
3 Month Clinical Results using Sub-millisecond 1064 nm Nd:YAG Laser for the Treatment of Onychomycosis

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Introduction

Onychomycosis is a common infection of the nail, and it affects approximately 6.5% to 8.7% of North American population¹. It affects immunocompromised individuals (e.g. HIV-positive patients), smokers and patients with psoriasis, peripheral vascular disease, and those with history of trauma to the nail or a family history of onychomycosis¹. It is caused predominantly by anthropophilic dermatophytes (*Trichophyton Rubrum*, *Trichophyton Mentagrophytes* etc.) and to a lesser extent by yeasts (e.g. *Candida Species*) and non-dermatophyte molds¹.

Various topical and oral therapies have been used in the past to treat onychomycosis. Topical therapy such as potassium permanganate soaks was the primary method of treatment until the introduction of oral antifungal agents².

Oral antifungal agents, developed in the late 1900s, have since been the mainstay for treatment of Onychomycosis. While modern oral antifungal agents like Itraconazole and Terbinafine have exhibited a modest clinical success rate, the common adverse effects are headache, gastrointestinal disorders and cutaneous disorders. Abnormal liver function has also been reported in some patients using Itraconazole and Terbinafine. These oral medications are thus not recommended for patients with chronic or active liver disease or patients with renal impairment².

A novel non-invasive approach for treatment of onychomycosis involves the application of laser energy to the nail plate with a sub-millisecond Nd:YAG laser (Cutera, Genesis Plus) emitting energy at a wavelength of 1064 nm. The GenesisPlus system seen in figure 1 below is developed by Cutera and combines a unique patented high powered laser system with microsecond pulsing capability and high repetition rates.

The GenesisPlus hand piece seen in figure 2 is light weight and ergonomically designed to move over the area of interest without inducing user fatigue. An infrared thermal sensor is built into the hand piece which monitors the skin temperature of the treated anatomy real time. The light emitting diodes (LEDs) on the front side of the hand piece are calibrated to reflect the temperature detected by the thermal sensors and in turn facilitate skin temperature feedback to the user.

The goal of this study is to evaluate the efficacy of this laser for treatment of onychomycosis. The report includes treatment protocol and results through 5 months after the first treatment.

Treatment Protocol

A clinical investigation was conducted at the Weiss Foot and Ankle Center in New Jersey. Patient screening was done by testing mycology samples of both halluces for the presence of fungal strains (Trichophyton Rubrum, Trichophyton Mentagrophytes, Candida Species, molds etc.). Patients were enrolled only after mycological and clinical diagnosis of onychomycosis. Exclusion criteria included the administration of systemic antifungal drugs and use of antifungal therapies which changed nail pigmentation at least 12 months prior to commencement of the study.



Fig 1



Fig 2

Figure 1 - 2. GenesisPlus Console system (left) and GenesisPlus hand piece (right). The Laser cavity is placed inside the console and the energy is delivered to the hand piece through a fiber optic. The LEDs on the front side reflect skin temperature.

A total of 7 patients were enrolled in the study and all nails on both feet were treated starting with the hallux. Laser therapy was performed using the following parameters: 16 J/cm² fluence, 0.3 ms pulse duration, 5 mm spot size, and a frequency of 2 Hz. The entire nail plate was treated extending past the cuticle.

The laser hand piece was held 4 cm over the nail perpendicular to the nail plate and this distance was maintained through the course of treatment. The hand piece was continually moved in a controlled manner over the nail surface first laterally and then longitudinally so that the entire nail plate was covered.

The hallux was treated with approximately 100 pulses in each pass. The rest of the small toes cumulatively received approximately 100 pulses in each pass. Similar protocol was followed for the other foot. In one treatment session four passes across each nail plate

were applied, with each foot receiving approximately 800 pulses per session. The patients underwent two treatments spaced 6 weeks apart.

Efficacy was assessed using digital photographs of the two halluces. Nails were photographed with a high resolution digital camera (Nikon D90 SLR) before treatment and at week 6 and 12 post first treatment. At week 6, the patients received a second treatment using the same parameters.

Time taken to treat both feet was approximately 15 -30 minutes. Patients were treated without using anesthesia and no adverse side-effects were observed post treatment.

Results

Digital photographs of halluces of both feet were used to determine the efficacy of the laser treatment on onychomycosis. The severity of infection was determined by the degree of fungal involvement of the nails and was graded on a scale of 0 to 4 (0 – none, 1 – Mild, 2 – Moderate, 3 – Significant and 4 – Severe).

