SULLIVAN/O'FLYNN LUNULA LASER CLINICAL TRIAL: STUDY DESIGN

PURPOSE OF STUDY

The purpose of this clinical study was to demonstrate the efficacy of the Erchonia LUNULA™, manufactured by Erchonia Corporation, for the treatment of onychomycosis of the toenail, when applying the LUNULA™ to the toenail for 12 minutes one time per week for 4 consecutive weeks, for a total of 4 treatment administrations.

STUDY DESIGN

This clinical study was a single site, single group (active procedure only) non-randomized non-blinded design.

STUDY SUBJECTS

- One hundred and nine (109) subjects were enrolled in the study.
- Of the 109 subjects, all had a great toenail with qualifying onychomycosis enrolled and 30 subjects had multiple toenails with qualifying onychomycosis enrolled, resulting in a total of 139 toenails enrolled in the study, as follows:
- ✓ Subject age averaged 41.75 years

CATEGORY OF % BASELINE TOENAIL ONYCHOMYCOSIS INVOLVEMENT

Toenails were further categorized according to the following four categories of % toenail onychomycosis involvement at baseline:

All Toenails	**# (%) All Toenails (n=139)**
0% - 24%	11 (8%)
25% - 49%	33 (24%)
50% - 74%	41 (29%)
75% - 100%	54 (39%)

TREATMENT PROTOCOL

Each study toenail received four 12 minute treatments 7 days apart.

Millimeter (mm) of clear (uninfected) nail bed and per cent (%) of toenail onychomycosis disease involvement were objectively and independently determined using topographical software digital photo-planimetry software and triangulation methodology translated to a clear linear measurement at baseline; at the end of the procedure administration phase, and at 12 weeks, 36 weeks and 48 weeks post procedure administration end.

Table 1: Mean mm clear nail across study duration

Evaluation Phase	mm clear nail
Baseline	5.90
Week 4	9.63
Week 12	11.53
Week 36	14.26
Week 48	15.09

Chart 1: Mean mm clear nail across study duration

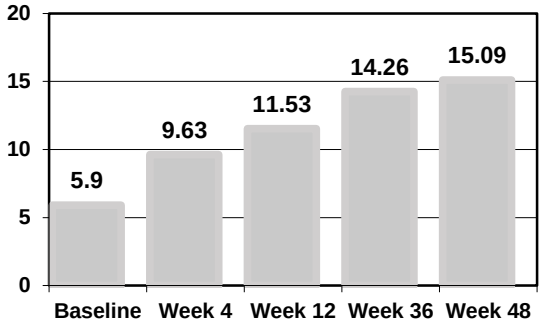

Table 2: Mean % onychomycosis disease involvement across study duration

Evaluation Phase	% Disease
Baseline	63.21
Week 4	37.72
Week 12	25.58
Week 36	8.06
Week 48	2.49

Chart 2: Mean % onychomycosis disease involvement across study duration

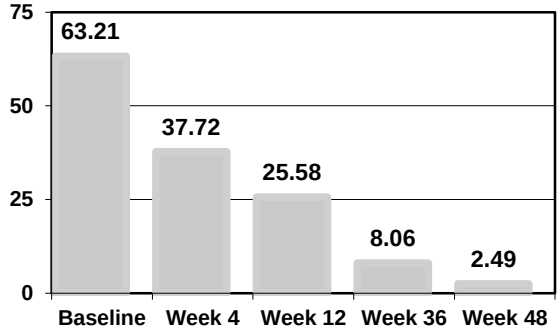

Table 3: Toenail Onychomycosis Disease Involvement Across Study Duration: *All Toenails*

n=139	Baseline	Procedure End	Week 12	Week 36	Week 48
Mean	63.21%	37.72%	25.58%	8.06%	2.49%
Standard Deviation	23.88	23.88	21.76	13.92	9.72

- It can be seen from Table 3 above that mean % toenail onychomycosis disease involvement decreased progressively and substantially across each successive evaluation point to a negligible remaining level.

ADVERSE EVENTS: No adverse event was reported for any subject throughout study duration.

CONCLUSION: The Erchonia LUNULA™ is an effective tool for treating toenail onychomycosis and preventing re-infection, significantly and progressively increasing mm of clear nail and decreasing % onychomycosis disease involvement over a 48 week period following completion of the 3-week procedure administration phase.