LunulaLaser™ BY ERCHONIA

Have Beautiful Feet Again

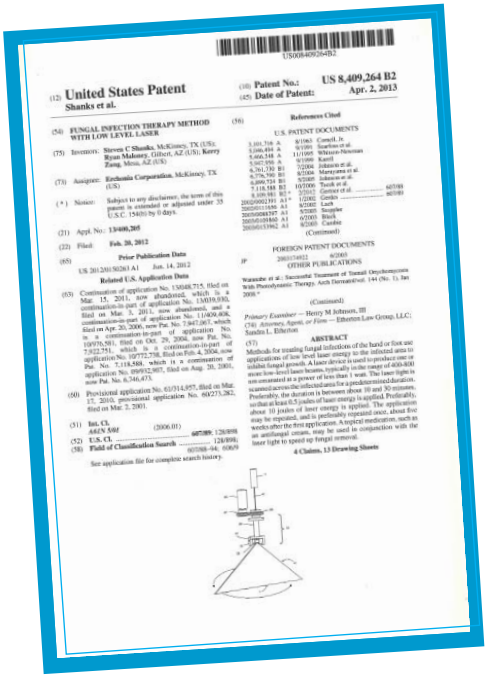
With the first and only non-thermal FDA cleared Laser device to treat onychomycosis

THE COMMITMENT TO RESEARCH

Since 1996, Erchonia, the manufacturer of Lunula, has been committed to fully elucidating the medical utility of low level laser therapy through rigorous clinical studies. For almost 2 decades, Erchonia has studied the clinical utility of low level laser devices for the treatment of numerous medical ailments. Their recent device, Lunula, looks to revolutionize the way the medical community treats onychomycosis.

Lunula has been markedly studied – from the early in-vitro analysis to the extensive in-vivo studies – and its clinical utility to treat painful and unsightly toenail infections has been substantiated. The unique dual-diode approach of Lunula effectively targets the causative infectious agent while fortifying the body's natural defense mechanisms. This multifaceted approach is the first of its kind, providing patients with a truly effective, yet safe, treatment for onychomycosis.

As you will quickly learn, Lunula is supported by an unwavering clinical foundation of both histological and clinical evidence that upholds the viability of this approach and ensures an effective treatment for your patients suffering with onychomycosis. In fact, Lunula is so unique, Erchonia has filed multiple method and device patents specific to Lunula.



(12) **United States Patent**
Shanks et al.

(10) **Patent No.: US 8,409,264 B2**
(45) **Date of Patent: Apr. 2, 2013**

(54) **FUNGAL INFECTION THERAPY METHOD WITH LOW LEVEL LASER**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/400,205**

(22) Filed: **Feb. 20, 2012**

Prior Publication Data

US 2012/0150263 A1 Jun. 14, 2012

Related U.S. Application Data

(63) Continuation of application No. 13/048,715, filed on Mar. 15, 2011, now abandoned, which is a continuation-in-part of application No. 13/039,930, filed on Mar. 3, 2011, now abandoned, and a continuation-in-part of application No. 11/409,406, filed on Apr. 20, 2006, now Pat. No. 7,947,067, which is a continuation-in-part of application No. 10/970,501, filed on Oct. 29, 2004, now Pat. No. 7,922,751, which is a continuation-in-part of application No. 10/772,758, filed on Feb. 4, 2004, now Pat. No. 7,118,588, which is a continuation of application No. 09/893,805, filed on Aug. 30, 2001, now Pat. No. 6,746,473.

(60) Provisional application No. 61/314,957, filed on Mar. 17, 2010, provisional application No. 60/273,282, filed on Mar. 2, 2001.

