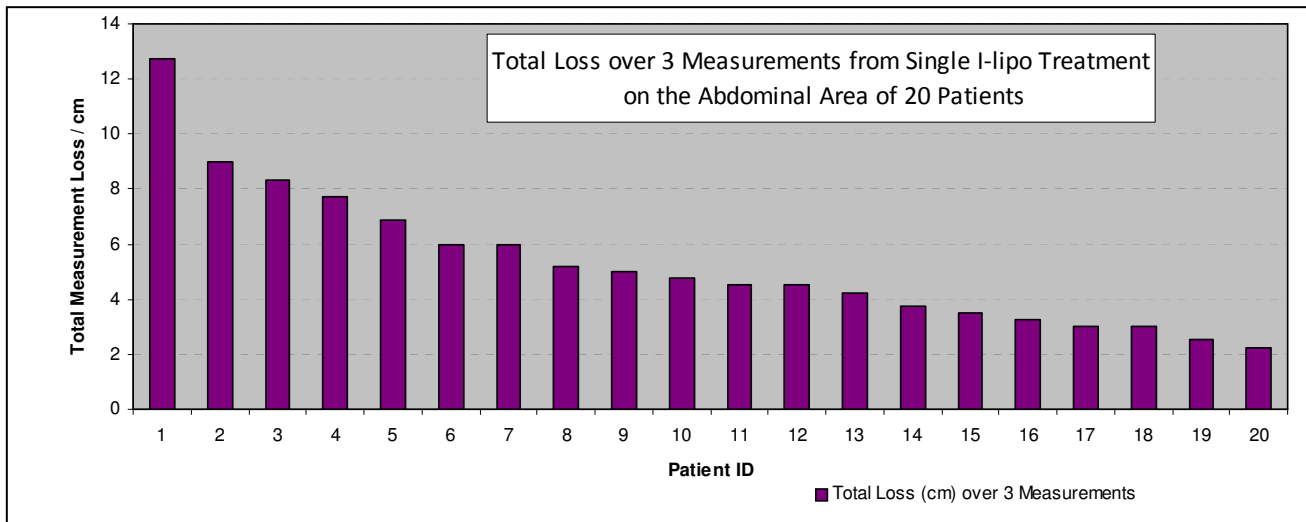
The circumference measurements were recorded using the same measuring tape, the MyoTape from Accufitness, which uses a torsion system to retract the tape around the area to be measured and minimises measurement error from the operator.

After measurement data had been collected the patient 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 lengthways adjacent to the umbilicus and subsequent pads adjacent to one another along the mediolateral axis of the abdomen within the horizontal guide points. The pads are secured in contact with the abdomen surface with an elasticated strap. Additional single diode probes are then secured to the superficial inguinal lymphatic nodes with micropore tape. Treatment commenced with laser irradiation of this left side of the body for 10minutes. After the 10 minutes the I-lipo automatically returns to standby and the pads were repositioned to the other side of the abdomen beginning again adjacent from the umbilicus and extending around the right side of the abdomen within the guide points. The lymphatic probes were also shifted by approximately 2-3cm inwards along the groin crease to maximise irradiation of the inguinal node clusters. This side of the body was then also given a 10-minute dose of laser irradiation. After treatment the pads and lymphatic probes are removed and the 3 individual circumference measurement points are reassessed.

No sensation or ill effects were reported by any of the participants.

- **Results**

Full measurement data for each of the 3 individual measurements before and immediately after treatment are given in Appendix 1. Total measurement loss over the 3 measurements for each patient is shown below in Graph 1 highlighting a minimum loss of at least 2.25cm up to the greatest loss seen in one patient of 12.75cm.



50% of the patients achieved a total measurement loss of between 3-5cm while 9 out of the 20 patients had a loss of more 5cm or more from this single treatment.

Similar data is reported from over 200 I-lipo clinical centres world-wide confirming the I-lipo lasers effectiveness for immediate 'inch loss' with no reported adverse effects during of post treatment.

2. Single patient case study undergoing a full treatment course with I-lipo

The following section describes the case study of a 46 year-old female patient through a full treatment course on the middle abdominal region. Eight separate treatments were performed over a four-week period, with typically two treatment sessions scheduled per week.

