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 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 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 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.

DID YOU KNOW? Lunula has been studied both in-vitro and in-vivo.

Lunula's clinical utility for the treatment of onychomycosis has been substantiated by two independent clinical investigations. It is important to mention that neither nail debridement nor topical/oral antifungals were administered during the studies. The first study evaluated 168 toes with an average baseline disease involvement of 81.15%. After a single Lunula treatment, disease involvement was reduced to 31.32% at study endpoint, an improvement in nail clarity of 63.58%. The second study, which was a FDA directed study, evaluated 105 toes, or 75 subjects, after four Lunula treatments 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. Equally important, the clinical responses observed in both trials were achieved without a single adverse event.

DID YOU KNOW? More than 10% of the general population has onychomycosis.

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.

Terbinafine12 weeks48 weeks226/390 (58%)Itraconazole12 weeks72 weeks41/107 (38%)Fluconazole24 weeks60 weeks20/41 (49%)Amorolfine24 weeks12 weeks60%

DRUG*	LENGTH OF TREATMENT	LENGTH OF FOLLOW-UP	MYCOLOGICAL CURE
Griseofulvin	78 weeks	77 weeks	2/36 (6%)

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

DID YOU KNOW?
The Lunula device requires very little set-up and no operator.

DID YOU KNOW?
Patients in a 168-toe study reported a 73.89% improvement in nail clarity in 3.5 months.

HOW THE COMPETITION STACKS UP TO LUNULA

LASER NAME	Lunula	Pinpoint	Laser Genesis Plus	CoolBreeze	Normir
Wavelength(s) Used	635 and 405 nm	1064 nm	1064 nm	1320 nm	870 and 930 nm
Non-Thermal	YES	NO	NO	NO	NO
No Physcical Contact with Toe	YES	NO	NO	NO	NO
No Required Debridement of Nails	YES	NO	NO	NO	NO
Treatment Spot Size	28.62 cm2	2-10 mm	2-10 mm	2-10 mm	2-10 mm
Complete Effective Treatment Coverage	YES	NO	NO	NO	NO
Treatment Time	12 min for 5 toes	4.5 min per toenail*	4.5 min per toenail*	3-5 min per toenail*	6 min per toenail*
Number of Treatments	4	4	4	~3	4
No Application of Topical Antifungal to Toes	YES	NO	NO	NO	NO
Toes Studied	105	17	N/A	N/A	26

Mean mm Nail Clear Nail at 3 Months	4.99	3.7	N/A	N/A	Not Reported
Percent of Subjects Showing Improvement at 3 Months	97%	71.4%	N/A	N/A	N/A

LUNULA'S PROVEN APPROACH

Lunula combines two therapeutically beneficial wavelengths: 405 and 635 nm. Each wavelength is capable of stimulating a specific cascade to effectively treat onychomycosis. Both wavelengths are enriched by a proprietary, rotating line-generated beam; a unique delivery mechanism that maximizes photon concentration and treatment surface area – ensuring that all infected toes are properly treated. As a result, the Lunula provides a treatment absent of any adverse events while inducing key pathways to effectively address unsightly onychomycosis.

The **635 nm** 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. Additionally, NO is a powerful antimicrobial agent, and will help destroy the infectious agent. For resident macrophages and neutrophils, two types of immune cells, the increased production of ROS is quickly converted into cytotoxic hydrogen peroxide (H2O2), which is used by the immune cells to destroy onychomycosis-causing fungus.

STUDIES PUBLISHED ON BENEFITS OF 635 NM WAVELENGTH

Author	Reported outcome
Zheng H et al (1992)	Activation of immune cells (macrophage) by increasing concentration of ROS with laser.
Dolgushin et al (2010)	Stimulation of neutrophil function by increasing ROS production following laser.
Schindl et al (1999)	Activation PI3 kinase/eNOS signaling following 632.8 nm laser.
MacMicking et (al(1997)	Nitric oxide (NO) reveals antimicrobial effects against infectious agents.

Gasparyan et al (2006)	Laser at 632.8 nm increases new blood vessel formation (angiogenesis).