(51) **Int. Cl.**
A61N 5/06 (2006.01)

(52) **U.S. Cl.** 607/89; 128/898

(58) **Field of Classification Search** 128/898; 607/88–94, 606/9

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

(Continued)

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(Continued)

OTHER PUBLICATIONS

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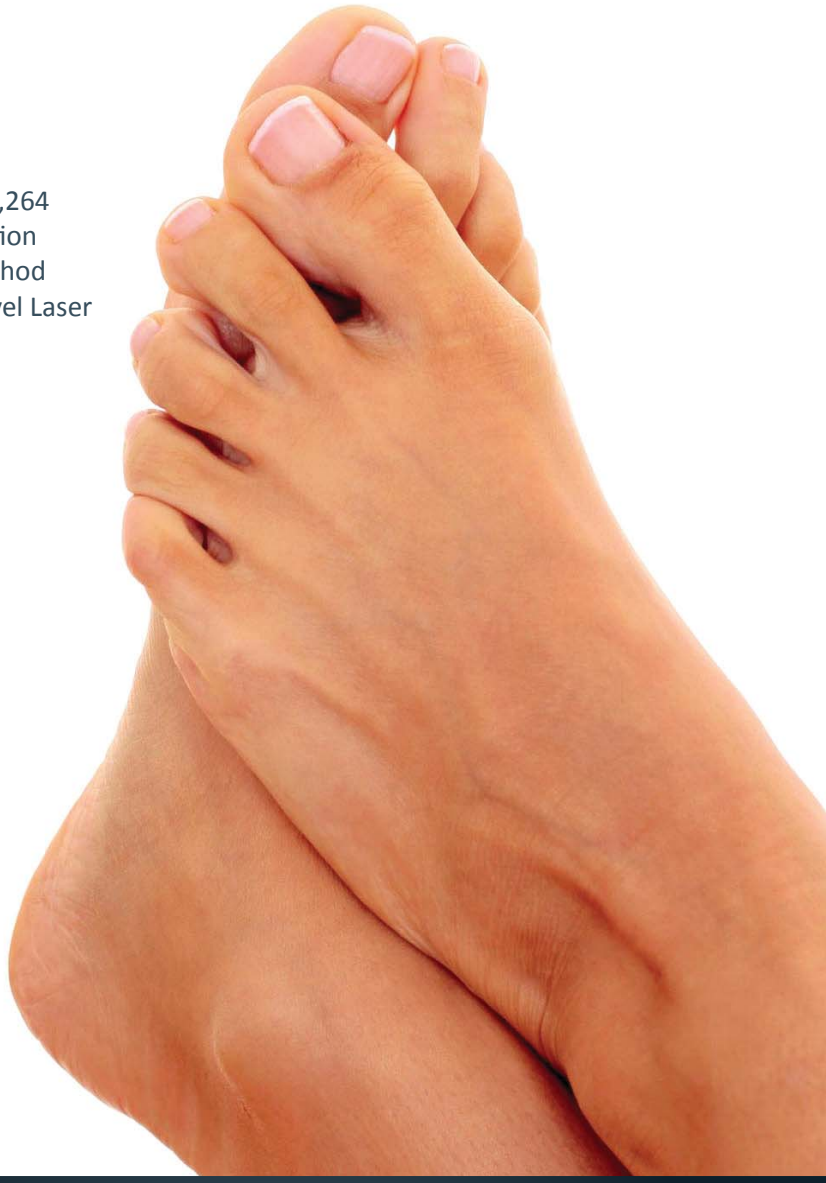
ABSTRACT

(57)

4 Claims, 13 Drawing Sheets

US Pat 8,409,264
Fungal Infection
Therapy Method
with Low Level Laser

US PAT 6,013,096; US PAT 6,746,473;US PAT 8,409,264; US PAT 8,814,924; US PAT 8,097,029; US PAT 7,118,588; US PAT 7,947,067; US PAT 7,922,751 and several U.S. and International Patents Pending.



