Evaluation of a short pulse Nd:YAG Laser Procedure for Infected Nails—A Retrospective International Multicenter Study of 262 Patients

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ABSTRACT

Study Purpose: To review the clearance of 262 patients (453 great toes) presenting with onychomycosis from three private practices that used the PinPointe™ FootLaser™ and a typical clinical protocol to determine outcomes in the percent of responders as well as percent of clear nail growth and lesion reduction in a subset of the patients. These patients were part of the multi-center study submission to obtain FDA clearance to market for the PinPointe FootLaser.

Study Design: In this retrospective study, patients received one PinPointe short-pulsed Nd:YAG FootLaser procedure. Before and after photographs of the great toe were taken at base line and post procedure follow up. Photographs were compared to determine response rate. In addition, planimetry using ImageJ software was used to determine clear nail growth as well as lesion reduction.

Study Results: The percent of patients presenting at long-term follow-up intervals with reduced lesion area were 67.7% at 3 months, 70.5% at 6 months, 76.8% at 9 months and 81.5% at one year. Planimetry showed that in the subset of toes where measurements were conducted there was a 100% response rate. A mean of 78% of absolute clear nail area was achieved with a 181% of clear nail growth.

Conclusions: Results indicate that the PinPointe FootLaser procedure can improve the percentage of clear nail and reduce the overall lesion size in clinically diagnosed onychomycosis.

INTRODUCTION

Onychomycosis is a pathogenic infection of the nail that affects an estimated 10-30 million people in the United States alone.[1] In the geriatric population, the prevalence is reportedly as high as 40%.[2,3] This infectious disease can be severe enough to drive millions of patients per year to seek medical treatment. In the setting of underlying conditions, onychomycosis may lead to more severe sequelae, such as opportunistic infections in the case of HIV[4] and amputation in diabetes.[5,6] Further, an infected nail serves as a reservoir of disease that can lead to recurrent *Tinea pedis*.[3] A chronic disease with a high chance of recurrence, onychomycosis is a condition without a cure and in need of methods offering better disease control.

Currently there are two FDA-approved oral antifungal drugs used to treat onychomycosis: 1) oral terbinafine (Lamisil©) and 2) itraconazole (Sporanox©). Oral terbinafine has an efficacy of 35-78%, and itraconzole has consistently lower efficacy.[7,8,9,10] As with any pharmaceutical therapy, these treatments confer potentially serious side effects and drug interactions.[11] In our experience, less than 10% of patients presenting with onychomycosis are eligible for treatment with terbinafine.

In addition to oral antifungal drugs, topical therapies are also indicated for the treatment of onychomycosis. Nail lacquers containing ciclopirox, amorolfine,

tioconazole or a combination of these agents comprise the majority of topical creams available to treat onychomycosis. Topical therapies involve weekly or daily application to the infected nail for a period of nine to twelve months. Despite diligence and consistency in application of the drug, topical therapies such as ciclopirox are effective in about 10% of patients.[13]

Our experience suggests that potentially 90% of patients suffering from onychomycosis may benefit from laser procedures. This paper describes the results of retrospective analysis of before and after photographs of great toes which received the FootLaser procedure. The laser procedure was consistent across practices. A subset of patients has been analyzed to show clearance in nail growth.

MATERIALS AND METHODS

Patients all provided informed consent to use their data anonymously for scientific publication. Patients had a clinical diagnosis of infected nail usually without laboratory verification. A total of 262 patient records with 453 infected great toes were collected, reviewed and analyzed post-procedure and follow up.

