ORIGINAL ARTICLES

Low-Level Laser-Assisted Liposuction: A 2004 Clinical Study of its Effectiveness for Enhancing Ease of Liposuction Procedures and Facilitating the Recovery Process for Patients Undergoing Thigh, Hip, and Stomach Contouring

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Introduction: *The purpose of this IRB approved, multicenter, partially double-blind study was to determine the effectiveness of low-level laser-assisted liposuction in decreasing the patients' degree of postoperative discomfort, reducing swelling, enhancing wound healing at surgical entry points, decreasing the use of recovery medications for pain management, facilitating fat extraction for the surgeon, enhancing the emulsification of extracted fat, and decreasing surgical time spent to obtain optimal results.*

Materials and Methods: *The Erchonia EML, 635-nm, 14-mW dual-diode low-level laser was used to irradiate the target tissue for 12 minutes after infiltration of tumescent fluid.*

Results: *Of the 36 test-group patients who received laser treatment, 75% met their major success criteria compared with 32% of the 34 placebo-group patients who received "fake" treatment. Success criteria were defined as at least a 30% difference between groups. Forty-three percent more of the test subjects than placebo subjects met success criteria, exceeding the target by 13%.*

Discussion: *The Erchonia EML Laser is an effective device for assisting liposuction procedures with low-level laser therapy. It significantly enhances the ease of performing liposuction procedures; reduces the time in surgery; enhances the ease of facilitating fat extraction; enhances the emulsification of extracted fat; facilitates the recovery process; decreases the patients' degree of postoperative discomfort, decreases swelling; and decreases the use of recovery medications for pain management for patients undergoing body contouring in the areas of the thighs, hips, and stomach.*

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The Erchonia EML Laser (Erchonia Medical Inc, Mesa, Ariz) was designed to administer low-level laser therapy (LLLT). It had been hypothesized that LLLT may reduce pain and promote nerve regeneration through anti-inflammatory and immune-enhancement properties of the therapy. Previous research, including 2 unpublished studies by R. Amy, S. Shanks, and K. Slattery, indicated LLLT to be a potentially safe and effective means of reducing pain.[1–8] This clinical study was designed to evaluate the potential of the Erchonia EML Laser in offering a novel means of delivering LLLT to reduce pain and enhance healing after liposuction.

Neira et al[9] and Neira[10] first documented with scanning electron microscopy (SEM) and magnetic resonance imaging that the Erchonia EML Laser could emulsify fat and accelerate wound healing after liposuction procedures. At the AACS 20th Annual Scientific Meeting in Florida on January 2004, Lim et al[11] repeated Neira's work and presented their results on 75 consecutive patients with the Erchonia EML Laser. Clinical observations included less pain and discomfort, less swelling and bruising, and surgical extraction of fat made easier, with quality of fat more liquid and emulsified. Lim et al[11] compared

conventional SEM, Cryo SEM, transmission electron microscopy, and light microscopy. All methods showed similar findings of a "vacuolation" in the fat cell membrane after laser treatment. In a controlled pilot study, Ramirez-Montanana et al[12] used light microscopy to illustrate histological changes of adipocytes that were consistent with Neira's original findings after the administration of the EML Laser for 3, 6, 9, 12, 15, 18, and 21 minutes. They showed that after 12 minutes of irradiation, 90% of the fat was released from the adipocyte. A previous clinical trial using the patient as the control had equivocal results because of a flaw in the study design.

The purpose of this institutional review board clinical study was to determine the clinical effectiveness of Erchonia EML Laser in assisting liposuction procedures with LLLT for enhancing the ease of performing liposuction procedures and facilitating the recovery process for patients undergoing body contouring in the areas of the thighs, hips, and stomach. The Food and Drug Administration preapproved the study-design protocol, and these results have been submitted to the Food and Drug Administration for marketing clearance.

Device Description

The Erchonia EML Laser is a 14-mW, hand-held dual-diode medical device that emits a 635-nm near-infrared light via an electric-diode energy source. It uses rechargeable batteries or a separate alternating-current power adapter.

