Erchonia's Lunula Laser: Two Clinical Studies

Retrospective analysis points to the effectiveness of this tool in treating onychomycosis.

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Note: *Study data supplied by Robert Sullivan BSc (HONS) PODIATRY, MSc POD SURGERY, Pg-CAcup, FIChPA, MInstChP*

As podiatric clinicians we have spent decades trying various treatments in order to eradicate nail fungus (onychomycosis). As a profession we are finally evolving and moving away from traditional systemic medications, topical preparations and surgical procedures and, for the first time, embracing technology.

Laser therapy has been used by podiatrists during the last decade in order to eradicate nail fungus both in the U.S. and around the world. Many of the lasers used are Nd:YAG thermal lasers. In 2012 a new innovative technology came onto the market which has changed the clinical practice of many practitioners in the fight against fungus: Low Level Laser Therapy (LLLT)—currently used in the treatment of onychomycosis (OM) for both fingers and toes.

Figure 1: The LunulaLaser

Traditional treatments available for OM include:

- Application of home remedies such as Vicks Vapour Rub or Tea Tree oil
- Application of topical preparations prescribed by clinicians or bought over the counter: Topical amorolfine, ciclopirox, and terbinafine; and the new topical antifungal agents efinaconazole and tavaborole. The patient must be vigilant in regularly applying the preparation over a significant period of time.
- Course of systemic medications prescribed by doctor: current therapies include oral griseofulvin, itraconazole, and terbinafine. Disadvantages to current therapies include clinical cure rates < 100 percent despite months of treatment and occasional drug interactions and toxicity from oral medications. A meta-analysis of available data found oral itraconazole 400mg pulse therapy was the most effective treatment with a mycological cure rate of 67 percent.
- Removal of nail by podiatrist: surgical treatment is usually reserved for drug-resistant infections but involves the use of anaesthetic, requires healing time, and can cause a port of entry for further infection during healing.
- Course of class IV thermal laser treatment by podiatrist: clinically, various laser devices using 1,064nm ND:YAG have been used for treating onychomycosis, either alone or combined with topical therapies. The fungicidal effect of these lasers is dependent on heating the affected area, which may be associated with pain and burning sensations in the treated nail bed and darkening under the nail or over the nail plate. Long-term studies demonstrate a role for 870nm and

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New Concepts and Studies

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930nm near-infrared light for the treatment of onychomycosis, and photodynamic therapy using red light (630nm) and methyl aminolevulinate as a photosensitizing agent has also been used for treating onychomycosis; however, reports of photodynamic therapy studies for treating onychomycosis are small, open-label studies that do not achieve mycological cure. Several energy-based devices are cleared for producing clear nails in patients with onychomycosis, but none are currently approved for treating onychomycosis.

The Lunula Laser Is Different from Other Treatments on the Market for OM

The Erchonia LUNULALASER™ (see Figure 1) is a dual-diode laser of 635 nm and 405 nm wavelength. The light emitting diodes are manufactured by DLC and classified by the Center for Devices and Radiological Health (CDRH) as Class II laser diodes. The LUNULALASER™ is a portable floor device with an AC power adapter.

We now have a low level laser that is FDA approved for the clearance of OM

Figure 2 lists the specifications for the LunulaLaser™.

The Erchonia LunulaLaser™ is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient.

As with all good research, more questions remain than are already answered by the initial hypothesis. We now have a low level laser that is FDA approved for the clearance of OM. But in the process of initial research other pedal conditions appeared to resolve with the use of the device. Improvements in skin tone, vascularisation and epithelialisation were seen as well. All of these improvements led to ongoing research based on the findings of the initial FDA study.

Improvements in skin tone, vascularisation and epithelialisation were seen as well.

Study 1: 2015: A Retrospective Evaluation of the Effect of the Erchonia LUNULALASER™ on the Increase of Clear Nail in Patients with Toenail Onychomycosis Version 1.0; September 29, 2015

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

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FIGURE 2:

Specifications for the LunulaLaser™

Power	16.0-18.5mW for the 635nm diode 21.5-24.0mW for the 405nm diode
Wavelength	635nm & 405nm
Waveform	Constant Wave (CW)
Energy Source	Dual diode collected then line dispersed (coherent)
Power Supply	100-240 VAC 50/60 Hz
Energy Delivery	Portable floor device
Treatment Time	12 minutes

TABLE 1:

Mean Change Scores: mm Clear Nail at Baseline (Pre-Procedure) and 6 Months Post-Procedure

n=54	Pre-Procedure	6 Months	Change
Mean	7.64	12.82	5.18
Standard Deviation	4.50	3.69	4.76

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.

Study Procedure: Great toenails had received 4 procedure administrations with the Erchonia LunulaLaser™ across a consecutive 3-week period: each procedure administration 7 days apart. Exposure time to the laser was 12 minutes, directed at and about 4 inches above the great toenail.

Sixty seven percent (67%) of all treated toenails evaluated in Study #1 met the individual toenail success criteria.

Subjects and Sample: Fifty-four (54) treated great toenails of varying degrees of onychomycosis involvement at study entry were evaluated in this study. Subjects were 18 years or older with current bacterial/fungal infection classified by the investigator and confirmed through lab testing as positive for onychomycosis.

Study Results

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 ($t = -8.0$; $df = 53$; $p < 0.0001$).

Statistical Analysis

Primary Efficacy Outcome Analysis

The aim of this study was to determine if there was a treatment effect of application of the Erchonia LunulaLaser™ for individuals with onychomycosis of the toenail.

