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# EFFECTIVENESS OF LOW-LEVEL LASER THERAPY FOR TREATMENT OF TOENAIL ONYCHOMYCOSIS

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**Background:** Fungal infection of the nails, or onychomycosis, cause nails to become discolored, thicken, crumble and separate. Currently affects approximately 10% of all U.S. adults, onychomycosis is difficult to treat and recurrence is common. The purpose of this clinical trial was to demonstrate the safety and efficacy of low-level laser therapy (LLLT) for treatment toenail onychomycosis.

**Study:** Subjects seeking treatment for toenail onychomycosis were enrolled. For ethical reasons, there was no placebo or control group. Using a dual diode (635nm & 405nm) device, LLLT was administered to affected toenails for 12 minutes once weekly for 4 weeks (Lunula™ Laser; Erchonia Corporation, McKinney, TX). Subjects were evaluated at baseline and immediately after the last treatment (Week 4) and after 12, 36 and 48 weeks. Changes in clear nail growth and percent of onychomycosis disease involvement was determined using digital photographs and topographical software. Each digital image was sent to an independent outside laboratory for objective evaluation. ClinicalTrials.gov Identifier: NCT02242019.


**Results:** Adult subjects (N = 109) with onychomycosis of the great toe (N = 109) or multiple toenails (N = 30) were ~enrolled. At 36 weeks, 96% of treated toenails met individual success criteria, defined as = 3mm of clear nail growth. The mean (SD) clear nail growth was 8.4 (4.1) mm ($p < 0.0001$). The mean percentage of onychomycosis disease decreased from 63.2 (23.9)% at baseline to 8.1 (13.9)% at 36 weeks ($p < 0.01$) and 86 subjects (62%) had achieved completely clear nails. Each efficacy parameter showed further improvement after 48 weeks. There were no reports of adverse events.

**Conclusion:** LLLT is a safe and effective tool for treating toenail onychomycosis. There was no evidence of re-infection over a 48 week period following four week treatments.