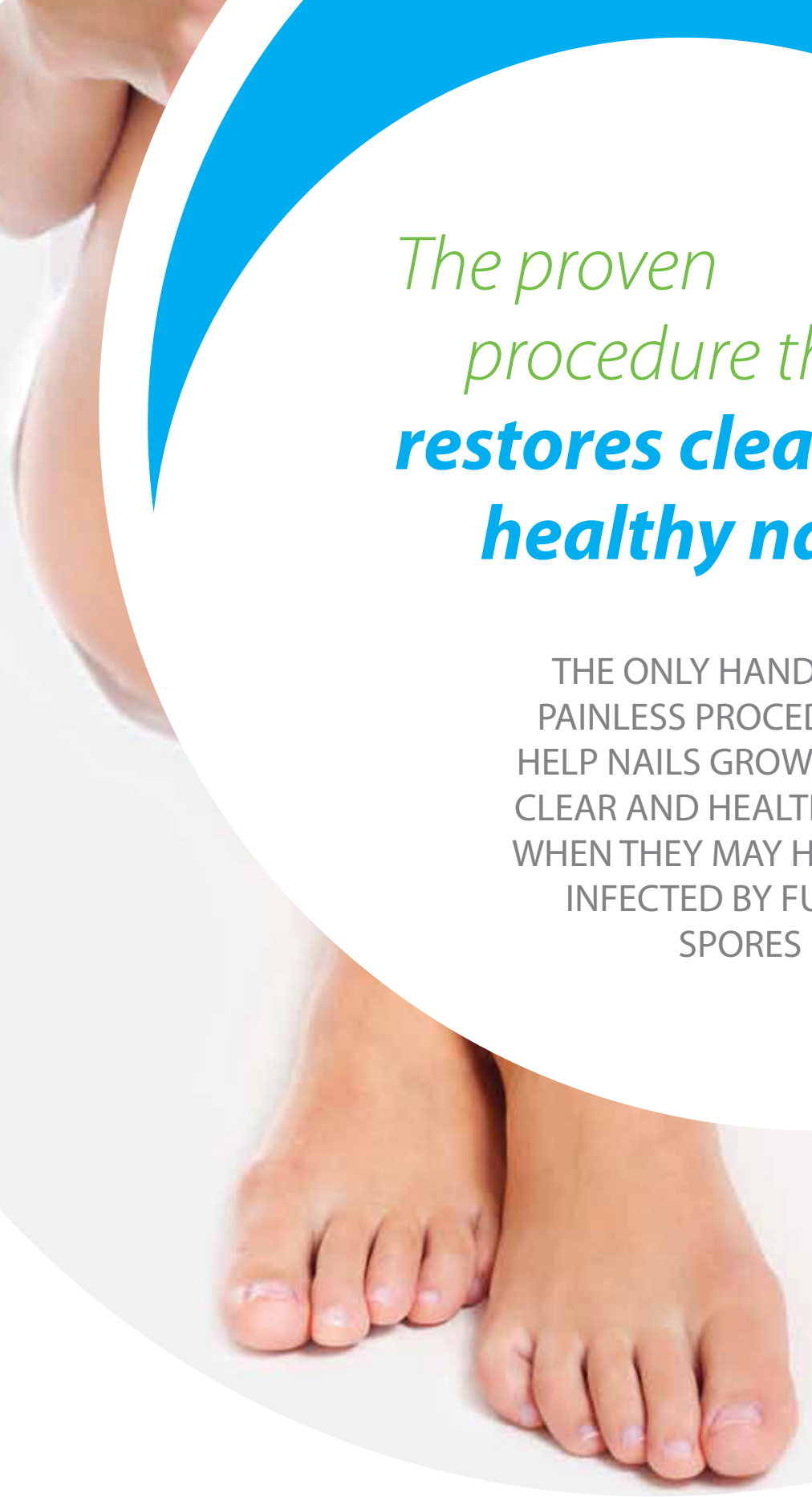


The proven procedure that ***restores clear and healthy nails***

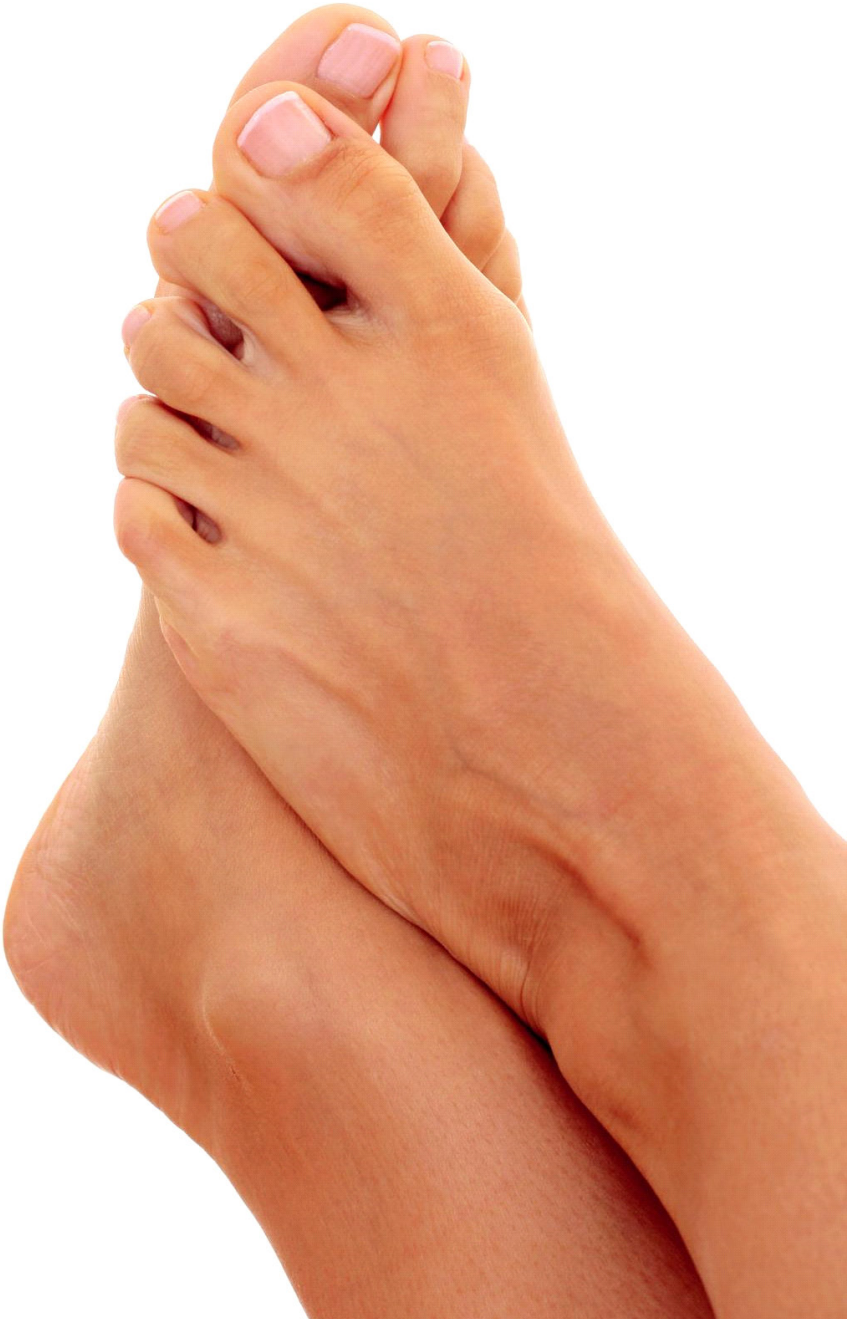
THE ONLY HANDS FREE, PAINLESS PROCEDURE TO HELP NAILS GROW STRONG, CLEAR AND HEALTHY - EVEN WHEN THEY MAY HAVE BEEN INFECTED BY FUNGAL SPORES

LunulaLaser® BY ERCHONIA®

THE COMMITMENT TO RESEARCH

Since 1996, Erchonia, the manufacturer of Lunula, has been committed to fully elucidating the utility of low-level laser therapy through rigorous clinical studies. For over a decade, Erchonia has studied the clinical utility of low-level laser devices for the treatment of numerous medical ailments, and their recent device, Lunula, looks to revolutionise aesthetic nail care.

Lunula has been markedly studied – from the early in-vitro analysis to the extensive in-vivo studies – and its utility to enable unsightly toenails to grow clear, strong and healthy even when they may have previously been infected with fungal spores. The unique dual-diode approach of Lunula fortifies the body's natural defense mechanisms against any infectious agent, and accelerates the growth of the nail. This multifaceted approach is the first of its kind, providing a truly effective, yet safe, way to anable your clients re-grow strong, clear and healthy nails.



DID YOU KNOW?

More than 10% of the general population have nails that have been damaged by fungal infections.

