

# A Retrospective Two Year Study of 199 Patients at 12 Clinical Sites, Following Treatment of Mycotic Toenails with the Noveon Laser

Both providers and patients reported satisfaction with this therapy.

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This study was designed as a retrospective, open-label, multiple-center study for collection of retrospective data, in order to evaluate the effectiveness of onychomycosis treatment with the Noveon® NaiLaser™. The Noveon is a photo-biologic, automatic, computer-controlled, and hands-free laser that is FDA-approved to treat onychomycosis, and accomplishes this task with minimal heat and no laser plume. Data was collected on 199

data. The top-line data was reported as (a) 95% of patients saw improvement in their condition from baseline, (b) there was an 87% reduction in toes assigned a score of 'severe infection' to a lower level infection score, (c) 32% of toes achieved a 'complete cure' (no visible sign of infection) and (d) there were no adverse effects reported for any patient.

## Introduction

In the last five years, podiatry has seen an explosion of interest in the

**In the last five years, podiatry has seen an explosion of interest in the use of laser therapy for the treatment of onychomycosis.**

subjects (687 toes) to evaluate the effectiveness of Noveon treatment in 12 different sites across the United States. Each doctor was asked to submit data with no preference given to quality of outcome. The goal was to compile data on results as they were occurring in real-time in the field, and doctors had no interaction with each other in preparing their

use of laser therapy for the treatment of onychomycosis. Yet as Gupta, et al. and Elewski, et al. (both dermatologists) have reported on numerous occasions, there has been a dearth of prospective and peer-reviewed data from the first generation laser technology for onychomycosis, the thermal Nd:YAG laser.<sup>1-5</sup>

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## New Concepts and Studies

***“New Concepts” is a forum for the presentation of (1) new technologies and products which have been the subject of clinical study, and (2) new studies involving existing products. Readers should be aware that Podiatry Management does not specifically endorse any of the technologies, concepts, or products being discussed.***

## Noveon Laser (from page 137)

In contrast, the newly FDA-approved Noveon photo-biologic laser, has published its prospective in vitro bench science (2009), prospective pivotal data (2010), and retrospective 270-day assessment of its pivotal trial (2012) in the *Journal of Photochemistry and Photobiology* and the *Journal of the American Podiatric Medical Association*.<sup>6-9</sup>

The following study is a retrospective, open-label, multiple-center collection of retrospective data evaluating the treatment of 199 subjects treated with the Noveon in 12 different sites across the United States.

The Noveon laser is the first laser to be FDA-approved with the real world provision of treating concurrent tinea pedis with topical approved OTC pharmacologic means, while employing the laser to treat onychomycosis. The data collected

from this retrospective study reflects this new and improved indication.

### Methods

Twelve doctors from different sites in the United States took part in the study. Each clinician submitted data with no preference given to quality of outcome, and had no interaction with other clinicians in preparing their data. For each individual patient, the clinician com-

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Figure 1: Baseline and Day 270 (4 Treatments)



Figure 4: Baseline and Day 180 (4 treatments)



Figure 2: Baseline and Day 210 (4 treatments)



Figure 5: Baseline and Day 120 (4 treatments)



Figure 3: Baseline and Day 180 (4 treatments)



Figure 6: Baseline and Day 60 (3 treatments)



Figure 3: Baseline and Day 180 (4 treatments)



Figure 6: Baseline and Day 60 (3 treatments)

*Noveon Laser (from page 138)*

pleted a one-page questionnaire, assessing (a) the degree of toenail infection before treatments and after all treatments, (b) how many treatments each patient received, (c) total elapsed time since treatment was

- Male: 78 (39.2%)
  - Average age: 54 years old
- The total number of infected toes treated was 687.

### **Treatment Protocol**

Doctors determined the appropriate treatment protocol with the

tinea pedis sprays on the feet to treat concurrent tinea pedis, and on the nails to prevent re-infection. The patients in the study received between two and six Noveon treatments each, with 90% of patients receiving either three or four treatments.

