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Clinical Insights

A New Protocol for the Clearance of Onychomycosis with Laser, Using a Novel 650-microsecond Pulsed Nd:YAG 1064nm Laser

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Abstract

A new protocol for the treatment of Onychomycosis with laser irradiation was developed and used on 192 subjects with multiple nails affected by Onychomycosis, as confirmed by PAS, KOH and culture tests. A novel Nd:YAG 1064nm laser with a 650 microsecond pulse duration and a peak power of 318 joules/cm^2 or 15,385 watts per pulse was used at two clinical sites over a period of 18 months. The protocol included two laser treatment sessions spaced approximately 4 weeks apart. Then, at a point 3 months after the second laser treatment session, each subject was again administered the PAS, KOH and culture tests, and 178 or 92.7% tested negative for the fungus. The two-treatment laser protocol was repeated on the 14 remaining subjects and 11 of them were clear of all fungal infection after two additional laser treatments. Therefore, 98.4% of all subjects have shown negative culture 3 months after completion of their laser treatment course. Toes were pre-cooled with ice and all subjects reported the laser treatment as either painless or highly tolerable with an occasional sensation of heat. There were no side effects of treatment, and all subjects were satisfied with the results. This clinical study demonstrates that Onychomycosis can be effectively and safely treated with a 650 microsecond Pulsed Nd: YAG 1064nm Laser.

Key Words

Onychomycosis, nail fungal infection,toe nail fungus, Nd:YAG, lasers, 650 microsecond (0.65 millisecond) Pulsed Nd: YAG 1064nm laser, 1064nm laser, podiatry laser, miro-pulse Nd:YAG laser, short-pulsed Nd:YAG laser

Introduction

Onychomycosis (a fungal infection of the nail, usually caused by a dermatophyte) constitutes an important public health problem because of its high prevalence (about 10% of the U.S. population) and associated morbidity. The disease can have certain negative consequences for patients, such as pain, and can potentially undermine work and social lives. Patients may fear that they will transmit their infection to family members, friends, or coworkers, fears that can lead to diminished self-esteem and the avoidance of close relationships[1]. Treatment modalities for Onychomycosis have historically included oral and topical antifungals, surgical or chemical avulsion, or a combination of these therapies. In an analysis of 26 published clinical studies for the oral treatment of toenail Onychomycosis, a complete cure was achieved in only 25–50% of patients receiving standard courses of therapy[2]. Meanwhile, oral antifungals are more toxic with a significant risk of liver toxicity, prolonged loss of taste, and life-threatening drug interactions[3]. Signifcant interest has developed recently in the potential use of light irradiation by laser to destroy fungal material through superheating (coagulation) of soft tissue affected with fungus. Exposure of fungi to high temperatures inhibits their growth as well as causing cell damage and death[4,5]. This type of therapy, if effective, has the added benefit of avoiding side effects mentioned above and other systemic concerns for the patient.

Study Design, Materials and Methods

A new protocol for the treatment of Onychomycosis with laser irradiation was developed and used on 192 subjects with nails affected by Onychomycosis. Subjects ranged in age from 14 to 71; 26% were male and 74% were female, covering the full range of skin tones from light to dark. A novel Nd:YAG 1064nm laser with a 650 microsecond pulse duration and a peak power of 318 joules/cm^2 or 15,385 watts per pulse was used (LightPod Nd:YAG laser, Aerolase Corporation, USA) at two clinical sites of Adler Footcare of Greater New York located in White Plains, NY and Manhattan, NY, over a period of 18 months. Subjects with visible signs of nail fungus were recruited, but those who were pregnant were excluded as pregnancy is a standard contraindication for laser therapy. Patients who had been taking oral medication for nail fungus were required to discontinue the medications before laser treatment commenced. The protocol began with the administering of PAS, KOH and culture tests to confirm the presence of Onychomycosis on each subject as a precondition of accepting them for the course of treatments. Those who were accepted for treatment were then required to sign informed consent for the laser treatment. The laser treatment specifications were as follows:

