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The Impact of Violet Laser on Body Circumference: Exploring a New Therapeutic Avenue

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ABSTRACT

Background: *This brief report presents the clinical findings of recent advancements that led to the first FDA market clearance utilizing violet laser for the achievement of body circumference reduction (K231474).*

Objective: *The study was open-label singe arm design to evaluate the efficacy of the violet laser to that of application of the precursor red laser.*

Methods: *The study procedure was identical to that evaluated in the comparative red laser study, with the difference being the reduction in per-treatment time from 40 minutes (red laser) to 20 minutes (violet laser).*

Results: *The mean circumference reduction was 3.91 inches, which is greater than the mean change of 3.72 inches attained in the compartive red laser application.*

Conclusion: *The study establishes the efficacy of violet laser as a viable treatment option for non-invasive body circumference reduction. The violet laser's higher photonic energy translates to clinically meaningful outcomes achieved in half the treatment time compared to the precursor red laser (NCT05674292).*

Keywords

Laser therapy, LLLT, Violet laser, Circumference reduction, Body contouring,

Introduction

Data from the Centers for Disease Control and Prevention (CDC) reveals a concerning trend of increasing waist circumference within the United States population over the past fifteen years; the average waist circumference (inches) for men has increased from 39.0” to 40.2” and for women, the increase is even more substantial rising from 36.3” to 38.6”, reflecting a growth of over two inches [1]. In addition to the physical limitations, reduced mobility and psychological impact of growing waist circumference, this rise coincides with mounting research highlighting waist circumference as a potentially stronger health risk indicator than body weight alone. Studies spanning over 60 years have demonstrated a clear association between larger waist size and a significantly higher risk of premature cardiovascular disease (CVD) and mortality, compared to individuals with smaller waists or weight distributed towards the lower body [2,3]. Recent research further emphasizes the risk of central adiposity (fat accumulation around the midsection) which is associated with a greater risk of developing heart disease, diabetes, and other chronic conditions compared to those who carry extra weight in their legs or buttocks [4]. The International Atherosclerosis Society (IAS) and International Chair on Cardiometabolic Risk (ICCR) recommend incorporating waist circumference measurement routinely into clinical assessments due to its crucial role in cardiometabolic risk stratification and development of downstream cardiometabolic complications. Notably, the IAS and ICCR suggests that reducing waist circumference should be a primary treatment target to mitigate adverse health risks for both men and women. A pooled

analysis of data from over 600,000 participants linked waist size to mortality risk with men over 40 with waist circumferences exceeding 43" having an estimated three-year shorter lifespan compared to those under 35" [5]. Similarly, women over 40 with waist circumferences exceeding 37" faced a potential five-year reduction in life expectancy. The study further revealed a linear association between waist circumference and mortality risk, with every additional 2 inches translating to a 7% and 9% increase in mortality risk for men and women. This association is particularly concerning in light of the fifteen-year data from the CDC showing an average increase of 1.75" between men and women in waist circumference.

Low-level laser therapy (LLLT) is a procedure cleared by the United States Food and Drug Administration (FDA) for achieving circumference reduction. It employs low-power lasers to create transient pores in adipocytes, facilitating the release of intracellular content and ultimately leading to a decrease in adipocyte volume (cellular deflation) without inducing cellular destruction [6,7]. The Erchonia 635nm red laser was the first laser technology developed for non-invasive circumference reduction. Early proof-of-concept studies conducted by Dr. Arturo Ramirez, MD, investigated the effects of the red laser irradiation on adipose tissue over time using a human tissue model and electron microscopy. Findings presented at the 34th National Congress of the Mexican Association of Plastic, Aesthetic, and Reconstructive Surgery (2003) showed that significant, transient pore formation in adipocytes was observed after eighteen minutes of red laser exposure, with no additional benefit on the pore formation following twenty-one minutes [8]. This preliminary evidence established the need for a twenty-minute red laser treatment duration per treatment area, totaling a 40 minute when administered posterior and anterior, a protocol that was subsequently validated in extensive clinical trials (NCT01376037, NCT00738426, NCT02167867).

