

# Clearing Onychomycosis through Low-Level Laser Therapy

The Nonthermal Lunula Laser offers painless, safe treatment for toenail fungus.

BY JOLYNN TUMOLO

**A** low-level laser that eradicates toenail fungus in just a few short treatments without heat, pain or any adverse effects? When podiatrist Robert Sullivan, MSc, clinical director of Middleton Foot Clinic in Ireland, came across Erchonia Corp. exhibiting its onychomycosis laser at a professional conference in Europe a few years back, he was dubious. And he didn't hesitate to share his thoughts.



Dr. Sullivan

"They were presenting their laser for sale based on a small research study. I thought that the population sample they had was too small and did not prove anything, so I challenged them on it," Sullivan recalled. "They told me that their lasers worked, and that they would stand by that fact. After a lot of talking and questions from me, they invited me to do a study. I was very skeptical."

Sullivan took them up on their offer. Over an 18-month period, he personally documented the effects of the low-level laser on 800 toes with onychomycosis. The success rate, he found, was an impressive 89%.

Some of the data from Sullivan's trial, ironically, made it into Erchonia's application for Food and Drug Administration approval to market the laser in the United States for

the treatment of onychomycosis. This past June, the Lunula Laser became the first low-level laser in the country to receive FDA 510(k) marketing clearance for onychomycosis.

Sullivan, by now a convert, was hardly surprised. The Lunula Laser had been an established part of his clinic's offerings for some time.

"I have used it in practice for the past 6 years," he said, "and have treated over 2,000 patients (with it)."

## The First Low-Level Laser for Onychomycosis

A portable device for use in healthcare practices, the Lunula Laser uses two low-level therapeutic wavelengths—405 nanometers (violet) and 635 nanometers (red)—to treat patients with onychomycosis. The

**Results come in as few as four weekly 12-minute sessions, which are painless and safe, according to Erchonia Corp.**

405-nanometer wavelength has antimicrobial, antibacterial and antifungal properties that attack toenail infection while the 635-nanometer wavelength ramps up the body's own immune response through improved circulation. A proprietary rotating line-generated laser beam maximizes both photon concentration and treatment surface area.

"Lunula is different insofar as it is cold laser and the client feels no heat. Sometimes there is a minor tingling," Sullivan explained. "Hot lasers treat only the nail, but the fungus can be resident in the skin around the nail. Lunula treats the entire dorsum of the foot and thus affects more of the fungus."

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Charlie Shanks

"It is a nonthermal laser that produces no heat, which means no discomfort for the patient, no smoke plume from the nail, and it's a completely unattended procedure," said Charlie Shanks, vice president of sales and marketing at Erchonia Corp. "The doctor can just turn the machine on for the 12-minute treatment and attend to other patients during that time."

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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.**

The Lunula Laser approval marked the 13th FDA market clearance for Erchonia devices. The US launch of the Lunula Laser this fall generated a buzz in the podiatry community, with sales exceeding the company's projections, Shanks said.

At the official presentation of Lunula Laser at the Superbones Superwounds West conference November 17-19 in Las Vegas, feedback from the 150 attendees, most of whom were podiatrists, was positive. Erchonia Corp. showcased the Lunula Laser at its exhibit booth and provided detailed clinical instruction on its use and documented effectiveness during two educational lectures and a workshop. Podiatrists especially appreciated the laser's portability, its ability to treat the whole foot and not just one nail at a time, and that anyone on staff can administer the unassisted procedure, representatives from Erchonia Corp. reported. The Lunula Laser's performance in clinical trials and its FDA 510(k) clearance inspired due respect from clinicians, too.

"We believe Lunula will be the gold standard treatment for onychomycosis in a very short period of time," said Shanks.



Steve Shanks

### From Concept to Clearance

The inspiration for using low-level laser therapy to treat toenail fungus was fueled by prior success combating methicillin-resistant *Staphylococcus aureus* (MRSA), according to Steve Shanks, founder and CEO of Erchonia. Kerry Zang, DPM, founder of the Arizona Institute of Footcare Physicians, Mesa, AZ, collaborated with Steve Shanks to play a key role in the laser's development.

"Originally, I spoke with Kerry," Steve Shanks said. "I had done some research on MRSA before. I thought, OK, if it can kill MRSA, maybe it's possible that we could treat onychomycosis. With the MRSA, we used 405 nanometers. I also know that red laser creates vasodilation. Obviously, these toes don't get a lot of blood flow; they have a fungus. That's why we combined the two wavelengths."

All in all, it was a 9-year span between the modality's conception to final FDA approval, recalled Dr. Zang, who served as lead podiatric medical research physician on the project. The process included numerous clinical trials.

In a pilot study finalized in December 2010, 168 toenails infected with onychomycosis, with an average nail involvement of 81.15%, underwent a 10-minute treatment



The Lunula low-level laser



with the Erchonia low-level laser. During evaluation an average 6 months later, the percentage improvement in clear, noninvolved toenails was 63.58% across all toes. No adverse events were reported.

In a subsequent study, researchers looked at the effect of two 10-minute low-level laser treatments, separated by a week, on 105 subjects with an average onychomycosis nail involvement of 57.39%. Three months after the final treatment, 62% of subjects had achieved a 25% or more increase in the percentage of clear noninvolved toenails. The mean percent improvement in clear nails was 30.36%. No adverse events were reported in the study, which was written in March 2011.

In another study finalized in December 2012, researchers gauged the efficacy of Lunula Laser treatment administered for 12 minutes once a week over 4 weeks. Among 109 participants, 139 toenails confirmed positive for onychomycosis through lab testing at baseline. Average onychomycosis nail involvement was 63.21%.

