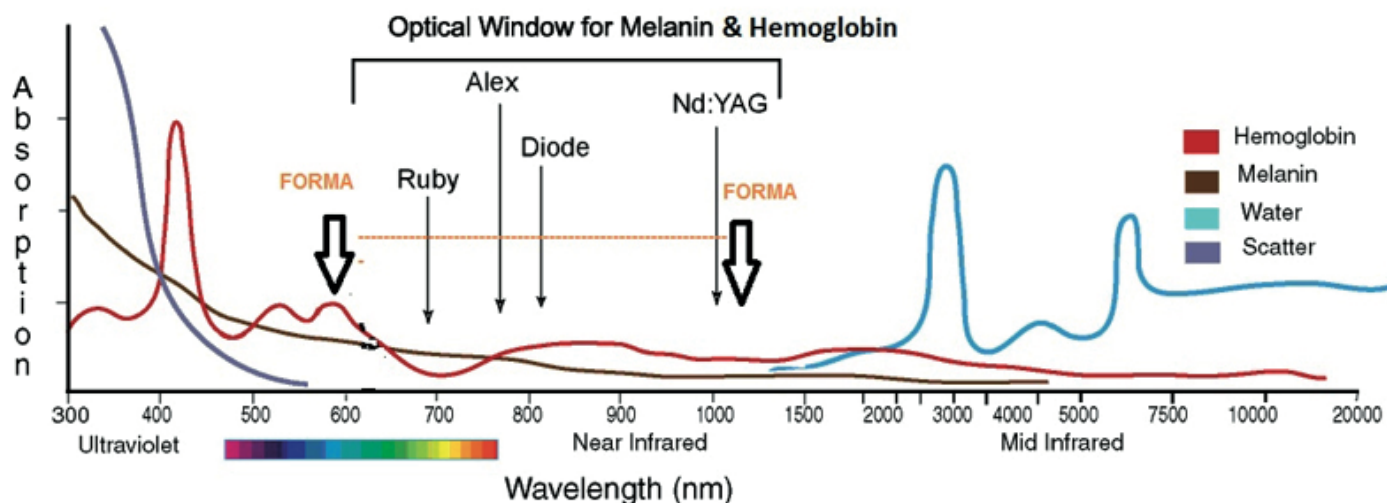


# High density Intense Pulsed Light Therapy in Onychomycosis) with Magma Long Pulse

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**Background:** Onychomycosis is one of the commonest dermatological conditions (prevalence between 7% - 10%). It is an infection of the nail apparatus by fungi that include dermatophytes, nondermatophyte moulds and yeasts (mainly *Candida* species). The toenails are affected in 80% of all cases of onychomycosis; dermatophyte infection, mostly due to *Trichophyton rubrum*, is the cause in over 90% of cases. Onychomycosis is classified clinically as distal and lateral subungual onychomycosis (DLSO), superficial white onychomycosis (SWO), proximal subungual onychomycosis (PSO), candidal onychomycosis and total dystrophic onychomycosis (TDO). Laboratory diagnosis is required and consists of microscopy to visualise fungal elements in the nail sample and culture to identify the species concerned. The common therapy includes both topical and systemic antimycotic agents. The primary aim of treatment is to eradicate the organism as demonstrated by microscopy and culture.

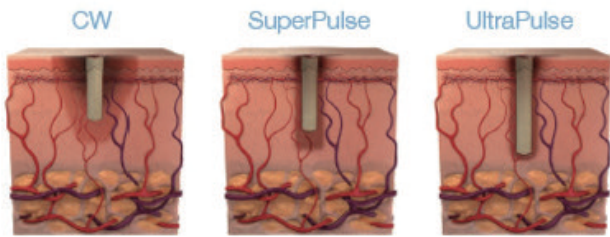
An innovative method of treating Onychomycosis is based on delivering a beam of intense pulsed light (IPL) radiation into a target area, to thermally deactivate pathogen microorganism without causing substantial unwanted injury. According to the Selective Photothermolysis principle, such radiation absorbed by the target tissue is converted to thermal energy that cause deactivation of the parasite organism by destroying it or render it unable to grow or reproduce itself. A polychromatic spectrum of wavelengths (530 nm – 1100 nm) can fairly be advantageous as it allows a wide range of chromophores absorption. Fungal coloration in the affected area tends to assume yellow to brown tones that act as chromophores and therefore absorb a part of the visible light energy (photons), which result in specific thermal damage.



randomly.

