**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 **Chart 1:** Mean mm clear nail across study

duration 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 |

**Table 2:** Mean % onychomycosis disease **Chart 2:** Mean % onychomycosis disease

involvement across study duration 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 |

**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.