Subject: Laser Treatment of Toenail Fungus

Background: Onychomycosis is a common fungal infection of the nail from dermatophytes, yeast or non-dermatophyte molds. It is estimated to account for 50-60% of abnormal nails, and can cause pain and disfigurement of the nail. Although treatment of onychomycosis may not always be necessary, options include topical, systemic antifungal drugs, laser treatment, photodynamic therapy (PDT), and surgery.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers laser treatment for onychomycosis experimental/investigational and it is therefore not covered.

Supporting Information:
Photodynamic therapy is a two-step drug and light therapy procedure used to induce selective damage to defined tissue. First, a topical photosensitizer is applied to the affected tissue. When the appropriate laser, or light source, is applied, the medication treated tissue is damaged without harming the surrounding normal tissue. Toenail onychomycosis is hard to treat and clinicians have begun to use forms of laser therapy to destroy the fungal infection.

Bristow (2014) reviewed a total of 12 eligible published studies evaluating the use of laser treatment for onychomycosis. The systematic literature search found that evidence pertaining to the efficacy of the procedure is limited and future studies with larger study populations are required for a full evaluation of this technology. Renner et al. (2015) used a diode laser treatment for onychomycosis to evaluate the efficacy of this treatment as a single therapy as well as in combination with an ongoing antimycotic treatment. Eighty-two toenails with a clinical diagnosis of onychomycosis were treated at least twice daily every eight weeks. All nails showed an improvement ranging between 14 and 56%. Two dermatologists evaluated 34 nails. Both reported significant improvement and/or good clinical improvement, which corresponds to about 41% for both evaluations. There was an improvement of about 25%. Specifically, the subgroup with positive antimycotic culture and no additional antimycotic treatment showed an improvement of about 25%. This improvement can be attributed to the effect of the diode laser treatment. Patient satisfaction was measured to an average value of 4.6 out of a maximum of 10 points. About 60% of the treated patients would recommend the treatment to their family members or friends. This investigation demonstrated that diode laser treatment of onychomycosis provides acceptable results with minimal to no side effects. Further clinical evaluations could help to establish better therapy protocols, especially for those patients who had no benefit from the laser treatment, or could also be used as an add-on to an existing therapy.

Ortiz et al. (2014) conducted a 24-week randomized placebo-controlled study to determine the efficacy and safety of 4 treatments with a 1,320-nm Nd:YAG laser in improving the appearance of onychomycosis in 10 patients. At 3-month follow-up, 50% of mycologic cultures were negative. Toenails had improvement in subungual debris, hypertrophy, and yellowing. The authors concluded that the 1,320-nm Nd:YAG laser may be a safe and effective therapy for improving the appearance to onychomycosis, however, further investigation is needed to explore optimal treatment setting and schedule.
Xu et al. (2014) compared the efficacy and safety of combined treatment with a long-pulsed 1,064-nm Nd:YAG laser and oral terbinafine with those of either treatment alone. A total of 53 patients, with a total of 90 infected nails, were randomly divided into 3 treatment groups: the T group received oral terbinafine, the L group received long-pulsed Nd:YAG laser treatment, and the T + L group received both treatments. The results indicated that 12 weeks of combined treatment with a long-pulsed Nd:YAG laser and oral terbinafine produce more rapid and effective mycological and clinical clearance in patients with onychomycosis than either treatment alone, without any obvious side effects.

El-Tatawy et al. (2014) compared the clinical and mycological efficacy of Nd:YAG laser versus topical terbinafine in the treatment of onychomycosis. The study included 40 patients with onychomycosis randomized to receive 4 sessions of Nd:YAG laser or topical terbinafine twice daily for 6 months. After 6 months, all patients in the laser group showed marked improvement, while in the topical group only 50% showed mild to moderate improvement. Additionally, 80% of patients in the laser group showed mycological clearance while all patients in the topical group still had positive cultures. The authors concluded that long pulse Nd:YAG laser therapy of onychomycosis is a safe and efficient method for treating onychomycosis.