The efficacy was graded in terms of visible improvement from 0 – 4 on the basis of cosmetic clearance of fungal involvement in the nails where 0 – 0 - 5% improvement, 1 – 6 - 25% improvement, 2 – 26 - 50% improvement, 3 – 51 - 75% improvement, 4 – 76 - 100% improvement. The grading of severity of nail involvement and visible improvement 3 months after the first treatment is summarized in table 1 below.

Hallux #	Degree of severity of Baseline nail	Improvement on 3 month Follow Up
1	4	0
2	4	0
3	4	1
4	4	1
5	4	1
6	2	3
7	2	1
8	4	2
9	1	1
10	1	0
11	2	0
12	3	2
13	2	3

Table 1. Summary of the infection severity and improvement grading.

The above table shows that 46% of the nails treated during this study were severely infected nails, 8% were significantly infected and 31% were moderately infected while 15% of the nails were mildly infected. 70% of all treated nails showed improvement after 2 laser treatments spaced 6 weeks apart out of which 71% of the significant to severely infected nails exhibited improvement while 67% of the mild to moderately infected nails showed visible improvement.

3 month results of some patients treated with GenesisPlus laser are shown in the following figures below:

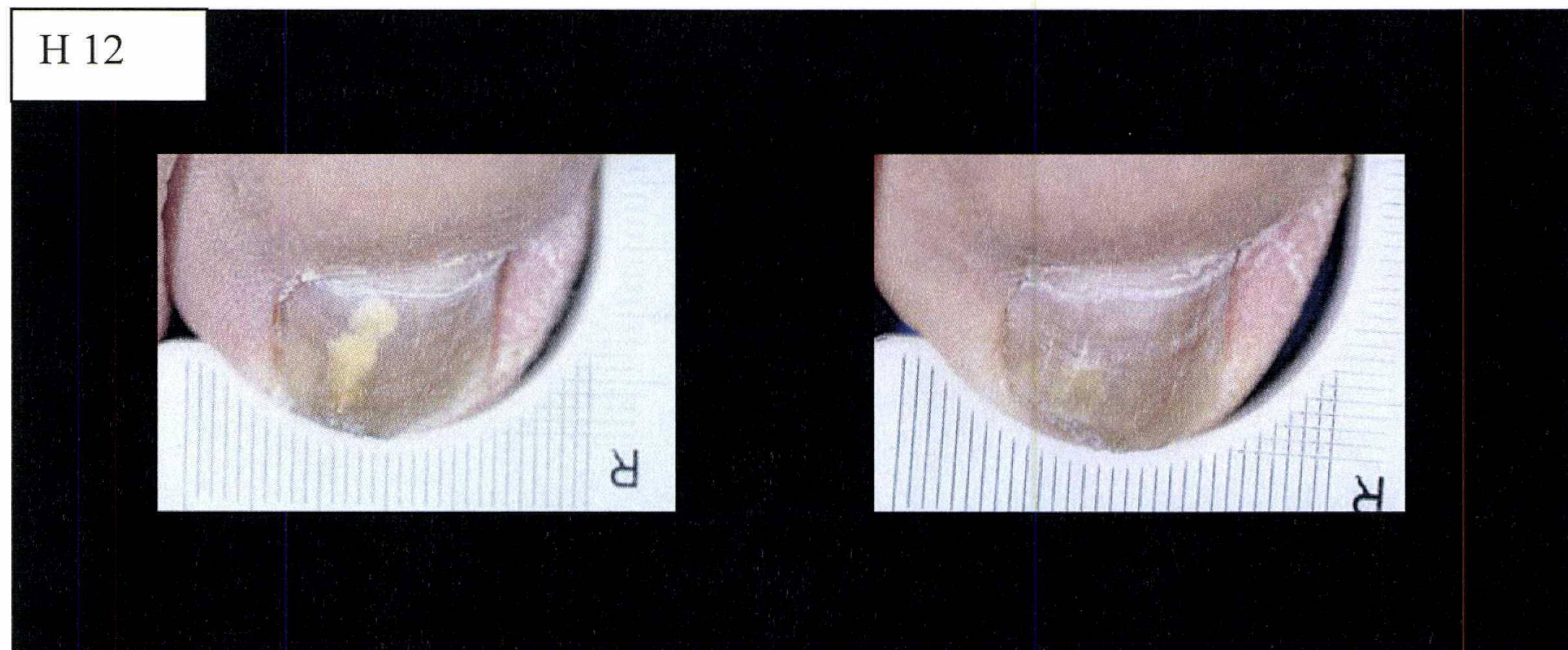


Figure 3. Progression of right hallux # 12 (from left to right): Baseline, 3 months post 1st treatment. Micology diagnosis of the baseline sample: Visible septate hyphae of *T. Rubrum*. Degree of nail involvement: Moderate

