Comparison of 635nm Red Light Transmission Through Skin and Subcutaneous Fat

Abstract: *This bench testing finds that Photonica Professional™ delivers 7.8 times more photonic energy to subcutaneous fat cells than does Zerona®, while also treating a larger area and with more uniform dosing.*

Terry J. Ward, M.H.A.
1980 N. Atlantic Avenue, Suite 1030
Cocoa Beach, Florida 32931

Ward Photonics LLC
1980 N. Atlantic Avenue, Suite 1030
Cocoa Beach, Florida 32931

Photonica Professional™

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1. BACKGROUND

There is a great demand to be slimmer and many people resort to cosmetic surgical procedures to become thinner, with more aesthetically appealing body contours. Others turn to non-invasive slimming technologies that destroy the fat cells with ultrasound, microwaves, heat, cold, or radio frequency radiation.

According to figures released at the annual International Master Course on Ageing Science (IMCAS) conference held on 28-31 January in Paris:

> Cosmetic surgery is on the rise globally, with the industry growing by 8.2% in 2015.
>
> Body-contouring procedures saw the biggest increase in popularity in 2015, increasing by 13.5% globally.
>
> Use of energy devices increased 9.3%, including lasers, ultrasound, radio frequency, etc.

Whether the fat cells are surgically removed with liposuction or destroyed with a non-invasive technology, there are substantial risks to the patient, including damage to the surrounding tissue, nerves, blood vessels, lymphatics, and collagen fibers. These procedures may be accompanied by blood loss, loss of nerve sensitivity, and extended post-procedure recovery time, often accompanied by a great deal of inflammation, bruising and pain. Once fat cells are removed or destroyed, subsequent weight gain cannot be normally distributed throughout the body's fat cells, inevitably resulting in dysmorphic fat accumulations in the subcutaneous and/or visceral fat.

Body contouring with red light therapy is safer than other procedures, offering non-invasive permanent fat removal by temporarily opening the fat cells and draining the contents using the body's natural process of lipolysis. There is no damage to tissue, no pain, no downtime, and no other negative outcomes. Since no cells are removed or destroyed, subsequent weight gain can be normally distributed throughout the body's fat cells.

Zerona® and Photonica Professional™ use 635nm red light technology to cause lipolysis in subcutaneous fat. Zerona® uses low-power lasers (US Patent 8932338) and Photonica Professional™ uses high-power, ultra-narrow bandwidth LEDs (US Patent 9044595). The primary difference between laser and non-laser light is that all of a laser's power is focused on a single point as a beam of "coherent" light. Lasers must therefore operate at extremely low power to avoid tissue damage. While low-level lasers like Zerona® are safe on the skin and present a risk of tissue damage only to the eyes, higher power lasers can burn through steel. Photonica Professional™ does not present a risk to the eyes or any body tissue, and is therefore safer than lasers.

Zerona® uses 5 lasers with 17.5mW each (87.5mW total power), all focused on five scanning pinpoints. Photonica Professional™ uses 150 custom LEDs with 1,600mW each (240,000mW total power) uniformly disbursed over an area approximately 23" by 17".

The design for Zerona® is based on Dr. Rodrigo Neira's groundbreaking research and Erchonia's clinical trials[1] from May 2007 to June 2008 with 67 patients aged 18–65 in which they found that 3.6" circumferential reduction could be achieved with 17.5mW lasers, but incorrectly concluded that the non-coherent *"LED did not generate a statistically significant reduction in the circumference measurement in inches."* It appeared to be settled science in many publications 2009-2011 that lipolysis would not occur with LEDs, but occurred only with the coherent light of a certain type of laser.

The design for Photonica Professional™ is based on the subsequent research of Terry J. Ward, M.H.A., who in 2011 discovered that the published research and clinical trials were fundamentally flawed and that he could achieve greater results with his non-laser lights than had been published by Jackson, et al. Ward concluded that "light is light" and was awarded a patent for his non-invasive fat removal method and machine, which uses LEDs with 2,742 times more total power than Zerona® and 19,200 times more power than the LED system studied in the Zerona® clinical trials.

The Zerona® treatment consists of a 20-minute exposure with five scanning lasers on the front of the patient and then 20 minutes on the back of the patient, with a total of 40 minutes exposure time for each treatment session. Sessions were scheduled three times a week for two weeks and "after" measurements were taken a week after the last treatment session, at the seventh office visit. The treatment protocol also includes three weeks of dieting, exercise, and the use of pills.