Prior to treatment the patient completed a 5-day diet and exercise diary to provide understanding of their dietary and eating habits. Whilst the patient was not required to actively reduce calorie intake from their norm during the study, certain tips for change were suggested to maximise metabolic and lymphatic health such as increasing water intake, reducing caffeine and replacing some unhealthy snacks with healthier options. Advice was also given regarding the daily time schedule of eating such as not missing meals or eating late in the evening. Other than this advice, the effects of adjusting diet on patient response during this study were not investigated and the

patient confirmed that during the period of study their diet had varied little from their normal behaviour in the four weeks prior to the study commencing.

Prior to treatment commencing the patient completed a full medical history and gave written consent to treatment.

Patient height and weight were measured before treatment using the SECA S225 Freestanding Height Meter and the SECA S797 Electronic Pillar Scales. Body fat index was calculated using Fat rack II Digital Skinfold Callipers and following manufacturer guidelines for accurate determination.

The measurements for the patient are given in Table 1 below:

Height/cm	Weight/Kg	Dress Size	BFI/%
172	89	16	39.0

Table 1. Patient Statistics Prior to Treatment

- **Treatment Method**

The treatment method used was as described during Section 1.

Photographs pre and post treatment were also taken from anterior, left, right and posterior aspects. Patient positioning was replicated as fully as possible with the patient standing with feet within floor markers, with their hands placed on head and relaxing fully the abdominal region. This positioning was also used when making circumference measurements.

After treatment the pads and lymphatic probes were removed and measurement and photographic data collection was repeated. Any sensations/observations made by the patient whilst undergoing the treatment were also recorded.

The patient was then directed to undertake 30-45 minutes of exercise before the end of the day. Ideally the exercise should be cardio-vascular in nature although must be within the capabilities of the patient.

- **Results**

Full pre and post treatment measurement data for the patient for all treatment sessions are given in Appendices 2.

Table 2 below details the total treatment loss and reduction in Body Fat Index after eight treatments for the patient.

	Measurements Before / cm			Measurements After / cm			Body Fat Index / %	
	Measurement 1	Measurement 2	Measurement 3	Measurement 1	Measurement 2	Measurement 3	Before	After
Patient A	111.5	115.0	114.5	102.5	106.0	108.5	39.0	35.3

