

## Case Studies

# Onychomycosis and nail dystrophy treated with the PinPointe FootLaser

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A new modality has become available for the treatment of onychomycosis. I wish to share some results that I have achieved using the new FootLaser made by PinPointe

A new modality is certainly called for in the losing battle against this insidious disease, which is prevalent in the population worldwide. Pharmaceutical companies claim that as much as 12% of the population is contaminated with fungal nail disease.

The two cases I report both suggest that tight-fitting shoes can cause intermittent and prolonged trauma that allows the skin defences to be breached. Devitalisation of the local area through compressive exsanguination or tissue

injury and continuous trauma to the nail creates subungual damage, and a nutrient-rich source of decaying matter offers avenues for pathogens to exploit.

Homeopathic and naturalistic remedies such as bleach, tea tree oil, vinegar, thyme, oregano oil, ClariPro, Zetaclear, Antimonolium Curdum, Aloe Vera and mouthwashes rarely work and are mostly a waste of time and money. Pharmacology is normally the most effective treatment for onychomycosis. Over-the-counter (OTC) medication is available in outlets

and pharmacies, and the products have had some form of empirical testing and reviews performed by the pharmaceutical industry. Prescription lacquers and oral remedies are example of OTC medication, as are the range of sprays and creams overtly marketed as antifungal medications. The list includes terbinafine, itraconazole, fluconazole, clotrimazole, tolnaftate, zinc undecenoate and undecenoic acid.

The PinPointe FootLaser is the first medical device to obtain regulatory clearance (US FDA, EU, Health Canada, Australia and others) for the safe and effective treatment of onychomycosis. The reported percentage of patients receiving benefit from this treatment, 71.4%, is substantial.<sup>1</sup> Treatment with the FootLaser is repeatable, has no systemic toxicity and laser treatment does not preclude the use of other modalities.<sup>2,3</sup>

In February 2009, I added the FootLaser to my armamentarium of remedies against this stubborn and pernicious disease. To date I have treated over 150 patients. To follow are case reports of two of my patients, both with outcomes that I have not seen before with other forms of therapy.

Independent analysis of data from 109 photos from 60 of my patients was performed in November 2010 and demonstrated: that, at three months, 67% of all treated toes showed improvement, compared with 80% at six months, 68% at nine months and 84% at 12 months. Again, the differences over time possibly reflect different patient populations as well as continued improvement.

### CASE STUDY 1

The patient was an active and dynamic



**Figure 1.** TOP. Patient 1 as she presented to my office in December 2009 with a clinical diagnosis and positive mycology of onychomycosis in all 10 toes. She received a single treatment on 14 December and a second treatment in October 2010. BOTTOM. Appearance of her nails at 13 months post-treatment. All 10 toes responded to treatment, most with 100% clear nail.



**Figure 2.** Time series composite of left (TOP) and right (BOTTOM) 1<sup>st</sup> toes of patient 1. The images show the rate and process of the lesion growing out over a period of 13 months.

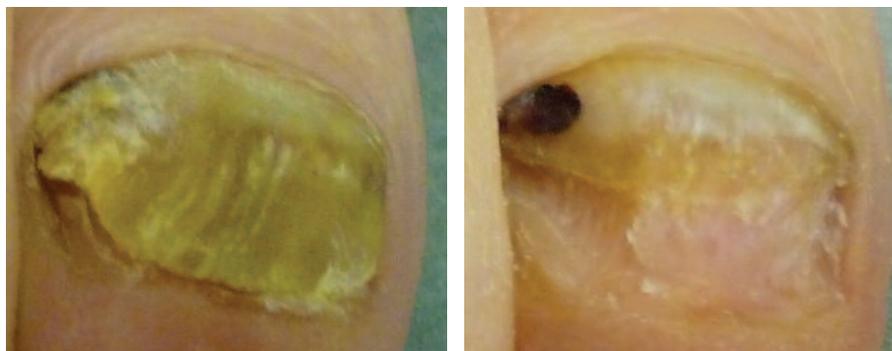
smartly dressed, 66-year-old female with pronounced onychomycosis and dystrophic nails on both feet; the right 1<sup>st</sup> nail (hallux) being the most severely affected. It was a condition she found embarrassing, uncomfortable, emotionally depressing and cosmetically abhorrent.