The treatment protocol considered here with Photonica Professional™ is referred to as "UltraSlim Cold Light®" and consists of an 8-minute exposure to the front, 8 minutes to the left side, 8 minutes to the back, and 8 minutes to the right side, with a total of 32 minutes exposure time for each treatment session. Since inch-loss results are immediate at each treatment session, the inch-loss benefits are solely due to the red light therapy and are not due to dieting, exercise, or use of pills.

2. OBJECTIVE

The objective of this study is to measure and compare the red light transmission of light from the Zerona® laser-emitting diodes and Photonica Professional™ light-emitting diodes through the skin and subcutaneous fat using a porcine cadaver as an analog.

3. STUDY DESIGN AND METHODS

Methods: A Zerona® laser was placed at its 8" therapeutic distance from the cadaver skin and a Photonica Professional™ array was likewise positioned 8" from the cadaver skin. Light measurements and photographs were taken facing the interior of the porcine cadaver and using a tripod for consistent measurements and photographs.

The red light that reached the tripod-mounted camera and light meter from the laser or LEDs had first penetrated the cadaver skin and penetrated one to two inches of subcutaneous fat. A FUJIFILM digital camera and Apple Light Meter Pro were used for recording still photographs, video recordings, and light measurements.

[1] *Jackson, Robert F.; Dedo, Doug D.; Roche, Greg C.; Turok, David I.; Maloney, Ryan J. (2009). "Low-Level Laser Therapy as a Non-Invasive Approach for Body Contouring: A Randomized, Controlled Study". Lasers in Surgery and Medicine 41 (10): 799–809. doi:10.1002/lsm.20855. PMID 20014253.*

Results: Based on the standard dose emitted to the skin (as measured in Joules), the coherent light of the lasers is 107.5 times more efficient at penetrating the skin and delivering photonic energy to the fat cells. However, Photonica Professional™ more than compensates for the transdermal inefficiency of its non-coherent light by emitting 840.0 times more power and delivering 7.8 times more photonic energy (Luminous Flux as measured in Lux) to the subcutaneous fat cells to biomodulate the lipolysis process:

	Zerona®	Photonica Professional™
Standard Dose Emitted To The Skin	0.06 J/cm^2	50.4 J/cm^2
Luminous Flux To The Subcutaneous Fat Cells	40.0 lx	313.6 lx

4. PRODUCT

Model: **Photonica Professional™**

Description: The **Photonica Professional™** is an FDA-cleared non-invasive light therapy system that is based on emitting a specific type of red light using high-frequency constant current switching to modulate power to an array of high-power, ultra-narrow bandwidth Light Emitting Diodes ("LEDs").

The red light implements biochemical reactions in the skin which increase the skin's collagen and elastin, thereby reducing the appearance of lines, wrinkles, and fine lines while also treating benign vascular and pigmented lesions, such as but not limited to solar lentigines, sun spots, liver spots and age spots. For the FDA-cleared indications for use (K150336), the treatment time is 20 minutes per exposure. The special red light is also known to reduce the lipid content of adipocytes ("fat cells") from targeted regions of a patient's body. This side-effect is used by some physicians for off-label fat removal.

Terry J. Ward, M.H.A., a Zerona® laser expert, and Heidi Araya, a NASA scientist, were awarded a patent by the United States Patent and Trademark Office (US 9,044,595) for their breakthrough method of permanent fat removal without dieting or exercise, using only the non-invasive red light therapy with Ward's invention. The special red light works by delivering sufficient energy to release intracellular fat into the interstitial space. The released intra-cellular fat is then removed through the body's natural functions.

In March 2016, Ward Photonics LLC released multi-site clinical trials for the Photonica Professional™ demonstrating that patients lost 1 5/8" to 10" combined from their waist, hips, and thighs, with an average loss of 3.5" and 98% of patients losing at least two inches of fat in only 32 minutes, without dieting or exercise.

Although the coherent light from lasers is more efficient at penetrating the skin due to its concentration on a single pinpoint, upon contact with the subcutaneous fat, the light scatters and becomes non-coherent in the adipose tissue. The Photonica Professional™ starts with non-coherent light, which requires more power because it is less efficient at penetrating the skin, but allows it to safely deliver 7.8 times more photonic energy (luminous flux) to the fat cells without tissue damage, as would occur with coherent laser light of that intensity.

Zerona® delivers all of its energy to a single point on the skin and uses scanning to distribute the power. At the point on the skin where the laser is focused, the laser is some 500,000 times more powerful than the light from Photonica Professional™, but because Zerona® moves the active pinpoint with a scanner, the total photonic energy (luminous flux) delivered to the fat cells is much lower than with Photonica Professional™.