LUNULA SAFELY TREATS TOENAIL FUNGUS IN AS LITTLE AS FOUR 12-MINUTE PAINLESS TREATMENTS

Lunula's clinical utility for the treatment of onychomycosis has been substantiated by independent clinical investigations. The European study consisted of 320 patients (2320 toes) subject to laser irradiation at 405nm and 635nm for twelve minutes at weekly intervals for four weeks. The United States study consisted of 54 great toenails subject to laser irradiation at 405nm and 635nm for twelve minutes at weekly intervals for four weeks. This study was used to obtain the Lunula Laser 510(k) FDA market clearance. Sixty seven per cent (67%) of all study treated toenails evaluated in this study met the study individual toenail success criteria. The average clear nail growth was an increase in 5.18mm.* Equally important, the clinical responses observed in all four trials were achieved without a single adverse event.

DID YOU KNOW?

Lunula has been studied both in-vitro and in-vivo.

*Individual Results May Vary.

HOW THE COMPETITION STACKS UP TO LUNULA

	Lunula Laser U.S. Clinical Study	Lunula Laser European Clinical Study	Pinpoint	Laser Genesis Plus	Cool Breeze	Noveon (Normir)	Podylas 30′
Wavelength(s) Used	635/405nm	635/405nm	1064nm		1320nm	870/930nm	1064nm
Non-Thermal	YES	YES	NO	NO	NO	NO	NO
Physical Contact with Toe	NO	NO	YES	YES	YES	YES	YES
Required Debridement of Nails	NO	NO	YES	YES	YES	YES	YES
Treatment Spot Size	28.62cm2	28.62cm2	2-10mm	2-10mm	2-10mm	2-10mm	2-10mm
Complete Effective Treatment Coverage	YES	YES	NO	NO	NO	NO	NO
Treatment Time	12 min/ 5 toes	12 min/ 5 toes	4.5 min/ toenail*	4.5 min/ toenail*	4.5 min/ toenail*	4.5 min/ toenail*	4 min/ toenail*
Number of Treatments	4	4	4	4	~3	4	4
Application of Topical Antifungal to Toes	NO	NO	YES	YES	YES	YES	YES
Toes Studied	54	2320	17	N/A	N/A	26	N/A
Mean mm Nail Clear Nail at 3 Months	5.18	N/A	3.7	N/A	N/A	Not Reported	N/A
Percent of Subjects Showing Improvement at 3 Months	67%	N/A	71.4	N/A	N/A	N/A	N/A

*Not including potential debridement time.

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3. Harris DM, J Strisower, B McDowell. Pulsed laser treatment for toenail fungus. SPIE Proceedings 7161A121, 2009.
4. Landsman AS, Robbins AH, Angelini PF, Wu CC, Cook J, Oster M, Bornstein ES. Treatment of mild, moderate and severe onychomycosis using 870- and 930-nm light exposure. JAPMA;100(3):166-177.
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ORAL MEDICATIONS

The limitations and risks of oral anti-fungal medications have been well documented. First, treatment of the body's most distal region – the toes - with an oral anti-fungal medication is often greeted with non-response or high rate of recurrence due to limited drug bioavailability routinely caused by insufficient blood flow. Next, the infectious agent is a eukaryote, and therefore, shares structural and biochemical similarities with our body's eukaryotic cell. As a result, our own important biochemical pathways can be negatively affected by oral anti-fungals. Although quite rare, hepatotoxicity has been reported in patients taking oral anti-fungal medication. To mitigate the risk of liver complications, patients with specific pre-existing medical conditions cannot be prescribed oral anti-fungal medications, ***but for those patients who are taking anti-fungals, they must undergo routine liver function tests throughout the treatment course.*** Non-response, high-rate of recurrence, limited to certain patients, and serious risk of adverse events – these represent the drawback of oral anti-fungal medications.

HISTOLOGY - LUNULA MECHANISM OF ACTION

LunulaLaser is a dual-diode, low-level laser device that delivers a multifaceted treatment of onychomycosis (OM) Lunulalaser follows the principles of photochemistry, a science that explores light's effect cell function and behavior. The photochemical mechanism enables Lunulalaser to give a direct, non-contact treatment that produces no macroscopic sensation: no heating, tingling, burning. The mechanism of photochemistry is likened to the agonist effect of a drug, which describes the use of a certain molecule to start a secondary cascade. Laser therapy uses photonic energy to modulate secondary cellular reactions without the patient feeling the device working.