### **Onychomycosis Assessment**

Each patient was assessed by visual inspection by the clinician for an estimate of onychomycosis infection. Clinicians may have employed additional diagnostic techniques, such as cultures, to clinically determine the presence of fungal and/or yeast infection. Clinicians were requested to compile visual data for each toe treated at two points in time.

1) The first observation ('before') reflected the degree of infection seen at the time treatment began.

2) The second observation ('after') reflected degree of infection seen after treatment was complete.

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## **Doctors determined the appropriate treatment protocol with the Noveon® NaiLaser™ for each patient based on their own criteria.**

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started, (d) the level of patient satisfaction, and (e) if any adverse effects were observed. Patient gender and age were also recorded.

The 12 clinical sites submitted data on a total of 199 patients treated with the Noveon, with a demographic breakdown of:

- Female: 121 (60.8%)

Noveon® NaiLaser™ for each patient based on their own criteria. The device is pre-set with "hands-free" treatment dosing (time, power, and spot size pre-sets) for both large and small toes, and can treat four toes simultaneously, large and small, on both feet. All patients were recommended to use OTC liquid antifungal

Noveon Laser (from page 139)

The suggested 'after' timeframe was 180 days, but doctors took observations at whatever timeframe was available to them. As a result, the 'after' observation timeframe varied from 120 days to 379 days. Clinicians were asked to visually assess the degree of nail infection present in each toe on a 4-point numerical scale as follows:

- a) '0'—no visually observable onychomycosis
- b) '1'—mild onychomycosis
- c) '2'—moderate onychomycosis
- d) '3'—severe onychomycosis covering 60% of the toe or more

The results of these assessments were 20 clinician-assigned data points per patient for a total of 3,980 data points across the 199 participating patients.

**Treatment Effectiveness (Figures 1-6)**

The study data show a dramatic reduction in severity of onychomycosis in the patient population when comparing before and after Noveon treatments. The study measured this improvement in a variety of ways based on visual assessments by doctors.

- a) Toes scored 'severe' dropped from 293 before to just 38 after—an 87% reduction.
- b) Toes scored 'none' (no visually detectable infection) jumped from 0 to 222.
- c) Average infection score

dropped from 2.26 before to 0.96 after (on '0' to '3' scale).

**Adverse Effects**

Doctors were asked if they observed any adverse effects in their patients during or after treatment and, if so, to describe what those were. No adverse effects of any kind were reported.

**Patient Satisfaction**

The vast majority of patients were pleased with their treatment and the reduction in onychomycosis severity.

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Clinicians asked patients to rate their satisfaction on a 4-point scale from very satisfied to dissatisfied. Over 80%—were 'satisfied' or 'very satisfied' with their Noveon® NailLaser™ results.

**Conclusions**

The retrospective study compiled onychomycosis treatment data from 199 patients (687 toes) and 12 doctors before and after treatment with Noveon® NailLaser™.

The data show that a diverse group of podiatric clinicians achieved success using this newly FDA-approved laser within their practices to treat onychomycosis with a high degree of patient satisfaction.

- 95% of patients experienced improvement.
- 87% reduction in toes assigned a 'severe' score.
- 32% of toes experienced a 'complete cure' (i.e., no visual signs of infection).
- No adverse effects.

This study adds evidence to an already existing large peer-reviewed data base, and prospective published Noveon studies, for the use of the Noveon laser for the treatment of onychomycosis. **PM**

*Disclaimer: Dr. Eric Bornstein is the Founder and Chief Science Officer of Nomir Medical Technologies and maintains a monetary interest in the company.*

**References**

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<sup>6</sup> Bornstein, Eric, et al. "Near-infrared Photoinactivation of Bacteria and Fungi at Physiologic Temperatures." Photochemistry and photobiology 85.6 (2009): 1364-1374.

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<sup>9</sup> Landsman, Adam S., and Alan H. Robbins. "Treatment of Mild, Moderate, and Severe Onychomycosis Using 870-and 930-nm Light Exposure Some Follow-up Observations at 270 Days." Journal of the American Podiatric Medical Association 102.2 (2012): 169-171.



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