

Erchonia Medical, Inc., Erchonia EML Breast Implant Clinical Study, Protocol Version 2, August 10, 2005.

This clinical study, completed in July, 2007, was a double-blind, randomized, placebo-controlled clinical study of 99 subjects – 48 test subjects and 51 placebo subjects. Subjects in this study were females aged 18-55 who voluntarily sought breast augmentation surgery, primarily for aesthetic purposes.

Analysis of the Effect of the Erchonia EML on Reducing Post-Surgical Pain Associated with the Breast Augmentation Procedure.

It was proposed that application of the Erchonia EML to each breast for 4 minutes (a total of 8 minutes for both breasts) with two 7 mw diodes producing near-infrared light (635nm) at approximately six inches within ten minutes prior to commencement of the breast augmentation procedure, and for an additional 4 minutes per breast immediately after completion of the procedure, and again at 24 hours after the procedure, would result in decreased pain in the surgical area at 24 hours post-surgery.

Therefore, the primary efficacy outcome measure was to compare the difference between test and placebo subjects' ratings for the overall degree of pain experienced at approximately 24 hours following completion of the laser-assisted breast implant procedure.

The measure was evaluated in the following way:

Individual subject success criteria

The individual subject success criteria was defined as a self-reported Degree of Pain rating using the standardized 0-100 VAS scale of less than 30 at 24 hours post-procedure, at which time the subject will have not taken any pain medication for at least four hours.

Overall study success criteria.

Overall study success criteria was defined as at least a 30% difference between groups, comparing the proportion of individual successes in each group. It was anticipated that about 60% of subjects in the test group would meet the individual success criteria and about 30% of subjects in the placebo group would meet the individual success criteria.

Null and alternative hypotheses

For this clinical study, the null and alternative hypotheses were set as follows:

Null Treatment Hypothesis: There will be no difference in treatment effect for subjects in the test group compared with subjects in the placebo group. That is, the proportion of subjects in the test group who meet the individual success criteria of a self-reported Degree of Pain rating of less than 30 on the VAS at 24-hours post-procedure will be no more or less than the proportion of subjects in the placebo group who meet the same individual success criteria.

Alternative Treatment Hypothesis: The treatment effect, as determined by the primary efficacy outcome measure of self-reported Degree of Pain rating at 24-hours post-procedure for subjects in the test group will be greater than that attained for subjects in the placebo group. That is, the proportion of subjects in the test group who meet the individual success criteria will be greater than the proportion of subjects in the placebo group who meet the individual success criteria, to the effect of 30% greater or more.

Statistical Analysis Results

Evaluation of Study Outcome Success Measure

Total: n=99

	n	# met ISC	% met ISC
Test	48	36	75%
Placebo	51	19	37%
		Difference	38%

Therefore, the overall study success criteria of a difference of 30% between individual group subject successes was met.

Additional Evaluations of Study Outcome

An *independent-samples two-tailed z-test of proportions* was conducted to assess for a statistically significant difference in the 24-hour post-procedure VAS ratings for subjects in the test versus the placebo group.

This statistical procedure compares means for two groups of cases where the subjects have been randomly assigned to one of the two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors.

The results are statistically significant in favor of a statistically significant lower VAS rating at 24 hours post-surgery for subjects who had been treated with the active laser compared with those who had been treated with the placebo laser. The difference is significant at $p < 0.005$.

	Test Group	Placebo Group	Total
n	48	51	99
$-\sum X$	992	1865	2857
$-\sum X^2$	40010	99779	139789
SS	19508.6667	31578.5098	57340.0202
mean	20.6667	36.5686	28.8586
Std.Dev.	20.3735	25.1311	24.1889

Mean_A—Mean_B	t	df
-15.902	-3.45	97

$p(2\text{-tailed}) = 0.000831$.

The difference is statistically significant at the $p < 0.005$ level.