

A Case Study of Red Light Therapy and its Effect on Reducing Circumference

Jamie Fettig, DC

Abstract

Red light laser therapy using 635nm red light laser technology has previously been shown to cause lipolysis in subcutaneous fat as a non-surgical method to promote weight loss and body contouring. This study hypothesizes that red LED light therapy using 635nm red light LED (light emitting diode) technology produces similar results to the laser device (red LASER 635nm) when performed using a specified treatment protocol.

The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the USA to determine the combined circumferential reduction of the waist, hips, and thighs with a single 28 minute treatment session using the subject Vevazz LED product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this procedure and to compare the procedure's effectiveness with non-invasive fat reduction.

Jamie Fettig, DC is the founder and president of Vevazz and Slim Line System, Inc. in Dallas, Texas.

The process of understanding fat and how to reduce it began in the 1920's with Charles Daujarrier of France. Since his initial research, many new methods and treatments have evolved into current day non-invasive weight loss. In 1974 Lipoplasty was brought front and center by Dr. Giorgio Fischer who with blades and a cannula cut away subcutaneous tissue. (1) Since these early procedures many things have changed and as time goes on more non-invasive techniques are being introduced.

In 2000 a procedure was added to Liposuction. This procedure was Red Light Therapy, also known as Low-Level Light Therapy. The red light therapy machine this study will use is the Vevazz. (2) Red light affects the human body in a positive and unique way, it has been shown to have positive effects on the reduction of the body's fat cells by reducing the size without damaging or destroying the cells. (3) The process of using Low-Light with a wavelength of 650nm passing through the skin red light therapy begins activating the Lymphatic system. This allows the fat cells, or adipocytes, to open and spill the contents out and to be flushed out the body. This causes the circumference of the area to decrease, with treatment alone.

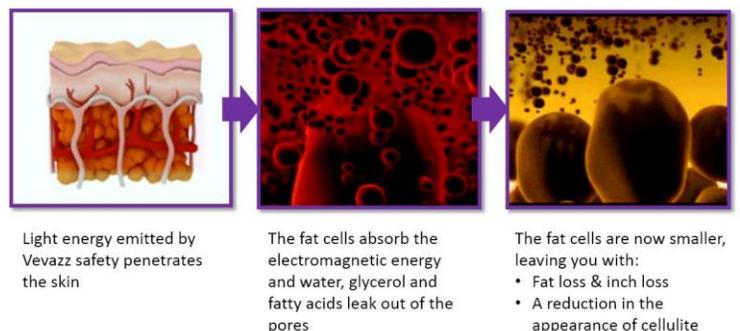
(4) This process shrinks the fat cells without damaging the cells, thus preventing the cells from coming back in unwanted places, and if the fat is re-accumulated it will only refill the cell rather than creating a new cell. Many studies have shown that Red Light Therapy is effective in fat and cellulite reduction and has improved the blood lipid profile without any significant side effects. (5) The obesity rate among adult Americans was estimated at 32.2% for men and 35.5% for women, and these rates were roughly confirmed by the CDC again for 2009-2010. (6) Obesity has many contributing factors other than just laziness. People struggle to lose, is diet and exercise are not the only things that cause weight gain or weight loss. The body is inherently lazy/efficient. It only does one thing of opposites. Muscle contraction opposites are shut down with reciprocal inhibition. Insulin and glucagon lower and raising of blood sugar, not done at the same time. Fat burning hormones and fat storage hormones, not done at the same time. (7) Chronic low-grade inflammation and cellular stress are linked to obesity, insulin resistance, and metabolic dysfunction.

Often people have areas of fat that will not reduce with conventional diet and exercise, therefore will require some type of alternative intervention. While treatment with Red Light Therapy immediately reduces the size of subcutaneous fat accumulations exposed to the lights, treatments do not prevent the patients from subsequently gaining weight or increasing the size of the fat accumulations.