LUNULA SAFELY ADDRESSES UNSIGHTLY TOENAILS IN ONLY FOUR 12-MINUTE PAINLESS APPLICATIONS

Lunula's effectiveness at growing clear and healthy nails has been substantiated by three independent clinical investigations. It is important to mention that no topical/oral antifungals were administered during the studies. The first study evaluated 168 toes with an average baseline affected nail involvement of 81.15%. After a single Lunula application, affected nail involvement was reduced to 31.32% at study endpoint, an improvement in nail clarity of 63.58%. The second study, evaluated 105 toes, or 75 subjects, after two Lunula applications separated by a single week. Subjects reported an average clear nail of 73.79% and 79.75% at post-procedure months 3 and 6, respectively. This was a statistically significant change compared with the average 43.4% clear nail measured at baseline. The third study consisted of 109 patients (139 toes) subject to laser irradiation at 405nm and 635nm for twelve minutes at weekly intervals for four weeks. The interim results from this Lunula Laser study show extremely high levels of efficacy over 48 weeks. Equally important, the responses observed in all three trials were achieved without a single adverse event.

DID YOU KNOW?

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

ORAL MEDICATIONS

The limitations and risks of oral antifungal medications have been well documented. First, treatment of the body's most distal region – the toes - with an oral antifungal 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 antifungals. Although quite rare, hepatotoxicity has been reported in patients taking oral antifungal medication. To mitigate the risk of liver complications, patients with specific pre-existing medical conditions cannot be prescribed oral antifungal medications, but for those patients who are taking antifungals 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 antifungal medications.

In addition to the serious side effects, the results are not impressive. Below is a chart that details reported results for common oral therapies.

DRUG*	LENGTH OF TREATMENT	LENGTH OF FOLLOW-UP	MYCOLOGICAL CURE
Griseofulvin	78 weeks	77 weeks	2/36 (6%)
Terbinafine	12 weeks	48 weeks	226/390 (58%)
Itraconazole	12 weeks	72 weeks	41/107 (38%)
Fluconazole	24 weeks	60 weeks	20/41 (49%)
Amorolfine	24 week	12 weeks	60%

* Patients must undergo liver function tests at baseline and weeks 4 or 6 to ensure there are no complications.

DID YOU KNOW?

The third study consisted of 109 patients (139 toes) subject to laser irradiation at 405nm and 635nm for twelve minutes at weekly intervals for four weeks. The interim results from this Lunula Laser study extremely high levels of efficacy over 48 weeks.

THE SCIENCE BEHIND LUNULA

Lunula combines two beneficial low level laser wavelengths: 405nm and 635nm. Each wavelength is capable of stimulating a specific cascade to help the body grow strong, clear and healthy nails. Both wavelengths are enriched by a proprietary, rotating line-generated beam; a unique delivery mechanism that maximises photon concentration and application surface area— ensuring that all toes received adequate stimulation. As a result, the Lunula provides a completely safe procedure absent of any adverse events while inducing key pathways to effectively address unsightly nails.

The 635nm wavelength stimulates Cytochrome C Oxidsase (CCO), an important enzyme necessary for the production of Adenosine Triphosphate (ATP) and Reactive Oxygen Species (ROS). Increased ATP activates PI3 kinase/eNOS signaling pathways, which increases Nitric Oxide (NO) production. NO is critical for new blood vessel formation increasing nutrient delivery and infiltration of immunological cells. For resident macrophages and neutrophils, two types of immune cells, the increased production of ROS is quickly converted into cytotoxic hydrogen peroxide (H2O2), which enhances the performance of the immune cells.

The 405nm wavelength targets NADPH Oxidase (NOX), a membrane bound enzyme, and increases NOX's production of ROS, which can be converted into H2O2. The increase in production of H2O2 that is enabled, helps to increase fungal spore susceptibility to the body's immune response.

405nm PUBLISHED STUDIES	
Author	**Reported Outcome**
Emmons et al. (1939)	Spore mutation induced
Klebanov et al. (2005)	Lipid peroxidation
Eichler M et al. (2005)	Activation of flavins
Lavi R et al. (2012)	Upregulation of ROS

635nm PUBLISHED STUDIES	
Author	**Reported Outcome**
Zheng H et al. (1992)	Activation of macrophage
Duan R et al. (2001)	Increased Respiratory Burst
Dube A et al. (2003)	Modulation of macrophage
Dolgushin et al. (2010)	Stimulation of neutrophil

When applied concurrently, the **two wavelengths represent a truly multifaceted treatment approach.**

- **FIRST** – By increasing fungal spore susceptibility to the body's immune response.
- **SECOND** – By fortifying the body's endogenous immune system.

DID YOU KNOW?

635nm improves the performance of local immune cells.