Anticipated Results

As the study progressed, it was determined that a sample size of at least 23 subjects per test group and per placebo group was sufficient to ensure that any significant differences found between groups could be considered statistically valid and representative of the general population sampled.[2,9,13]

Overall study-success criteria were anticipated as at least a 30% difference between groups, comparing the proportion of individual successes in each group with the primary measure of self-reported degree of discomfort rating on the Visual Analogue Scale (VAS) at 24-hours postprocedure. Individual-subject success was defined as a self-reported degree of discomfort rating on the VAS of less than 30 at 24-hours postprocedure. It was anticipated that about 50% of subjects in the test group and about 20% of subjects in the placebo group would meet the individual-success criteria.

The alpha value of 2*alpha (0.10) was used for applying statistical results analysis to a 1-tailed test.[14]

Procedure

Study Population

Seventy qualified subjects enrolled and completed their participation in this clinical study: 36 subjects were in the test group and 34 subjects were in the placebo group. All subjects who qualified satisfied each of the following criteria: presented with the indication for liposuction of body contouring only; were of relatively normal weight; showed overall firm elastic skin; passed the "snap test"; had localized areas of protruding fat; had a body mass index score of less than 30, that is, not obese; presented areas for liposuction, which included 1 or more of the right or left sides of the stomach, thigh, hip, and neck only; were deemed suitable for the anesthesia component of the liposuction procedure according to the guidelines distributed by the American Society of Anesthesiologists for preanesthesia care[15]; and were between the ages of 18 and 55.

Subjects had none of the following exclusive conditions: developmental disabilities; significant psychological disorders for which treatment was necessary, including anxiety and depression; psychiatric hospitalization; previous surgeries to any of the areas to receive liposuction; pregnancy or lactation; presence of infection or wound in the intended areas of treatment; arthritis or other disorders or injuries that directly affect the areas to be treated, including any implants such as pins; involvement in litigation or receiving disability benefits related to any kind of disability, injury, or other problems in any of the areas to receive the liposuction; current use of narcotics, opiates, or steroids; inability to refrain from taking any pain-relief over-the-counter or prescription medications, including medications prescribed for the relief of arthritis and osteoarthritis-related symptoms and any nonsteroidal anti-inflammatory drugs (NSAIDs) for the 48-hour period immediately before to the liposuction procedure administration; inability to refrain from taking any over-the-counter or prescription medications for the indication of the relief of pain or swelling other than those specified by the investigator of the clinical study; any over-the-counter or prescription medications for the relief of arthritis and osteoarthritis-related symptoms; any NSAIDs during the first week after completion of the liposuction procedure; inability to take specified rescue pain medication for the relief of postoperative pain because of allergy, intolerance, or any other reason; and inability

to take specified antibiotic medication for reducing the risk of postoperative infection because of allergy, intolerance, or any other reason.

Subjects were recruited from the assessment investigators' normal pool of patients who came to their clinics for evaluation for liposuction, signed the informed consent form, and satisfied all the study-eligibility criteria. Subjects were not offered any form of compensation to participate in this clinical study, nor were they charged for the cost of the laser procedure or related evaluations.

Study Design

This clinical study was of a placebo-controlled, randomized, double-blind design. There were 2 treatment groups in the clinical study. Subjects in the test group received the actual treatment procedure with the Erchonia EML laser—the device was activated during administration of the laser component of the treatment procedure. Subjects in the placebo group received a "fake" treatment procedure with the Erchonia EML laser—the device was not activated during administration of the laser component of the treatment procedure, although the administration protocol was strictly followed.

Randomization of subjects to treatment groups was determined in successive groups of 10. Within each group of 10, 5 subjects were randomly assigned to the test group and the other 5 subjects to the placebo group. This random procedure was then repeated for the next group of 10 subjects, then for the next group of 10 subjects, and so forth and was followed for subjects at each of the test sites.