Zerona® is 248.25 times more efficient at penetrating the skin, delivering 739.78 lx/mW/cm2 to the fat cells while the Photonica Professional™ delivers only 2.98 lx/mW/cm2. Photonica Professional™ compensates for lower efficiency by using a greater irradiance.

Photonica Professional™ consists of a main control unit, LED panel, and cable connections. The main control unit contains the main input, fuses, power supply, control circuits, Start button, and Minutes selector switch.

The power switch has a failsafe system that ensures the voltage from a wall socket can never come in contact with the user. A hospital-approved isolation transformer is mounted on the base of the medical pole cart and also supports the main control unit and the light fixture, with an articulated arm. System operation is preset. The unit operates at a wavelength of approximately 635nm, with a total power output of approximately 300 watts.

This technology is based on high-power, ultra-narrow bandwidth LEDs in the red spectrum. Due to a 60° lens on each LED, there is very little variation in light output across the treatment area.

The device is intended for prescription use by a physician or their staff in an office environment or health facility.

5. MEASUREMENTS

On 3 March 2012, Terry J. Ward, M.HA. and Heidi Araya filed a patent application (granted by USPTO in 2015 as US 9044595) for “System and method for reducing lipid content of adipocytes in a body” using 635nm non-laser incoherent light. A prior invention using lasers with coherent light was patented by Dr. Rodrigo Neira et al (granted by USPTO in 2015 as US 8932338) and brought to market as Zerona®.

Three weeks after filing for their first patent, on 22 March 2012, Ward and Araya conducted this bench testing using a porcine cadaver to compare red light transmission through skin and subcutaneous fat using 635nm light from a Zerona® laser and from an array of Ward’s custom LEDs as used in the Photonica Professional™.

Zerona® uses 5 laser-emitting diodes operating at 17.5mW each and a scanning method to time-multiplex the laser’s placement over an area of the skin with a distance of 8” between the laser and the skin. Only 5 pinpoints are illuminated at any point in time.

Photonica Professional™ uses 150 light-emitting diodes at 1,600mW each, uniformly covering an area 23” by 17” with placement of the LED emitter at a distance of 6.8” from the skin. The entire treatment area is illuminated at all times.

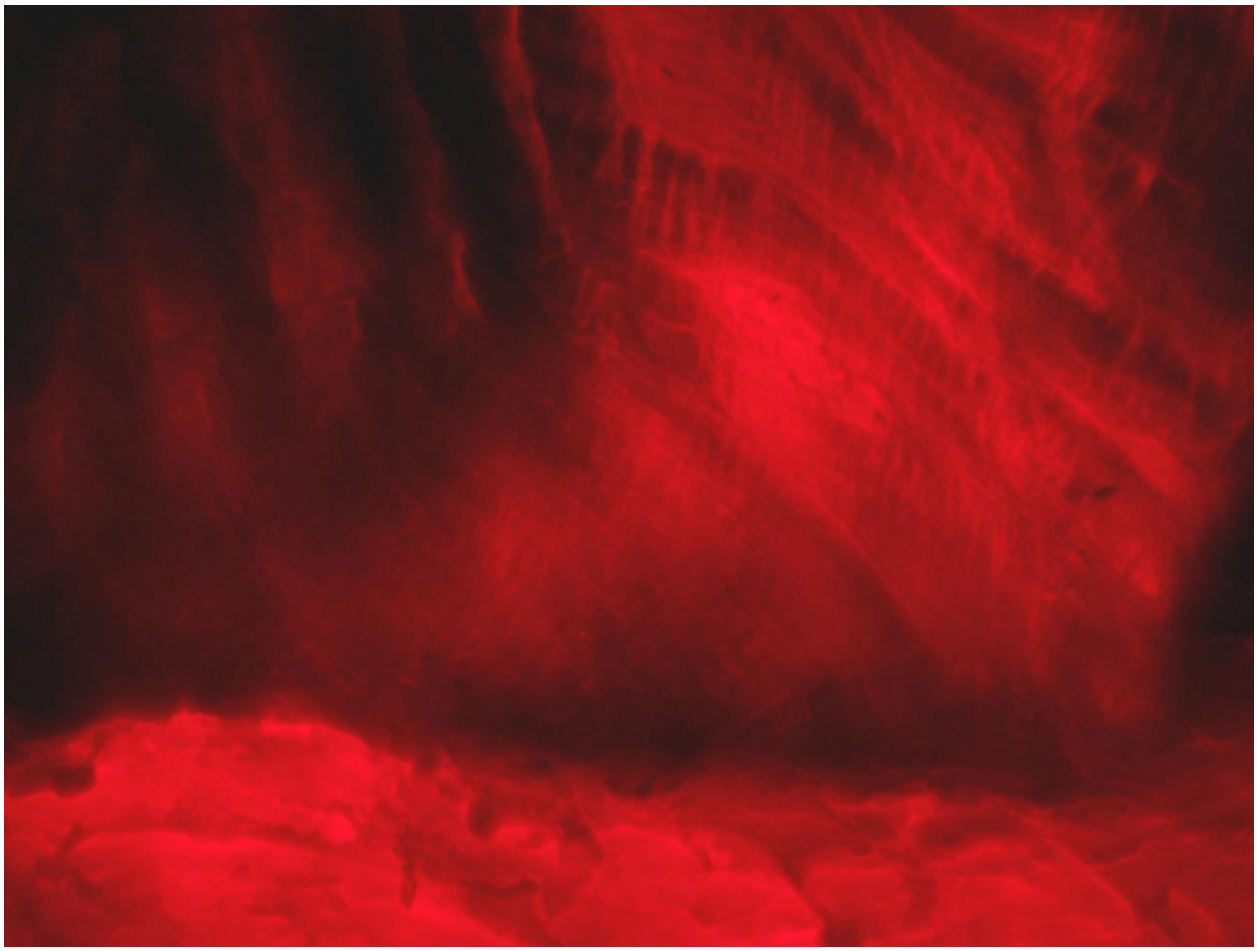
For comparison purposes, the Zerona® laser was placed at its 8” therapeutic distance from the cadaver skin and the Photonica Professional™ array was likewise positioned 8” from the cadaver skin. Light measurements and photographs were taken facing the interior of the porcine cadaver and using a tripod for consistent measurements and photographs.