In around 2000, whilst out walking in rough adventurous terrain, she damaged both of her great toes to such an extent she feared she would lose them. It would seem that a combination of poor toebox space and slack fastening of the footwear caused repeated compression of the nail plates, leading to subungual trauma and onycholysis.

Over the next two years she noticed that they never fully recovered to their former condition but began to 'look worse'. The patient presented to a podiatrist in 2008, where routine cutting and thinning of the nails was initiated along with instructions on foot hygiene and advice to use OTC antifungal preparations. Later in 2008, after lab confirmation of dermatophyte infection, the patient was prescribed oral terbinafine.

As a consequence of the medication she developed uncomfortable abdominal swelling, giving her the appearance of being some months pregnant and she found it impossible to remain on the medication longer than two months.

By the time she arrived at my clinic in December 2009 she was disheartened that



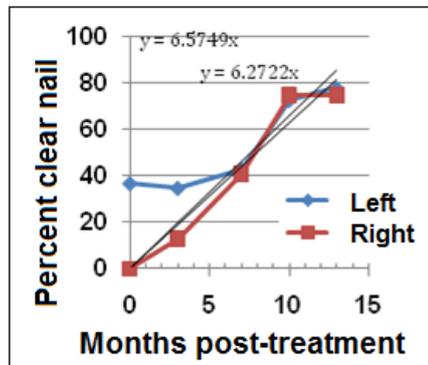
**Figure 3.** Patient 1 right first toe before (left) and after (right) debridement.

nothing had worked to eradicate the condition and was emotionally worn down by the effect of having a disfiguring disease (as she saw it). A medical history was documented, her feet were examined and an explanation of the modality of the PinPointe FootLaser was explained.

The patient was reminded of the options available including pharmacological, surgical and FootLaser. I explained the benefit of a toxicity-free approach, the fact that the FootLaser treatment is largely without any sensation, is condensed into the treatment time and has a level of success that surpasses all of the topicals and at least matches the outcome for oral medications, if not more effective. I also explained the need for her

to keep her review appointments and that she needed to provide a high level of foot hygiene and antifungal care to prevent recolonisation by opportunistic pathogens. The patient was also informed that recovery is highly variable from patient to patient. Factors such as trauma, poor hygiene, poor circulation, duration and severity of the infection, age and general health may all influence recovery. Finally, I told her that not every condition may resolve and a secondary treatment may be required in about 15-20% of patients. Following this explanation she consented to having the treatment.

The patient's feet were cleaned and pre-treatment photographs were taken (Figures 1 & 2). All nails were debrided to



**Figure 4. Continuous increase in percent clear nail over a 13-month period. Photographs from each follow-up period were computer analysed to quantify the change in area of clear nail. First left toe (BLUE) and 1<sup>st</sup> right toe (RED). The straight lines are linear regressions fit to the data that indicate lesion clearing at a rate of about 6% of the total nail plate per month.**

what I considered an optimal level. As much contaminated tissue needed to be removed as possible and all debris cleared away, including subungual debris. This leaves a good working surface that offers less interference to the laser-energy discharge and penetration into the tissues. However, this is done in a fashion that avoids trauma to the vital soft tissues. Photographs were taken again after debridement (Figure 3).

The FootLaser was methodically and meticulously applied to all nails in a 1mm spot matrix pattern. In addition to the nail plate itself, the nail margins, nail-root matrices and surrounding tissues were also lasered. The treatment area extended from approximately 4mm proximal from the eponychium to the end of the nail beds. The pattern was repeated twice over each nail.

