

Dr. Robert Grzywacz, DPM
PinPointe FootLaser Toenail Fungus (Onychomycosis) Treatment Study
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I have been using the PinPointe FootLaser for treating my patients with onychomycosis since November 2008 and have now done over 350 procedures. I routinely take digital photos of the infected toes before treatment and at follow up visits so that the patient and I can follow the progress. As I have a satisfied patient base, I was interested in scientifically analyzing my results contained in this report.

The photos to be analyzed were from patients who were treated from November 2008 through October 2009 on one or both feet using the standard protocol of two laser passes. These patients were followed at approximately three month intervals through March 2010. Great toe photos were obtained on patients treated and followed up to a maximum of 16 months post-treatment. The condition of the other toes was ignored.

The primary outcome of interest is the change in percent clear nail. To determine this, a trained technician views one of the photos of a great toenail on a computer screen. The area of clear nail and the area of the entire nail plate are measured using image processing software (planimetry). From these measurements percent clear nail is computed. These percentages are then analyzed to evaluate the change in clear nail at follow up visits.

Patients were included in the analysis if they had a usable baseline photo and at least one useable follow-up photo. To be included, the quality of the photos had to be suitable for planimetry and the toe had to demonstrate visible fungus. Photos were grouped into 3 month intervals and labeled "0," "3," "6," "9," or "12," months. The sample sizes are generally based on great toes from both feet per patient, although this was not always the case due to lack of infection or unusable photos. In the end, 65 patients and 100 toes were included in this analysis. There were 35 patients with both great toes and 30 patients with only one great toe infected.

Tables 1A and 1B show the percent clear nail at baseline and at each follow-up interval. To address the differing patient groups at each follow-up time, significance for each interval was determined separately by a paired t-test, with no adjustment for multiplicity. Tabulations were done for two groupings of the data: (1A) all infected toes and (1B) for toes with > 50% infection at baseline.

Mean changes from baseline in the increase of percent clear nail were 7.7% at three months, 9% at six and nine months, and 11.7% at twelve months. These correspond to relative improvements from 20% to 33% (difference in percent clear nail divided by baseline percent clear nail). Fifteen month data were too sparse for meaningful comparisons. When only toes with nails that were at least 50% infected were analyzed, improvement ranged from 10.8% at three months to 14% at 12 months, or approximately 3% more clear nail than the previous numbers. Again, the relative improvement ranged from 45% to 55% (difference in percent clear nail divided by baseline percent clear nail). All statistical comparisons from three to twelve months were highly significant at $p < 0.001$.

In general, for all groupings, the data shows sustained improvement from three to twelve months, with a slight increase at twelve months over that seen at previous follow-up intervals. Statistically significant increases in clear nail over time were seen for all groupings.

To further describe treatment results, Table 2 shows the number of toes improved by months post treatment and by amount of improvement (increase in percent clear nail). At three months 79% of all treated toes showed improvement, compared to 75% at six months, 76% at nine months, and 81% at twelve months, again indicating sustained improvement.

In conclusion, highly significant improvement in the percent clear nail following two-pass laser treatment was seen at three months, with improvement at six and nine months similar to the three month values.

Twelve month values showed additional improvement over the three, six, and nine month values. 80% of my patients gained a positive improvement from a single FootLaser treatment that continues to improve out to one year.

