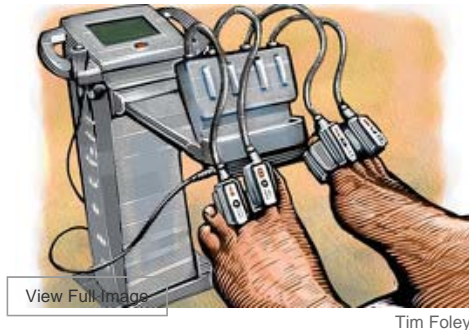


Fungus Got Your Toes? Zap It

By LAURA JOHANNES



A growing number of doctors are offering an expensive laser procedure they say zaps away a common fungus that causes ugly, discolored nails. Published data on laser treatment for nail fungus is scant, but early results suggest it is a reasonable option for people who don't want the side effects of oral medications.

Onychomycosis, or fungal infection of nails—most often on the toes—affects about 12% of Americans, according to the American Academy of Dermatology. Some people are genetically prone to it. Others, including swimmers and other athletes, may be more likely to get it because they go barefoot in public areas or because their feet are often damp, scientists say. In its mild

forms, nail fungus is merely a cosmetic problem, but over time it can cause toenails to grow abnormally and become painful when walking.

Toenail laser treatment offers a new alternative to oral medication, which carries a risk of liver damage, and a nail lacquer, which has poor efficacy.

The cost of zapping nail fungus with a laser can range \$750 to \$1,500 for a treatment course. It isn't generally covered by insurance. Whether you choose oral medications or lasers, it can easily take a year for nails to clear entirely.

So far only one company's laser has received Food and Drug Administration clearance, which is a streamlined review process for medical devices, for toenail fungus: PinPointe USA Inc., of Chico, Calif., received clearance in October to market its laser for "the temporary increase of clear nail" in patients, according to the FDA clearance letter. Two companies, Nomir Medical Technologies Inc. of Brooklyn, N.Y., which first applied in 2009, and CoolTouch Inc., of Roseville, Calif., have applied for FDA clearance for the nail-fungus purpose and are waiting for an FDA decision.

Several other lasers, cleared by the FDA for other purposes, are being used "off label" by doctors to treat toenail fungus.

Solid evidence of the lasers' effectiveness, is scant. In clinical practice, results have varied, according to doctors who have used the laser. New Jersey podiatrist Anas Khoury, who has no affiliation with any laser company, says he has been using Nomir's Noveon laser for toenails for about four months and says it works in about 80% of his patients. "My patients and I are very happy with it," he adds.

Philadelphia podiatrist Warren Joseph, who is a consultant for Nomir and a former consultant for PinPointe, says: "I think it is a really interesting, viable alternative but I want to see published data." His advice to patients: "Ask for the evidence—and not just before-and-after pictures."

Treatments typically take 30 to 45 minutes for up to 10 toes. Depending on the severity of the problem and the laser used, patients may need one to four treatments.

How the lasers work varies and how they affect toenail fungus isn't fully understood in all cases. Nomir says its lab research shows its laser kills fungus. CoolTouch says it believes its laser inhibits fungal growth, paving the way for the body's own defenses to clear the nail.

So far only Nomir has published evidence of efficacy, but its study is small and short term. A company-funded study of 34 patients and 26 treated toes published last year in the *Journal of the American Podiatric Medical Association* found that after four laser treatments, 85% of the nails showed new growth without fungus. Of the total, 65% showed at least three millimeters of clear new nail and 26% had at least four millimeters. The study took its final measures six months after treatment, but hasn't yet published the data.

PinPointe supplied *The Wall Street Journal* a summary of unpublished data from a study looking at 265 patients over two years. In the summary, 71.4% of the patients experienced continuous improvement over a year after a single session with its laser.

If you are willing to risk side effects, the best tested—and likely most effective—treatment for toenail fungus remains oral medications such as Novartis AG's Lamisil, says Bryan C. Markinson, chief of podiatric medicine at Mount Sinai School of Medicine in New York. Dr. Markinson has been a paid adviser to Novartis and owns stock in Nomir and serves on its medical-advisory board.

According to Lamisil's FDA-approved prescribing information, 3.3% of patients in clinical trials had abnormal levels of liver enzymes, a possible warning sign of liver damage, compared with 1.4% of people taking a placebo. In rare cases, people have needed liver transplants or died from liver failure after taking Lamisil.

To prevent fungus recurrence, you must follow a scrupulous hygiene program, including anti-fungal spray for feet and shoes, not going barefoot, keeping feet clean and dry and changing socks daily, doctors say.

"Patients and some doctors have this expectation that because it's a laser treatment, once you zap it and it's gone forever," says Dr. Markinson. "That totally ignores the fact that this is an infectious disease and that recurrence is a certainty" unless good prevention measures are taken.

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