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*Introducing Peer Review  
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Independence ... Initiative ... Individualism

# Onychomycosis – PinPointe™

## FootLaser™ treatment

### provides a safe and effective alternative -



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**T**his article describes a new treatment modality using a Nd:YAG laser for the treatment of onychomycosis, a common condition to the Podiatrist. The prevalence of onychomycosis in the UK is estimated between 3% and 22% [1]. Mycotic infection accounts for half of nail conditions [2] with over half of the cases being seen in the toe nails [3]. Podiatrists are all too familiar with the challenges of treating - either symptomatically or curatively - mycotic nails. This includes inability to self care, embarrassment, discomfort, infection, onychophosis and onychodystrophy.

If left untreated the nail infection can spread to the skin as well as other toe nails with subsequent nail dystrophy. There have been several studies [4,5] demonstrating the psychological impact and reduced quality of life. The association with cellulitis for those at risk [6], together with primary tinea pedis and secondary bacterial infections, which, in the at-risk patient may compromise tissue viability.

The aetiology of onychomycosis is primarily invasion of opportunistic dermatophytes into and under the nail plate. *Trichophyton rubrum* and *Trichophyton mentagrophytes* accounting for about 90% of the infections. Yeasts - *Candida* and moulds for example *Aspergillus sydowii* and *Scytalidium hyalinum* are also detected.

The British Medical Journal listed occlusion as the biggest risk factor in the development of mycotic disease and the dark, warm, moist environment facilitated by general poor hygiene of the foot. The pathogenesis is typically invasion of skin followed by invasion of the nail unit, typically via the hyponychium. The resulting subungual hyperkeratosis and onycholysis provide further ingress with the potential to invade the entire nail with resulting dystrophy.

Diagnosis of onychomycosis can be difficult and an experienced Podiatrist would be familiar with its various presentations. Laboratory diagnosis is not conclusive. The presence of plantar desquamation or interdigital tinea improves confidence in clinical diagnosis [7].

Medicine has been quick to embrace laser technology. Dermatology is one medical field that has especially benefited from the high-powered thermal lasers. Laser irradiation can be highly selective by targeting specific pathogens. Variation of the laser wavelength, energy density, timing parameters and treatment procedure will all influence the clinical outcome. The laser parameters for treatment of onychomycosis have been optimised through years of research and are set on the FootLaser to these specific settings (a class IV neodymium YAG laser). The PinPointe™ FootLaser™ uses the two principles of photothermal ablation and near infrared inactivation.

The PinPointe FootLaser has been cleared for the treatment of onychomycosis by the FDA in America and has a CE mark for this use within Europe.

The treatment of onychomycosis can be symptomatic, topical, oral, surgical and now laser. Published data on the efficiency of

various non-prescription over the counter medicaments is sparse. Amorolfine lacquer (Curanail™), indicated for mild to moderate infection of up to two nails has a background of a prescription medication and has typical clinical effectiveness of 30% [8].

Terbinafine has been the oral drug of choice for many practitioners with over 20 years availability. The three-month cure rates range from 37.5% to 65% [9, 10, 11]. Itraconazole is 27% to 41% [9, 10, 12]. A combination of oral and topical treatment has achieved a reported 72% to 93% success [11,13].

Oral treatments are not free from potential side effects. Commonly headache, pruritis and taste disturbance have been reported. Cutaneous, hepatic and haematological effects are severe in 1 in 2000 patients [8]. Although terbinafine is generally safe, many patients and doctors are reluctant to take this route. Some Primary Care Trusts have non-treatment directives towards onychomycosis as well as reluctance by GPs to prescribe. There are no NICE guidelines relating to fungal treatments.

The PinPointe FootLaser achieved an 88% efficacy in a pilot study conducted by Brian McDowell, DPM in California [14]. Since its first use in America in 2008, the treatment has been improved and modified by providers. Recent retrospective analyses of private practice data have shown a range in efficacy from 60 to over 90%. The PinPointe FootLaser is FDA-cleared as being safe based on clinical data submitted to the agency. It has been demonstrated that the photo-thermal temperatures achieved are below the range of potential physiologic damage (44 degrees). Local analgesia is contraindicated during the procedure to enable feedback regarding sensation and heat. Following treatment, topical antifungal medication is applied and preventative methods and risk factors are discussed.

Toenail growth is estimated at 1.62 mm per month with the hallux nail growing at a faster rate than lesser nails [15]. It may be several months before clinical clearance of the nail is noted. Delayed clinical cure has been reported in several studies. In one [16], mycological cure following oral terbinafine was achieved in 82% patients compared to a 68% clinical cure (the placebo group achieving a 12% mycological cure, compared to zero clinically).

The benefits of the PinPointe FootLaser are clear. The treatment is safe, can be effective in a single treatment episode, there is no oral medication to take and there is no requirement to monitor blood chemistry. There are no specific patient groups whereby treatment is contraindicated but those with peripheral neuropathy or significant peripheral vascular disease may be more sensitive to the photo thermal effects so a restrained technique should be employed.