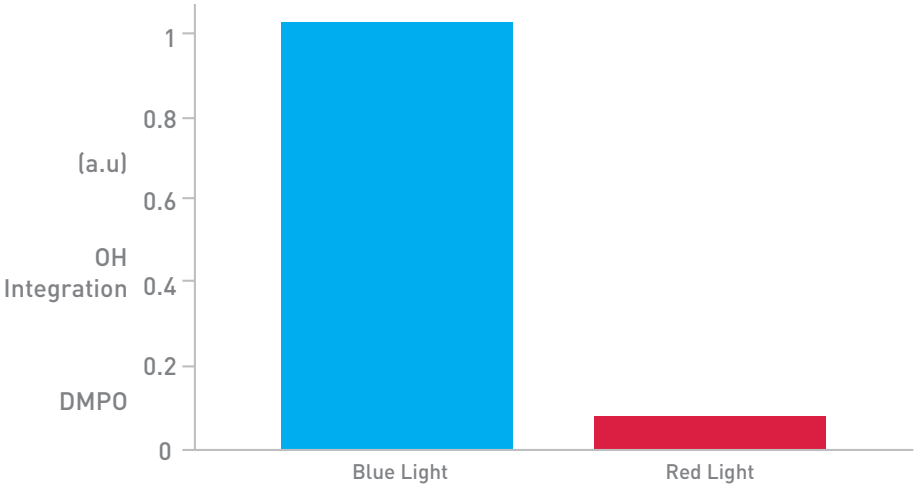
DID YOU KNOW?

The Lunula device requires very little set-up and operator time.

THE EFFECT OF LASER

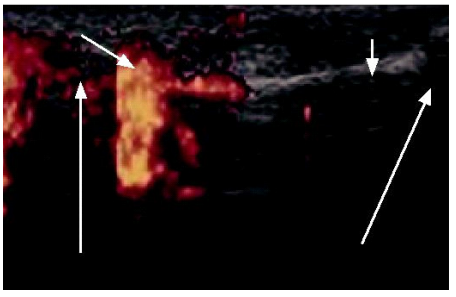
The application of 405nm has been reported to significantly increase the production of ROS. When compared to other wavelengths, 405nm yields the highest production of ROS (Figure 1).

FIGURE 1. ROS generation following laser therapy at ~405 nm and Red Laser Courtesy of Lavi et al. (2012)

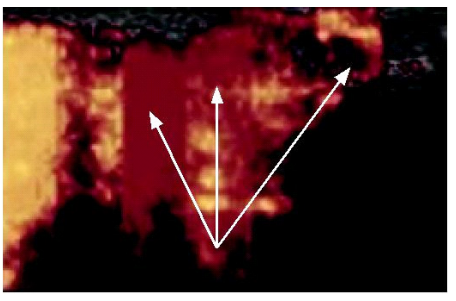


ROS levels using DMPO-OH (1µg/mL) after 170 second stimulation of sperm membrane.

Peripheral blood flow impairment can affect the body's endogenous immune response to any infectious agent. Without the infiltration of leukocytes, monocytes, and macrophage, the infectious agent is able to spread along the nail plate and bed. The 635nm wavelength has been proven to increase peripheral blood by stimulating key pathways responsible for angiogenesis (new blood vessel formation). Increased blood flow provides greater nutrient delivery to tissues for rejuvenation, accelerating nail growth and enabling a more effective immune response. The images below demonstrate the improved blood flow benefit of the 635nm wavelength.



Baseline



Post-Procedure

THE CLINICAL TRIALS

The following results were achieved without a single adverse event reported.

CLINICAL TRIAL: 2ND STUDY DESIGN

This study adhered to International Conference on Harmonisation guidelines and was approved by an independent Institutional Review Board.

STUDY SUBJECTS (N=105 TOENAILS)

- Male: (N=41)
- Female: (N=64)
- Average Age: 59.5 years
- Standard Deviation Age: (12.9)

APPLICATION PROTOCOL

Each affected toenail received four 12-minute Lunula applications 7 days apart.

ASSESSMENTS

Each toenail was evaluated at baseline and 2, 3, and 6 months after the final Lunula application. The primary measure of efficacy was the percent change in clear nails at the 3-month evaluation point.

At least 60% of affected toenails must have met the ≥ 25% increase in clear nail for the Lunula to be efficacious.

BASELINE TOENAIL INFECTION

All patients (n = 105) were partitioned into a specific baseline category depending on the toes percent nail clarity:

- <25% (N = 30)
- 26-50% (N = 35)
- 51-75% (N=40)

The broad range of toes enrolled has enabled the researchers to fully elucidate the effectiveness of the Lunula.

DID YOU KNOW?