With success defined as 3 millimeters or more of clear toenail growth at 36 weeks after treatment, the study found 96% of treated nails met success criteria (Erchonia had aimed for a 60% success rate). By week 48, the mean percentage of onychomycosis toenail involvement had dropped to 2.49%, with the measurement of clear nail averaging 15.09 millimeters. No adverse events were reported.

A retrospective study, submitted to the FDA in October 2015 and which ultimately led to the Lunula Laser's approval, focused on a compilation of before-and-after photos of 54 great toenails, with varying degrees of onychomycosis involvement at baseline confirmed through lab testing. The treatment protocol was 4 sequential weekly 12-minute procedures with the Lunula Laser.

According to the results, some 67% of treated toenails met study success criteria, defined as 3 millimeters or more of clear nail growth at 6 months after the last procedure compared with baseline (Again, Erchonia had aimed for 60%). The magnitude of the increase in clear nail from baseline to

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6 months was 5.18 millimeters on average—2.18 millimeters more than pre-established success criteria.

“The Erchonia Lunula Laser is an effective tool for increasing clear nail in toenails infected with onychomycosis,” the study concluded, “significantly increasing millimeter of clear nail over a 6-month period following completion of the 4-week procedure administration phase.”

The FDA agreed and granted marketing clearance and the following indication for use: the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Trichophyton mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

“This concept was thoroughly researched,” said Dr. Zang, a fellow of the American College of Foot and Ankle Surgeons and diplomate of the American Board of Podiatric Surgery. “From first submission to FDA to final approval was 2,457 days.”

## Patient and Practice Impact

Behind the data are personal stories of patients looking for a noninvasive treatment for toenail fungus that

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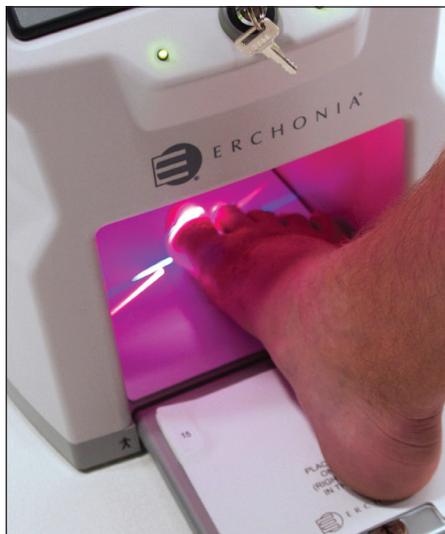
## Before starting treatment with the Lunula Laser, Dr. Zang educates patients on how to maximize healing and protect against reinfection.

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won't interfere with medicines they may be taking, cause discomfort, or lead to microbial resistance. For many, the Lunula Laser has been a game changer.

“Onychomycosis is really a psychosocial condition. Patients don't like having a fungus growing on them, so they seek treatment,” said Dr. Zang. “Many of our patients who seek treatment are men, between the age of 30 and 50, recently divorced and who are just starting to date again.”

Before starting treatment with the Lunula Laser, Dr. Zang educates patients on how to maximize healing and protect against reinfection. If a spouse or significant other also has onychomycosis, he agrees to treatment only if both undergo it at the same time. While patients receive Lunula Laser treatment, their shoes are slipped into a gas sterilizer. Dr. Zang provides antifungal spray for patients to use after wearing closed toe shoes, and he explains that toes should be scrubbed daily while showering. Pedicures should be received only at reputable salons with sterilized equipment and should involve the patient's own nail polish and remover—



A foot being lasered

which should be newly purchased following Lunula Laser treatment. Patients are also advised to spray down showers with Tilex or another cleaner after their last onychomycosis treatment.

“I remind patients that fungus is everywhere in our environment and that their risk of reinfection is ever present,” Dr. Zang said in a FAQ on the Lunula Laser website. “In order to control fungus, they must practice daily foot hygiene.”

In recent years, laser therapy has grown in popularity due to the often inconsistent results of mainstay therapies, according to Dr. Zang. The unique low-level laser approach Lunula offers will appeal to patients wanting a safe and subtle treatment option, he predicted, and will add to a practice's revenue stream.

“Lunula should have a strongly positive impact on private practices as this technology will allow them to treat patients with a device that is effective 80% or more of the time, painless, and doctor-friendly, as the treatment can be administered by a medical assistant and is absolutely safe and without any negative side effects,” Dr. Zang said.

## The Difference Lunula Can Make

In Ireland, nail fungus can be a big problem—even more so than in the United States, according to Sullivan.

“The climate in Northern Europe is very damp and can be very cold. Shoes come off for only a few weeks of the year,” he said. “When a podiatrist here sees a fungal nail, it usually involves the total nail and is often up to a centimeter thick.”

Lunula Laser treatment can make a significant difference, physically and emotionally.

“Reducing this thickness gives the client vast relief. Treating and eradicating the fungus gets rid of the psychological factors,” Sullivan said. “One client told me that it was like having her feet back again.”

Having a Lunula Laser onsite has freed up clinical time and generated its own patient load at Middleton Foot Clinic.

“What other clinicians need to know is that this is a hands-free, revenue-efficient way to treat fungus on the nail that has a high success rate with no noted side effects,” he said.

Through research and experience, Sullivan's initial disbelief at Erchonia's Lunula Laser claims has shifted to belief, with a fair amount of devotion thrown in for good measure.

“This laser is produced by people who care about people. The support I have received from Steve Shanks and his team makes you feel part of an organization of caregivers and not just a guy who uses their lasers,” he said. “When you buy this product, you get real support, real commitment, real results.” **PM**



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