CLINICAL PROTOCOL

Patients all received routine medical management of their conditions. The clinical protocol included pre-procedure debridement, which incorporated removal of distal onycholytic nail plate and thinning of hypertrophic nail plate to a thickness of 1 mm or less using a high-speed burr. Toes were not anesthetized for the procedure. The laser used was the PinPointe short-pulsed Nd:YAG FootLaser (NuvoLase Inc., Chico CA 95973). A single spot consisted of a pulse train of ten 255 mJ, 90 µs duration pulses at 1064 nm, delivered into a 1.5 mm spot with ergonomic timing and audible alert to allow precise movement by the practitioner. Laser spots were delivered in a grid pattern with 1.0-1.5 mm spacing. The total light dose averaged 115 J/cm^2 per pass over the entire nail plate plus a 2-5 mm margin. One or two laser passes were used with the FootLaser on one or both great toes. Other toes usually received the FootLaser procedure but are not included in this analysis. A topical antifungal was applied after the procedure and the patient was instructed in its daily use.

Additional foot hygiene instructions were given and patients were followed at approximately three-month intervals. Patient's used the SteriShoe® product to sanitize their shoes. Great toe photos were obtained of toes before the procedure and at followed ups, to a maximum of 10 months post-procedure. The photographs were compared to assess response rate. In a subset of five toes planimetry was used to calculate clear nail growth and lesion reduction.

PLANIMETRY OF PHOTOGRAPHS

Patients were included in the analysis if they had a usable baseline photo and at least one useable follow-up photo. The photo had to be of sufficient quality to clearly visualize the extent of the entire nail plate. Planimetry was performed to measure lesion reduction and clear nail growth on a subset of patients.

The total nail plate area is defined by the anatomical boundaries of the hyponychium distally, the lateral folds medially and laterally and the eponychium (cuticle) proximally. The hyponychium is a stationary anatomical landmark and is identified as the distal boundary independent of the variable distal location of the nail plate. In most cases the area bounded by the hyponychium distally and the infected /clear nail boundary proximally is the "lesion." The area from the boundary to the eponychium is "clear nail." The boundary between lesion and clear nail was often evident but sometimes ambiguous.

Since this was a retrospective study, the images of the great toe that were submitted for analysis lacked a distance scale and Adobe Photoshop was used to achieve a consistent magnification. Photos were neither enhanced nor filtered hence the margin between clear and infected nail was unaffected. Using Adobe® Photoshop®, a technician traced the area of clear nail and the area of infected nail. To achieve consistency with measurements and evaluation the following defining criteria was used: Clear nail was defined with objective criteria as a uniform pink coloring, reddish, flesh or pale; smooth surface and normal thickness. Areas that are slightly discolored but smooth and normal thickness are generally considered clear. Infected nail was defined with objective criteria as a milky white, black, brown, yellow or occasionally green color.

Areas with distal or proximal spikes are considered infected. The nail plate may be smooth but more often flakey, distorted, roughened, ridged and/or thickened. The nail plate may be separated from the nail bed (onycholytic) (Figures 1,2)The photos which outlined the clear and infected nail area were opened in ImageJ software and measurements were taken. The area was calculated in pixels which was then used to represent the area of the lesion at the baseline and the follow up time point.

The baseline lesion area was defined as the total infected area including discoloration, thickening and yellowing of the nail at baseline. The follow up lesion area is defined as the total infected area including discoloration, thickening and yellowing of the nail at the follow up time point. The lesion reduction (% of baseline) was then calculated by dividing the absolute lesion decrease (%) by the baseline lesion area (%).

Student's T-test was performed and p-values lower than 0.5 were considered significant. Standard deviation was calculated to determine the variation that existed from average.

RESULTS

Patient photos meeting study criteria yielded results from 262 patients. Of these, 51% were male and 49% were female. The mean age of the patients was 53.8 years (range= Ages10-87, SD=14.6). The ethnicity was 90% Caucasian, with an additional 4% Asian, 3% Hispanic, 2% African-American and 1% other. The useable photo sample included 453 great toes that had received the laser procedure.

The percent of patients presenting at long-term follow-up intervals with reduced lesion area were 67.7% at 3 months, 70.5% at 6 months, 76.8% at 9 months and 81.5% at one year.