The **405 nm** wavelength targets NADPH oxidase (NOX), a membrane bound enzyme, and increases NOX's production of ROS, which can be converted into H2O2. As H2O2 starts to degrade the fungal cell wall and membrane fungi function and behavior will be greatly impaired. This can result in fungal death. Additionally, degradation of the fungi membrane and cell wall will increase fungal susceptibility to the body's immune attack.

STUDIES PUBLISHED ON BENEFITS OF 405 NM WAVELENGTH

Author	Reported outcome
Emmons et al (1939)	Fungal damage reported following stimulation with near-UV. light (~405 nm).
Klebanov et al (2005)	Membrane degradation reported as a result of increased ROS levels following laser at ~405 nm.
Eichler M et al (2005)	Increased ROS production following stimulation of NOX receptor with ~405 nm laser.
Lavi R et al (2012)	Increased level of ROS following stimulation with ~405 nm.

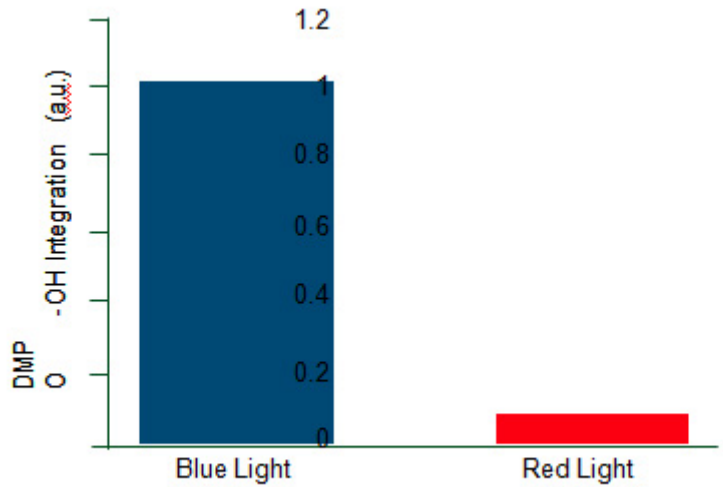
When applied concurrently, the two wavelengths represent a truly multifaceted treatment.

- FIRST – By increasing the production of ROS to damage the fungi and increase its susceptibility to an immune attack.
- SECOND – By increasing ATP and ROS to increase immune response by increasing blood flow and improving immune cell function.

HISTOLOGY

The production of ROS is crucial for the successful treatment of onychomycosis. The application of 405 nm has been reported to significantly increase the production of ROS and activate key secondary cascades to weaken fungi defense against the body's immune response, which in turn, kills the fungus. When compared to other wavelengths, 405 nm yields the highest production of ROS (Figure 1).

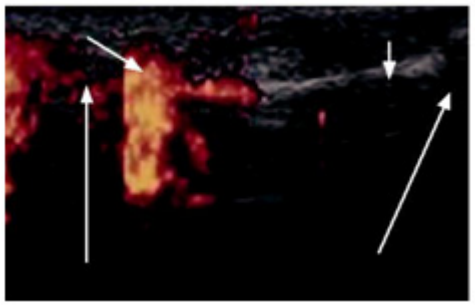
FIGURE 1. ROS generation following laser therapy at ~405 nm and Red Laser Courtesy of Lavi et al. (2012)



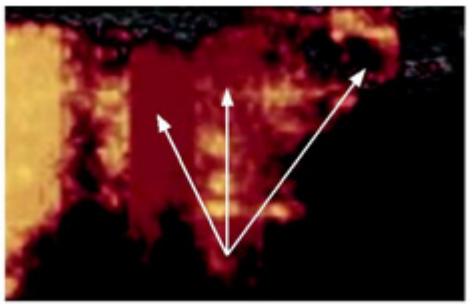
ROS levels using DMPO-OH (1µg/mL) after 170 second stimulation of sperm membrane.

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

BLOOD FLOW OF GREATER TOE WITH ONYCHOMYCOSIS



Baseline



Post-Procedure

Now available for sale in the US. The Lunula Laser is the 1st and only FDA Market Cleared laser device for the temporary increase of clear nail for patients with Onychomycosis.

ERCHONIA® Laser Healthcare™

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