The first commercially available LLLT device (Erchonia Zerona) to receive FDA clearance in 2012 (510k K121695), utilized red laser irradiation. The FDA grants clearance to low-risk medical devices, confirming they are safe and effective for their intended use, while it approves drugs, requiring them to meet strict standards for safety, efficacy, and quality through comprehensive clinical testing. To obtain a new indication for use (IFU) under the 510(k) pathway, manufacturers must submit data demonstrating the device's safety and effectiveness for its specified purpose. Recent advancements have led to the first FDA cleared IFU for a violet laser application for circumference reduction (K231474), which was obtained based on both the safety and effectiveness data presented in this report.

Methods

Design

The clinical study was an open-label single-arm design to evaluate the efficacy of violet laser diodes (Erchonia Violet Zerona®) in providing non-invasive circumference reduction, compared to the application of red laser light treatment (Erchonia Zerona®) in the reference study. The data used as the comparative (reference) data set in this study is sourced from the data attained from the red laser application clinical trial conducted in 2014 whose results successfully supported FDA 510(k) clearance (K143007).

All qualifying study subjects were aged 18 years and older and recruited from among the investigators' normal pool of patients who voluntarily came to their offices for evaluation for a body contouring procedure or through an IRB-approved print ad placed in local publications. Qualifying subjects were neither charged nor compensated for their participation in the clinical study, including the cost of the laser procedures.

Intervention

A scanner device that emitted nonthermal laser device was utilized (Erchonia Violet Zerona®). This device employed a (6) 405nm nanometer laser diodes each producing an output power of 23mW (± 2mW). The device maintained a wavelength tolerance of ±10 nm. To ensure participant safety, protective safety glasses were provided and required to be worn during all treatment procedures.

Each subject received six (6) treatments across a two-week period: three treatments per week; each treatment every other day. Each treatment was a total of 20 minutes, involving 10 mintues of laser on the the anterior, followed by 10 mintues on the posterior side.The study procedure was identical to that evaluated in the comparative study (red laser), with the difference being the reduction in per-treatment administration time from 40 minutes (red laser) to 20 minutes (violet laser).

Study Endpoints

The study primary outcome measure of combined waist-hips-bilateral thighs circumference (inches) was measured at baseline and at completion of the two-week treatment phase (study endpoint). Body Mass Index (BMI) was also measured at these assessment points.

Study primary outcome success was evaluated as the mean change in combined circumference measurement (inches) at study endpoint relative to baseline. The study was pre-established as a non-inferiority design comparing application of the violet laser with the processor device that emitted red laser per the comparative data attained from the 2014 trial. Success for the current study group was pre-determined as mean change in combined circumference measurements of -3.72 ± 5% inches (-3.53 to -3.91 inches).

Ethics

The study protocol received approval from a commercial institutional review board, WCG IRB Connexus® located in Puyallup, WA, under the study numbers 1333895 (Glow Sculpting Spa), and 20222664 (Bloomfield Laser & Cosmetic Surgery Center). The study is registered by NCT05674292 under clinicaltrials.gov. Before engaging in any study-related activities, all participants provided their informed consent by signing the necessary documentation.

Results

Subject Demographics and Clinical Characteristics

All 25 enrolled participants completed the study pre protocol without deviations. 21 (84%) of the participants were female. Mean subject age was 49.96 ± 13.64 years. Mean baseline body mass index (BMI) was 26.43 ± 2.49 kg/m², and mean baseline combined waist-hips-bilateral thighs circumference was 123.16 ± 9.09 inches.

Efficacy

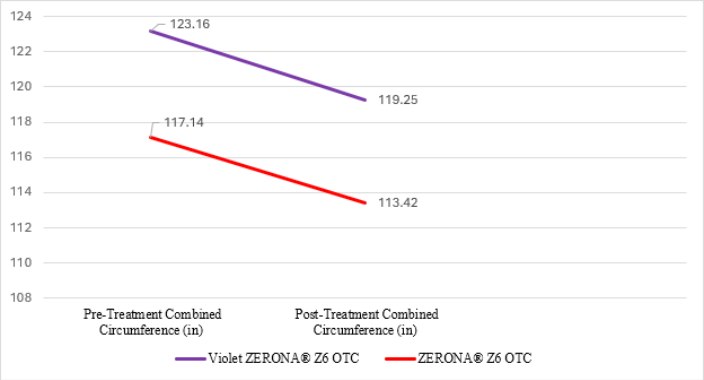
The mean change in total body circumference measurement at study endpoint relative to baseline was -3.91 inches, falling within the pre-specified maximally clinically acceptable difference range (-3.53 to -3.91 inches), and exceeding the pre-established lower boundary of -3.53 inches by -0.38 inches; thereby establishing study primary success (Table 1). Secondary assessment supported the primary success outcome. Individual responder success rate, defined per the reference study as at least a 3.0-inch reduction (≥-3.0 inches) in combined circumference measurements for the waist, hips, and bilateral thighs from baseline to endpoint, was 76% for the current study subject group compared with 73% for the reference study subject group. This fell within the prespecified maximally clinically acceptable difference range (68% to 78%) and exceeded the pre-established lower boundary of 68% by 8%.

