Improving the Appearance of Clear Nail in Patients with Onychomycosis Using a MicroPulse Nd:YAG Laser: A Case Study

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INTRODUCTION

Onychomycosis, a disease caused by dermatophytes, non-dermatophytes and Candida species of fungus, is the most common infection of the nail, affecting 2-8% of the general population, and increasing to 12-28% in adults 60 years or older. Nails that are infected with onychomycosis have yellowish or brownish discoloration, a thickened nail plate, and crumbling edges. These qualities can lead to toenail discomfort, secondary bacterial infections and psychosocial issues such as anxiety, depression, loss of self-esteem, avoidance of intimacy and impaired relationships, all of which can severely affect a patient’s quality of life. Several factors, including diminished blood circulation, longer cumulative time of exposure to fungi, nail trauma and a compromised immune system make people more susceptible to infection. High rates of persistence and recurrence make onychomycosis very difficult to treat.

The primary methods for treating onychomycosis are systemic administration of oral antifungal drugs and topical antifungal creams applied directly to the infected nails. The most common oral antifungal drugs include Terbinafine, Fluconazole, and Itraconazole. Long-term cure rates for oral antifungals range from 21% to 53%. Systemic treatments require liver tests before, during, and after treatment, and can have serious side effects, including diarrhea, dyspepsia, rashes, taste disturbances and abdominal pain. Patient compliance to the blood testing and requirement to discontinue use of all alcoholic beverages during the course of treatment, can be a challenge. Topical antifungal agents used to treat onychomycosis include nail lacquers containing ciclopiroxolamine, amorolfin, toconazole or a combination of these agents. Results from several clinical studies indicate that topical cure rates can range from 21% to 36%. Factors that make topical antifungals unsuccessful include long-term application (9-12 months), lack of patient compliance, serious side effects and failure to apply the medication appropriately to the nail bed.

Laser therapy has recently become a viable option, due to its rapid procedure duration, possibility for efficacy without systemic treatment or blood monitoring, few contraindications and no significant side effects. In addition to these benefits, several studies have demonstrated that laser therapy is both safe and effective in improving the cosmetic appearance of nails infected with onychomycosis. This case study evaluates the PinPointe™ FootLaser™ as an acceptable and reliable option for the temporary improvement of clear nail in patients with onychomycosis.

METHODS

Blue Ridge Foot Centers and Carolinas Laser Toenail Centers have been using the PinPointe laser for over three years. Prior to the laser procedure, if needed, patients receive extensive debridement using nippers, curette and a mechanical filer to remove the distal onycholytic nail plate and thinning of the hypertrophic nail plate to 1mm thickness. A smoke evacuator is used to clear the nail of the debris. Patients are then lased with the micro-pulsed Nd:YAG laser. The laser utilizes the 1064nm wavelength, 255 mJ of energy, a pulse width of 100 μm, spot size of 1.5 mm and a power setting of...
Lesion reduction: the absolute lesion decrease % divided by the baseline lesion area (%).

Image analysis with Adobe Photoshop was used to achieve consistent magnification of the nails. A trained technician traced the area of clear and infected nail for an accurate evaluation of nail improvement. Photos were neither enhanced nor filtered, hence the margin between clear and infected nail was unaffected.

Magnified photos were then analyzed using ImageJ software, a National Institutes of Health (NIH) based program designed specifically for image analysis and processing. The software program converts images into their individual pixels so that different areas within the image can be analyzed. To calculate the size of the area, clear nail area or the infected nail area was selected and converted into pixels. These measurements were then used to analyze the changes in clear nail area and lesion reduction at follow-up visits. Standard deviation was calculated to determine the variation that existed from the average.

Subjective aesthetic assessments were measured by the physician using the Global Aesthetic Improvement Scale (GAIS). GAIS is a 5-point scale to evaluate the treatment outcome of the infected area. Subjects filled in a patient satisfaction questionnaire during follow-up visits at three and seven months.