The study published in the Journal of Obesity Surgery researched LED-Light Therapy and body contouring and discovered after 4 weeks the patients had a significant reduction in the circumference of the waistline. (8) Red Light non-invasive body contouring now represents the fastest growing areas of aesthetic medicine. Alternatives to Red Light Therapy can be very expensive and require invasive surgery such as Liposuction, or Abdominoplasty. (9) The laser-based devices are "... segment by product type category is estimated to reach a value of more than US\$ 100 million by 2022 end, reflecting a 1.3x increase in its valuation in 2017. The technique is highly adopted in dermatology clinics and beauty clinics owing to easy and convenience of use and quicker results. This segment is also expected to grow at a higher rate throughout the period of forecast and poised to show the highest value share thus leading the global market." (10)

A multi-site retrospective analysis has been performed on the records of 77 patients, which demonstrates the efficacy of the device using the Vevazz LED protocol with a 7-minute exposure to the front of the body, 7 minutes to the left side, 7 minutes to the back, and 7 minutes to the right side, with a total of 28 minutes exposure time for each treatment session.

Figure 1. The process of fat cells shrinking



Objective

The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the USA to determine the combined circumferential reduction of the waist, hips and thighs with a single 28 minute treatment session using the subject Vevazz LED product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this procedure and to compare the procedure's effectiveness with non-invasive fat reduction.

Further, 100% of patients had clinically significant results at one visit with Vevazz LED, considering that all patients lost at least 1.0" with one treatment. By comparison, traditional Liposuction is limited to removal of no more than 500 ml of fat at one surgery, due to the attendant trauma and potential side effects. For the study, 64 of the patients are female (83%) and 13 are male (17%). Females ranged in age from 18 to 77, with an average age of 41.7 years. Males ranged in age from 35 to 68, with an average age of 43.3 years. Overall, patients ranged in age from 18 to 77, with an average age of 42 years. Vevazz LED paddles were positioned directly over the skin with four 7-minute exposures. Measurements were taken immediately before and after treatment.

For males, the paddles were positioned: Front: Over the chest and abdomen, extending 23" toward the suprapubic area. Back: Starting at the top of buttocks, extending 23 inches toward the upper back. Left: From the left hip area, extending 23 inches toward the left underarm area. Right: From the right hip area, extending 23 inches toward the right underarm area. For females, the paddles were positioned: Front: From below the bra and extending 23 inches to include the top of the thighs. Back: Covering the "back" measurement area and extending 23 inches to include the top of the thighs. Left: The paddles are placed to cover the left "love handle", the outside of the left thigh, and the inside of the right thigh along with the lower abdomen. Right: The paddles are placed to cover the right "love handles", the outside of the right thigh, and the inside of the left thigh, along with the lower abdomen.

Table 1: Device Specifications

Device	Vevazz LED
Trade Name	Vevazz LED
Regulation Description	Low Level Laser System for aesthetic use
Regulation Number	21 CFR 878.5400
Device Class	II
Review Panel	General and Plastic Surgery
Product Code	OLI

Figure 2. Device Used



Results

Patients lost a minimum of 1". The maximum loss is 7 1/2". For males, inch loss is computed by adding the inch loss measurements for back, upper-abdomen, mid-abdomen, flanks and lower abdomen. For females, inch loss is computed by adding the inch loss measurements for back, waist, mid-abdomen, hips, and thighs.

No adverse or side effects were reported. Vevazz LED achieved an average combined circumferential reduction of the waist, hips, and thighs of 2.5" at one visit using the same measurements. Further, 100% of patients had clinically significant results at one visit with Vevazz LED, considering that all patients lost at least 1.0" with one treatment. By comparison, traditional liposuction is limited to removal of no more than 500 ml of fat at one surgery, due to the attendant trauma and potential side effects. The Vevazz LED delivers substantially equivalent Total Treatment Dose of 650 nm ±25 light to the subcutaneous fat cells in 28 minutes at one visit rather than in 32 minutes at one visit.

In all studies, Red Light has proven to be safe and effective, but not enough research has been done to include treatment for people with active cancer within the past year, liver or kidney disease, or if they use certain medications. They are not good candidates for the treatment due to the unknown risk associated with the conditions.

