Summary of Erchonia Pain Reduction Studies

A. Musculoskeletal/Soft Tissue Pain

Laser	Success Criteria of 30% or more	Placebo	% Difference
FDA Approved 830nm	*** 55.8%**	*** 40%**	**15.8%**
Erchonia 635nm	*** 80%**	*** 14%**	**66%**

Laser	All Patients with any relief	Placebo	% Difference
FDA Approved 830nm	*** 75.6 %**	*** 69%**	**6.6%**
Erchonia 635nm	*** 94%**	*** 30%**	**64%**

*** Data taken from 510 K submission for FDA clearance Comparisons to other lasers not available due to no known clinical data provided to the FDA**

Erchonia Test Group

Forty (40) out of the fifty (50) test group subjects (80% of all test group subjects) met or exceeded the individual success criteria of demonstrating a 30% improvement in Degree of

Pain rating Pre- and Post- Procedure measurement following only a **single 3 minute** treatment compared to 55% of the other “FDA approved laser” patients meeting individual success criteria that received treatments **3 times a week** for **5 weeks.** There is a 66% difference between the Erchonia Test and Placebo Group compared to only a 16% difference for the other FDA approved laser Study.
Comparing the data for patients getting “any” improvement in pain reduction, there is only a 6% difference between placebo and the other FDA approved laser and an incredible 66% difference between the Erchonia treated groups, meaning that the “sham” or “placebo” results of the other FDA approve Laser are almost as effective as their “real” FDA approved laser!!!!!

B. Post –OP Pain

Table 2: Individual Success Criteria met by treatment group

	Test subjects	**Placebo subjects**
Total n	36	34
n meeting success criteria	27	11
% meeting success criteria	**75%**	**32%**

There is presently a **difference of 43% between groups**, such that 43% 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%. These results are

from an IRB approved, multi-center, double-blind, randomized, clinical trial.

C. Burn Pain

Table 3. Pain Management results of 2nd and 3rd degree burns.

	In-Patient	Out-Patient
Total N= 25	11	14
Average size burn= 7.1% TBSA	50% TBSA	.75% TBSA
Average decrease in pain= 60%	25%	80 %

Patients reported that their pain reduction lasted 6-18 hours after wound care. These pilot study results are the foundation for a multi-center, IRB approved, clinical trial performed by plastic surgeons in Burn Centers across the USA.

Conclusion:
These studies indicate that the Erchonia Lasers are consistent and effective in reducing pain (at least 60%) regardless of origin, whether it be musculoskeletal, post-operative, or wound care.