**GAIS Evaluation**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Very much improved – optimal cosmetic results</td>
</tr>
<tr>
<td>4</td>
<td>Much improved – marked improvement in appearance from initial condition, but not completely optimal for this subject</td>
</tr>
<tr>
<td>3</td>
<td>Improved – obvious improvement in appearance from initial appearance, but an additional procedure is indicated</td>
</tr>
<tr>
<td>2</td>
<td>No change – the appearance is essentially the same as the original condition</td>
</tr>
<tr>
<td>1</td>
<td>Worse – the appearance is worse than the original condition</td>
</tr>
</tbody>
</table>

**RESULTS**

The patient’s two big toes were measured by planimetry and showed a significant increase in clear nail growth and lesion reduction (Figure 1,2). The mean baseline clear nail area for the patient’s two toes was 17% (±32%) of the nail. After 14 months post procedure, the mean clear nail area was increased to 49% (±5%) of the nail. Using these two measurements, the absolute increase in clear nail was calculated to be 32%. (Table 1).
Clear Nail Growth Determined by Area Calculated in ImageJ (cm²)

<table>
<thead>
<tr>
<th>Follow-Up Period</th>
<th># of Toes</th>
<th>Mean Baseline Clear Nail Area</th>
<th>Std. Dev.</th>
<th>Mean Follow-up Clear Nail Area</th>
<th>Std. Dev.</th>
<th>Absolute Increase in Clear Nail</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Months</td>
<td>2</td>
<td>17%</td>
<td>11%</td>
<td>49%</td>
<td>5%</td>
<td>32%</td>
</tr>
</tbody>
</table>

Table 1 Improvement as quantified by increase in clear nail

The mean lesion area of the patient’s two big toes was determined to be 83% (±11%) of the nail and was reduced to 51% (±5%) of the nail at 14 months follow up. Based on the mean baseline lesion area and the mean follow up lesion area, absolute lesion reduction was calculated to be 32% and lesion reduction vs. baseline was calculated to be 75%. (Table 2). The physician rated the patient’s clinical outcome a 4 on the Global Aesthetic Improvement Scale (GAIS).

Lesion Reduction Determined by Area Calculated in ImageJ (cm²)

<table>
<thead>
<tr>
<th>Follow-Up Period</th>
<th># of Toes</th>
<th>Mean Baseline Lesion Area</th>
<th>Std. Dev.</th>
<th>Mean Follow-up Lesion Area</th>
<th>Std. Dev.</th>
<th>Absolute Lesion Reduction</th>
<th>Lesion Reduction (% Baseline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Months</td>
<td>2</td>
<td>83%</td>
<td>11%</td>
<td>51%</td>
<td>5%</td>
<td>32%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Table 2. Improvement as quantified as the lesion area reduction (% of baseline)

DISCUSSION

In our experience, the PinPointe laser procedure not only allows for significant growth of clear nail in toes infected with onychomycosis, but also produces high patient satisfaction. In this case study, the efficacy of the micro-pulsed 1064nm Nd:YAG laser was evaluated based on clear nail growth and reduced lesion area. The patient experienced a significant improvement in both areas. The clear nail area of the patient increased from 17% of the nail to 49% of the nail, and there was a 75% reduction in lesion area. In addition to the significant efficacy of the PinPointe laser procedure as demonstrated by planimetry measurements, the physician also noticed a significant improvement in the nail. Using the Global Aesthetic Improvement Scale, the physician rated the patient’s improvement as a 4, indicating that the nails were much improved and there was marked improvement in appearance from the initial condition. The results of this case study suggest that the PinPointe FootLaser is an effective option for the temporary increase of clear nail in patients with onychomycosis.

CONCLUSION

The PinPointe Foot Laser is an effective option that produces high patient and physician satisfaction. The laser procedure allows for clear nail growth without significant side effects or complications.
REFERENCES


12. National Institutes of Health

www.cynosure.com