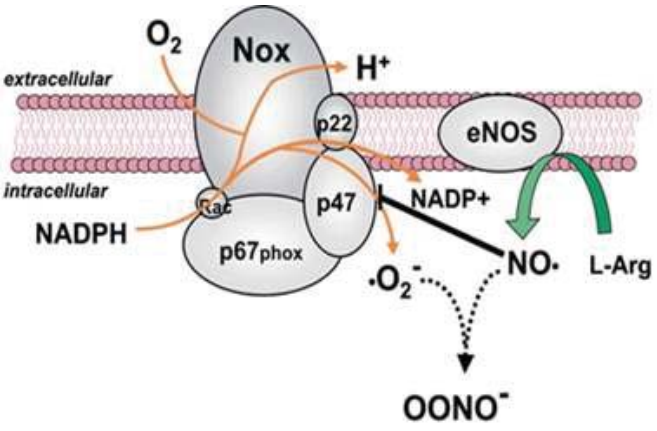
LunulaLaser impressive clinical response stems from its two therapeutic wavelengths: 405 nm (violet) and 635 nm (red). Each wavelength performs a very specific function to provide a comprehensive treatment of OM. The manner in which the wavelengths are delivered represents an innovative and proprietary feature of LunulaLaser. Lunula administers the laser as a line-generated beam, which maximizes the treatment surface area. The fungal pathogen may not only affect multiple toes, but also may be found deep within a dystrophic nail or along the nail bed and root. The line-generated beam ensures that, regardless of where the fungal pathogen resides, an effective treatment will be administered.

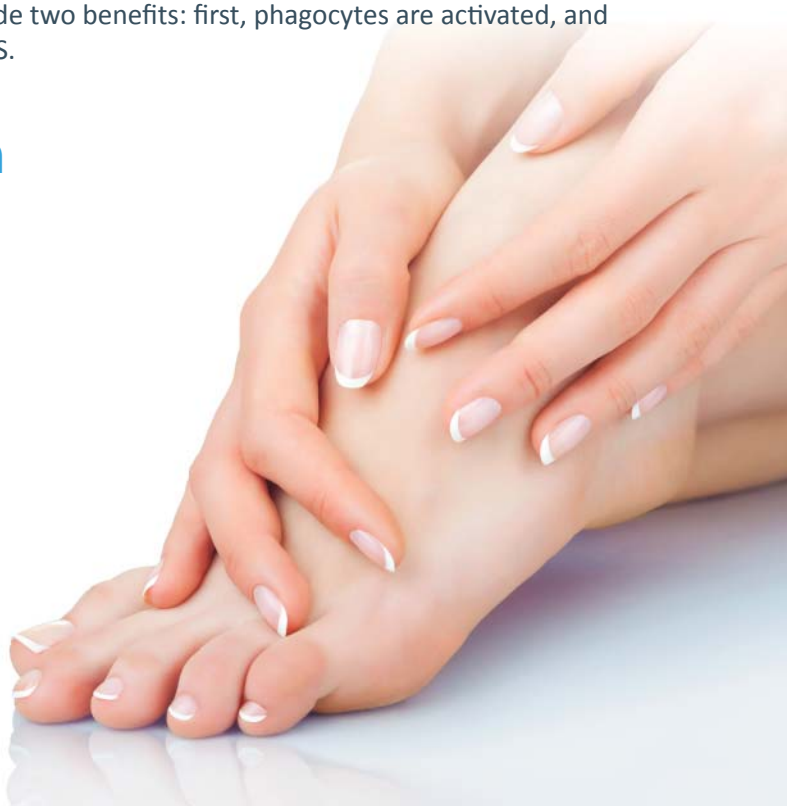
405nm (VIOLET)

