Laser treatment of onychomycosis using a novel 0.65-millisecond pulsed Nd:YAG 1064-nm laser

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Abstract
Onychomycosis is a common disorder of the nails. Treatment modalities include oral and topical antifungals, surgical treatment or a combination of these therapies. Cure rates remain low with relatively high relapse rates seen after successful treatment. The purpose of this study was to evaluate the treatment of onychomycosis using a novel 0.65-millisecond (ms) pulsed 1064-nm laser. Eight subjects were treated over two to three sessions spaced at least 3 weeks apart. Of the eight subjects evaluated, seven had negative post-treatment cultures after the second or third session. Treatments were well tolerated by all subjects. These data suggest that treatment of onychomycosis with a 0.65-ms pulsed Nd:YAG 1064-nm laser should be studied further to determine the long-term clinical and microbiologic effect. The optimal number of treatment sessions for each patient needs to be determined.

Key Words: antifungal therapy, lasers and light sources, Nd:YAG laser, onychomycosis

Introduction
Onychomycosis is a common disease of the nails, occurring in 2–8% of the general population, rising to 14–28% in those over 60 years of age (1). Its causes include dermatophytes, non-dermatophyte molds and Candida species. The nail plate may become thickened with yellowish or brownish discoloration, brittle with crumbling edges and, in addition, 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.

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). Recurrences (relapse or re-infection) occur in 10–53% patients (3).

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 (1064 nm) that will pass through the nail plate and into the nail bed, resulting in superheating of the fungal material. Exposure of fungi to high temperatures inhibits their growth as well as causing cell damage and death (6,7). Traditional 1064-nm lasers utilize a pulse duration between 5 and 30 milliseconds (ms), in excess of the approximately 0.7-ms thermal relaxation time of skin tissue (8). With such ultra-long pulse durations, the tissue must be cooled continuously to avoid severe treatment-related pain and injury to the surrounding skin. Such an approach is not practical for onychomycosis given the uneven surface geometry and thickness of the affected nail.

The purpose of this pilot study was to evaluate the treatment of onychomycosis using a 0.65-ms pulsed 1064-nm laser with a hand piece that does not contact the treatment site and does not require tissue cooling.

Materials and methods
Participants were chosen from patients presenting to a general dermatology practice who were found...
to have dystrophic nails clinically consistent with fungal infection. To qualify for enrollment, patients were required to have confirmation of fungal infection in either a toenail or fingernail. After scrubbing the nail with alcohol, nail clippings and, when possible, subungal debris were sent to a commercial laboratory for culture or to a dermatopathology laboratory for confirmation by periodic acid-Schiff (PAS) staining. Informed consent was required from all patients.

The affected nails were photographed and laser treatment was commenced. A 1064-nm Nd:YAG laser (LightPod Neo™; Aerolase, Tarrytown, NY, USA) was used applying a 2-mm spot, with the energy fluence set at 223 J/cm² in the absence of any cooling sprays, gels or topical anesthetics. Each infected nail was treated in a criss-cross pattern with two alternating passes of laser pulses to cover the full nail—one pass applied vertically and the second horizontally—over the nail surface. Treatment time was approximately 45 seconds or less per nail treated. Subjects returned for a total of two to three treatments with each session spaced at least 3 weeks apart.

An antifungal cream was provided to each subject after treatment, to be applied to the nails daily as a preventive measure against re-infection. Cultures were obtained after the second or third session by first scrubbing the nail plate with alcohol, discarding the most distal clippings and then obtaining nail clippings from as proximal as possible in order to avoid having the antifungal cream being included in the culture specimen.

Efficacy of treatment was assessed by repeat culture and visual and photographic inspection. Photographs were obtained at baseline, at the second or third treatment session in some patients, and then during follow-up visits 4–6 or more months after the final treatment.

Results

Eleven patients who presented to a general dermatology practice were noted to have dystrophic nails clinically consistent with fungal infection. Eight of these 11 patients had such confirmation, either by culture (n = 4, all processed by a commercial laboratory) or by PAS staining (n = 4). There were five male and three female patients ranging in age from 48 to 91 years. Seven patients had infections of their toenails and one patient had infection of a fingernail (Table I).