Table 2. Total Treatment Measurement and BFI Loss

- **Before and After Photographs**

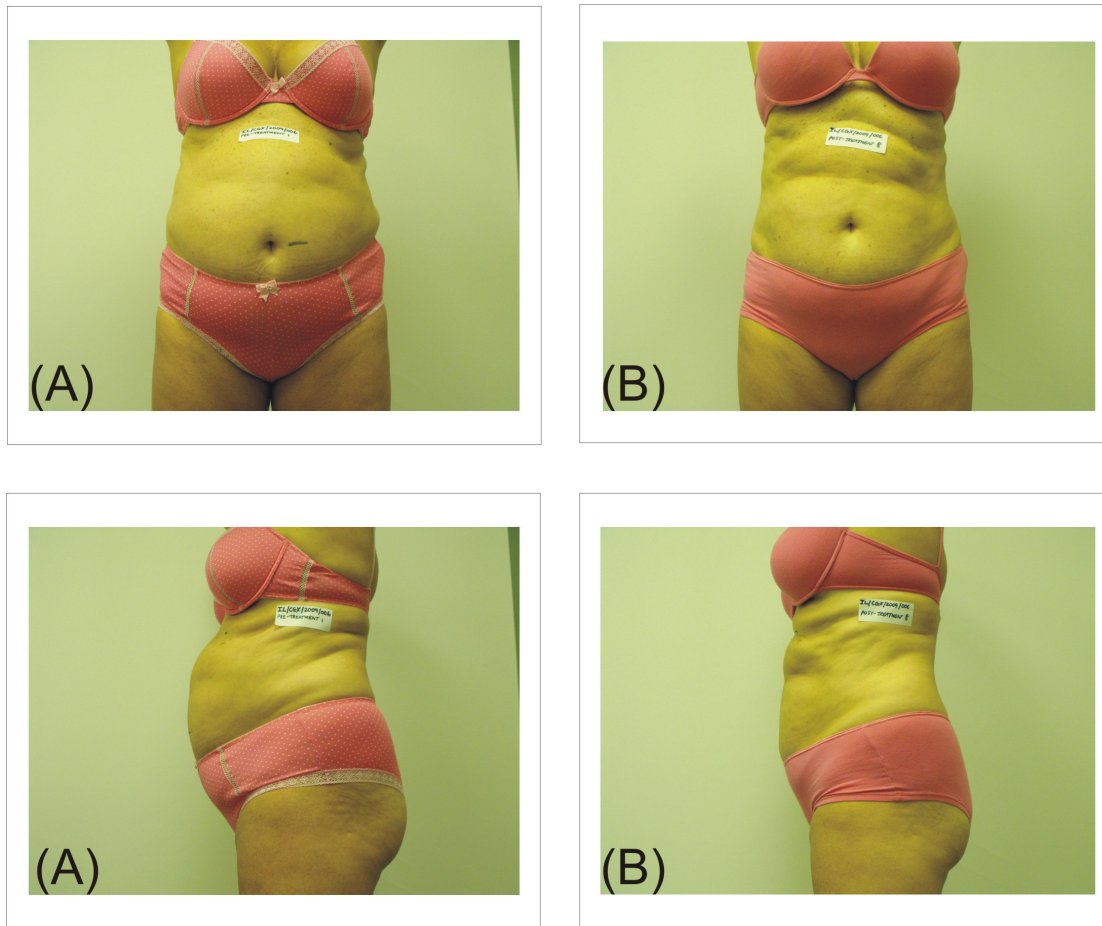


Fig. 3. Anterior and Left Side View
(A) Before treatment, (B) After 8 treatments

- **Discussion**

During the course of four weeks, the patient has experienced a 24cm reduction over three measurements within the abdominal area. Along with this reduction they have reduced their body fat index from 39% to 35.3% and their weight by 5.3Kg. These changes have been produced without dramatic change to daily calorie intake and while exercise has been undertaken, it has been restricted to 30-45 minutes, twice per week, after each treatment session to ensure that fat mobilised during the I-lipo treatment is used to produce the ATP required for the exercise.

By using the I-lipo, the patient has been able to specifically target an unwanted adipose deposit and ensure that this area provides the metabolites subsequently burned off with post treatment exercise. This is different to situations such as a patient under very strict dietary restrictions and with vastly increased exercise regimes who might expect to reduce their weight and body Fat Index during a four week period, but that this loss would come from unspecific areas of the bodies subcutaneous fat accumulation depending on which cells are more sensitive receptors to the circulating endocrine hormones that target the adipose cells during periods of energy demand.

To further support the observations and evidence of the ability of I-lipo to reduce adipose volume in specific treatment areas a pilot study using Ultrasound scanning to measure adipose layer thickness is being undertaken at the at the Midlands Ultrasound and Medical Services in the UK. This study is using real-time ultrasound techniques to visualise and measure the reduction in subcutaneous adipose deposits in the lateral and mid-lower abdominal regions before and after I-lipo treatment.

Interim conclusions are to be fully presented at the ESCAD conference in NICE in September 2009 but to date 20 patients have been assessed with reductions in fat layer thickness immediately post-treatment of 30-50% and no reports of side effects from treatment and an example of the results are shown below.

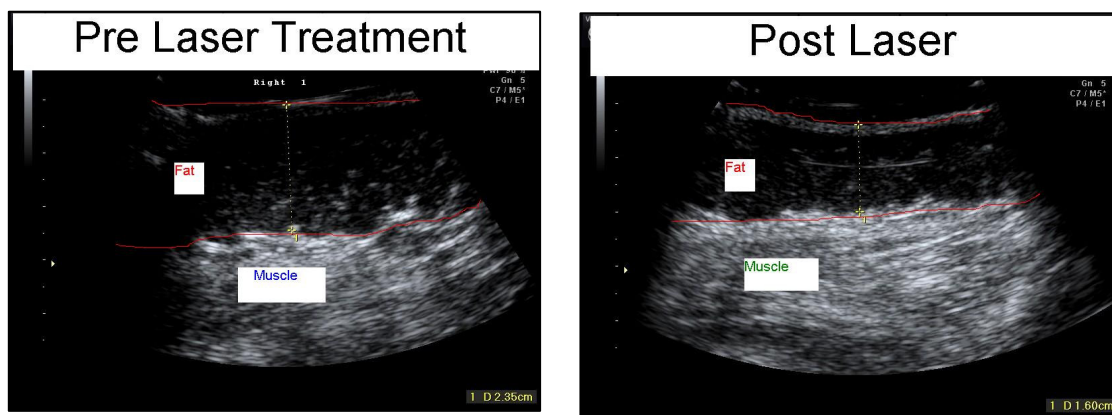


Fig 3. Ultrasound analysis before and after i-lipo treatment

Before the I-lipo treatment the thickness of the adipose layer can be measured at 2.35cm which is reduced to 1.60cm immediately after a single I-lipo treatment.

