

Title: Laser Treatment of Onychomycosis Using a Novel 0.65 Millisecond Pulsed Nd:YAG 1064nm Laser

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ABSTRACT

Treatment modalities for onychomycosis have historically included oral medications, topical antifungals, surgical treatment or a combination of these therapies. Topical treatments are challenging due to the difficulty in delivery of drug through an often thickened nail plate. Cure rates remain low with relatively high relapse rates seen after successful treatment.¹ The purpose of this study was to evaluate the treatment of onychomycosis using a novel 0.65 millisecond pulsed 1064nm laser. Eight subjects were treated over 2 to 3 sessions spaced at least 3 weeks apart. Of these 8 subjects evaluated, 7 had negative post-treatment cultures; the appearance of the treated nails was substantially improved based on photographic evidence, with a reduction of discoloration in the portions of the nails that had previously exhibited the presence of the fungus, and with new nail growth lacking the discoloration altogether. The treatments were well tolerated by all subjects. These data suggest that laser treatment should be considered in the treatment of onychomycosis.

Key words:

Onychomycosis

Nd:YAG laser

millisecond (msec)

Periodic Acid-Schiff Stain (PAS)

Nanometer (nm)

BACKGROUND

Onychomycosis is a common disease of the nails. Its causes include dermatophytes, non-dermatophyte molds and *Candida* species. The nail plate may become thickened, with yellowish or brownish discoloration; it can become brittle with crumbling edges and it is not uncommon for the nail plate to separate from the nail bed. Patient complaints range from embarrassment and loss of self esteem to pain and discomfort. As cited in a review article by Finch, et al., there is a 2–8% incidence in the general population rising to 14-28% in those over 60 years of age¹.

Treatment modalities for Onychomycosis have historically included oral medications, topical antifungals, surgical or chemical avulsion, or a combination of these therapies; outcomes have varied widely. In an analysis of 26 published clinical studies for oral treatment of toenail Onychomycosis, a complete cure was achieved in only 25% to 50% of patients receiving standard courses of therapy². Differences in study design and definition of “cure” may contribute to the wide ranges reported. Recurrences (relapse or re-infection) are reported to range from 10% to 53%³.

Recently, there has been an increased interest in phototherapy technologies for the local treatment of bacterial and fungal infection.⁴ Light-based devices including lasers have shown promise as treatment modalities.⁵ The Nd:YAG laser is such a device, with a wavelength (1064nm) that will pass through the nail plate and into the nail bed superheating the fungal material. Traditional 1064nm lasers utilize a pulse duration between 5 to 30 msec or greater. This is in excess of the thermal relaxation time of skin tissue, approximately 0.7 msec.⁶ With these ultra long pulse durations, the tissue must be cooled continuously to avoid severe treatment pain and surrounding skin injury. This approach is not practical for Onychomycosis given the surface geometry and thickness of the affected nail. The purpose of this study was to evaluate the treatment of onychomycosis using a novel 0.65 millisecond pulsed 1064nm laser (LightPod[®] Neo[™] from Aerolase, Tarrytown, NY) with a handpiece that does not contact the treatment site and does not require tissue cooling.

METHODS

Eleven patients who presented to a general dermatology practice were noted to have dystrophic nails clinically consistent with fungal infection. Onychomycosis was confirmed by culture in 4 of the patients (all cultures were processed by a commercial lab) and by periodic acid-Schiff (PAS) staining in 4 additional patients. These eight patients (5 male, 3 female), ranging from 48 to 91 years of age, with mycologic confirmation of fungal infection of the toenails or fingernails were enrolled. The remaining three patients who were culture negative on presentation were not included in the study. Consent was obtained, the affected nails were photographed, and laser treatment commenced. A LightPod[®] Neo[™] 1064nm laser was used applying a 2mm spot, with energy fluence set at 223 joules/cm² in the absence of any cooling sprays, gels or topical anesthetics. Each nail of the given subject's involved toes or fingers was "painted" with two alternating passes of laser pulses to cover the full nail, one pass applied vertically down each nail and the second applied horizontally. Subjects returned for a total of 2 to 3 treatments with each session spaced at least 3 weeks apart; cultures were taken after the second or third session. An antifungal cream was provided to each subject after treatment, to be applied to the nails daily as a preventative measure against re-infection.

