

The use of a 1064nm laser in the treatment of Onychomycosis

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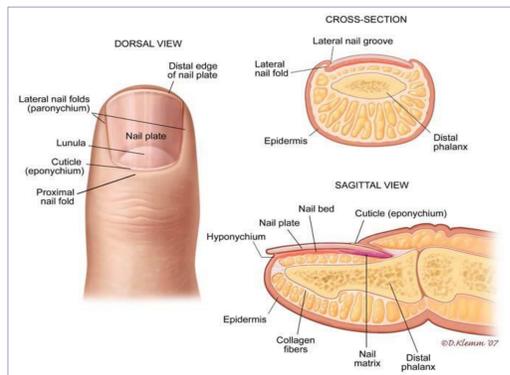


BACKGROUND

- Onychomycosis is a fungal infection of the nail which may result in serious sequelae in the immune and vascular compromised patient.
- It affects 6-8% of the population, with an increased predilection for patients with DM and PVD¹.
- Most common causative agent is *Trichophyton Rubrum*, a dermatophyte that has been shown to increase the risk of bacterial cellulitis of the foot and leg².
- Current treatments include topical vs. oral anti-fungals.
- Topical treatments are considered safe, however are shown to be only minimally efficacious in the treatment of onychomycosis^{1,3}.
- Oral anti-fungals have higher documented rates of success⁴, however their risk of drug-drug reactions⁵, as well as the need to monitor liver function tend to exclude many patients from this treatment.

STUDY PURPOSE

- This study sought to evaluate a safe and effective treatment for onychomycosis that would not exclude patients with known co-morbidities.
- Only one study has established the use of an 870-930nm wavelength laser for the treatment of onychomycosis⁶.
- Although no large scale study exists to evaluate the use of a 1064nm laser, an in-vitro study showed promising results for the 1064nm laser's use in treating onychomycosis⁷.
- The fungicidal effects offered by the 1064nm laser are mainly from its wavelength and not from thermal effects to the nail⁷, as such it should not administer any long term damage to normal healthy tissue, including the nail matrix.



Trichophyton rubrum usually invades the nail plate, nail matrix, lunula and nail bed^{1,18}



MATERIALS AND METHODS

• This study used a 1064XLASE medical diode laser system manufactured by A.R.C. Laser, CE#1275. This laser is already FDA approved for a variety of medical & surgical applications. This study was also approved by the Institutional Review Board at Saint Barnabas Hospital.

• Inclusion criteria were patients who had dystrophic nail(s) with a clinically appearing diagnosis of onychomycosis. Patient's must have had palpable pedal pulses and/or an Ankle Brachial Index (ABI) of >0.9.

• All pediatric patients (<18 years of age) were excluded from the study, as well as any patient who had taken an oral antifungal within 6 months prior to onset of this treatment.

• Nail specimens were obtained from all patient's at the onset and conclusion of the total treatment regimen. These will be utilized at a later date for objective analysis.

• Each patient was administered 4 treatments, each 2 weeks apart, and was evaluated for follow up 6 weeks after treatment completion.

• During each visit, pictures were obtained of the nail(s) being treated, to be used for evaluation at the study conclusion. A panel of four volunteers analyzed and graded the pictures for any noticeable "clearing" of the nail plate. This was documented as 0% change, up to 25% change, or up to 50% change.

• During the treatment delivery an IR (infrared) thermometer was used to monitor for increased tissue temperatures. If the temperature rose above 106 °F the treatment was ceased until temperatures normalized⁸.

• Laser parameters for each treatment were set at: 10 watts, 10ms duration, 4ms interval, motion average of 1cm/second.

• Lastly, all patients were prescribed a topical antifungal to be used on all areas of skin (excluding the nail) to prevent any concomitant *Tinea Pedis* from re-introducing fungal elements into the nail.

RESULTS

- A total of 58 patients enrolled in our study, of which a total of 30 patients (194 toenails) completed four treatments (51.72%).
- Patient satisfaction was 80% (n=24).
- Average energy administered to hallux nails was 324.31 J and to all nails was 234.80 J per treatment.
- Average nail temperature increase during treatment = 6.13 °F.
- Study panel reported zero clearing in 31.67% (n=9.5), up to 25% clearing in 33.33% (n=10), and up to 50% clearing in 35% (n=10.5) of the study patients.
- There were no adverse reactions reported.



Pre-Treatment



S/P 4 treatments (7weeks)

CONCLUSIONS

- The laser treatment yielded a high patient satisfaction (80%) and subjective noticeable improvement to the nail was noted in 68.33% of patients which is comparable to the current "gold standard" of oral Terbinafine (Lamisil) reported to improve onychomycosis in 74% of patients⁹.
- There were no adverse reactions in this study. Given its comparable rate of improvement to current treatment modalities we feel it is a viable option for all patients, and specifically for the immuno/vascular compromised patient.

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