Following the laser treatment, terbinafine spray was applied to the nails, toes and interdigital areas and terbinafine cream was applied to the skin on the plantar surfaces to help prevent recolonisation. The post-care advice was explained, and an advice sheet given together with antifungal cream and spray. A letter was sent to her GP detailing the treatment and contact made with her current podiatrist explaining the procedure.

In March 2010 the patient returned for a three-month interim follow-up examination. At this point and it was apparent that there were positive improvements in the nails, although bruising was evident in the nail due to the patient choosing stylish footwear that

traumatised the tissues. The right 1<sup>st</sup> toe was displaying a transverse ridge with dense keratinised tissue distally. All lesser nails showed greater clarity within the structure and they cut with a crisp and clear audible click, indicating improved integrity. The left 1<sup>st</sup> nail showed a more normal nail plate production in progress and an advancement of contamination from the nail matrix of 2-3 mm. Importantly, the patient was very happy with the early stages of the treatment. All nails were cleaned and debrided to remove excess keratin and dystrophic nail, and photographs taken. The patient was instructed to continue with her antifungal and hygiene care.

The patient returned in July 2010 for her 7-month progress evaluation and nail care. Once more photographs were taken, the nails reduced, onychophosis and subungual debris removed and 1% clotrimazole spray applied. Photographs of the nails after the reductions were taken. By now the nails demonstrated significant positive change and the most visually abnormal nail had almost grown out.

In October 2010, 10-months post-treatment, the patient requested a second laser treatment 'to be on the safe side,' as she put it. I advised that it was unlikely to be necessary but the patient was far happier for me to apply the FootLaser again. This time only the margins and a single pass was performed over all nails. Photographs were taken pre- and post-debridement antifungal spray applied.

In January 2011, 13 months after the initial treatment, the patient once more presented for routine care and an evaluation. Photographs were recorded pre- and post-debridement and 1% clotrimazole spray applied to protect the area. All nails show increased clarity, integrity and health (Figure 1).

### Analysis and discussion

I sent my before and after photographs of the patient's left and right 1<sup>st</sup> toes to a research company that uses a trained technician and a computer algorithm to measure the area of clear nail on each image. The results are presented in Figure 4. What is plotted is the percent of clear nail measured from each follow-up photograph before debridement. The left toe (blue) appears stalled at the onset, then, at 7-months it 'catches up' with the right. Both nail plates grow clear nail at a rate of about 6% of the nail plate surface per month. This is about the same growth rate as the nail plate itself.

I also noticed from this analysis that the clearing seems to stop at about 80%. Perhaps the continued trauma from tight-

fitting stylish shoes is what is preventing the patient's recovery from reaching 100%, or at least preventing accurate visual confirmation of 100% clearance.

At this point, the evaluation of the nails showed a change in texture vitality and structure. What was once a fungally infected, damaged and gryphotic right first toenail has now returned to an almost normal nail in every way. The patient is enormously happy with her outcome. I am left with the satisfaction that the PinPointe FootLaser has safely and successfully treated her fungal infection and in the process has apparently stimulated a rejuvenation of the nail bed and tissues in the nail root matrix. This is the first time I have seen this to occur in my entire career since graduating in 1981.

### CASE STUDY 2

Patient 2 was a physically active working male aged 63 with dystrophic and mycotically infected nails. The infection was clinically restricted to both 1<sup>st</sup> toes. Dermatophyte infection was confirmed by InTray DM at day 7 following initial assessment, however his physician had also diagnosed it some time before. He was uncomfortable with the thickness of the nails and also dissatisfied by the physical appearance, particularly in barefoot holiday settings. To the best of his recollection he had had his condition for 'several years'.

During this time the patient had tried a wide variety of topical, proprietary nail treatments and the condition continued to worsen. He did not consider oral medication as an option that he wished to pursue due to its restrictions on consumables and the impact that had on his lifestyle. Having heard radio advertisements about the new FootLaser, he arrived for treatment at my clinic on 17 November 2009.