The quantity of energy and the consequent temperature, applied to the target (nail bed) must be sufficient (presumably around 45°C) to achieve the fungus deactivation, but not enough to cause collateral damage on adjacent tissue. This key factor is contemplated in the so called “Thermal Relaxation Time” (TRT) concept. TRT parameter is used for estimating the time required for heat to conduct away from directly heated tissue region. It represents the time taken for heated tissue to lose ~50% of its heat through diffusion. The epidermis TRT duration is 10 ms; exposure times should not exceed this value. Pulse duration assumes, therefore, together with its wavelength a critical importance in determination of lesion clearance and minimising side effects. Pulse duration choice is as important as that of the wavelength.

**IMPACT OF PULSE MODE ON TREATMENT OUTCOMES**



PULSE MODE	CW	SuperPulse	UltraPulse
Pulse Widths	Long	Short	Shortest
Thermal Zone	Widest	Narrow	Narrowest
Discomfort	High	Medium	Low
Downtime	Long	Short	Shortest

**Method:** a group of 10 patients (5 males and 5 females) was selected according to the following parameters:

*Inclusion criteria:*

1. Microscopic analysis and fungal culture lab test were performed in all affected nails and showed Hyphaes positive. Mycological species were identified in culture as Trichophyton Rubrum. (PSO and DLSO)

2. Patient’s age in the range of 30 – 55. The insurgence of pathology referred, within the last 5 years (< 5 years)
3. All patients were informed about the study aim, means and express their willingness to participate
4. All patients have signed before the treatment’s procedure an informed consent form

*exclusion criteria:*

1. Other onychopathies or deformation, nail deformations.
2. Non - Dermatophytes onychomycosis
3. Evidence of Intercurrent mucocutaneous diseases like Psoria sis, Lichen Planus, atopic dermatitis or phenomenon of Raynaud
4. Total dystrophic Onychomycosis or 10 fingers involvement
5. Diabetes type I
6. Pregnancy
7. Assumption of photosensitizing medications
8. Immune suppressed patients
9. Anticoagulant therapy
10. Systemic antimycotic agents in the last 6 months
11. Topical anti fungal medications in the last 3 months

All patients were asked to apply Xerial® 40 gel (40% urea, Serine, Histidine, Protease, etc.) twice a day for four weeks period, prior to the initial treatment and afterwards between the sessions, directly on the affected nails. Consequently, a certain keratinolytic action was induced on the nail plate and a significant reduction of the nail thickness was obtained especially on the hyperkeratotic nails. In such way, the penetration of the light beam into the nail bed was more efficient and powerful. After the application of conductive water base transparent gel (Parker® 03), 6 – 9 flashes were administrated on each affected nail, once every 7 days for 10 weeks, using FormaTM (Forma-tk Ltd. Israel) IPL technology with 530 nm – 1100 nm applicator. The pulse duration was 5.9 ms, delivering 21.8 J/Cm2 of fluence. No local

anesthesia or cooling was required. 12 weeks after completing the session's cycle, a second microscopic analysis and fungal culture lab test were taken. During this period all patients were asked to apply a topical antimycotic prophylaxis in socks and shoes area (Solution [topical spray] Lamisil®, Lamisil® ATTM 1%) in order to reduce the risk of re-contamination by exogenous or endogenous source.

***Results: laboratory analysis of all 10 patients, 12 weeks after the final session pointed out the following results:***

Mycological culture tests have shown a negative result 3 months after the last treatment in 70% of the group. Most of patients demonstrated a significant improvement in the nail morphology (less turbidity) and lesion clearance; visible improvements in the nail plate can be summarised in the following table. A partial and variable neo genesis of the nail matrix and nail plate underneath the lesion area was observed (especially the lunula zone), (as shown in the pictures). Microscopy direct examination found traces of spores / hyphaes in few patients although mycology culture resulted negative.



**Conclusions:** the results of the present study have demonstrated the efficiency of Forma™ IPL in terms of fungus deactivation and nail turbidity improvement (see pictures), in chronic PSO and DLSO caused by *Trichophyton rubrum*. Different other factors might influence the efficiency of the treatment such as hygienic conditions, regularity in the application of topic antimycotic agents (prophylaxis), etc. Based on the encouraging results obtained in this research, it would be advisable to conduct further hospital study that can evaluate other aspects of clinical and statistical evidence, confirm- ing the scientific validity to state this technological system as a therapeutic method of choice in the treatment of Onychomycosis.

Percent of Patients (%)	Visible improvement in Nail morphology (%)
20	75-100
30	50-75
30	20-50
20	-25