

**A.R.C.
LASER**

enlighten your surgery.

FOX

ONYCHOMYCOSIS LASER THERAPY

**1064
nm**

UNIQUE LASER

ULTRA PORTABLE

EFFICIENT

FOX 1064 nm, 10W

IDEAL FOR:

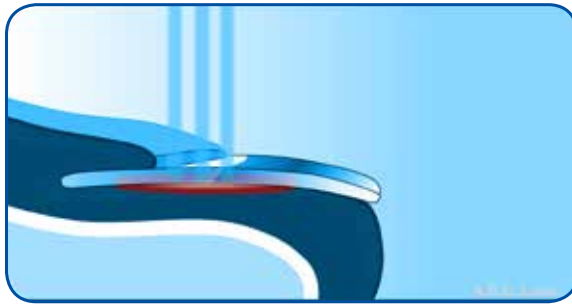
- ONYCHOMYCOSIS
FUNGAL NAIL
INFECTION



LASER...INNOVATION

MADE IN GERMANY

www.arclaser.com



FOX Laser offers an effective, pain free method of treating patients with fungal nail infection (onychomycosis) as an alternative to topical or systemic therapy.



FOX Diode Laser
1064 nm

FOX Laser – Perfect Nails without Medication 1064 nm

Questions and Answers

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Can the FOX Laser be used to treat nail fungus?

Yes, the A.R.C. FOX Diode Laser is an effective treatment of nail fungus infections caused by dermatophytes (*Microsporum*, *Trichophyton* and *Epidermophyton*), yeasts (*Candida albicans*) or mold fungus. In particular, this includes the most common pathogen: *Trichophyton rubrum* (ca. 80 %) ¹. This fungus subsists, like all other dermatophytes, on keratin and consequently causes nail fungus ².

¹ Ghannoum, M.A., Hajjeh RA, Scher R, et al., "A large-scale North American study of fungal isolates from nails: the frequency of onychomycosis, fungal distribution, and antifungal susceptibility patterns." *J Am Acad Dermatol* 43, 641-648 (2000).

² Elewski, B.E., "Onychomycosis: pathogenesis, diagnosis, and management." *Clin Microbiol Rev.* 1998 Jul;11(3):415-29.

How does the FOX Laser work?

The FOX Laser uses the 1064nm wavelength (close to infrared light) to easily treat and eradicate nail fungus leading to the increase of clear nails in patients with ony-



6 months after laser treatment
A.R.C. Laser Oct. 2012

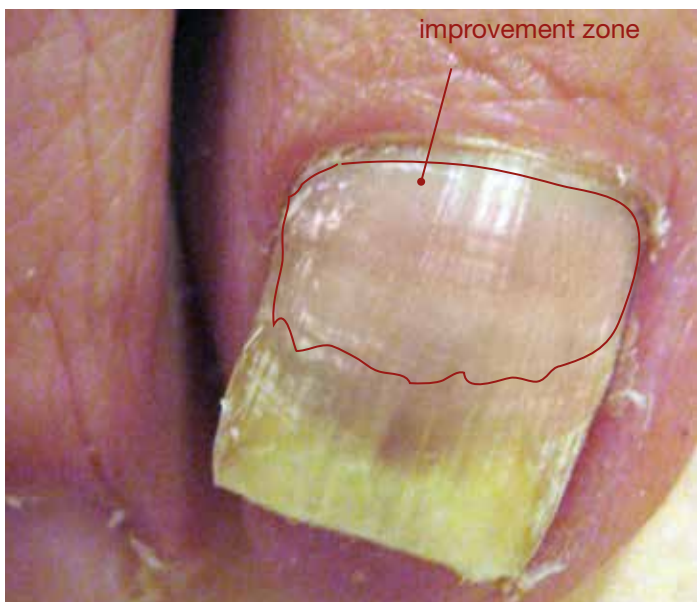
chomycosis (e.g. dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.). ³ The laser radiation penetrates the nail plate, the paronychium and the eponychium as it reaches the infected nail bed. The laser energy is only absorbed by the pathogens in the nail bed and not in the surrounding tissue. As a result, the increase in temperature will damage the cell wall causing the cells to die and inhibiting further growth. ⁴