Because the laser light on the test device had to be off during the placebo trials, it was not possible for the investigator who administered the "treatment" to be blind to which group the subject belonged. Therefore, to approximate a double-blind study design as closely as possible, a team of 2 investigators was assigned per subject. One investigator (the treatment investigator) administered the laser treatment (real or fake) to the subject. This investigator was the only one to know to which group the subject was assigned. The other investigator (the assessment investigator) was responsible for evaluating the subject for suitability as a subject in the clinical study, taking all the pre- and postprocedure measurements for the clinical study for qualifying subjects, and performing the liposuction procedure. According to the tumescent guidelines, the tumescent solution takes approximately 15 to 20 minutes to reach full effect after infiltration. It is during this time that the treatment investigator administers the laser treatment for 12 minutes. The assessment investigators entered the operating room to perform the liposuction procedure after the treatment investigator finished administering the laser treatment; therefore, the assessment investigator did not know to which group the subject was assigned.

Subjects were either fitted with protective darkened glasses to filter out the laser light or placed under general anesthesia so that they were not able to determine whether or not the laser was activated during treatment.

Treatment Procedure

All subjects received the same treatment protocol regardless of whether they were assigned to the test or placebo group. The only difference was that the laser device was activated for subjects in the test group and was not activated for subjects in the placebo group. However, subjects were not able to determine whether or not the device had actually been activated.

Subjects were prepared by the tumescent technique and received the classic Klein solution of 1000 mL of normal saline with 50 to 100 mL of 1% lydocaine with 1:100 000 adrenaline used as needed. For Erchonia EML Laser Treatment procedure and protocol, subjects were either under the effect of general anesthesia or correctly fitted with the darkened protective glasses. With the Erchonia EML2000 laser, a proprietary pulsed laser light was applied to each of the predetermined treatment areas for 12 minutes. The laser was set to produce 14 mW with a wavelength of 635 nm. The laser was held perpendicular to the skin at a distance of approximately 15 cm and was passed slowly and evenly across the entirety of the skin area being treated throughout the duration of the procedure. After administration of the first laser treatment with the Erchonia EML on the first target area by the treatment investigator, the assessment investigator began the standard liposuction procedure on that target area until the desired outcome was achieved. Liposuction commenced on each target area within 60 minutes after laser treatment.

Study Outcome Measures

As soon as their role in the laser-assisted liposuction procedure was completed, the assessment investigators recorded their perceptions of the emulsification of extracted fat, amount of time spent by volume of fat removed, swelling, and wound closure.

Table 1. Individual Success Criteria Met by Treatment Group

	Test Group	Placebo Group
Total no.	36	34
No. meeting success criteria	27	11
% Meeting success criteria	75	32

All subjects recorded degrees of discomfort measurements, recovery medications taken, and other medications during the first postoperative 24 hours, on days 2 through 7, and after 2 and 4 weeks.

Results

Forty-three percent more test-group subjects than placebo-group subjects recorded a discomfort level of less the 30 on the VAS at 24 hours after the liposuction procedure was completed, exceeding the pre-established target of a 30% difference between groups by 13% (Table 1).

The average VAS degree of discomfort rating at 24-hours postprocedure for test-group subjects was 22.85 points lower than that for placebo-group subjects (Table 2). This 22.85-point difference between groups is statistically significant ($t = -4.46$, $df = 68$, $P < .0001$).

Degree of Discomfort Rating Across the Duration of the Study

Although the average VAS rating for degree of discomfort decreased across the 4 time points for both test- and placebo-group subjects as would be expected, the differences in average degree of discomfort VAS ratings showed lower average ratings for test-group subjects compared with placebo-group subjects at all time points (Table 3). The differences are statistically significant at all time points:

- 24 hours: average VAS rating 22.85 points lower for test-group subjects compared with placebo-group subjects ($t = -4.46$, $df = 68$, $P < .0001$)
- 7 days: average VAS rating 13.96 points lower for test-group subjects compared with placebo-group subjects ($t = -3.62$, $df = 68$, $P < .0005$)
- 2 weeks: average VAS rating 14.92 points lower for test-group subjects compared with placebo-group subjects ($t = -4.14$, $df = 67$, $P < .0001$)
- 4 weeks: average VAS rating 9.17 points lower for test-group subjects compared with placebo-group subjects ($t = -3.97$, $df = 66$, $P < .0001$)

Table 2. Average 24-Hour Postprocedure Degree of Discomfort by Treatment Group

	Test Group	Placebo Group
Total no.	36	34
Average VAS rating*	24.56	47.41

*VAS indicates Visual Analogue Scale.