A systematic review by Ledon et al. (2012) focused on laser and light therapies for onychomycosis. Their analysis found a clear need for further research, particularly randomized controlled trials, investigating the eradication and cure of onychomycosis. They go on to note lasers and light systems are relatively noninvasive treatments that are on the forefront of fulfilling that need, and although not FDA approved for cure, these laser treatments are currently being used clinically nationwide.

A small trial of 37 toes treated with a Nd:YAG laser was discussed by Kimura et al. (2012). Patients were followed for 16-weeks. Treatment was well tolerated by patients and no adverse events were reported. 81% of nails had moderate to complete clearance at 16 weeks' post-treatment. Nineteen toenails were completely clear and all tested negative for fungal infection on microscopic analysis. Kimura et al. felt preliminary results show the laser modality is safe and effective in the short-term. Further studies are needed to better assess the clinical and mycological benefits and optimize treatment protocol and parameters.

Qiao et al. (2010) reported on an evidence-based review of literature to evaluate the efficacy and safety of photodynamic therapy (PDT) for superficial mycoses. No RCTs were found. The review found the overall tolerability of PDT was good. PDT’s place for superficial mycoses remains unclear. Qiao et al. determined further clinical trials are needed to evaluate efficacy and to optimize treatment protocols to cope with recurrence.

Manevitch et al. (2010) used femtosecond infrared titanium sapphire lasers on nail cuttings from patients with onychomycosis caused by Trichophyton rubrum. Efficacy of the laser treatment was evaluated by subculture. Scanning electron microscopy was used to determine the laser-induced collateral damage. Fsec laser fluence of 7 x 10(31) photons m(-2) s(-1) or above successfully inhibited the growth of the fungus in all samples examined, whereas laser intensities above 1.7 x 10(32) photons m(-2) s(-1) affected the structure of the nail plate. Manevitch et al. concluded the femtosecond laser could be used to treat T. rubrum-mediated onychomycosis. Landsman et al. (2010) shared their experience with the Noveon, a dual wavelength near-infrared diode laser, used to treat onychomycosis. The 870- and 930nm near-infrared light wavelengths have unique photolethal effects on fungal pathogens. In the randomized controlled study, treatments followed a predefined protocol and laser parameters and occurred on days 1, 14, 42, and 120. Toes were cultured and evaluated, and measurements were taken from standardized photographs obtained periodically during the 180 day follow-up period. 26 toes were evaluated by an expert panel, blinded regarding treatment versus control, found at 180 days, 85% of eligible treated toenails were improved by clear nail linear extent, 65% showed at least 3mm and 26% showed at least 4 mm of clear nail growth. Of 16 toes with moderate to severe involvement, 10 improved, as shown by clear nail growth of at least 3mm. Simultaneous negative culture and periodic acid-Schiff was noted in 30% at 180 days. The results led the researchers to conclude there is a role for the laser in the treatment of onychomycosis, regardless of degree of severity.

Landsman and Robbins (2012) shared follow-up results of their 2010 trial with the Noveon laser. At 270 days, 38% of the treated population had negative culture and microscopy, qualifying as mycological cures.
Hochman (2011) reported data from 8 subjects treated with 2-3 sessions with a .65 millisecond pulsed 1064-nm laser. 7 of the 8 subjects had negative post-treatment cultures after the second or third session. 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.

Available published peer-reviewed literature supporting the efficacy of this intervention is limited and the mechanisms of action and optimal regimens remain unclear. More robust data to support routine use of this treatment is needed.

Hayes, Inc. (2016) investigated 18 abstracts consisting of randomized controlled trials, systemic reviews, retrospective chart reviews, comparison studies, case studies, a prospective clinical study, and a prospective pilot trial to present conflicting findings regarding the technology of laser treatment for toenail fungus. The evidence in peer-reviewed literature suggests that further studies are needed to confirm long-term efficacy for the treatment of onychomycosis by laser treatment.

The U.S. Food and Drug Administration granted a 510(k) approval for PinPointe on October 15, 2010 for the “for use for the temporary increase of clear nail in patients with onychomycosis.”

**Coding:**

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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**References:**


**Summary of Changes**

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