Violet has been demonstrated to have an antimicrobial effect by upregulating the production of ROS, leading to the generation of hydrogen peroxide, hypochlorous acid and hydroxyl radicals. When applied concurrently, the combined antimicrobial and biostimulative effects appear to provide a therapeutically beneficial combination, as demonstrated by the mean percent changes in clarity. A potential phototarget for the 405 nm wavelength is also a system responsible for catalyzing the generation of ROS, nicotinamide adenine dinucleotide phosphate oxidase (NOX). NOX transfers electrons from cytosolic NADPH to flavin adenine dinucleotide (FAD), then to extracellular molecular oxygen to generate superoxide. The third and fifth transmembrane domains of NOX bind two prosthetic heme groups that shuttle electrons from FAD to oxygen. It has been suggested that the prosthetic heme, which has been recognized as a photosensitizer, responds to the delivery of blue light. Stimulation of NOX could potentially provide two benefits: first, phagocytes are activated, and second,dermatophytes are susceptible to the toxic effects of ROS.

COMBINATION OF 635nm AND 405nm

eNOS→Nitric Oxide (NO)
Cytochrome c oxidase→Reactive Oxygen Species (ROS)





UNITED STATES CLINICAL STUDY

BACKGROUND: The purpose of this study was to demonstrate through retrospective analysis the efficacy of the Erchonia LunulaLaser, manufactured by Erchonia Corporation, for the increase of clear nail in patients with toenail onychomycosis, when applying the LunulaLaser to the toenail for 12 minutes one time per week for a total of 4 procedure administrations.

STUDY DESIGN: This study was a retrospective analysis of a compilation of pre-procedure and six-month post-procedure photographs of fifty-four (54) great toenails with varying degrees of onychomycosis disease involvement selected from amongst an existing pool of photographs taken during three prior Erchonia Corporation research studies wherein 4 sequential weekly 12-minute procedures with the LunulaLaser were administered. The evaluating investigator was blinded to corresponding pre and post-procedure photographs through application of a randomized numeric coding methodology.

STUDY MEASURES: The linear measurement of millimeter (mm) of clear nail from the proximal nail fold to the most proximal area of nail dystrophy was objectively measured from unmarked digital photographic images using the validated GNU Image Manipulation Program (GIMP 2.8) software system, a multi-platform image/photo manipulation software system, at baseline evaluation (prior to LunulaLaser procedure administration) and at 6 months following completion of the LunulaLaser procedure administration protocol.

Primary Outcome Measure: Change in mm of Clear Nail from Baseline to Study Endpoint:
The primary efficacy outcome measure in this study was the mm of clear nail growth at 6 months post procedure administration end relative to Baseline (pre-procedure administration). Individual toenail success was defined as 3 mm or more of clear nail growth at 6 months post-procedure end relative to baseline. Overall study success was defined as an anticipated 60% of treated toenails meeting the individual toenail success criteria.

Sixty seven per cent (67%) of all study treated toenails evaluated in this study met the study individual toenail success criteria, exceeding the pre-established overall study success goal of 60% by 7%. The magnitude of the mean change in mm of clear nail from baseline to 6 months post-procedure for all treated toenails was an increase of 5.18 mm, 2.18 mm in excess of the pre-established 3 mm increase success criteria. A t-test for paired samples found this mean change of +5.18 mm in clear nail to be statistically significant ($t=-8.0$; $df=53$; $p<0.0001$).

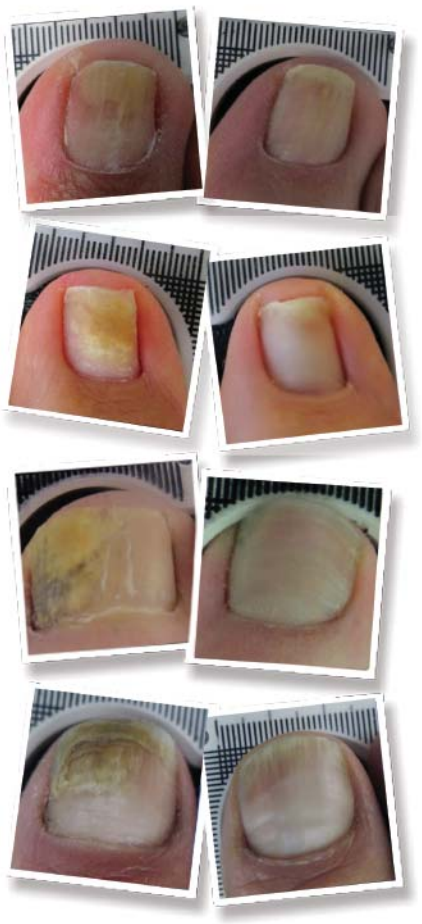
CONCLUSION: The Erchonia LunulaLaser is an effective tool for increasing clear nail in toenails infected with onychomycosis, significantly increasing mm of clear nail over a 6 month period following completion of the 4-week procedure administration phase.