Increase in Clear Nail Area and Lesion Reduction in Subset of Toes

A subset of 5 toes that were measured by planimetry showed that 100% of patients responded and had an increase in clear nail growth at follow up. The mean baseline clear nail area was 28% (±32%) of the nail. After an average of 7 months post procedure the clear nail area was increased to 78% (±6%) of the nail. Using these two measurements, the clear nail growth (% baseline) was calculated to be 181%. (Table 1, Figure 3).

DISCUSSION

This study evaluated the PinPointe Short-Pulsed Nd:YAG as a laser procedure option for the temporary improvement in clear nail in patients with onychomycosis. The PinPointe laser utilizes the 1064 nm wavelength which has the ability to pass through the nail plate into the nail bed of the toe. As a result, the fungal material in the nail bed is heated to very high temperatures which inhibits growth, causes damage, and targets dermatophyte cells. As the temperature beneath the nail plate increases, chemical reactions that promote fungal cell growth occur less efficiently and growth slows. Eventually as the temperature reaches a certain point, growth completely stops and cell components such as enzymes and cell membranes are damaged by the heat. Hashimoto and Blumenthal studied the effect of heat on dermatophyte arthropores and found that arthrospores of T. Rubum, the primary dermatophyte that causes onychomycosis, were sensitive to heat. This indicated that heat may destroy most of the dermatophytes and the spores they produce. Vural et al further studied the inhibitory effect of heat on dermatophyte cells. They found that the laser procedure with the 1064 nm wavelength resulted in a much slower growth rate, indicating that the laser energy was inhibiting the growth of the dermatophytes. They suggested that the 1064 nm might be useful in targeting not only the dermatophyte cells but the blood supply associated with their viability because this wavelength is readily absorbed by Hemoglobin.

Studies evaluating the efficacy of oral and topical antifungal treatments measured improvement and reported data based on complete cure of onychomycosis. The success of topical treatments was low (7% for Sporanox) due to the inability of the medication to reach the nail bed, long treatment time (9-12 months) and dependency on patient compliance.[14,16] Efficacy of oral terbinafine was variable (35%-78%) which can be attributed to antibiotic resistance and dependency on patient compliance.[8,9,10]

In this study, efficacy of the 1064 nm laser was measured based on clear nail growth and reduced lesion area. Both measurements showed a significant improvement with 78% clear nail growth and a decrease in the lesion from 72% at baseline to 22% after an average of 7 months. The laser procedure

also improved the quality of the nail (Figure 2) further increasing patient satisfaction. When comparing this study to the use of oral and topical antifungals, the use of the 1064 Nd:YAG laser has provided an alternative option which has demonstrated significant efficacy for the temporary improvement in clear nail in patients with onychomycosis.

In addition to a very prominent laser procedure effect, it is possible that long term efficacy of at least 1 year is influenced by the improved medical management, changing to appropriate footwear, prescribed regular use of topical antifungal treatments, ways to avoid toe trauma and reinfection is a partial list of advice given to patients in this study. One expects that these will all improve the clinical outcome, although used alone, historically, these remedies have been disappointing. Still, the possible effects of aftercare should be considered in interpreting these retrospective data. The most conservative conclusion of this study could be that a procedure with the laser, embedded in a program of proper management, results in overall improvement in the percentage of clear nail.

The sample in this study represents a cross section of the actual patient population. These were patients with a clinical diagnosis of toenail infection who had elected the FootLaser procedure with the cosmetic goal of improvement in nail appearance and increase in clear nail without toxic systemic side effects. The laser procedure was not restricted to only patients with laboratory confirmed dermatophyte infections. Podiatrists are experienced in diagnosis of psoriatic nails, onycholysis, onychogryphosis, onychomycosis and trauma. It is understood that the infected nail is typically a mixed species infection including dermatophytes, molds, yeasts and bacteria.

CONCLUSION

The use of the PinPointe FootLaser has proven to be an effective procedure option for the temporary improvement of clear nail in patients with onychomycosis. Patients in this study experienced 181% new nail growth reducing the average lesion from 72% at base line to 22% at follow up.

