

Noveon Laser Retrospective Study

Onychomycosis Treatment Findings

Highlights

- **199 patients at 12 clinical sites**
 - **95% of patients saw improvement in their condition**
 - **87% reduction in toes assigned a ‘severe’ infection score**
 - **32% of toes achieved a ‘complete cure’ (no visible sign of infection)**
 - **No ‘adverse effects’ reported for any patient**
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The Noveon Laser Retrospective Study involved 199 patients at 12 different clinical sites. The study was designed to assess Noveon efficacy in treating onychomycosis under normal practice conditions.

Methodology

Twelve doctors from around the country participated in the study. Each doctor was asked to submit data with no preference given to quality of outcome or other factors. The goal was to compile data on results as they were occurring in the field. The doctors had no interaction with each other in preparing their data. All patient data was collected in 2011.

For each patient, the doctor completed a one-page questionnaire. The questionnaire asked the doctor to assess the degree of toenail infection for each patient before treatments began and after all treatments were completed. It also asked (a) how many treatments each patient received, (b) the total elapsed time since treatment was started, (c) the level of patient satisfaction, and (d) if any adverse effects were observed. Patient gender and age were also recorded.

Patient Demographics

The 12 clinical sites submitted data on a total of 199 patients treated with Noveon Laser. Patients per doctor data ranged from a maximum of 30 to a minimum of 7 with the average being 16.6.

The demographics of the patient population are as follows:

- Female: 121 (60.8%)
- Male: 78 (39.2%)
- Average age: 54 years old

Disclaimer: Noveon Laser has been cleared by the FDA for treatment of general podiatry and dermatology conditions. It has not been cleared specifically for onychomycosis.

In terms of the prevalence of onychomycosis infection among the patient population, the following data were exhibited at the outset of treatment:

- Total number of infected toes: 687
- Average number of infected toes per patient: 3.5

Treatment Protocol

Doctors determined the appropriate treatment protocol for each patient based on their own criteria. Patients in the study received between 2 and 6 Noveon Laser treatments each with 90% of patients receiving either 3 or 4 treatments. A total of 668 Noveon treatment sessions were administered.

Onychomycosis Assessment

For the purposes of the study, we relied on visual inspection by the doctors for their assessment of onychomycosis infection. Doctors may have employed additional techniques, such as cultures, to clinically determine the presence of fungal and/or yeast infection.

Doctors were asked to compile visual data for each toe at two points in time. The first observation ('before') reflected the degree of infection seen at the time treatment began. The second observation ('after') reflected degree of infection seen after treatment was complete.

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.

Doctors were asked to visually assess the degree of nail infection present in each toe on a 4-point numerical scale as follows:

- **'0'** – **no visually observable** onychomycosis
- **'1'** – **mild** onychomycosis
- **'2'** – **moderate** onychomycosis
- **'3'** – **severe** onychomycosis covering 60% of the toe or more

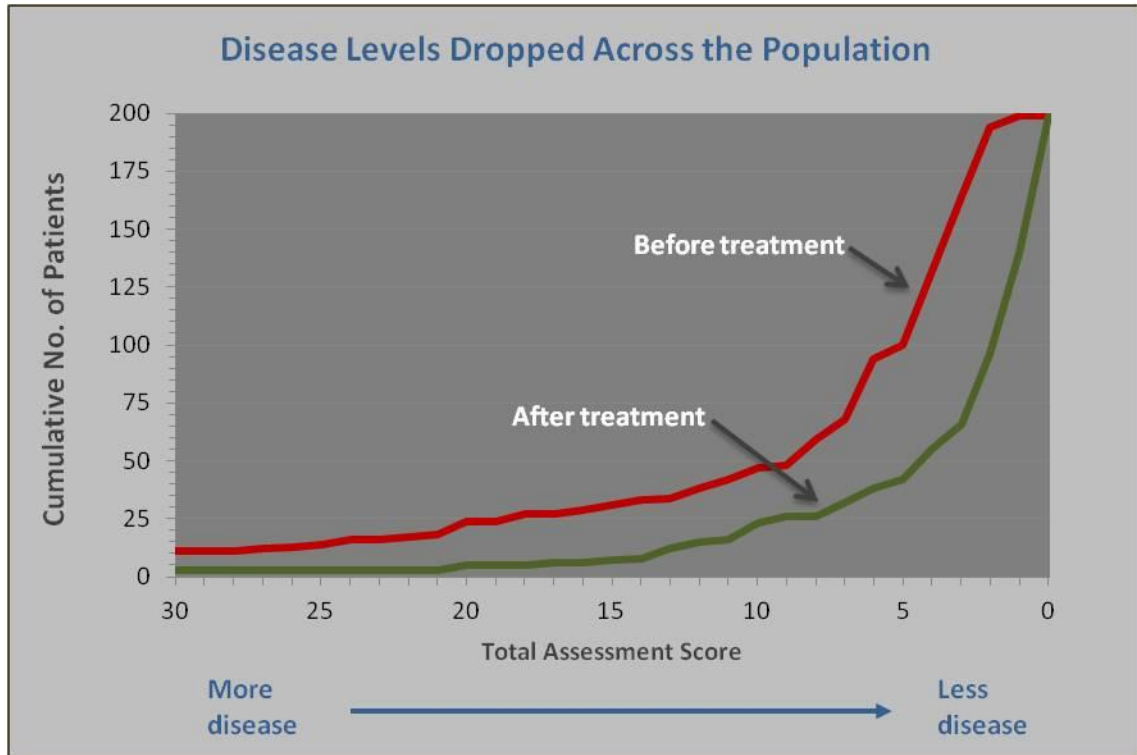
The result of these assessments was 20 doctor-assigned data points per patient for a total of 3,980 data points across the 199 participating patients.