405nm has been proven to increase ROS and activate key secondary cascades

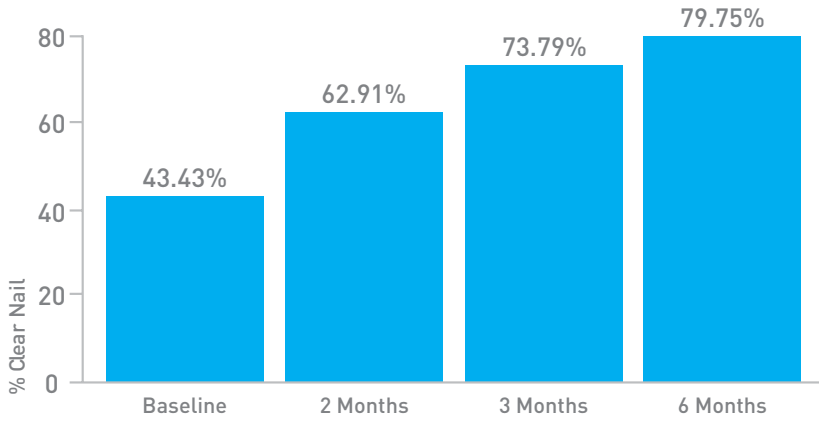
DID YOU KNOW?

At evaluation months 3 and 6 the percentage of clear nail increased by 30.4% and 36.32%, respectively

RESULTS

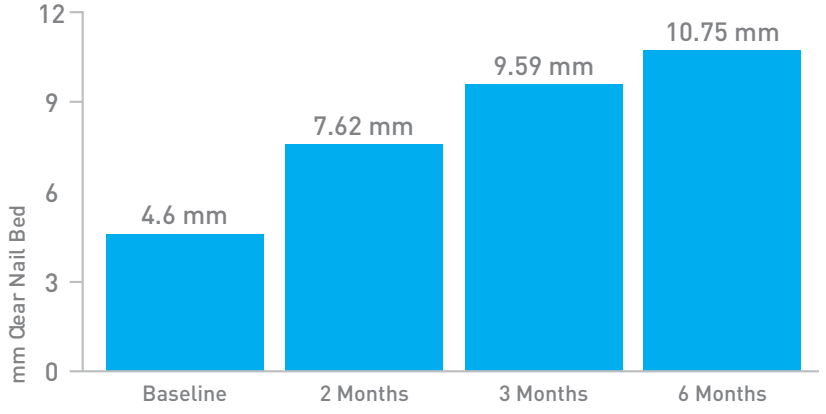
The mean percent of clear nail significantly increased from 43.43% at baseline to 79.75% at 6 months, representing a 36.32% improvement.

FIGURE 1. Mean Change in Percent Clear Nail Beds



The mean extent of clear nail significantly increased from 4.6 mm at baseline to 10.75mm at 6 months representing 133% increase in clear nail.

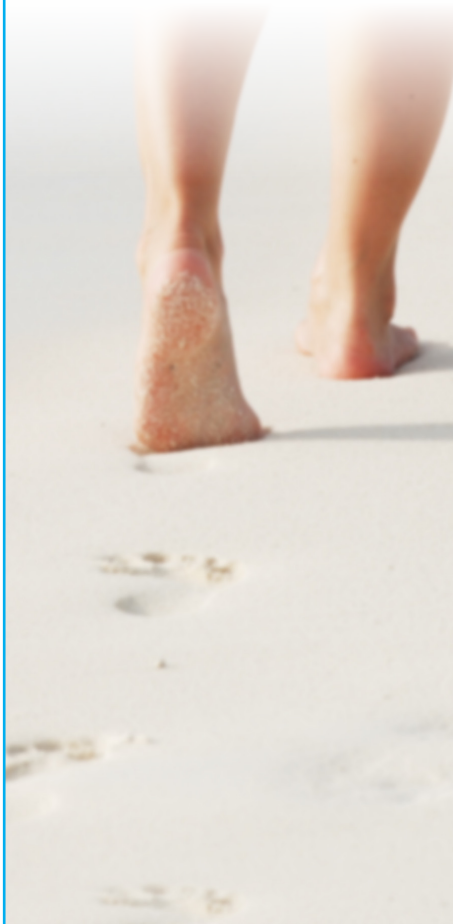
FIGURE 2. Mean Change in the Extent of Clear Nail Beds



These results were achieved without a single adverse event reported.

DID YOU KNOW?

The mean extent of clear nail significantly increased from 4.6 mm at baseline to 10.75mm at 6 months representing 133% increase in clear nail.