Table 3. Degree of Discomfort Ratings Across the Study Duration by Treatment Group*

	Test Group		Placebo Group	
Time After Operation	*n*	Average VAS Rating	*n*	Average VAS Rating
24 h	36	24.56	34	47.41
7 d	36	12.19	34	26.15
2 wk	35	7.23	34	22.15
4 wk	34	3.15	34	12.32

*VAS indicates Visual Analogue Scale.

Rescue Medication Use

All subjects were provided with Lortab 10/500 1 PO Q (or, in the case of intolerance to Lortab, a comparable pain-reducing medication) and were instructed to take a single dose as needed to control any postoperative pain or discomfort they might experience but no more often than every 4 to 6 hours. All subjects recorded each time a dose was taken during the first 7 postoperative days. They were also instructed not to take any other over-the-counter or prescription pain-relief medication over the course of the 7 days immediately after completion of the laser-assisted liposuction procedure.

Any subject who undergoes a liposuction procedure, regardless of whether or not it is within a clinical trial setting, is provided with a prescription for medication for the relief of any postoperative pain or discomfort after completion of the procedure. For the purposes of this clinical study, this medication was standardized so that differences in outcome measures related to pain and discomfort would not be confounded by differences in prescribed medications.

According to the dosage specifications, each subject could take up to 6 doses of the rescue pain medication on each of the 7 postoperative days, if necessary, for a total of 42 possible doses during the 7 postoperative study days (Table 4).

Test-group subjects took an average 5.14 (16.51%) fewer doses of the study rescue medication for the relief of pain or discomfort during the first 7 postoperative

Table 4. Average Percentage of Total Rescue Medication Doses Taken During the 7 Postoperative Days by Treatment Group

	Test Group (n = 36)	Placebo Group (n = 34)	All Subjects (n = 70)
Doses	8.43	13.57	22.0
%	23.41	39.92	31.43

days. This difference is statistically significant (t = –3.26, df = 68, P = .000871 [$P < .001$]).

Although the average percentage of total rescue medication doses taken each day decreased as the days progressed for both test- and placebo-group subjects as expected, the differences in average percentage of total possible rescue medication doses taken each day show fewer doses taken by test-group subjects than by placebo-group subjects on each of the 7 days (Table 5). The differences are statistically significant on each day:

- Day 1: Test-group subjects took an average 14.56% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –2.04, df = 68, P = .023 [$P < .05$]).
- Day 2: Test-group subjects took an average 22.79% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –3.16, df = 68, P = .0012 [$P < .005$]).
- Day 3: Test-group subjects took an average 16.91% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –2.37, df = 68, P = .0103 [$P < .05$]).
- Day 4: Test-group subjects took an average 15.87% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –2.58, df = 68, P = .0060 [$P < .01$]).
- Day 5: Test-group subjects took an average 19.39% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –3.32, df = 68, P = .0007 [$P < .001$]).
- Day 6: Test-group subjects took an average 16.75% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –3.15, df = 68, P = .0012 [$P < .005$]).
- Day 7: Test-group subjects took an average 9.24% fewer doses of the total rescue medication doses possible compared with placebo-group subjects (t = –2.26, df = 68, P = .014 [$P < .05$]).

Table 5. Average Percentage of Total Rescue Medication Doses Taken Each Day of the 7 Postoperative Days by Treatment Group

Day	Test Group (n = 36)	Placebo Group (n = 34)	All Subjects (n = 70)
1	47.69	62.25	54.76
2	37.50	60.29	48.57
3	29.17	46.08	37.38
4	19.91	35.78	27.62
5	12.96	32.35	22.38
6	9.72	26.47	17.86
7	6.94	16.18	11.43

Ease of the Process of Fat Extraction

Immediately after completion of the laser-assisted liposuction procedure, the assessment investigator recorded the ease of the assessment process of fat extraction measure for each area treated.