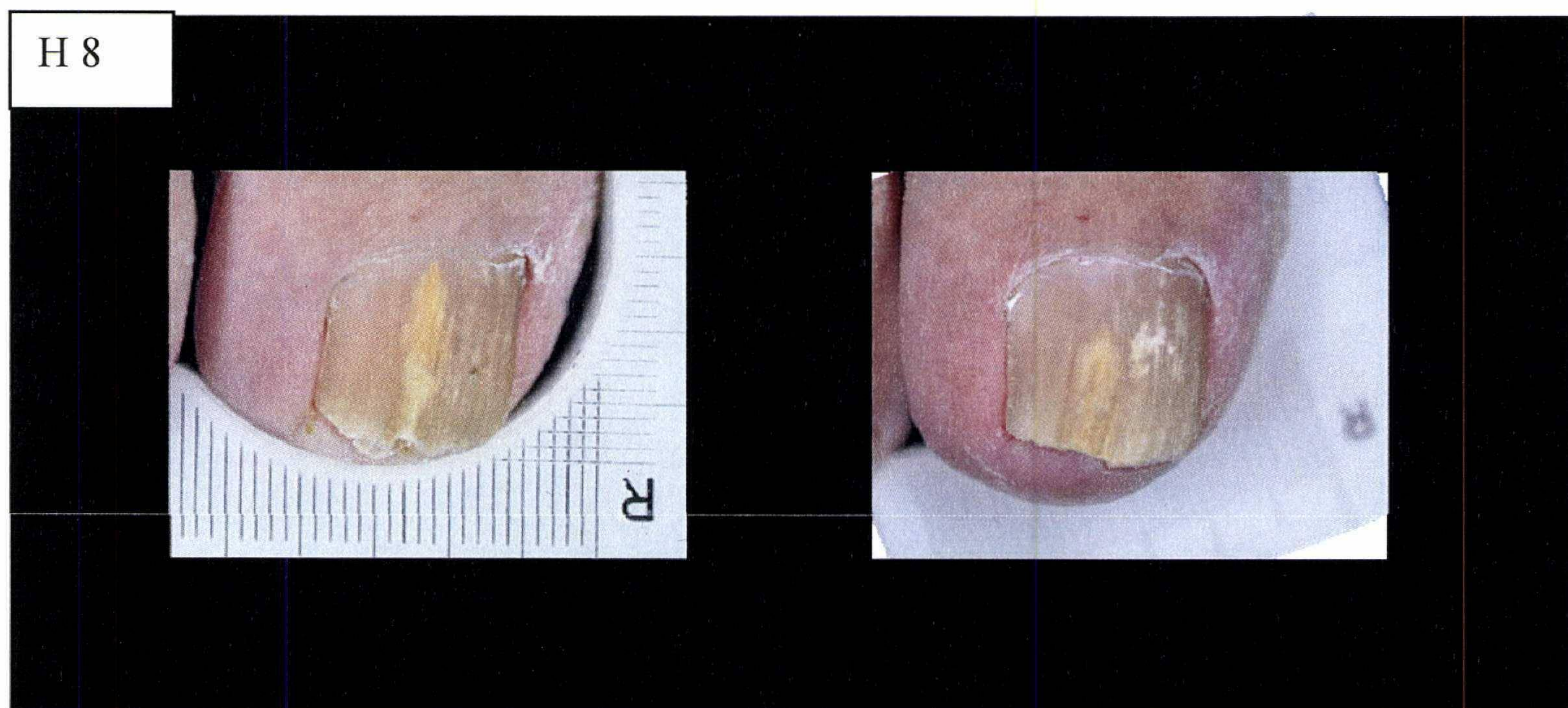


Figure 4. Progression of right hallux # 8 (from left to right): Baseline, 3 months post 1st treatment. Micology diagnosis of the baseline sample: Visible septate hyphae of *T. Rubrum*. Degree of nail involvement: Severe