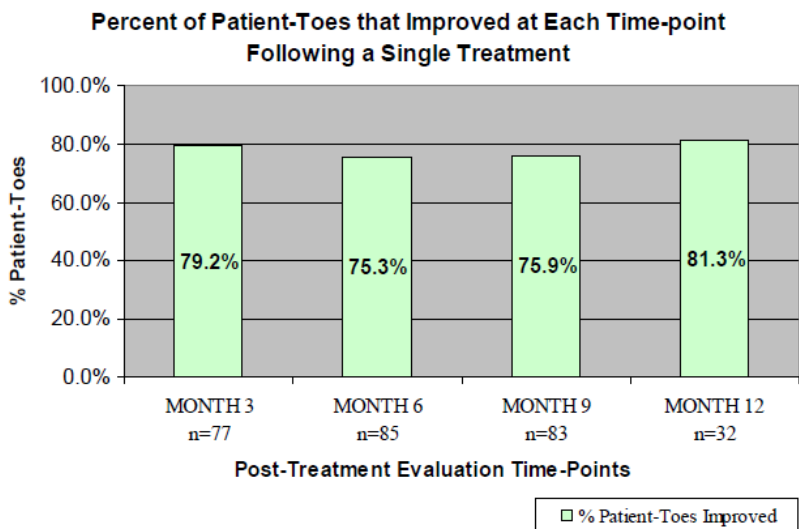


Figure 1. The percent efficacy is the percent of patients that have measureable improvement. These data demonstrate a sustained efficacy of about 80% during the first year following a single PinPointe FootLaser treatment.

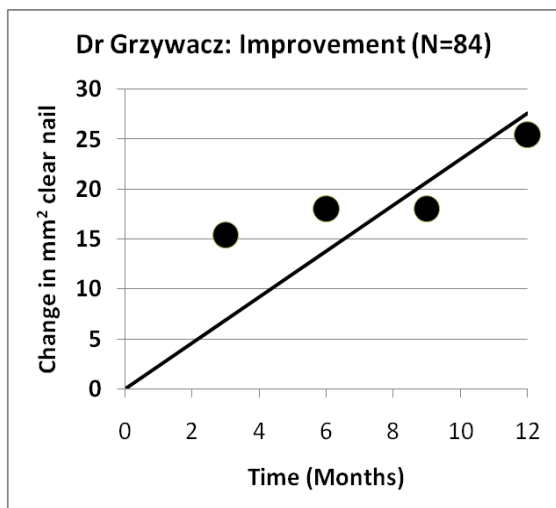


Figure 2. These data show a population estimate of the actual progressive change in the area of clear nail in mm² during the first year following treatment. Individual responses will vary from this average trend.

TABLE 1A PERCENT CLEAR NAIL BY TIME OF FOLLOW-UP					
ALL INFECTED TOES		MEAN PERCENT CLEAR NAIL			
FOLLOW-UP PERIOD	# TOES	BASELINE	FOLLOW-UP	IMPROVEMENT	P-VALUE
2-4 months (3 months)	77	40.1%	47.8%	7.7%	<0.001
5-7 months (6 months)	85	36.9%	45.9%	9.0%	<0.001
8-10 months (9 months)	83	36.4%	45.4%	9.0%	<0.001
11-13 months (12 months)	32	35.6%	47.3%	11.7%	<0.001

TABLE 1B PERCENT CLEAR NAIL BY TIME OF FOLLOW-UP					
TOES > 50% INFECTED AT BASELINE		MEAN PERCENT CLEAR NAIL			
FOLLOW-UP PERIOD	# TOES	BASELINE	FOLLOW-UP	IMPROVEMENT	P-VALUE
2-4 months (3 months)	48	23.8%	34.6%	10.8%	<0.001
5-7 months (6 months)	59	24.3%	36.7%	12.4%	<0.001
8-10 months (9 months)	58	24.2%	36.0%	11.8%	<0.001
11-13 months (12 months)	25	25.6%	39.6%	14.0%	<0.001

TABLE 2 PATIENT TOES IMPROVED BY TIME AND AMOUNT OF INCREASE				
Improvement in Percent clear nail	Months post treatment			
	3 months (N=77)	6 months (N=85)	9 months (N=83)	12 months (N=32)
ANY	79%	75%	76%	81%
>10%	36%	43%	43%	47%
>20%	16%	22%	19%	25%
>30%	3%	7%	12%	9%
>40%	0%	5%	5%	9%
>50%	0%	0%	2%	0%