CLINICAL TRIAL: 3RD STUDY DESIGN

DID YOU KNOW?

The mean mm of nail clearance from Baseline to 48 week end point increased by 9.19 mm.

PURPOSE OF STUDY

The purpose of this clinical study was to demonstrate the efficacy of the Erchonia Lunula Laser, manufactured by Erchonia Corporation, for stimulating the growth of strong, clear and healthy toenails, when applying the Lunula Laser to the toenail for 12 minutes one time per week for 4 consecutive weeks, for a total of 4 application administrations.

STUDY DESIGN

This clinical study was a single site, single group (active procedure only) non-randomized non-blinded design.

STUDY SUBJECTS

- One hundred and nine (109) subjects were enrolled in the study.
- Of the 109 subjects, all had a great toenail with qualifying nail problems enrolled and 30 subjects had multiple toenails with qualifying nail problems enrolled, resulting in a total of 139 toenails enrolled in the study, as follows:
- Subject age averaged 41.75 years

DID YOU KNOW?

Mean % of clear nail across study duration increased.

CATEGORY OF % BASELINE TOENAIL AFFECTED INVOLVEMENT

Toenails were further categorized according to the following four categories of % affected toenail involvement at baseline:

All Toenails	#(%) All Toenails (n=139)
0% - 24%	11 (8%)
25% - 49%	33 (8%)
50% - 74%	41 (8%)
75% - 100%	54 (8%)

APPLICATION PROTOCOL

Each study toenail received four 12 minute applications 7 days apart. Millimeter (mm) of clear (uninfected) nail bed and per cent (%) of toenail affected involvement were objectively and independently determined using topographical software digital photo-planimetry software and triangulation methodology translated to a clear linear measurement at baseline; at the end of the procedure administration phase, and at 12 weeks, 36 weeks and 48 weeks post procedure administration end.

Table 1

Mean % affected involvement across study duration

Evaluation Phase	mm clear nail
Baseline	5.9
Week 4	9.63
Week 12	11.53
Week 36	14.26
Week 48	15.09

Chart 1

Mean mm clear nail across study duration.

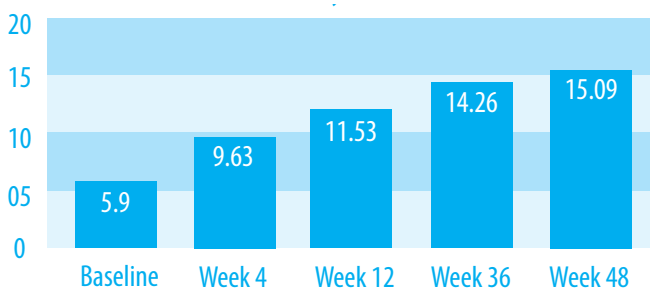


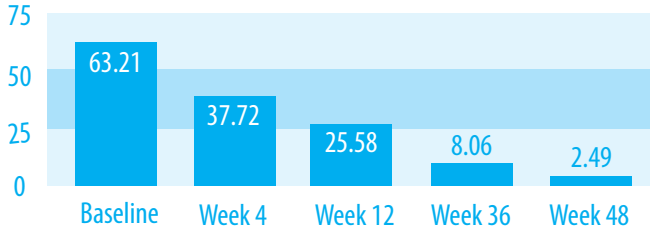
Table 2

Mean % affected involvement across study duration

Evaluation Phase	Affected %
Baseline	63.21
Week 4	37.72
Week 12	25.58
Week 36	8.06
Week 48	2.49

Chart 2

Mean % affected involvement across study duration.



*Toenail clearance results compiled from U.S. study submitted to FDA September, 2014.

Table 3

Toenail affected Involvement Across Study Duration: *All Toenails*

n=139	Baseline	Procured End	Week 12	week 36	week 48
Mean	63.21%	37.72%	25.58%	8.06%	2.49%
Standard Deviation	23.88	23.88	21.76	13.92	9.72

It can be seen from Table 3 above that mean % toenail affected involvement decreased progressively and substantially across each successive evaluation point to a negligible remaining level.

ADVERSE EVENTS:

No adverse event was reported for any subject throughout study duration.