RESULTS

In 7 of 8 patients the post-treatment culture was negative (Table 1). The appearance of most of the treated nails was substantially improved based on photographic evidence (Figure 1) and patient satisfaction. In the nails that exhibited a mycologic cure, there was a reduction of discoloration in the portions of the nails that had previously been involved with new nail growth lacking the discoloration altogether. The treatments were well tolerated by all subjects, who reported little to no pain and the occasional sensation of a "pin prick" or "hot spot". Temporary darkening under the nail plate in two patients resolved within several weeks.

DISCUSSION

Onychomycosis is difficult to treat. This pilot study highlights the potential use of lasers in the treatment of this condition. The results of this pilot study indicate that a short pulsed 1064nm laser (Aerolase LightPod Neo) without skin cooling, can safely and effectively be used to eradicate onychomycosis. This novel laser performs the treatment with acceptable levels of comfort and without any significant complications or side effects. Because the handpiece does

not contact the skin or nails, and does not require the use of any cooling devices, it is a clean, simple, sanitary procedure.

The optimal treatment regimen is not clear. It is possible that with a larger sample size and more frequent cultures one might demonstrate clearance with fewer treatment sessions. Although patients are encouraged to keep the nails short and filed down with topical treatments it is interesting to note that patient 7, the only treatment failure, had filed his nail extensively. Perhaps such a thin nail negatively impacted treatment with light energy.

A nail plate with a normal appearance is not always attainable after a successful therapeutic onychomycosis regimen. Permanent nail anomalies may persist after elimination of the fungal pathogen in spite of the resolution of infection.²

The patients in this study were not followed long term after treatment to assess total clinical response or rate of possible recurrence. The small sample size makes it hard to extrapolate to the general population but the results of this pilot study are certainly encouraging

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Figure 1



a.



b.



c.



d.



e.



f.

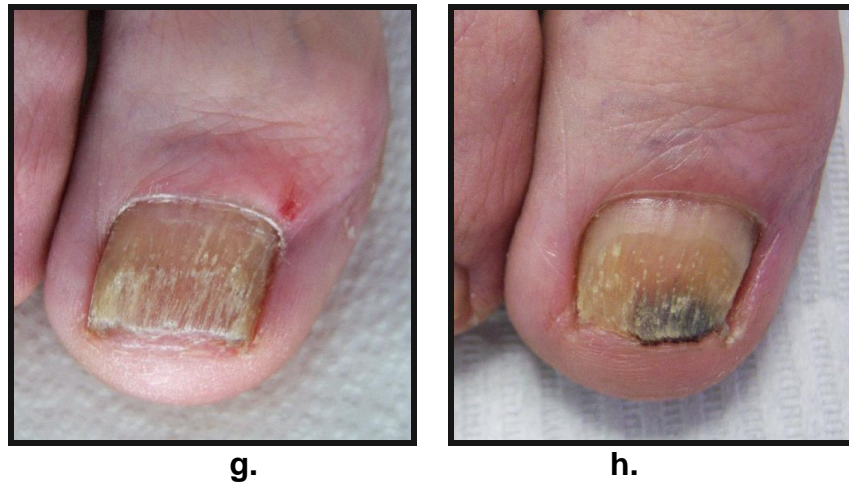


Fig 1: (a) Patient 1, before first treatment, (b) Patient 1, six weeks after first treatment, (c) Patient 5, before first treatment. d) Patient 5, five months after first treatment (e) Patient 6, before first treatment (f) Patient 6, ten months after first treatment (g) Patient 7, before first treatment (h) Patient 7, three weeks after third treatment, dark area still evident, culture was positive for *T. Rubrum* at this visit.

Table 1

	PT	Age	Gender	Nails involved	Initial results (CX/ PAS)	# of Tx's	Final Cx
TM	1	75	M	R 1	T. Rubrum	3	Neg. - after 2nd Tx
CB	2	77	M	R 1, L 1	T. Rubrum	2	Neg. - after 2nd tx.
ES	3	49	F	R 1, L 1	PAS +	3	Neg. - after 2nd Tx
LM	4	50	F	R 5	PAS +	3	Neg -after 3rd tx
VW	5	76	M	R 1,2,3,	PAS +	3	Neg -after 3rd tx
SA	6	48	F	L 2	Cx +	3	Neg -after 3rd tx
RG	7	67	M	R 1	PAS +	3	Positive (T Rubrum) after 3rd tx
FM	8	91	M	R 4* fingernail	Cx + (Candida)	2	Neg- after 2nd Tx