Table 1: Combined Body Circumference Measurements Across Study Duration by Device.

WAVELENGTH APPLICATION			
Combined Circumference (inches)		Violet Laser (n=25)	Red Laser (n=22)
Pre-Treatment (Baseline)	**Mean (SD)**	123.16 (9.09)	117.14 (7.57)
	Range (min, max)	105.5, 141	104, 133
Post-Treatment (Study Endpoint)	**Mean (SD)**	119.25 (8.63)	113.42 (6.54)
	Range (min, max)	102.5, 137.0	21, 29
Pre-Post Change	**Mean (SD)**	-3.91 (1.65)	-3.72 (2.25)
	Range (min, max)	-0.5. -7.5	0.25, -10.0
	95% CI	-4.56 - -3.26	-4.66 - -2.78

The mean change of -3.91 inches in total body circumference measurement at study endpoint relative to baseline for subjects treated with the violet laser in the current study fell within the prespecified maximally clinically acceptable difference range of -3.53 to -3.91 inches and is -0.19 inches greater than the mean change of -3.72 inches attained for the red laser group in the reference device study and -0.38 inches above the lower bound of the prespecified maximally clinically acceptable difference range (-3.53 inches). T-tests for two paired samples were performed to evaluate the mean change in pre-to post-treatment change in combined body circumference measurements within each device treatment group. The mean change was found to be statistically significant within each of the current and reference device treatment groups ($p<0.001$):

- Violet ZERONA® Z6 OTC: $t=+8.63$; $p<0.001$
- ZERONA® Z6 OTC: $t=+11.86$; $p<0.001$



Graph 1: Comparison of Combined Body Circumference Measurements.

Comparison of Historical Control

While the current trial and the comparative data set[9] applied identical study qualification criteria, important limitations related to the use of historical controls may still exist, as outlined in the table below.

Table 2: Comparison to historical control.

	Gender	Age (mean)	Body Weight (mean)	BMI (mean)
Red Laser (n=22)	Female (n=19) Male (n=3)	29.82	152.75	24.68
Violet Laser (n=25)	Female (n=21) Male (n=4)	49.96	164.9	26.43

Although both studies enrolled similar proportions of male and female participants, there are notable differences between the study populations that could impact comparability. Participants in the violet laser group had slightly higher average body weight and BMI, which could result in a greater potential for circumference reduction. More notably, the violet laser group had a significantly higher average age than the red laser group, introducing factors such as slower metabolism and agerelated hormonal changes that may make circumference reduction more challenging.

Safety

No adverse events were reported by any subject throughout the study duration.

Summary

Photons exhibit an inverse proportional relationship between their energy (electronvolt [eV]) and wavelength (nm). This study aimed to determine if a 405 nm violet laser (3.06 eV) could achieve comparable circumference reduction with shorter treatment durations compared to a commercially available device utilizing a 635 nm red laser (estimated at 1.95 eV). Our findings, which culminated in the first FDA clearance for a non-invasive violet laser treatment for circumference reduction, demonstrated that the violet laser is as efficacious as the established red laser in achieving clinically significant reductions. Notably, violet laser treatment requires only half the per-session administration time, offering a substantial patient convenience benefit.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: TS and SS are employees of the study sponsor, Erchonia Corporation. As the study sponsor, Erchonia was responsible for device setup, training, and preparation of this manuscript. Glow Sculpting Spa and Bloomfield Laser & Cosmetic Surgery Center performed the research at their respective independent sites and have no conflicting interests and received no financial support for the research.

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