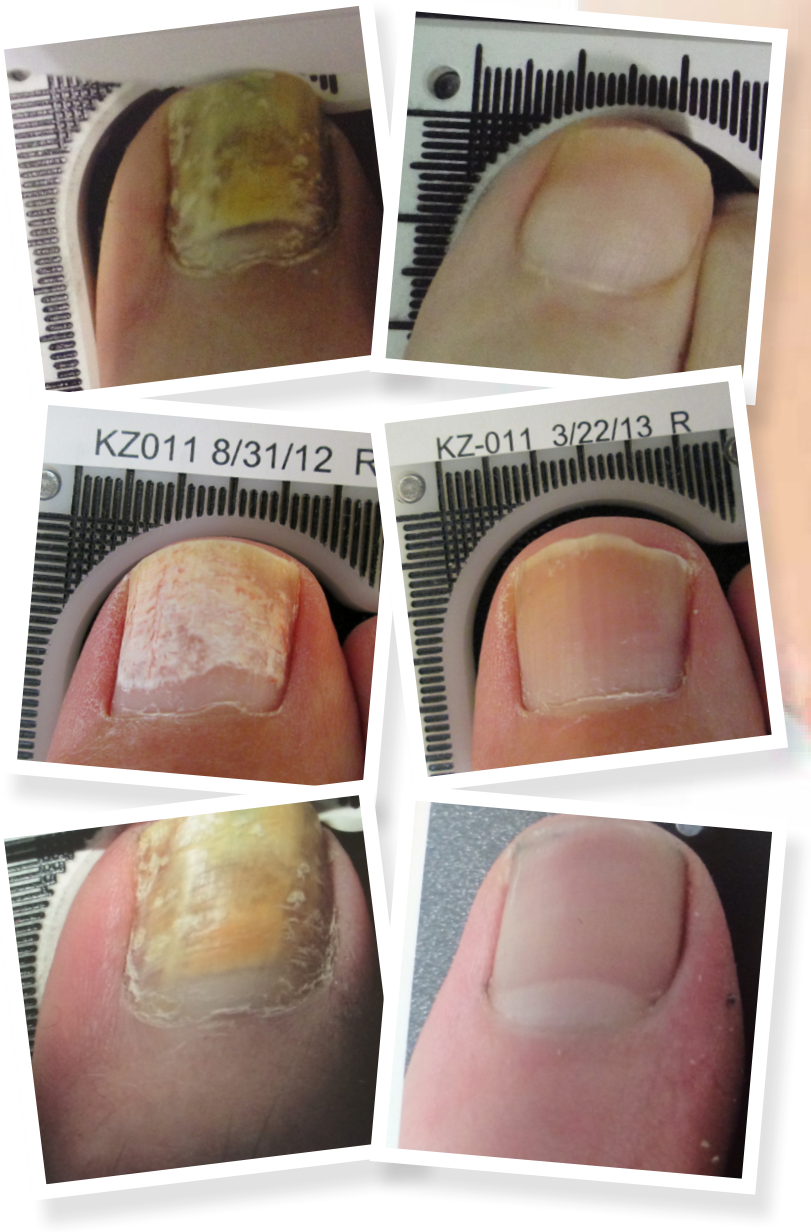
CONCLUSION:

The Erchonia Lunula Laser is an effective tool for enabling unsightly toenails to grow clear , strong and healthy even when they may have previously been infected with fungal spores, demonstrated by significantly and progressively increasing mm of clear nail and decreasing % affected involvement over a 48 week period following completion of the 3-week procedure administration phase.