FDA Clearance - K153164

PROVEN RESULTS

Lunula Laser requires very little time or set-up for physicians or their staff and the device has a pre-set treatment time and output energy. In fact, as little as four painless 12-minute sessions are needed to achieve results like these photos.

BEFORE & AFTER*



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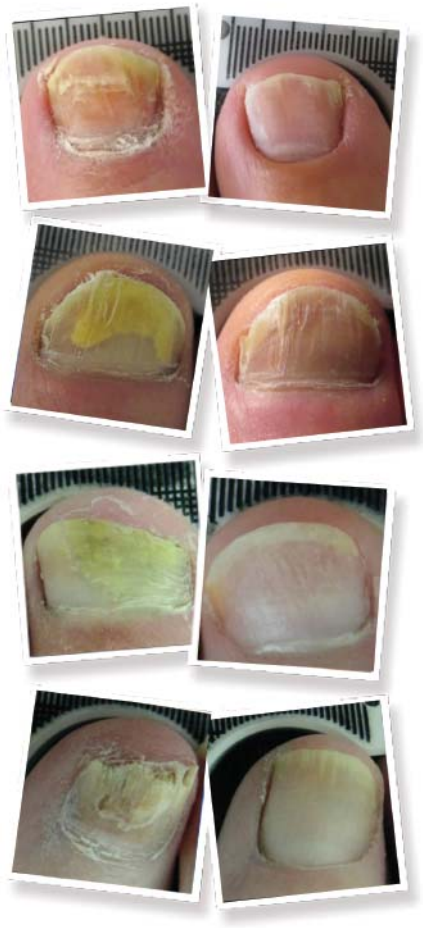

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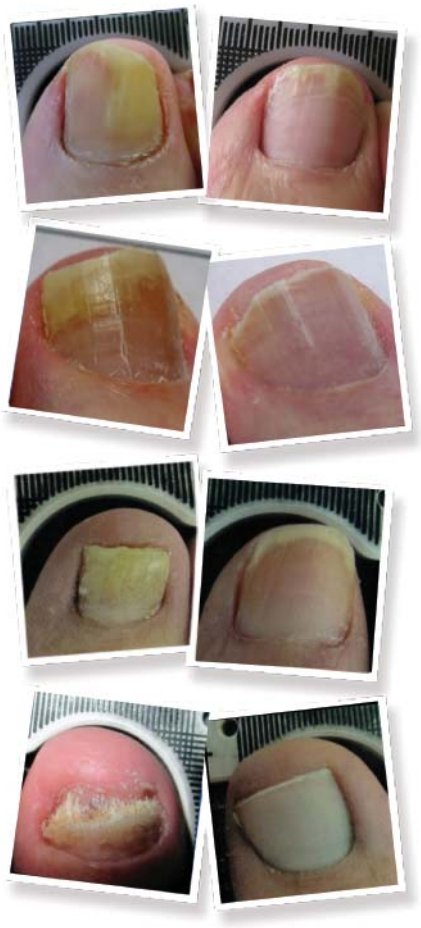

*These photographs were evaluated by a blinded investigator using an image manipulation software system that has been validated.

*Individual Results May Vary

Watch Lunula in Action!

LunulaLaser™ BY ERCHONIA

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