His pastimes included competitive squash, extensive hill and robust fell walking. An examination of his footwear indicated the need for a larger size but complications were created by the narrowness of his feet causing difficulties in obtaining the best fit, as length is sometimes sacrificed for a narrower width to ensure better grip on the foot. I explained the need for improved toebox space during the post-laser recovery period.

On examination there was gross thickening of both 1<sup>st</sup> toe nail plates consistent with prolonged trauma and substantial subungual debris. This material was harvested for culture, which demonstrated dermatophyte contamination by day 7.



**Figure 5.** Time series composite of left (TOP) and right (BOTTOM) 1<sup>st</sup> toes of patient 1. The images show the rate and process of the lesion growing out over a period of 13 months.

A medical history was documented and an explanation of the modality of the PinPointe FootLaser explained. Then the consent forms were completed and pre-treatment photographs taken (Figure 5). All nails were extensively debrided and all loose subungual debris removed using clippers and Podospray foot drill with combinations of tungsten carbide burrs.

The FootLaser was methodically and meticulously applied to all nails in a lateral then longitudinal 1mm spot matrix pattern. The nail margins, nail-root matrices and surrounding tissues were laser proximal. Treatment began at approximately 4mm from the eponychium and extended to the very end of the nail beds. All 10 toes were treated and particular attention was applied to both 1<sup>st</sup> nails. The patient expressed his relief at the procedure being entirely painless.

Following the laser, terbinafine spray was applied to the nails, toes and interdigital areas, and then terbinafine cream was applied to the skin on the plantar surfaces. The post-care advice was explained, and an advice sheet given along with antifungal cream and spray. A letter was sent to his GP detailing the treatment and contact made with his current podiatrist explaining the procedure.

In March 2010 the patient returned for a 4-month post-treatment interim examination. At this point new photographs were taken, and it was apparent that there were positive improvements in the nails. Although the nails were still thick they showed good

structural integrity and improved clarity within the structure. When cut, all nails yielded a crisp and clear audible click and had good tensile strength, indicating improved integrity. Both 1<sup>st</sup> nails showed an improved connection to the nail bed at the distal margin. The nail on the first toe on the left foot showed a visible band of ~3mm width, indicating a difference in its structure compared with the rest of the nail. I speculated that this was perhaps newly re-keratinising nail plate and nail tissue.

All nails were cleaned and debrided to remove excess keratin and dystrophic nail and photographs taken. The patient was instructed to continue with his antifungal hygiene care. The patient was comfortable and satisfied with the look at this early stage.

The patient returned in July 2010, 8-months post-treatment for his second progress evaluation, and nail care. Once more photographs were taken, the nails reduced and onychophosis and subungual debris removed and 1% clotrimazole spray applied. Photographs of the nails after the reductions were taken.

By now the nails had already demonstrated significant positive change and most visually abnormal nail had almost completely grown out (Figure 5).

On February 11 2011, 15 months following FootLaser treatment the lesions in most nails had completely grown out. Yet, the computer analysis on this patient returned '100% infected' due to the persistent whitish discoloration. However,

this is certainly not the case since the patient is extremely pleased with the overall cosmetic improvement. He has had a lengthy period of time (July 2010 until March 2011) without any clinical interventions of any type and his nails have continued to show improvement in texture, clarity and health. The only negative I can find is the damage done to his nails from impact from his physical activities. I have yet to persuade him that his feet are longer than he thinks.

I am impressed with the changes that occurred in the nails of this patient following one intervention with the PinPointe FootLaser. It has led me to believe that the laser has some other (as yet unknown) rejuvenating influence on the germinating tissues. Although I have no direct evidence, my own personal experience with the laser and my years as a practising clinician lead me to believe as I continue to work with the laser that I am witnessing treatment outcomes that have not been witnessed before.

## REFERENCES

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