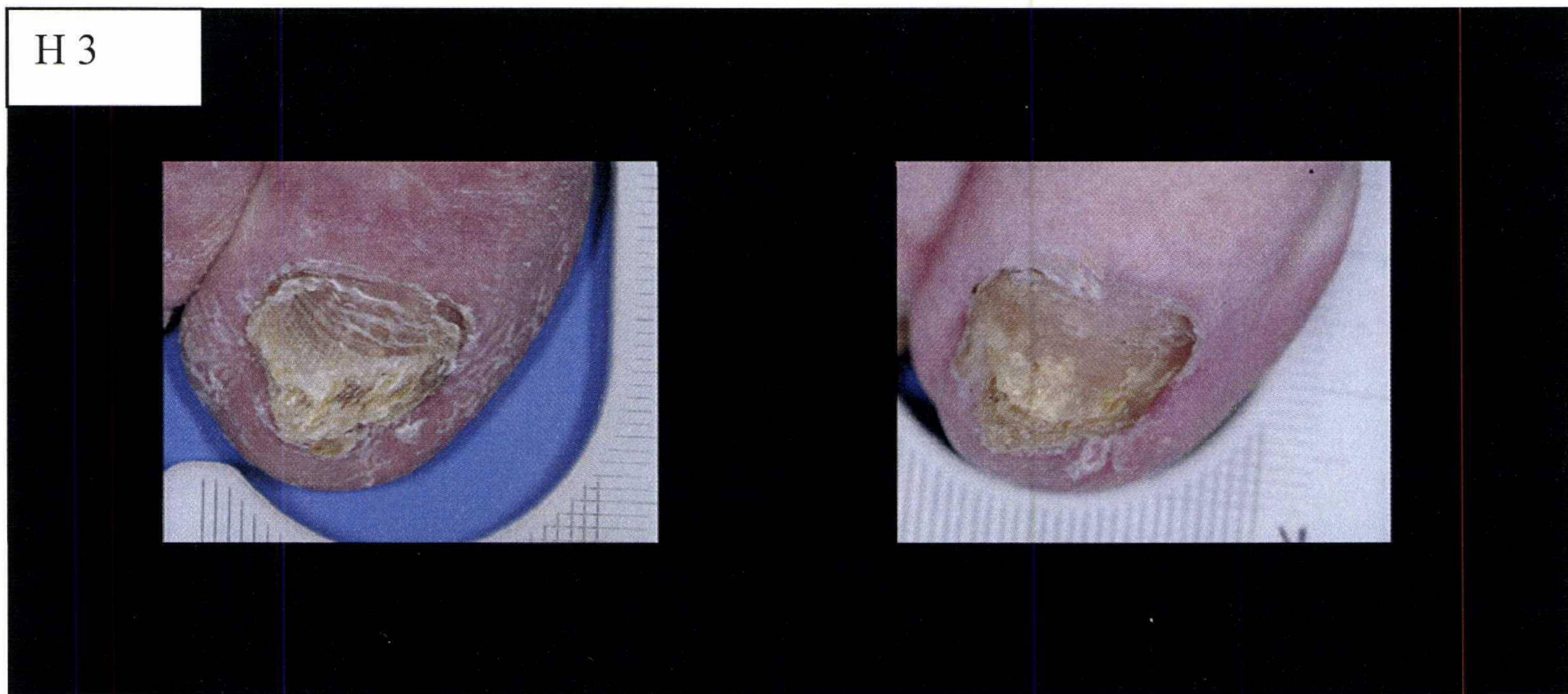


Figure 5. Progression of right hallux # 3 (from left to right): Baseline, 3 months post 1st treatment. Micology diagnosis of the baseline sample: Visible septate hyphae of *T. Rubrum*. Degree of nail involvement: Severe