Shown as Figure 1 are photographs of the exterior and interior of the porcine cadaver ("pork belly") used for these tests. The combined thickness of the skin and fat varied over a gradient of one to two inches.

FIGURE 1: Porcine Cadaver ("Pork Belly") Used For These Tests

Shown below in Figure 2 is a photograph of the interior or the cadaver while illuminated with an array of Photonica Professional™ LEDs driven at 1,600mW each. The tissue shown at right in Figure 1 is clearly identifiable in Figure 2 as the thicker and denser tissue allows less red light transmission to the camera.

FIGURE 2: Porcine Cadaver illuminated with 1,600mW LEDs as used in Photonica Professional™



The brighter areas in Figure 2 indicate that the cadaver presents less resistance to the light transmission, however, the red light clearly penetrates all of the tissue, even that which is 2" thick.

The light level received at the camera is 313.6 Lux.

Shown below as Figure 3 is the same cadaver, in the same position, with the camera in the same position and with the same exposure settings as used for Figure 2. Instead of the 1,600mW light-emitting diodes used for Figure 2, the photograph shown as Figure 3 was made using one 17.mW Zerona® laser.

The illuminated area is barely visible at right. The light level received at the camera is 40.0 Lux. The Photonica Professional™ delivered 7.8 times more photonics energy ("Luminous Flux") to the fat than did the Zerona® laser.

