Treatment of Mild, Moderate, and Severe Onychomycosis Using 870- and 930-nm Light Exposure

Some Follow-up Observations at 270 Days

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We have previously reported the results of a clinical trial in which the Noveon laser was used to treat onychomycosis. In the 180-day follow-up therein it was noted that positive clinical impact was demonstrable by a clearly measurable decrease in positive fungal culture and a concomitant decrease in positive microscopy with periodic acid-Schiff-stained nail scrapings. Review of 270-day mycological data, which are now available, confirmed that there was further decrease in both measures. Indeed, 38% of the treated population had negative culture and microscopy, qualifying as “mycological cures.” These mycological cures occurred in cases categorized as mild, moderate, and even severe disease. (J Am Podiatr Med Assoc 102(2): 169-171, 2012)

In a previous publication we reported our experience using the Noveon (Nomir Medical Technologies, Brooklyn, NY) laser to treat onychomycosis in a randomized, institutional review board–approved study. That study was designed as a Food and Drug Administration pivotal trial. The end points for that study were specifically chosen to demonstrate clinical efficacy and safety.

The end points were:

1. Clinical efficacy
   a. Demonstration of at least 3 mm of clear nail growth in a significant number of the study group.
   b. Mycological improvement judged by negative culture or periodic acid-Schiff (PAS) microscopy.
   c. Clinical improvement as judged by the investigators and an independent panel.

2. Documentation of the lack of serious adverse outcome.

That report documented in detail, the methods employed, the patient population, the protocol followed, and the results obtained through a 180-day follow-up period of observation. The starting point for follow-up was coincident with the first of four treatments, given respectively on days 1, 14, 60, and 120 of the study.

In this correspondence we wish to provide additional results through extended follow-up to day 270, on 36 of the 40 treated toes in that series of patients. All participants had been advised to continue clinical care to avoid recurrence, re-infection, or progression of disease. This guidance included proper nail clipping, as well as use of antifungal topical cream to control tinea pedis.

No delayed adverse events of any kind were observed.

Clinical Assessment

There were photographic data available for only 34 of the 40 toes. Of those 34, 35% were determined to have continued improvement by direct inspection, in measurement of linear clearing of the nail plate, or in measurement of increased clear area of the nail plate. Thirty-eight percent were considered not to have changed since the 180-day assessment, and 20% were considered to have worsened.

There were 3 toes (8%) of the overall treated population of 40, that were considered to have attained a completely normal appearance at some point during the 270-day period of follow-up, that is
were classified in the category as “clinical cure.”

The first case was judged severe at the outset, as the infection clearly involved the entire nail. The other two cases were judged to be mild to moderate at the outset of the study. In neither of these two cases was there any evidence of deformity or dystrophic appearance of the nail at the outset.

Importantly, in no case was deformity or dystrophic appearance noted to evolve during the 270-day period of follow-up. This fact is consistent with the expected level of safety of the treatment to the nail matrix or growth center.

**Mycological Assessment, Mycological Cure**

The results of serial samples from those toes that were originally culture positive, and the results from those that were originally PAS positive were separately tracked throughout the follow-up period and are shown in Figure 1. The observed trend line of decreasing positivity of each is corroborated by a steady increase in the number of toes with simultaneous negative culture and PAS (“mycological cure”) as illustrated in Figure 2. Importantly, at the 270-day mark, 15 of 40 (38%) of all treated toes were mycologically cured. The severity of the disease at the outset of treatment of those 15 toes was: 33% mild, 20% moderate, and 47% severe.

**Complete Cure**

As noted above, overall at 270 days there were 3 toes (8%) that were classified as clinical cures. All three were mycological cures as well, and therefore each qualified as a “complete cure.”

**Onychomycosis Cure**

There were 16 instances (40%) in which there was negative mycology, as judged by negative culture, negative microscopy, or both, and with only minimal distal subungual hyperkeratosis, minimal nail plate thickening, or both. These meet the criteria defined by Scher et al that would qualify each as an “onychomycosis cure.”

**Comment**

There are two important conclusions to be drawn from this review of the available 270-day data:

1. Indication of persistent infection in the treated population continued to fall throughout the 270-day follow-up period as measured by culture, by microscopy of PAS-stained nail samples, or by both in combination.

2. In addition, the data clearly show this outcome can be effected regardless of the severity of the disease. As such, it gives strong indication that the Noveon laser offers a unique, low-risk option to potentially eliminate and then control the infecting fungal agent.
However effective this device may be, it must not be viewed as a panacea unto itself. Its use must be part of careful clinical adherence to a well-defined program that will hopefully avoid recurrence. Since there is no drug left by the laser in the nail, as is the case with oral or topical pharmaceuticals, it is mandatory that the patient be guided to vigorously follow proper methods to avoid reinfection.3

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Conflict of Interest: Dr. Robbins was formerly an employee of Nomir Medical Technologies, Inc and continues to have a financial interest in the company.

References