ACKNOWLEDGMENTS

The co-authors have no financial interest in the PinPointe FootLaser.

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Figure 1. Subject ES Planimetry Analysis

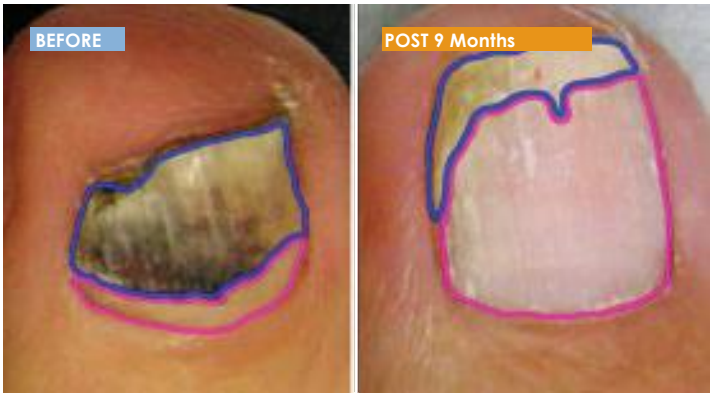

Figure 2. Subject LA Planimetry Analysis

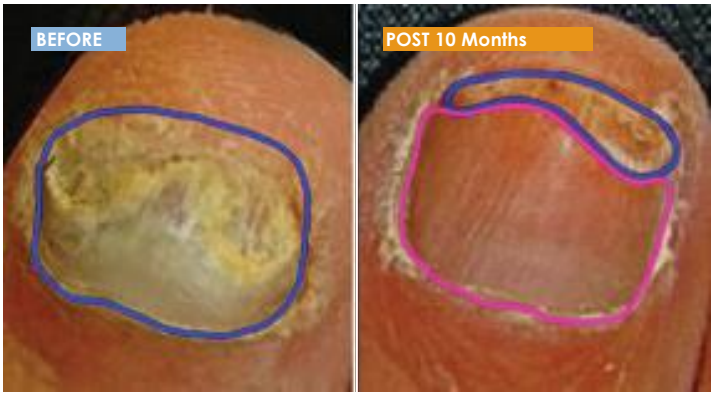

Figure 3. Average percent of nail that was infected or clear at baseline and follow up

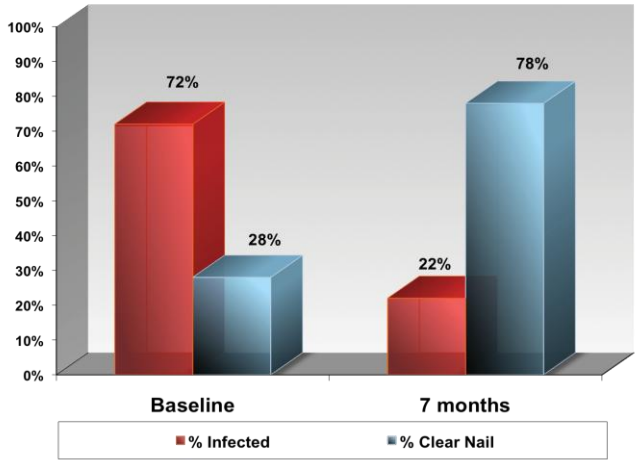

Table 1. Improvement is quantified by increase in clear nail growth

Clear Nail Growth Determined by Area Calculated in Image J

Follow-Up period Average	# of toes	Mean Baseline Clear Nail Area	Std. Dev.	Mean Follow-up Clear Nail Area	Std. Dev.	Clear Nail Growth (% Baseline)	% of Patients with Increase in Clear Nail
7 months	5	28%	32%	78%	6%	181%*	100%

*p-value=.016, p-value lower than .05 is considered significant

The mean lesion area at baseline was determined to be 72% (±22%) of the nail and was reduced to 22% (± 6%) of the nail at follow up. Based on the mean baseline lesion area and the mean follow up lesion area, lesion reduction was calculated to be 69%. (Table 2, Figure 3).