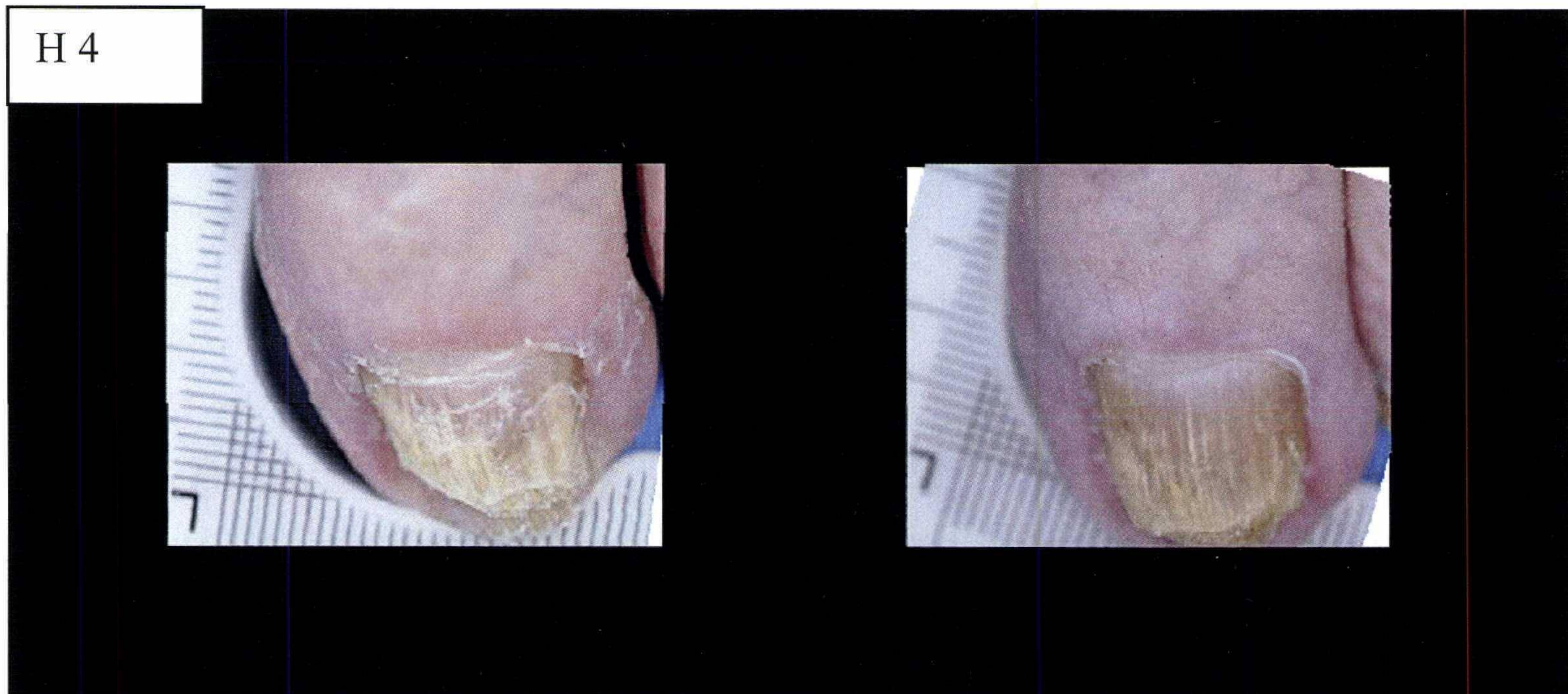


Figure 6. Progression of left hallux # 4 (from left to right): Baseline, 3 months post 1st treatment. Micology diagnosis of the baseline sample: Visible septate hyphae of *T. Rubrum*. Degree of nail involvement: Severe

Summary

Two GenesisPlus laser treatments on nails infected with onychomycosis are shown to have an efficacy of 70%. Efficacy is largely unaffected by the degree of severity of nail involvement. Although visible improvement is generally seen following nail growth (from the proximal end of the nail plate towards the distal end) where clearing is seen at the lunula, figure 6 shows clearance at the central part of the nail plate. Figure 5 shows a visible improvement towards the proximal part of the nail plate accompanied by a marked improvement in skin texture around the nail plate.

Laser treatment is seen to be more effective on the fungal striations present in the baseline pictures of figures 3 and 4. The early investigation confirms the efficacy of GenesisPlus Sub millisecond 1064 nm Nd:YAG laser in improving the cosmetic appearance of nails exhibiting mild to even severe form of onychomycosis.

References

1. Gupta AK et al. Onychomycosis: Classification and Diagnosis. *Journal of Drugs in Dermatology* 2004; 3(1): 51 – 56.
2. Gupta AK et al. Onychomycosis Therapy: Past, Present and Future. *Journal of Drugs in Dermatology* Sept 2010; 9(9): 1109 – 1113.