Table 2: Measurements acquired with a self-tensioning tape measures

Back	Circumference at level of nipples
Upper-Abdomen	Distance above umbilicus
Mid-Abdomen	2-3 inches above the umbilicus
Flanks	Circumference around the "love handles"
Lower-Abdomen	Distance from umbilicus

Table 3. The results of the retrospective analysis are summarized in the table below:

Number of Sites:	4
Enrollment Size:	77
Patient Population	For the study, 64 of the patients are female (83%) and 13 are male (17%). Females ranged in age from 18 to 77, with an average age of 41.7 years. Males ranged in age from 35 to 68, with an average age of 43.3 years. Overall, patients ranged in age from 18 to 77, with an average age of 42 years.
Study Design	<p>Vevazz LED paddles were positioned directly over the skin with four 7-minute exposures. For males, the paddles were positioned:</p> <ul style="list-style-type: none"> • Front: Over the chest and abdomen, extending 23" toward suprapubic area. • Back: Starting at the top of buttocks, extending 23 inches toward the upper back. • Left: From the left hip area, extending 23 inches toward the left underarm area. • Right: From the right hip area, extending 23 inches toward the right underarm area. <p>For females, the paddles were positioned:</p> <ul style="list-style-type: none"> • Front: From below the bra and extending 23 inches to include the top of the thighs. • Back: Covering the "back" measurement area and extending 23 inches to include the top of the thighs. • Left: The paddles are placed to cover the left "love handle", the outside of the left thigh, and the inside of the right thigh along with the lower abdomen.

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Measurements and Timing	<p>Measurements were taken immediately before and after the 28-minute treatment using a self-tensioning tape measure, measurement forms, and instructions (Measurement Guides) exactly as used in the clinical trials for the predicate Photonica Professional.</p> <p>Since measurements were taken immediately before and after the treatment, the observed results are therefore immediate.</p>																																																		
Treatment	<p>The treatments consist of four 7-minute exposures with the 650nm light positioned directly over the skin.</p> <p>Vevazz LED uses large paddles consisting of 28 LEDs in a series/parallel electrical connection. Each LED produces 50 mw/cm² of light energy with a wavelength of 650 nm; +/- 25 nm uniformly over the treatment area.</p>																																																		
Results	<p>Inch loss by gender is:</p> <table border="1"> <thead> <tr> <th>Gender</th> <th>Patients</th> <th>Age</th> <th>Inch Loss</th> <th>Std. Dev.</th> </tr> </thead> <tbody> <tr> <td>Males</td> <td>13</td> <td>43.3</td> <td>1 5/8</td> <td>1 2/8</td> </tr> <tr> <td>Females</td> <td>64</td> <td>41.7</td> <td>2 2/5</td> <td>1 6/8</td> </tr> <tr> <td>Total</td> <td>77</td> <td>42.0</td> <td>2 1/80</td> <td>1 1/2</td> </tr> </tbody> </table> <p>Inch loss by treatment site is:</p> <table border="1"> <thead> <tr> <th>Site</th> <th>Patients</th> <th>Age</th> <th>Inch Loss</th> <th>Std. Dev.</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>8</td> <td>49.1</td> <td>3 4/7</td> <td>1 2/8</td> </tr> <tr> <td>B</td> <td>16</td> <td>48.7</td> <td>1 2/3</td> <td>1 5/8</td> </tr> <tr> <td>C</td> <td>23</td> <td>40.7</td> <td>2 1/2</td> <td>2</td> </tr> <tr> <td>D</td> <td>30</td> <td>37.2</td> <td>2 1/6</td> <td>1 6/8</td> </tr> <tr> <td>Total</td> <td>77</td> <td>43.9</td> <td>2 1/2</td> <td>1 5/8</td> </tr> </tbody> </table> <p>Patients lost a minimum of 1". The maximum lost is 7 1/2".</p> <p>For males, inch loss is computed by adding the inch loss measurements for back, upper-abdomen, mid-abdomen, flanks and lower abdomen.</p> <p>For females, inch loss is computed by adding the inch loss measurements for back, waist, mid-abdomen, hips and thighs.</p>	Gender	Patients	Age	Inch Loss	Std. Dev.	Males	13	43.3	1 5/8	1 2/8	Females	64	41.7	2 2/5	1 6/8	Total	77	42.0	2 1/80	1 1/2	Site	Patients	Age	Inch Loss	Std. Dev.	A	8	49.1	3 4/7	1 2/8	B	16	48.7	1 2/3	1 5/8	C	23	40.7	2 1/2	2	D	30	37.2	2 1/6	1 6/8	Total	77	43.9	2 1/2	1 5/8
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Adverse Events	There were no device-related adverse events																																																		
Substantially Equivalent to Predicate	Vevazz LED achieved an average combined circumferential reduction of the waists, hips, and thighs of 2.5" at one visit using the same measurements schema as in the Photonica Professional study which found an average loss of 3.5" with one 32-minute treatment.																																																		

References

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