Table 2. Improvement is quantified as the lesion area reduction (% baseline)

Lesion Reduction Determined by Area Calculated in Image J

Follow-Up period Average	# of toes	Mean Baseline Lesion Area	Std. Dev.	Mean Follow-up Lesion Area	Std. Dev.	Lesion Reduction (% Base-line)	% of Patients with Reduced Lesion Area
7 months	5	72%	22%	22%	6%	69%*	100%

*p-value=.016, p-value lower than .05 is considered significant

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Improving the Appearance of Clear Nail in Patients with Onychomycosis Using a MicroPulse Nd:YAG Laser: A Case Study

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INTRODUCTION

Onychomycosis, a disease caused by dermatophytes, non-dermatophytes and Candida species of fungus, is the most common infection of the nail, affecting 2-8% of the general population, and increasing to 12-28% in adults 60 years or older.[1,2] Nails that are infected with onychomycosis have yellowish or brownish discoloration, a thickened nail plate, and crumbling edges.[2] These qualities can lead to toenail discomfort, secondary bacterial infections and psychosocial issues such as anxiety, depression, loss of self-esteem, avoidance of intimacy and impaired relationships, all of which can severely affect a patient's quality of life.[3,4] Several factors, including diminished blood circulation, longer cumulative time of exposure to fungi, nail trauma and a compromised immune system make people more susceptible to infection.[5] High rates of persistence and recurrence make onychomycosis very difficult to treat.

The primary treatment methods for treating onychomycosis are systemic administration of oral antifungal drugs and topical antifungal creams applied directly to the infected nails.[6] The most common oral antifungal drugs include Terbinafine, Fluconazole, and Itraconazole.[6] Long-term cure rates for oral antifungals range from 21% to 53%.[7] Systemic treatments require liver tests before, during, and after treatment, and can have serious side effects, including diarrhea, dyspepsia, rashes, taste disturbances and abdominal pain.[6] Patient compliance to the blood testing and requirement to discontinue use of all alcoholic beverages during the course of treatment, can be a challenge. Topical antifungal agents used to treat onychomycosis include nail lacquers containing ciclopiroxolamine, amorolfine, toconazole or a combination of these agents.[6] Results from several clinical studies indicate that topical cure rates can range from 21% to 36%.[8] Factors that make topical antifungals unsuccessful include long-term application (9-12 months), lack of patient compliance, serious side effects and failure to apply the medication appropriately to the nail bed.[9,10]

Laser therapy has recently become a viable option due to its rapid procedure duration, possibility for efficacy without systemic treatment or blood monitoring, few contraindications and no significant side effects.[11] In addition to these benefits, several studies have demonstrated that laser therapy is both safe and effective in improving the cosmetic appearance of nails infected with onychomycosis.[2,3] This case study evaluates the PinPointe™ FootLaser™ as a acceptable and reliable option for the temporary improvement of clear nail in patients with onychomycosis.

METHODS

Blue Ridge Foot Centers and Carolinas Laser Toenail Centers have been using the PinPointe FootLaser for over three years. Prior to the laser procedure, if needed, patients receive extensive debridement using nippers, curette and a mechanical filer to remove the distal onycholytic nail plate and thinning of the hypertrophic nail plate to 1mm thickness. A smoke evacuator is used to clear the nail of the debris. Patients are then lased with the micro-pulsed Nd:YAG laser. The laser utilizes the 1064nm wavelength, 255 mJ of energy, a pulse width of 100 µm, spot size of 1.5 mm and a power setting of 6 watts. Each pulse delivers 10 micropulses over 0.5 seconds and 25.5 J/cm^2 with a pulse width of 100 µm. Laser spots were administered in a grid pattern with 1.0-1.5mm spacing.

The physician holds the handpiece perpendicular to the nail while making two passes of the laser, alternating between transversely and longitudinally. Each pass also includes 2-3mm around the nail. For patients suffering with severe cases of nail disorders caused by onychomycosis, additional passes may be required.

