



Retrospective 6 Month Study Of New Laser Modality Demonstrates Improved Effectiveness In Treating Onychomycosis

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Objective

This study evaluated the effectiveness of a single treatment with the PinPointe™ FootLaser™ for onychomycosis at 6-months post-treatment. Effectiveness was measured as the number of patients demonstrating a positive mean change in percent (%) clear nail area as compared to pretreatment baseline.

Methods

This study was designed as a retrospective, single-center study. Data was collected retrospectively and evaluated in a blinded, prospective manner to evaluate the safety and efficacy of treatment.

Subjects with visual evidence of onychomycosis (right and/or left great toenails) received a single treatment with the PinPointe™ FootLaser™ using either a 1-pass (255 J/cm²) or 2-pass (510 J/cm²) method. Baseline, 3 and 6 Month photographs were reviewed in blinded fashion by 3 photoraters experienced in the diagnosis and treatment of onychomycosis, but with no role in the treatment. Planimetry was used to measure the percentage lesion-free nail areas and the median values of the photorater results were used for efficacy calculations.



Fig. #1 - Application of light energy

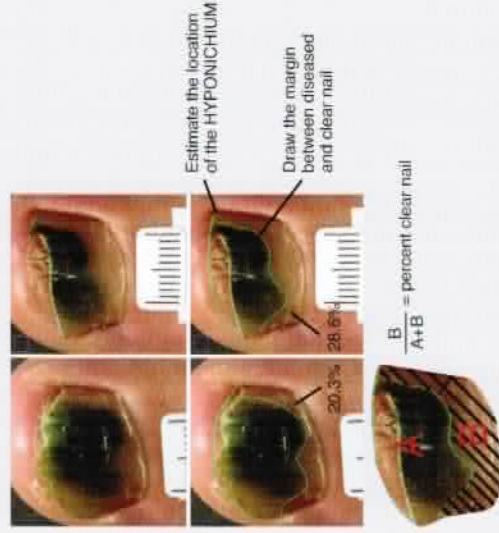


Fig. #2 - Planimetry of Lesion Free Area

Results

Seventy-one (71) patients with a mean age of 58.0 ± 13.9 years were enrolled. At 6 months post-treatment, 65% of patients showed improvement with a statistically significant mean improvement in lesion-free area of 9.8% (p < 0.001). For patients receiving a 2-pass treatment, 68% demonstrated improvement with a statistically significant mean improvement of 11.3% at 6 months (p < 0.001). For patients with less than 30% lesion-free area at baseline, 79% demonstrated an average improvement of 15.8% at 6 months. No adverse events related to the study device were reported for any subjects over the study period.

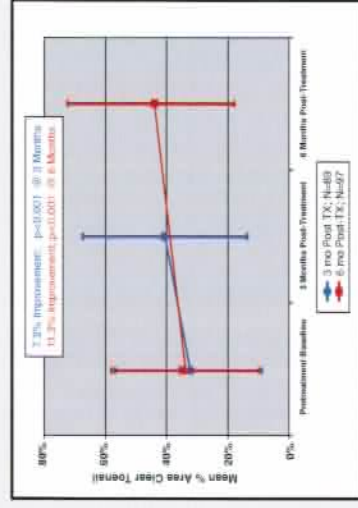


Fig. #3 - Results at 3 months and 6 months



Fig. #4 - Sample Results at 7 months and 5 months respectively

Conclusions

Single treatment with the PinPointe FootLaser demonstrated statistically significant improvement in percent of clear nail area at 6 months post-treatment in this single center retrospective study of patients with clinical diagnosis of onychomycosis. Effectiveness improved with degree of fungal nail involvement. A prospective randomized trial to further evaluate the effectiveness and safety of treatment in onychomycosis is underway.