This study is to provide reference data and techniques for a full ethics committee approved randomised double-blinded study to be undertaken later in 2009.

Conclusion

The I-lipo low level laser device offers a patient a fast, non-invasive and pain-free treatment option for immediate and long-term sub-cutaneous fat reduction of problem fatty areas on the body.

Observations made of circumference measurements during the single one off treatments confirm the ability of I-lipo to provide an instant inch loss effect on a treatment zone.

The sceptical mind might consider that this inch loss is purely temporary or perhaps attributed to water loss providing short-term compaction of the adipose cells and as with most aesthetic inch loss techniques, it would be expected that effects would be lost after 2-3 days. Observations made over a four-week period during the study in section 2 demonstrate continued inch loss with additional laser treatments. The targeting of the subcutaneous adipose layer by the I-lipo is also confirmed from the real-time ultrasound observations. Thus a course of i-lipo treatments in conjunction with an appropriate diet and exercise regime offers the ability for significant long-term reshaping of chosen anatomical areas.

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Appendix 1

Measurement data for Single Treatment Effects on the Abdominal Region of 20 individual Patients.

Age	Male/Female	Treatment area	Measurements Before /cm	Measurements After /cm	Total cm loss/ 3 measurements
34	F	Abdo	110	109	6
			112	108	
			111.5	110.5	
60	F	Abdo	102	99	5
			104	103	
			107	106	
46	F	Abdo	101.5	99	12.75
			108.25	104	
			113	107	
28	F	Abdo	90	89.25	4.25
			93.5	93	
			96.75	93.75	
34	F	Abdo	94.2	93.5	5.2
			99	96.5	
			97.75	95.25	
40	F	Abdo	117.5	116	4.75
			123	120	
			121.25	121	
32	F	Abdo	78.5	77	3
			78	75.75	
			92	90.75	
38	F	Abdo	122	121	3.5
			123.5	122.25	
			121.5	120.25	
58	F	Abdo	91	91	2.25
			97.5	97	
			97.25	95.5	
28	F	Abdo	99	98.75	4.5
			107.25	104	
			109.5	108.5	
44	M	Abdo	90.5	89.25	7.75
			91.5	89	
			91.75	87.75	
47	M	Abdo	92.25	91	3.75
			92	91	
			93	91.5	
37	F	Abdo	99	99	3.25
			104	102.5	
			110.5	108.75	
24	F	Abdo	100.3	99.5	2.55
			104.5	103	
			100	99.75	
32	F	Abdo	103.5	102.25	3
			108	106.75	

			105.5	105.5	
25	F	Abdo	111	107	9
			107	104	
			116.25	114.25	
39	F	Abdo	82.6	80	6
			80.1	77.5	
			84.4	83.2	
19	F	Abdo	88.9	86.5	6.9
			91	89	
			91.5	89	
44	F	Abdo	112.8	110.2	8.3
			114.5	111.5	
			115.5	112.8	
37	F	Abdo	89	89	4.5
			93.5	91.2	
			95	92.8	

Appendix 2

Measurement data for Patient before and after multiple treatments.

Session	Measurement 1 Before	Measurement 1 After	Measurement 2 Before	Measurement 2 After	Measurement 3 Before	Measurement 3 After
1	111.5	109.0	115.0	114.0	114.5	114.5
2	110.5	109.5	113.0	112.0	113.5	112.0
3	108.0	108.0	113.0	112.0	113.5	112.5
4	108.5	106.5	111.5	110.0	112.5	111.0
5	107.5	106.0	110.0	110.0	112.5	110.5
6	107.0	106.0	111.0	108.5	111.5	110.5
7	107.0	105.0	111.0	108.5	110.5	109.0
8	103.5	102.5	108.5	106.0	110.0	108.5
9	101.0	98.0	106.0	103.0	109.5	107.0