On a scale of 0 to 100, assessment investigators rated how easy or difficult it was to extract fat from the subject during the liposuction process, where 0 indicated *very easy* and 100 indicated *very difficult.*

For all treatment areas, the average VAS rating for the ease of fat extraction was significantly lower for test-group subjects than for placebo-group subjects (Table 6). The differences are statistically significant for each area treated:

- Stomach-right: VAS rating 59.36 points lower for test-group subjects compared with placebo-group subjects (t = –13.27, df = 56, $P < .0001$)
- Stomach-left: VAS rating 59.27 points lower for test-group subjects compared with placebo-group subjects (t = –13.41, df = 56, $P < .0001$)

Table 6. Average Ease of the Process of Fat Extraction VAS Rating by Treatment Group and Treatment Area*

	Test Group		Placebo Group	
	n	Average VAS Rating	n	Average VAS Rating
Stomach-right	30	12.07	28	71.43
Stomach-left	30	12.23	28	71.50
Thigh-right	22	12.27	18	75.17
Thigh-left	22	12.59	18	76.67
Hip-right	22	12.50	21	74.43
Hip-left	22	15.64	21	73.86

*VAS indicates Visual Analogue Scale.

Table 7. Average Emulsification of Extracted Fat VAS Rating by Treatment Group and Treatment Area*

	Test Group		Placebo Group	
	n	Average VAS Rating	*n*	Average VAS Rating
Stomach-right	30	10.73	28	74.50
Stomach-left	30	10.63	28	74.26
Thigh-right	22	11.55	18	76.22
Thigh-left	22	11.82	18	76.06
Hip-right	22	11.55	21	74.09
Hip-left	22	14.86	21	74.95

*VAS indicates Visual Analogue Scale.

- Thigh-right: VAS rating 62.90 points lower for test-group subjects compared with placebo-group subjects ($t = -15.14$, $df = 38$, $P < .0001$)
- Thigh-left: VAS rating 64.08 points lower for test-group subjects compared with placebo-group subjects ($t = -15.75$, $df = 38$, $P < .0001$)
- Hip-right: VAS rating 61.93 points lower for test-group subjects compared with placebo-group subjects ($t = -13.86$, $df = 41$, $P < .0001$)
- Hip-left: VAS rating 58.22 points lower for test-group subjects compared with placebo-group subjects ($t = -9.88$, $df = 41$, $P < .0001$)

Emulsification of Extracted Fat

On a scale of 0 to 100, assessment investigators rated their perceptions of the emulsification or consistency of the fat that was extracted from the subject during the liposuction procedure, where 0 indicated *very smooth* and 100 indicated *very chunky*.

For all treatment areas, the average VAS rating for the emulsification of extracted fat was statistically significantly lower for test-group subjects than for placebo-group subjects (Table 7):

- Stomach-right: VAS rating 63.77 points lower for test-group subjects compared with placebo-group subjects ($t = -17.05$, $df = 56$, $P < .0001$)
- Stomach-left: VAS rating 63.63 points lower for test-group subjects compared with placebo-group subjects ($t = -16.87$, $df = 55$, $P < .0001$)
- Thigh-right: VAS rating 64.67 points lower for test-group subjects compared with placebo-group subjects ($t = -17.49$, df = 38, $P < .0001$)
- Thigh-left: VAS rating 64.24 points lower for test-group subjects compared with placebo-group subjects ($t = -16.34$, $df = 38$, $P < .0001$)

Table 8. Average Volume of Fat Removed by Treatment Group and Treatment Area

	Test Group		Placebo Group	
	n	Average Volume Extracted (mL/min)	*n*	Average Volume Extracted (mL/min)
Stomach-right	30	83.98	28	65.09
Stomach-left	30	85.00	28	68.86
Thigh-right	22	146.48	18	86.60
Thigh-left	22	146.33	18	82.06
Hip-right	22	144.60	21	88.18
Hip-left	22	140.17	21	88.28

- Hip-right: VAS rating 62.54 points lower for test-group subjects compared with placebo-group subjects ($t = -15.92$, $df = 41$, $P < .0001$)
- Hip-left: VAS rating 60.09 points lower for test-group subjects compared with placebo-group subjects ($t = -11.63$, $df = 41$, $P < .0001$)

Volume of Fat Removed by Amount of Time Spent

Assessment investigators recorded the number of minutes it took to achieve the desired result and the corresponding volume of fat removed (in milliliters) during that time (Table 8).