³ Richard T. Bauer, DPM (PGY-2), Eliezer T. Eisenberger, DPM (PGY-2) Faculty: Emilio Goetz, DPM, Saint Barnabas Hospital, Bronx NY; The use of a 1064nm laser in the treatment of Onychomycosis

⁴ Christy Badgwell Doherty, MD Sean D. Doherty, MD, and Theodore Rosen, MD; Thermotherapy in dermatologic infections; *J Am Acad Dermatol* 2010;62:909-27

What preparation is necessary for laser treatment?

It is necessary to complete the appropriate podiatric diagnosis (pathology) to confirm that the condition is in fact fungal nail infection. All nail polish must be removed.



15 Years of nail fungus - 6 months after laser treatment
A.R.C. Laser Oct. 2012

Depending upon the degree of severity, it may be necessary to trim and debride the nail (removal of protrusions and reduction of the thickness of the nail plate to ca. 1 mm). It is recommended for the patient to wear freshly washed socks (60° C) after the laser treatment.

Can it treat all types of infections?

It is common for nail fungus to coexist with other types of fungal infections of the skin. In fact, this occurs in approximately 50 % of all nail anomalies and in one third of all fungal infections of the skin.⁵ If there is any evidence of the coexistence of tinea pedis in the treatment area (paronychia, eponychium, etc.), treatment with the FOX laser is not recommended.

Due to the tinea pedis, the skin may already be inflamed and the laser could worsen the condition. Other conditions to take into account prior to treatment include traumatic injury to the nail, Diabetes mellitus, peripheral vascular diseases (PVD) or ingestion of immuno-suppressive agents.

⁵ Szepietowski, JC, et al. "Factors Influencing Coexistence of Toenail Onychomycosis with Tinea Pedis and other Dermatomycoses." Arch Dermatol (2006). 142:1279-1284.

Is the treatment painful?

Vital for the success of the FOX laser treatment is the warming of the nail bed to approximately 45°C and that the warmth be maintained for at least 40 seconds. Even

though the patient will feel the warming sensation, no anesthesia is necessary. By using a moderate pulse energy and a constant motion over the nail, the desired dosage of laser energy can be uniformly delivered into the nail bed with minimal patient discomfort.

Can this treatment be performed on all skin types?

During the FOX laser treatment, the paronychia and eponychium will be uniformly irradiated to destroy fungal structures. The laser radiation will be absorbed more quickly by a patient with darker skin leading to a faster temperature rise. Therefore, it will be necessary to speed up the motion to avoid over treating.

What are the contraindications?

- patients with neuropathy (e.g. due to wound healing deficits or circulatory disorders, and possibly diabetics)
- patients with inflamed tissue or extensive tinea pedis in the area to be treated



Nail fungus - 3 month after 1st laser treatment
A.R.C. Laser Oct. 2012

FOX Laser – Perfect Nails without Medication 1064 nm

Questions and Answers

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2 months after 1st laser treatment
A.R.C. Laser Sept. 2012



3 months after 1st laser treatment
A.R.C. Laser Oct. 2012

How long will the treatment last?

Depending upon the size of the nail, the FOX laser treatment typically takes 1-3 minutes per nail or 15-20 minutes to treat all 10 nails. The laser beam is continuously in motion over the targeted area during the treatment. Depending upon the severity of the nail fungus, up to 3 treatment sessions at 6-8 week intervals may be necessary.

What will be the predicted cure rate?

In clinical studies, improvement has been observed in 68-80% of patients after 3 treatment sessions, but there is no guarantee of success. Results depend upon minimizing the risk of recurrence with adequate hygiene precautions (disinfection of the shoes, washing of the socks with 60° C, etc.). In addition, it is recommended to use an anti-mycotic cream between the toes and on top of the nails.

Are there any limitations after the FOX laser treatment?

After laser treatment, there will be a persistent sensation of warmth in the nail bed which may be uncomfortable. However, patients can return to normal activities.