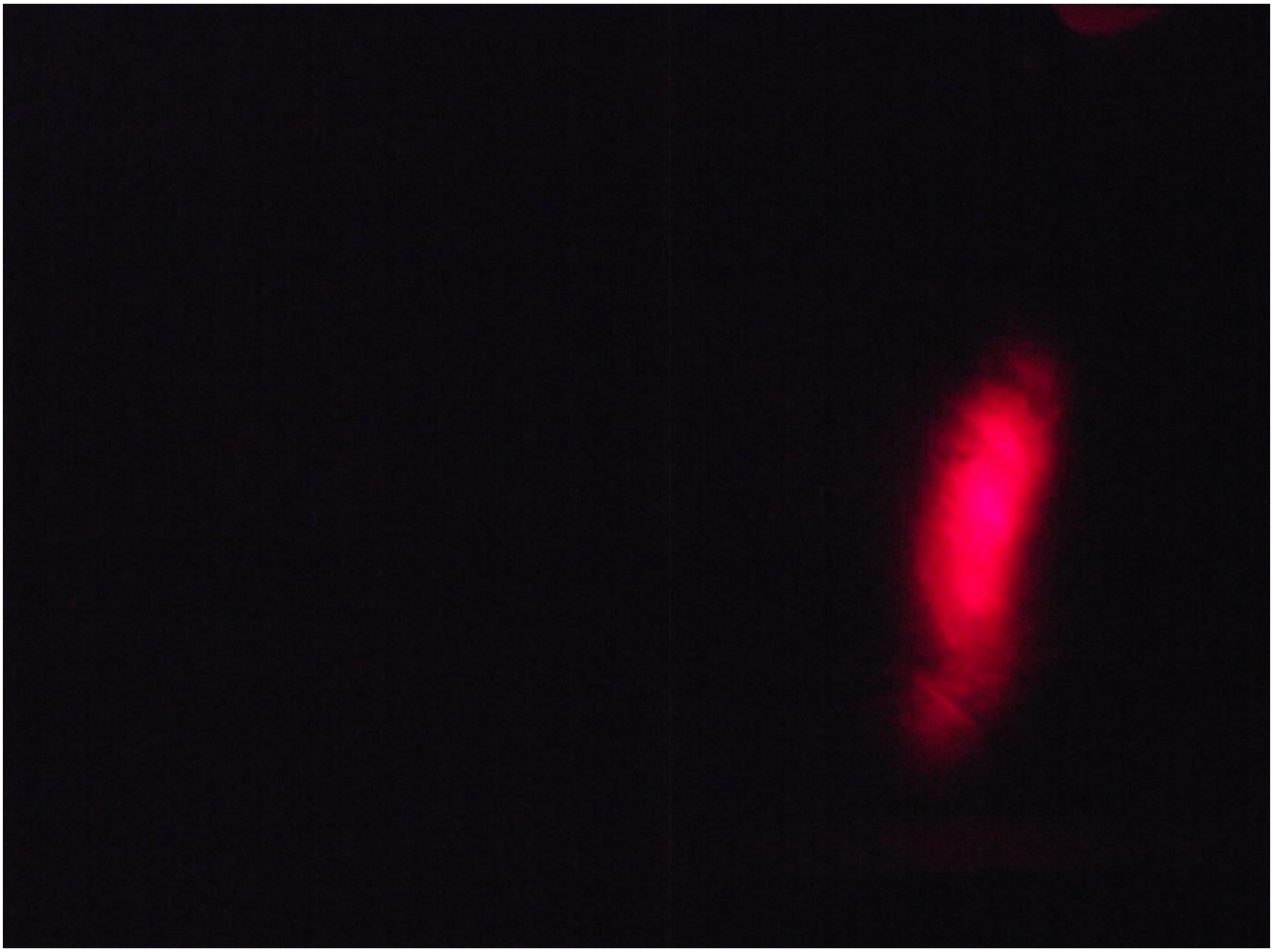
FIGURE 3: Porcine Cadaver Illuminated With One 17.mW Zerona® Laser

Figure 4 shows the same image as in Figure 3, but with the exposure adjusted to allow better visualization of the area covered by the laser.

As shown in Figure 4, the Zerona® treatment area is much smaller than with the Photonica Professional™ array.

Secondly, the area treated with the Zerona® is not uniformly exposed to the light. The center of the scanned area receives much more photonic energy than the perimeter. The Photonica Professional™ delivers more consistent dosing of photonic energy.

FIGURE 4: Porcine Cadaver Illuminated With One 17.mW Zerona® Laser (LIGHT ADJUSTED)



6. ANALYSIS

This comparison of 635nm red light transmission clearly demonstrates that LEDs are less efficient than lasers, however:

1. Photonica Professional™ treats a larger area than the Zerona® lasers.

2. Photonica Professional™ delivers 7.8 times more photonic energy to the subcutaneous fat than the Zerona® laser.

3. Photonica Professional™ provides uniform coverage and dosing of the treatment area.

4. The laser's coverage of the treatment area is not uniform, but is concentrated in the center of the smaller treatment area.

7. FINDINGS

Photonica Professional™ exceeds the performance of Zerona® for delivery of photonic energy, coverage area, and consistency of dosing over the treatment area.

These finding are consistent with clinical trials which find that 32 minutes of treatment with Photonica Professional™ alone achieves inch-loss results comparable to the results with 6 one-hour Zerona® treatment sessions and three weeks of dieting, exercise, pills, and 7 office visits.

8. CONCLUSION

Red light therapy is a safer alternative for body contouring than surgical procedures or noninvasive procedures which remove or destroy fat cells. Also, Photonica Professional™ is safer and more effective than laser-based red light therapy systems such as Zerona®.

Ward Photonics LLC should apply for FDA clearance for circumferential reduction of the waist, hips, and thighs as an additional Indication For Use, with treatment exposures of 8 minutes rather than the 20-minute exposures used for the indications for use cleared by FDA in 2015.

Signature

Terry J. Ward, M.H.A.

Released April 12, 2016