For all treatment areas, a greater average volume of fat per minute was removed for test-group subjects than for placebo-group subjects, with the difference statistically significant for all areas except for the right and left stomach. Therefore, the Erchonia EML Laser treatment enabled more fat to be removed more quickly through liposuction, hence decreasing the amount of surgical time needed.

- Stomach-right: average of 18.89 mL/min more fat extracted for test-group subjects compared with placebo-group subjects ($t = 1.25$, $df = 56$, $P = .108$)
- Stomach-left: average of 16.14 mL/min more fat extracted for test-group subjects compared with placebo-group subjects ($t = 1.05$, $df = 56$, $P = .149$)
- Thigh-right: average of 59.88 mL/min more fat extracted for test-group subjects compared with placebo-group subjects ($t = 1.75$, $df = 38$, $P = .044$ [$P < .05$])
- Thigh-left: average of 64.27 mL/min more fat extracted for test-group subjects compared with placebo-group subjects ($t = 1.90$, $df = 38$, $P = .033$ [$P < .05$])
- Hip-right: average of 56.42 mL/min more fat ex-

Table 9. Average Degree of Swelling Rating by Treatment Group and Treatment Area*

	Test Group		Placebo Group	
	n	Average VAS Rating	*n*	Average VAS Rating
Stomach-right	30	14.40	28	62.71
Stomach-left	30	13.00	28	62.67
Thigh-right	22	14.83	18	66.83
Thigh-left	22	14.65	18	65.56
Hip-right	22	12.68	21	69.95
Hip-left	22	12.86	21	70.86

*VAS indicates Visual Analogue Scale.

tracted for test-group subjects compared with placebo-group subjects ($t = 2.14$, $df = 42$, $P = .019$ [$P < .05$])

- Hip-left: average of 51.89 mL/min more fat extracted for test-group subjects compared with placebo-group subjects ($t = 1.93$, $df = 42$, $P = .03$ [$P < .05$])

Degree of Swelling

On a scale of 0 to 100, assessment investigators rated their perceptions of the degree of swelling for each subject for each of the treatment areas, where 0 indicated *no swelling* and 100 indicated *extremely swollen.*

For all treatment areas, the average VAS rating for the degree of swelling was significantly lower for test-group subjects than for placebo-group subjects (Table 9). The difference is statistically significant for all areas:

- Stomach-right: VAS rating 48.31 points lower for test-group subjects compared with placebo-group subjects ($t = -10.29$, $df = 55$, $P < .0001$)
- Stomach-left: VAS rating 49.67 points lower for test-group subjects compared with placebo-group subjects ($t = -10.26$, $df = 54$, $P < .0001$)
- Thigh-right: VAS rating 52.00 points lower for test-group subjects compared with placebo-group subjects ($t = -10.47$, $df = 37$, $P < .0001$)
- Thigh-left: VAS rating 50.91 points lower for test-group subjects compared with placebo-group subjects ($t = -9.62$, $df = 37$, $P < .0001$)
- Hip-right: VAS rating 57.27 points lower for test-group subjects compared with placebo-group subjects ($t = -11.40$, $df = 39$, $P < .0001$)
- Hip-left: VAS rating 58.00 points lower for test-group subjects compared with placebo-group subjects ($t = -11.58$, $df = 39$, $P < .0001$)

Conclusion

The Erchonia EML Laser is an effective device for assisting liposuction procedures with LLLT. It significantly enhances the ease of performing liposuction procedures; reduces the time in surgery; enhances the ease of facilitating fat extraction; enhances the emulsification of extracted fat; facilitates the recovery process; decreases the patients' degree of postoperative discomfort; decreases swelling; and decreases the use of recovery medications for pain management for patients undergoing body contouring in the areas of the thighs, hips, and stomach.

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