

A single-center, prospective, open-label, pilot study of the safety, local tolerability, and efficacy of ultraviolet-C (UVC) phototherapy for the treatment of great toenail onychomycosis

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Introduction

Subungual onychomycosis is a common problem affecting approximately 2 to 14% of the general population. Currently available therapies including topical and systemic antifungal medications are mostly limited by their lack of efficacy or potential for serious side effects. This open label, prospective, pilot study was aimed at evaluating the safety, tolerability, and efficacy of ultraviolet 'C' in the range of 240 nm to 280 nm (UVC) to treat great toenail onychomycosis.

Methods & Materials

30 healthy adult subjects aged 28 to 71 with mild to moderate onychomycosis involving no more than 35% of the great toenail who had microscopic evidence of dermatophyte infection (confirmed by a positive KOH) were equally randomized to receive four weekly UVC light treatments with either a low pressure mercury lamp (LPML group=delivering a total UVC dose of 22 J/cm²) or via a xenon pulsed light device (XPL=delivering an approximate total UVC dose of 2-4 J/cm²) (Both Kerderm, LLC, Hampton, VA). The investigator's global assessment (IGA) scale and the distance of disease area (DDA) were used at the week 2, 3, 4, 8, 12, 16 and 28 follow-up visits to assess treatment efficacy. Treatment safety and tolerability was also evaluated at each visit.

This study was sponsored by Keraderm, LLC.

Results

Three out of the 15 patients treated in the LPML group (20%) showed an improvement on their IGA scale from baseline compared to week 28 (p=0.08). In the XPL group 11 out of the 15 treated subjects (73%) showed a statistically significant improvement on their week 18 IGA score when compared to baseline scores (p<0.01). For subjects who discontinued, the last observation was carried forward. (Table 1)

Clinical response to treatment was also evident from differences on the week 28 distance to disease area (DDA) score compared to baseline. In the LPML group the mean distance of outgrowth was 2 mm. This difference was also statistically significant for the XPL group where the mean distance gain on week 28 compared to baseline was 4.4mm (p<0.01). (Table 1)

Table 1: Comparison of nail characteristics between baseline and week 28 Wilcoxon rank

	LPML			XPL		
	Baseline	Week 28	p value	Baseline	Week 28	p value
IGA median	3	3	0.08	3	2	0.001
DDA (mm) median	6	9	0.001	6	9	<0.001

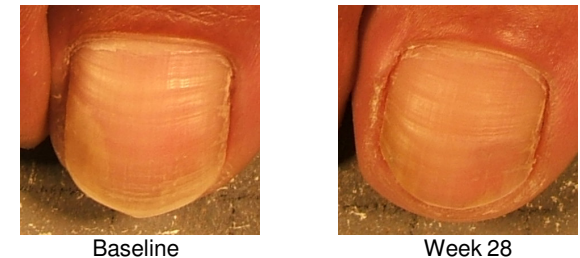
Treatment with both UVC devices was well tolerated by subjects. Minor and uncommon side effects included temporary mild erythema of the irradiated toe. An image depicting the result of a patient in the XPL group is presented in Figure 1.

Patients in the XPL group showed a larger absolute change from their baseline IGA score measured at week 28 compared to the patients in the LPML group (p<0.001). A similar observation was true for the absolute change in the DDA between both groups (p<0.05). (Table 2)

Table 2: Comparison of nail improvement between LPML and XPL groups. §Fisher's exact *Mann-Whitney

	LPML	XPL	p value
No. of subjects with improvement in IGA §	3	11	<0.001
Median DDA change*	1 mm	3 mm	<0.05

Figure 1: Images of a subject in the XPL group



Conclusions

Treatment of subungual onychomycosis with UVC light delivered to the nail bed via a xenon pulsed light device shows promise in this small pilot study with 73% of the subjects in the XPL group showing improvement in clinical disease severity compared to 20% in the LPML group. Future double-blinded studies are required to further support these results.