Shoes and nail polish can be worn immediately after treatment.



FOX Laser – Perfect Nails without Medication 1064 nm

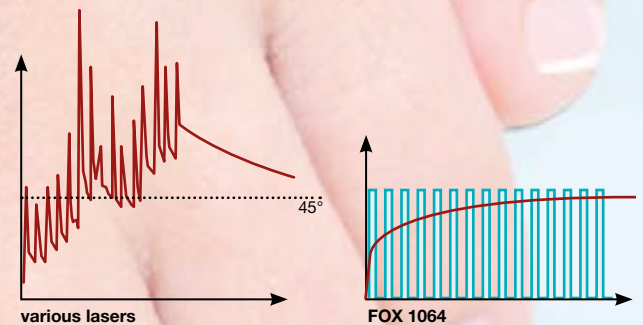
No Peaks - No Pain



FOX 1064

No Peaks - No Pain

Continuous output power from the FOX Laser avoids spikes of high power and enables a gentle treatment. The energy is delivered in precisely metered amounts into the nail bed creating pain-free warmth for your patients.



Perfect Nails without Medication 1064 nm

Advantages

FOX – safe & effective laser therapy!

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More that 500 systems are in use worldwide – the procedure is safe, quick and easy to perform.

FOX laser therapy is well tolerated and very effective for the temporary increase of clear nail in patients with onychomycosis. Since it is small and lightweight, the FOX Laser is truly portable.

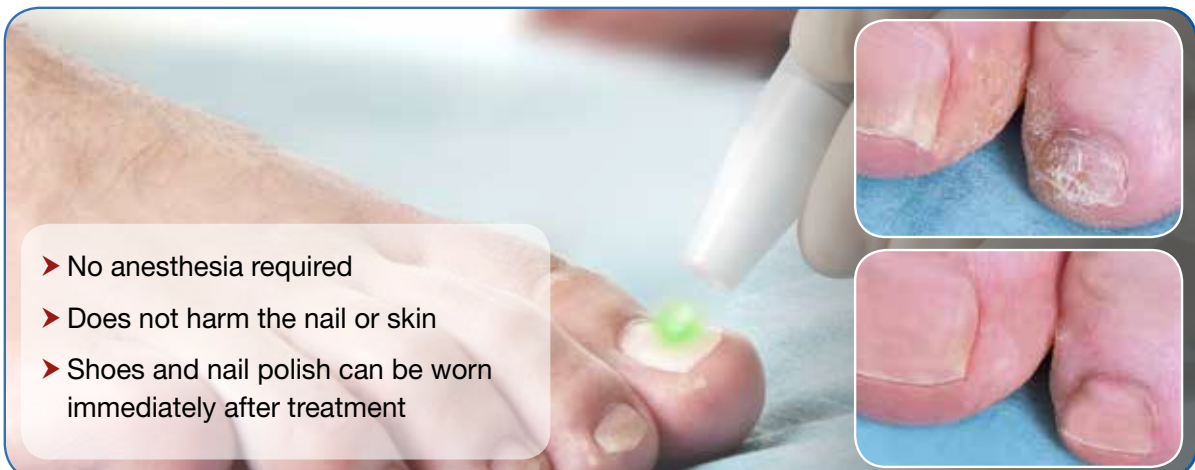
The laser beam penetrates through the nail, elevating the temperature to a level which inactivates the fungus.

- Made in Germany
- Small and Portable
- Proven Results
- Best Value
- Fast Return on Investment
- NO Consumable Expense



Ease to operate – Minimum risk of complications

FOX laser treatment is safe and effective.