Patients are provided with a proper post procedure foot care regimen. The anti-fungal medication Clarus® (brand name of tolnaftate oil and cream) is applied on and around the toenails daily. The tips, as well as the entire surface of the nail, are filed once a week using a clean emery board and nail trimmers are used by the patient. All tools should be cleaned with rubbing alcohol prior to use. Patients are allowed to use Dr.'s Remedy® nail polish but are instructed not to leave it on for more than 3-5 days. Shoes, flip-flops and sandals are disinfected using either Mycomist spray or Sterishoe® devices and the bottom of the shower/tub is cleaned using Clorox® Clean-Up® Spray. Additionally, Biotin supplements at 2.5mg a day, are used to strengthen nails.

CASE REPORT

A 31-year-old Caucasian female, taking no medication, presented a lack of clear nail due to onychomycosis of the big toe. The patient received three passes of the PinPointe FootLaser on each toe, due to the severity of the infection, using the above parameters. All toes on both feet received the procedure but only the big toes were used for analysis. The patient returned for follow-up visits at months three, seven and ten.

Photographs were taken at baseline and at follow-up visits to assess lesion reduction and clear nail growth. To achieve consistency with measurements and evaluation of the laser procedure, the following definitions were used:

Clear nail: uniform in color (pink, reddish, flesh or pale) with smooth surface and normal thickness

Infected nail: abnormal in color (milk white, black, brown, yellow, green) with flakey, distorted, roughened, ridged, or thickened nail plate that may be onycholytic

Lesion area: total infected area, including discoloration, thickening and yellowing of nail

Lesion area at follow-up: total infected area at follow-up

Clear nail growth: new clear nail that has grown (%) in comparison to the baseline clear nail area

Absolute clear nail: the baseline lesion area (%) minus the follow-up lesion area (%)

Lesion reduction: the absolute lesion decrease % divided by the baseline lesion area (%)

Image analysis with Adobe Photoshop was used to achieve consistent magnification of the nails. A trained technician traced the area of clear and infected nail for an accurate evaluation of nail improvement. Photos were neither enhanced nor filtered, hence the margin between clear and infected nail was unaffected.

Magnified photos were then analyzed using ImageJ software, a National Institutes of Health (NIH) based program designed specifically for image analysis and processing. The software program converts images into their individual pixels so that different areas within the image can be analyzed. To calculate the size of the area, clear nail area or the infected nail area was selected and converted into pixels. These measurements were then used to analyze the changes in clear nail area and lesion reduction at follow-up visits. Standard deviation was calculated to determine the variation that existed from the average.

Subjective aesthetic assessments were measured by the physician using the Global Aesthetic Improvement Scale (GAIS). GAIS is a 5-point scale to evaluate the treatment outcome of the infected area. Subjects filled in a patient satisfaction questionnaire during follow-up visits at three and seven months.

GAIS Evaluation

5	Very much improved – optimal cosmetic results
4	Much improved – marked improvement in appearance from initial condition, but not completely optimal for this subject
3	Improved – obvious improvement in appear-ance from initial appearance, but an additional procedure is indicated
2	No change - the appearance is essentially the same as the original condition
1	Worse – the appearance is worse than the original condition

RESULTS

The patient's two big toes were measured by planimetry and showed a significant increase in clear nail growth and lesion reduction (Figure 1,2). The mean baseline clear nail area for the patient's two toes was 17% (±32%) of the nail. After 14 months post procedure, the mean clear nail area was increased to 49% (±5%) of the nail. Using these two measurements, the absolute increase in clear nail was calculated to be 32%. (Table 1).