Laser source: Nd:YAG pulsed solid-state laser
Wavelength: 1064nm
Spot diameter: 2mm and 5mm
Pulse duration: 650 microseconds (or 0.65 milliseconds)
Power output: 35 to 318 joules/cm^2 (15,385 watts per pulse)

Laser treatment began with two laser sessions spaced approximately 4 weeks apart. Before treatment, the subjects' toes were cooled with ice packs for approximately 15 minutes each to

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reduce the heat sensation from treatment. Debriding was performed as necessary on thicker and mycotic nails. Next, laser pulses were applied in two full passes to the entire nail including peripheral skin using a 5mm spot diameter and laser fluence of 36-41 joules/cm^2 at 650 microsecond pulse duration (up to 15,385 watts per pulse) on all ten toes. One pass was performed in a lateral direction and the second pass in the distal direction to ensure full coverage of the nail with laser pulses. Next, a third pass with a 2mm spot diameter and laser fluence of 223 joules/cm^2 and the same 650 microsecond pulse duration was applied to the nails that were visibly affected with fungus. After each laser treatment session, patients were given topical antifungals (Nizoril and Tolnaftate) as well as a pair of SteriShoe ultraviolet shoe trees that each of them purchased for use in the shoes they would wear the following day; these modalities were provided as a means of inhibiting reinfection of the nails between laser treatment sessions. Then, at a point 3 months after the second laser treatment session, each subject was again administered the PAS, KOH and culture tests.

With those subjects who tested positive for the fungus at the 3-month mark, the two-treatment laser protocol was repeated. At the second 3-month follow up (i.e. after the second course of 2 treatments), these subjects were again administered the PAS, KOH and culture tests.

Results

Of the 192 subjects who initially tested positive for Onychomycosis using PAS, KOH and culture tests, 178 or 92.7% of them, tested negative for the fungus at a point 3 months after a series of two laser treatments. Visual observation of the treated nails for all 192 subjects after two treatments as shown in Figure 1:

Improvement by Visual Observation	Percent of Toes
Unchanged	7.3%
Moderate Clearance	5.2%
Major Clearance	50.5%
Full Clearance	37.0%
Total	100%

Figure 1

The two-treatment laser protocol was repeated on the 14 subjects (7.3% of total number of subjects) who tested positive for the fungus after the first 2 treatments. At 3 month follow up after the two additional laser treatments, those 14 subjects were again administered the PAS, KOH and culture tests; 11 of these subjects were clear of all fungal infection. Therefore, 98.4% of all subjects have shown negative culture 3 months after the completion of their course of laser treatments. All subjects reported the laser treatment as either painless or highly tolerable with an occasional sensation of heat. There were no side effects of treatment, and all subjects were satisfied with the results.

Conclusions

This clinical study demonstrates that the application of multiple passes of 650 microsecond pulsed Nd:YAG 1064nm Laser energy, with fluences ranges between 36 and 223 j/cm^2 over 2 to 5mm spot diameters and with total energy irradiated in excess of 15,000 watts per pulse, can eradicate Onychomycosis within affected nails in 98% of cases using the above protocol and laser parameters. The mechanism of destruction of the fungus is theorized to be a process of superheating of the soft tissue contaminated with fungal material, which is consistent with the coagulation and destruction of soft tissue structures that has been well documented in other applications of podiatry and dermatology. It is suggested that such coagulation and overheating of the fungal materials can and should occur within the nail structure, in the nail bed and the matrix tissue beneath the nail bed, as well as in the skin around the nail. It has been shown in laser research that the 1064nm wavelength of irradiated light is absorbed in pigment, water and hemoglobin which results in the bulk heating of all those soft tissue and skin tissue structures; also that this specific wavelength of laser light provides the deepest depth of laser energy penetration6. Providing the 1064nm wavelength with a 650 microsecond pulse duration is effective for delivering high energy and heat deep into the skin tissue and therefore into the nail matrix where fungus can reside, in a way that is tolerable to the patient.

References

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