- No anesthesia required
- Does not harm the nail or skin
- Shoes and nail polish can be worn immediately after treatment

FOX Laser – Perfect Nails without Medication 1064 nm

Documentation



09.10.2012
Patient: 79 Years



19.03.2013



11.10.2012
Patient: 81 Years



19.03.2012



19.11.2012
Patient: 52 Years



14.01.2013



26.11.2012

Patient: 68 Years - left foot



22.04.2013



26.11.2012

Patient: 68 Years - right foot



22.04.2013



17.12.2012

Patient 48 Years



19.04.2013

FOX Laser – Perfect Nails without Medication 1064 nm

Documentation



April 2013



June 2013



October 2013



December 2013



January 2014



March 2014

Pictures of this Page with courtesy of
Dr. Stephan Davis (Gatineau, QC, Kanada)



1064nm Onychomycosis laser treatment

USER DOCUMENTATION

WOLF, FOX 1064 nm



The use of a 1064nm laser in the treatment of Onychomycosis

Richard T. Bauer, DPM (PGY-2) , Eliezer T. Eisenberger, DPM (PGY-2)
Faculty: Emilio Goetz, DPM

MATERIALS AND METHODS

This study used a FOX 1064nm medical diode laser system manufactured by A.R.C. Laser GmbH. This laser is already FDA approved for a variety of medical & surgical applications. This study was also approved by the Institutional Review Board at Saint Barnabas Hospital.

Inclusion criteria were patients who had dystrophic nail(s) with a clinically appearing diagnosis of onychomycosis. Patient's must have had palpable pedal pulses and/or an Ankle Brachial Index (ABI) of >0.9.

All pediatric patients (<18 years of age) were excluded from the study, as well as any

patient who had taken an oral antifungal within 6 months prior to onset of this treatment.

Nail specimens were obtained from all patient's at the onset and conclusion of the total treatment regimen. These will be utilized at a later date for objective analysis.

Each patient was administered 4 treatments, each 2 weeks apart, and was evaluated for follow up 6 weeks after treatment completion.

During each visit, pictures were obtained of the nail(s) being treated, to be used for evaluation at the study conclusion. A panel of four volunteers analyzed and graded the pictures for any noticeable "clearing" of the nail plate. This was documented as 0% change, up to 25% change, or up to 50% change.

During the treatment delivery an IR (infrared) thermometer was used to monitor for increased tissue temperatures. If the temperature rose above 106 °F the treatment was ceased until temperatures normalized.

Laser parameters for each treatment were set at: 10 watts, 10ms duration, 4ms interval, motion average of 1cm/second.

Lastly, all patients were prescribed a topical antifungal to be used on all areas of skin (excluding the nail) to prevent any concomitant Tinea Pedis from re-introducing fungal elements into the nail.



Trichophyton rubrum usually invades the nail plate , nail matrix, lunula and nail bed

RESULTS

A total of 58 patients enrolled in our study, of which a total of 30 patients (194 toenails) completed four treatments (51.72%).

Patient satisfaction was 80% (n=24).

Average energy administered to hallux nails was 324.31 J and to all nails was 234.80 J per treatment.

Average nail temperature increase during treatment = 6.13°F.

Study panel reported zero clearing in 31.67% (n=9.5), 25% clearing in 33.33% (n=10), and up to 50% clearing in 35% (n=10.5) of the study patients. There were no adverse reactions reported.



Pre-Treatment



S/P 4 treatments (7weeks)

CONCLUSIONS

The laser treatment yielded a high patient satisfaction (80%) and subjective noticeable improvement to the nail was noted in 68.33% of patients which is comparable to the current "gold standard" of oral Terbinafine (Lamisil) reported to improve onychomycosis in 74% of patients. There were no adverse reactions in this study. Given its comparable rate of improvement to current treatment modalities we feel it is a viable option for all patients, and specifically for the immuno/vascular compromised patient.

Saint Barnabas Hospital, Bronx NY





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LASER...INNOVATION
MADE IN GERMANY

SPECIFICATIONS FOX 1064 nm

	1064 nm	10 Watt
Pulse Width / adjustable	0.1 ms to cw	
Pulse Intervall	0.1 ms to cw	
Aiming Beam	Green 532 nm, < 1 mW	
Dimensions (WDH)	142 x 163 x 174 mm	
Weight	1.2 kg	
Input Voltage	Integrated Batteries, rechargeable	

* at the distal end

Specify wavelength at order.
Changes in design and
specifications to enhance
performance will be incor-
porated without any further
notice.