Clear Nail Growth Determined by Area Calculated in ImageJ (cm^2)

Follow-up Period	# of toes	Mean Baseline Clear Nail Area	Std. Dev.	Mean Follow-up Clear Nail Area	Std. Dev.	Absolute Increase in Clear Nail
14 Months	2	17%	11%	49%	5%	32%

Table 1 Improvement as quantified by increase in clear nail

The mean lesion area of the patient's two big toes was determined to be 83% (±11%) of the nail and was reduced to 51% (±5%) of the nail at 14 months follow up. Based on the mean baseline lesion area and the mean follow up lesion area, absolute lesion reduction was calculated to be 32% and lesion reduction vs. baseline was calculated to be 75%. (Table 2). The physician rated the patient's clinical outcome a 4 on the Global Aesthetic Improvement Scale (GAIS).

Lesion Reduction Determined by Area Calculated in ImageJ (cm^2)

Follow-up Period	# of toes	Mean Baseline Lesion Area	Std. dev.	Mean Follow-up Lesion Area	Std. Dev.	Absolute Lesion Reduction	Lesion Reduction (% Baseline)
14 Months	2	83%	11%	51%	5%	32%	75%

Table 2. Improvement as quantified as the lesion area reduction (% of baseline)

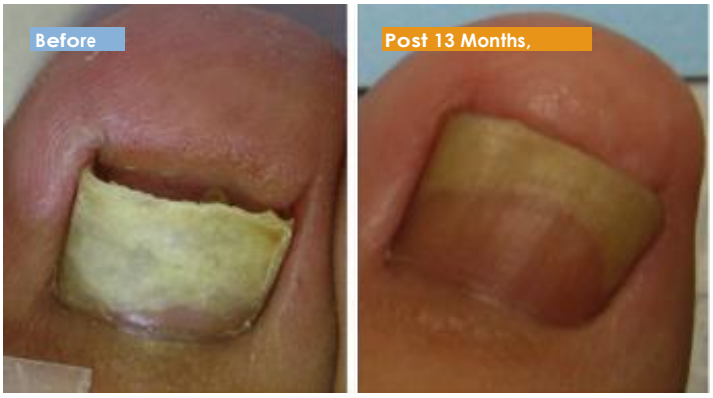

Figure 1. Patient's left foot

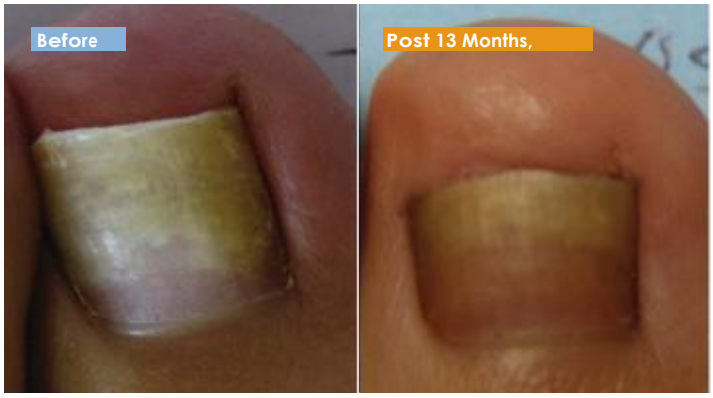

Figure 2. Patient's right foot

DISCUSSION

In our experience, the PinPointe laser procedure not only allows for significant growth of clear nail in toes infected with onychomycosis, but the laser procedure also produces high patient satisfaction. In this case study, the efficacy of the micropulsed 1064nm Nd:YAG laser was evaluated based on clear nail growth and reduced lesion area. The patient experienced a significant improvement in both areas. The clear nail area of the patient increased from 17% of the nail to 49% of the nail, and there was a 75% reduction in lesion area. In addition to the significant efficacy of the PinPointe laser procedure as demonstrated by planimetry measurements, the physician also noticed a significant improvement in the nail. Using the Global Aesthetic Improvement Scale, the physician rated the patient's improvement as a 4, indicating that the nails were much improved and there was marked improvement in appearance from the initial condition. The results of this case study suggest that the PinPointe FootLaser is an effective option for the temporary increase of clear nail in patients with onychomycosis.

CONCLUSION

The PinPointe FootLaser is an effective option that produces high patient and physician satisfaction. The Laser procedure allows for clear nail growth without significant side effects or complications.

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