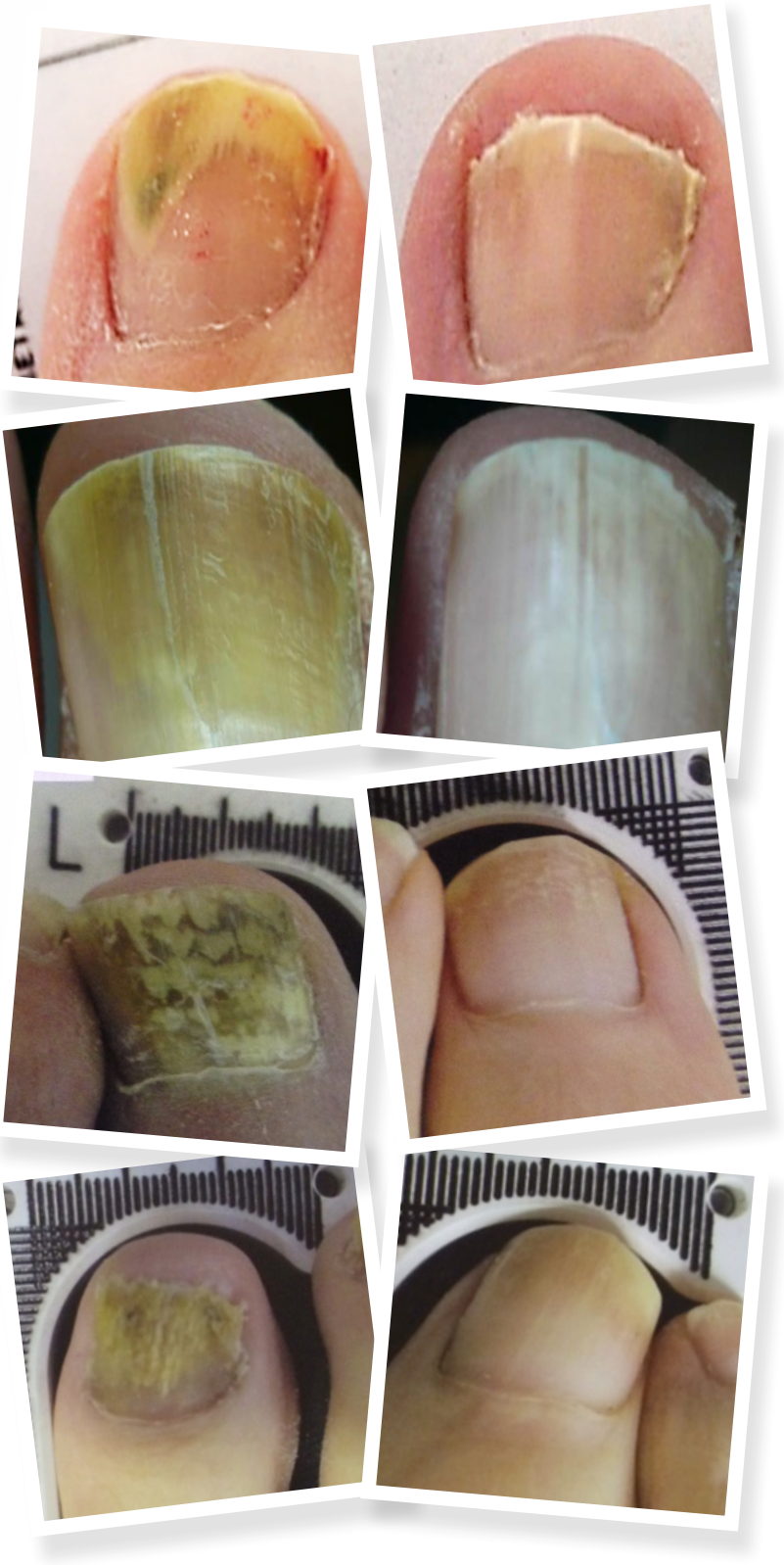
PROVEN RESULTS

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

BEFORE & AFTER



BEFORE & AFTER



THE CLINICAL TRIALS

The following results were achieved without a single adverse event reported.

HELP CLIENTS SUFFERING FROM THE PAIN AND EMBARRASSMENT OF UNSIGHTLY NAILS. RESTORE CLEAR, HEALTHY NAILS TODAY

LunulaLaser BY ERCHONIA®

ERCHONIA®

World Leader in Low Level Laser Technology

SPECIFICATIONS

Configuration: 2 Line Generated Class 2 Laser Diode Modules
Wavelength: 635nm & 405nm
Modulation: Constant Wave (CW)
Display: Full Color TFT Touch Screen Control Center
Power Source: 100-240VAC 50-60Hz
Chassis: Powder Coated Aircraft Aluminum Base Plate and Door for Ease of Cleaning.
Housing: Injection Molded Process with Non-Allergen Material/Plastic
Weight: 23lbs. (10.43 kg)
Accessories: 2-Keys, Power Cord
Full Two Year Warranty
Compliant to: ISO 13485 Medical Device Quality, IEC 60825-1 Laser Safety, IEC 60601-1
Safety, IEC 60601-2 EMC, CB Mark, CE, CMDCAS
Laser Class 2 / Device Class II (USA); 2a (EU)

US PAT 8,814,924; US PAT 7,947,067; US PAT 7,118,588; US PAT 6,013,096; US PAT 6,746,473. Method Patents: US Pat 8,409,264; US Pat Pending 20110213446; US Pat Pending 20110224759. For additional US and International patents and patent pending information go to www.erchonia.com.

About the Manufacturer: Erchonia is the global leader in low level laser healthcare applications. For nearly 2 decades Erchonia has been conducting research & development with the world's leading physicians to advance the science of low level lasers. Prior to market introductions, all Erchonia lasers are proven to be safe and effective through Level (1) independent clinical trials. Currently thousands of Erchonia lasers are used daily to contour the waist, hips, thighs and arms, treat chronic neck and shoulder pain and to treat acne and the appearance of cellulite. For additional information, visit www. erchonia.com.

ERCHONIA®

World Leader in Low Level Laser Technology

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