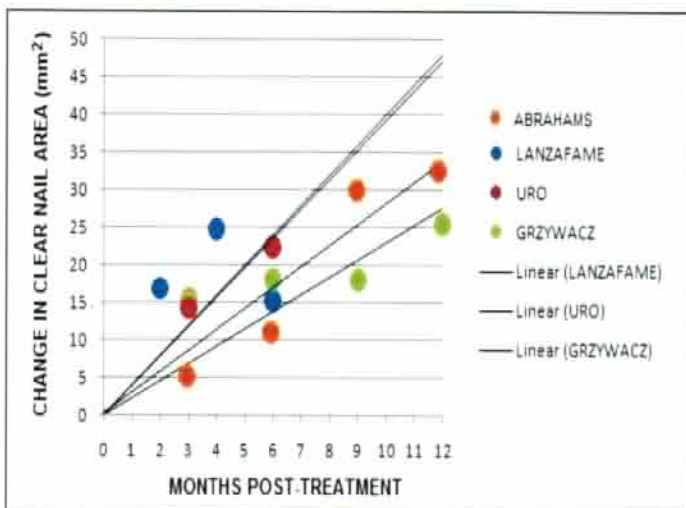
Treatment with the PinPointe FootLaser consists of aggressive debridement, cleansing and application of the PinPointe FootLaser. This 1-2mm diameter spot of pulsed laser light is applied to the surface of the nails and surrounding tissue including the proximal germinal matrix. At least 3 passes over the infected nails are carried out, although all nails are treated twice as a minimum. Topical terbinafine 1% is prescribed and

patient instructed to use twice daily for a week to treat underlying mycotic skin infection. The average time for combined consultation and treatment is approximately two hours for extensive cases. The nails are reviewed after 6-8 months after which approximately 6-8mm nail growth may have occurred and progress is monitored via photographic comparison. A second treatment to infected nails can be applied if required to eliminate any residual areas of mycosis or suspicion.

A preliminary review of retrospective patient data for The London Nail Laser Clinic, London, showed encouraging results and provided a foundation for future research. All patients attending for a review consultation between May 2010 and July 2010 were analysed. Of this group, 63 patients demonstrated hallux infection with pre and post treatment comparable photographs in this sequential, retrospective study. Digitised images were analysed by blinded photo-raters for percentage clear nail changes. Mean increase in clear nail was progressive over the 12 month follow up interval. Statistical comparisons ( $p < 0.001$ ) were highly significant at six and nine months where the sample size was adequate - 64% of treated toenails showed improvement at six months and 96% at nine months. At twelve months, 70% of nails had improved.

A retrospective study of 71 patients treated by Dr. Michael Uro, Foot Doctor Laser Center, Sacramento showed that 65% patients showed statistically significant clinical improvement at six months. More extensive infection (greater than 70% mycotic involvement) within the nail exhibited a superior clearance with 79% of these patients showing increase in clear nail at six months.

A conglomerate of data obtained by Podiatrists at three clinics during 2010 (Abrahams & Abrahams, London, Uro & Uro, Sacramento and Grzywacz, Las Vegas) involving 321 hallux nails demonstrated an efficacy range of 60-90% throughout a 12 month period with an increase of effectiveness with increased mycotic involvement. No adverse events were reported within the 197 patients included.



The development of the only new treatment for onychomycosis for over two decades is an exciting development to the Podiatrist and the medical community. The provision of a skilful but essentially simple direct treatment approach targeted towards the Podiatrist, is to be embraced by the profession.

Whilst onychodystrophy cannot be treated, the underlying infected nail, associated tinea pedis and general quality and condition of the nails and feet can be improved. Simple onychomycosis with associated yellow, orange and white discoloration due to fungal spores without dystrophy responds very well in the authors experience and as shown in photographic analysis.

## EXAMPLES OF TREATED NAILS WITH TIME DIFFERENCE BETWEEN TREATMENT AND REVIEW LISTED



The London Nail Laser Clinic

5 months



The London Nail Laser Clinic

6 months



The London Nail Laser Clinic

3.5 months

For more extensive cases with long term infection, research has suggested the combination of oral and topical treatments improve outcomes. At the very least, the combination of the PinPointe FootLaser together with oral terbinafine in some cases should improve results and this is an area of research to explore.

The PinPointe FootLaser is not available for sale, but PinPointe USA provides what could be described as a partnership plan. Pioneered in the USA, providers are now in the UK, Turkey, Germany and Australia as well as most States in America. The fungal nail industry is worth millions of pounds with pharmaceutical companies *Novartis* (Lamasil™) and *Galderma* (Curanail™) as well as various non pharmacy/prescription companies such as *Diaderm* (ClearZal™), Tea Tree Oil and a plethora of potions on the Internet promoting their products to those that suffer with this embarrassing and often distressing problem. Patients are keen to resolve their infection and struggle with the plethora of ineffective or time-consuming treatments.

Nd:YAG lasers cost upwards of £50,000 and are used in various fields. The PinPointe FootLaser is unique – designed and built specifically for onychomycosis. It is the only laser system for toenails cleared by the FDA in America with over 3 years clinical