The primary efficacy outcome measure in this retrospective study was the mm of clear nail growth at 6 months post-procedure administration end relative to Baseline (pre-procedure administration).

Study Success Criteria

- *Individual great toenail success criteria* was defined as 3 mm or more of clear nail growth at 6 months post-procedure administration end as evaluated relative to baseline (pre-procedure administration).
- *Overall study success criteria* was defined as an anticipated 60% of treated great toenails meeting the individual success criteria.

Evaluation Time Point: The study end evaluation time point at which study success was analyzed was 6 months following completion of the fourth and final study procedure administration with the Erchonia LunulaLaser™.

Statistical Methods for Evaluation of Primary Efficacy

- Calculation of the proportion of great toenails that

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demonstrated individual great toenail study success

- T-test analysis to evaluate the mean change in mm clear nail of the great toenails from baseline to 6 months evaluation

Primary Outcome Measure Analyses

Proportion of Successes

- Sixty seven per cent (67%) (36/54) of all study treated toenails met the study individual success criteria

In Study #1, 89% of great toenails demonstrated an increase in mm of clear nail across the evaluation period.

at 6 months post-procedure administration end evaluation, exceeding the pre-established overall study success goal of 60% by 7%.

- Furthermore:
  - 48/54 (89%) of study great toenails demonstrated an increase in mm of clear nail across the evaluation period
  - Only 6/54 (11%) of study great toenails demonstrated a decrease in mm of clear nail across the evaluation period

Table 1 shows the mean and standard deviation of mm of clear nail at baseline (pre-procedure) evaluation and at 6 months post-procedure administration end (study endpoint) evaluation and the change in mm of clear nail between the two evaluation points for all 54 retrospectively evaluated great toenails.

The mean increase in mm of clear nail from pre-procedure (baseline) administration evaluation to 6 months post-procedure administration end evaluation (study endpoint) for all 54 evaluated great toenails was +5.18 mm.

A *t-test for paired samples* revealed the mean change of +5.18 mm in clear nail from pre-procedure administration to 6 months post-procedure administration end to be *statistically significant*: $t = -8.0$; $df = 53$; $p(\text{two-tailed}) < 0.0001$.

Adverse Events: No adverse event was reported or observed for any subject throughout any of the three clinical trials from which this study's retrospective sample was drawn.

Conclusion: The Erchonia LunulaLaser™ is an effective tool for treating toenail onychomycosis, significantly increasing mm of clear nail over a 6 month period following completion of the procedure administration phase.

Study 2, 2019

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 and a maintenance phase starting eight weeks after the fourth treatment for a further five treatments procedures at eight weeks intervals.

Study Design: This study was a analysis of a compilation of pre-procedure and post-procedure photographs of twenty (20) great toenails with varying degrees of onychomycosis disease involvement, but not exceeding 50%. The evaluating investigator was blinded to corresponding pre- and post-procedure photographs through application of a randomized numeric coding methodology.

Subjects and Sample: twenty (20) treated great toenails of varying degrees of onychomycosis involvement, but not exceeding 50%, at study entry were evaluated in this study. Subjects were 18 years or older with current fungal infection classified by the investigator and confirmed through lab testing as positive for onychomycosis.

Study Results

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 one and three 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 three 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.

In Study #2, a t-test for paired samples found the mean change of +6.21 mm in clear nail to be statistically significant ($t = -8.0$; $df = 53$; $p < 0.0001$).

Sixty seven per cent of all study treated toenails evaluated in the active study protocol met the study individual toenail success criteria, exceeding the pre-established overall study success goal . The magnitude of the mean change in mm of clear nail from baseline to 3 months post-procedure for all treated toenails was an increase of 6.21 mm, 3.21 mm in excess of the pre-established 3 mm increase success criteria. A t-test for paired samples found this mean change of +6.21 mm in clear nail to be statistically significant ($t = -8.0$; $df = 53$; $p < 0.0001$).

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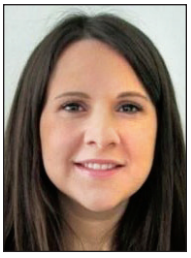
Adverse Events: No adverse event was reported or observed for any subject throughout.

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 15 month period following completion of the 4-week procedure administration phase and five further applications as outlines above.

Both clinical studies show the effectiveness of using the Erchonia LUNULALASER™ in the clinical treatment of onychomycotic nails.

Both clinical studies show the effectiveness of using the Erchonia LUNULALASER™ in the clinical treatment of onychomycotic nails. The device is a clear clinical innovation in the field of podiatry enabling clinicians to provide a fast, painless, effective treatment for a problem that, for so many years, has plagued patients and frustrated clinicians who have been unable to find satisfactory treatments which are effective, free from adverse reactions, painless, and that are easy for patients to receive. Much more clinical research needs to be carried out as anecdotal evidence suggests that the Lunula is not a 'one trick pony' and may well enable the effective treatment of other pathologies found in the podiatry clinic. **PM**



Martine Abrahams is Director and podiatrist at The London Nail Laser Clinic. She qualified from the Birmingham School of Podiatry in 1996 and spent the first ten years of her career in the NHS in London before working in private practice. In 2009 Martine set up the London Nail Laser Clinic with the sole aim of treating fungal nail infections using the latest laser technology. The Clinic has been using the Erchonia LUNULALASER™ since 2012. Martine is a clinical consultant for Erchonia and carries out training for new Lunula providers as well as offering ongoing support. She has lectured to many medical practitioners within Europe and further afield on the use of laser therapy for onychomycosis and other nail disorders.