Treatment Effectiveness

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

The following charts illustrate the positive impact of Noveon in reducing nail disease within the patient population.

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Horizontal axis: 'Total assessment score' is the per patient sum of toe assessments using a '0' (none) to '3' (severe) scale. Example: 5 infected toes each scoring '2' equals total score of 10.

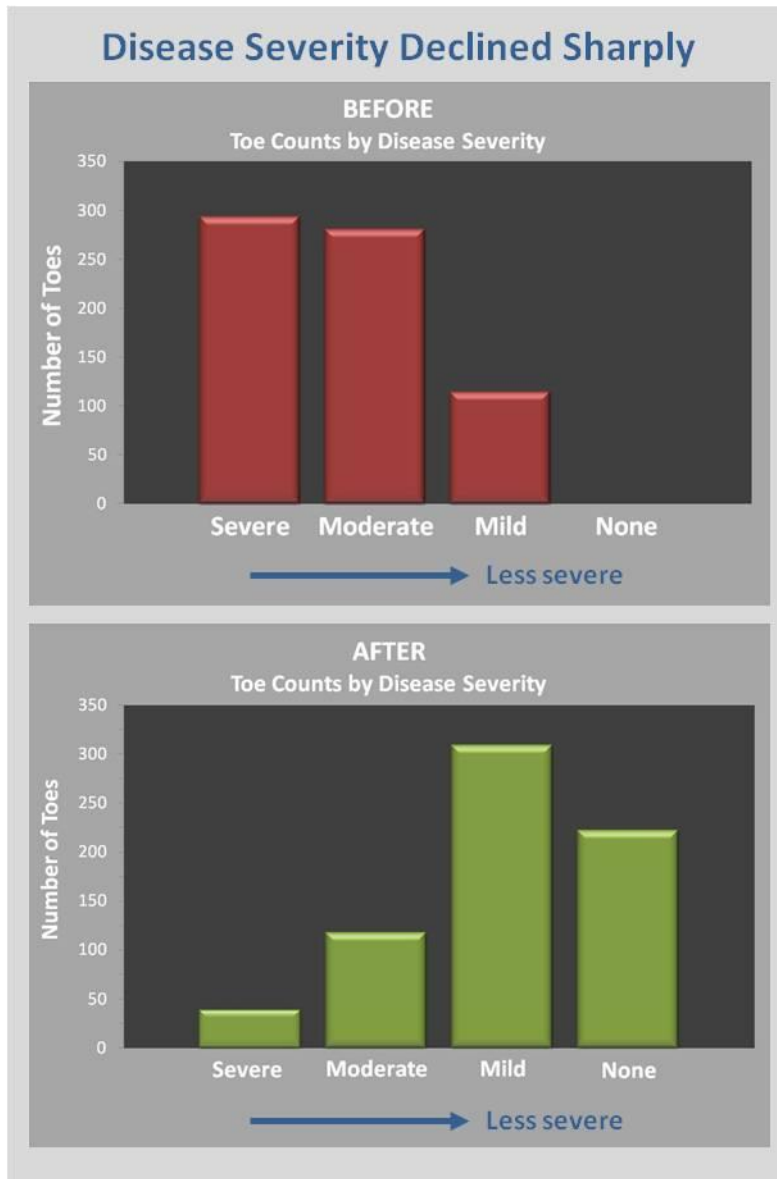
Vertical axis: Shows the cumulative number of patients at each score. A lower number is better.



Horizontal axis: 'Toe position' is a numbered ordering of the toes from left to right as if looking down at your own toes. Position #1 is the left pinky toe. Position #10 is the right pinky toe. Positions #5 and #6 refer to the left and right great toes, respectively.

Vertical axis: Measures cumulative onychomycosis assessment scores for each toe for all patients. A lower score means less disease. A higher score means more disease.

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Horizontal axis: Measures the severity of onychomycosis. Severity decreases from right to left.

Vertical axis: Tallies the total number of individual toes for each level of severity.

The charts above show a strong shift from left to right – meaning a sharp decline from more severe to less severe disease. The shift is approximately 2 bars (meaning 2 points on the 4-point assessment scale).

- Toes scored 'severe' dropped from 293 before to just 38 after – an 87% reduction.
- Toes scored 'none' (no visually detectable infection) jumped from 0 to 222.
- Average infection score dropped from 2.26 before to 0.96 after (on '0' to '3' scale).

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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 patients themselves were generally happy with their Noveon treatment results. Doctors asked patients to rate their satisfaction on a 4-point scale from very satisfied to dissatisfied. The vast majority – over 80% - were ‘satisfied’ or ‘very satisfied’ with their results.



Conclusions

The Noveon Laser Retrospective Study compiled onychomycosis treatment data from 199 patients and 12 doctors before and after treatment with Noveon Laser.

The study data show that a diverse group of podiatrists is having solid success using Noveon Laser under normal practice conditions. With few exceptions, Noveon patients completed treatment with significantly less infection than when they started treatment.

- 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

For more information, please contact Rick MacDonald at rmacdonald@nomirmedical.com or 508-405-2701.

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