Post-treatment culture was negative in seven of eight patients. In one patient who presented with PAS + nail clippings, the post-treatment culture grew *Trichophyton rubrum*. This was the only patient with a positive post-treatment culture and coincidentally he was the only one who had filed his nail extensively prior to each treatment. This resulted in an extremely thin nail plate at the time of treatment. Visually, the appearance of most of the treated nails improved substantially (Figure 1). 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.

Treatments were well tolerated by all subjects, who reported little to no discomfort except for the occasional sensation of a ‘pin prick’ or ‘hot spot’. Temporary darkening under the nail plate occurred in two patients and resolved within several weeks.

Discussion

Onychomycosis is difficult to treat, with high rates of persistence or recurrence of fungal infection. Currently accepted treatments include oral, topical, and surgical therapies. Topical therapies are limited by sub-therapeutic concentrations of antifungal medication reaching the nail bed. Lack of patient compliance also limits cure rates. Oral therapies are complicated by potential drug interactions, and allergic or systemic effects. Surgical treatment or chemical avulsion of the nail plate can result in prolonged pain.

This pilot study highlights the potential use of a short-pulsed 1064-nm Nd:YAG laser without concomitant skin cooling to safely and effectively eradicate onychomycosis. This novel laser performs the treatment with acceptable levels of comfort and

Table I. Patient demographics and results after Treatment.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Sex</th>
<th>Nails involved</th>
<th>Initial results (CX/PAS)</th>
<th>No. of treatment sessions</th>
<th>Final culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>75</td>
<td>M</td>
<td>R 1</td>
<td>CX +</td>
<td>3</td>
<td>Negative – after 2nd Tx</td>
</tr>
<tr>
<td>2</td>
<td>77</td>
<td>M</td>
<td>R 1, L 1</td>
<td>CX +</td>
<td>2</td>
<td>Negative – after 2nd Tx</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>F</td>
<td>R 1, L 1</td>
<td>PAS +</td>
<td>3</td>
<td>Negative – after 2nd Tx</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>F</td>
<td>R 5</td>
<td>PAS +</td>
<td>3</td>
<td>Negative – after 3rd Tx</td>
</tr>
<tr>
<td>5</td>
<td>76</td>
<td>M</td>
<td>R 1, 2, 3</td>
<td>PAS +</td>
<td>3</td>
<td>Negative – after 3rd Tx</td>
</tr>
<tr>
<td>6</td>
<td>48</td>
<td>F</td>
<td>L 2</td>
<td>CX +</td>
<td>3</td>
<td>Negative – after 3rd Tx</td>
</tr>
<tr>
<td>7</td>
<td>67</td>
<td>M</td>
<td>R 1</td>
<td>PAS +</td>
<td>3</td>
<td>Positive (<em>T. rubrum</em>) – after 3rd Tx</td>
</tr>
<tr>
<td>8</td>
<td>91</td>
<td>M</td>
<td>R 4 fingernail</td>
<td>CX +</td>
<td>2</td>
<td>Negative – after 2nd Tx</td>
</tr>
</tbody>
</table>

R = right; L = left; CX = culture; PAS = periodic acid-Schiff stain; Tx = treatment session; *T. rubrum* = *Trichophyton rubrum*.
without any significant complications or side effects. Because the hand piece does not contact the skin or nails and does not require the use of any cooling devices, it is a clean, simple, and sanitary procedure.

The optimal regimen has yet to be defined. Patients in this study received either two or three laser treatments. In four patients, negative cultures were obtained after two treatments. It is possible that as few as one treatment session may be all that is required.

When applying topical treatments, patients are encouraged to keep nails short and thin by filing. However, this may actually adversely affect treatment with this laser. Patient 7, the only one whose infection was not eliminated, had filed his nail extensively.

In summary, this pilot study highlights the potential for the use of a novel 0.65-ms pulse duration 1064-nm laser for the treatment of onychomycosis. It has few adverse effects and may have eliminated the pathogen. It does not require cooling of the skin in contrast to lasers with longer pulse durations. Additional research may ascertain whether complete clinical cure can be obtained with this treatment.

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References