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**Photo-Inactivation Of Fungal Pathogens
That Cause Onychomycosis In Vitro And In Vivo
With The Noveon® Dual Wavelength Laser System**

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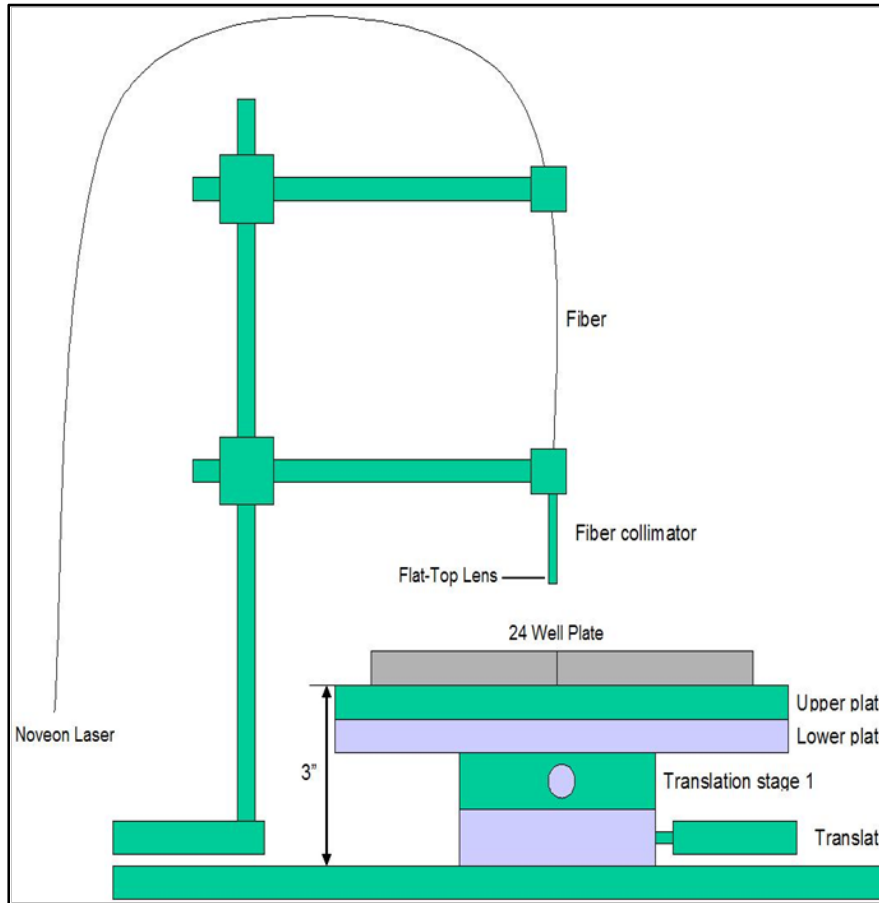
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Background:

- **We have investigated (in vitro and in vivo) topical infrared photo-inactivation of the major fungi that cause onychomycosis with a Noveon laser (Nomir Medical Technologies, Inc., Waltham, MA).**
- **This device employs two distinct near infrared wavelengths (870 nm and 930 nm) that are known to cause cellular photo-damage via an endogenous reactive oxygen species mechanism of action, in the absence of exogenous dyes or chemicals.**
- In May of 2001, the U.S. Food and Drug Administration (FDA) issued a public health advisory on the potential cardiac effects associated with systemic itraconazole use and the potential hepatic risks associated with both itraconazole and terbinafine.
- There is also, an extensive list of associated drugs that cannot be taken concurrently with either systemic antifungal therapy. Since both itraconazole and terbinafine are presently still the main treatment options for systemic onychomycosis therapy, topical application of safe infrared phototherapy would be potentially preferable to systemic therapy.

Methods: In Vitro



- In vitro *C. albicans* (ATCC 14053) and *T. rubrum* (ATCC 52022) were grown with well established fungal protocols.
- Isolates were seeded in 24-well plates in 2 ml of Phosphate-buffered saline and irradiated with 1.5 cm flat-top lenses at an energy density of 4074 J/cm² for 12 minutes. 100 μ l from each well (treatment and control) were plated in triplicate on fungal medium.
- After 24 hours, control and treated colonies were manually counted.

Methods: In Vivo



- In vivo, the great toe nails of seven patients with positive fungal cultures were topically irradiated four times (days 1, 7, 14 and 60).
- Nail temperatures were recorded with an infrared thermometer. After day 7, a commercial, over-the-counter tinea pedis spray was employed between the toes 2x/day, to inhibit nail re-inoculation.
- Energy densities employed were 539 J/cm^2 over 6 minutes. Debridement of thickened nails was accomplished if necessary.

Results:

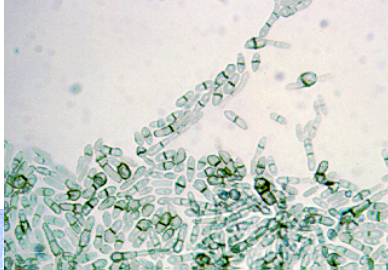
In vitro

- **100% eradication** of all fungal isolates following irradiation with the Noveon laser system.
- **Experimental temperatures did not exceed 40.5 C**, well within normal thermal tolerances for these species.

In vivo

- **Mycological negative at 60 days** (through culture) for all patients.
- **Experimental temperatures did not exceed 38 C**, well within the physiologic norm.
- **No negative sequelae were recorded.**

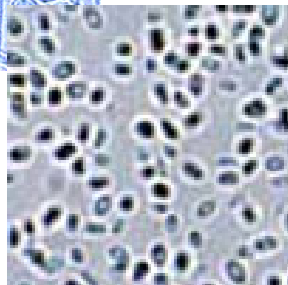
Fungal Families Eradicated by Treatment



Phaeoannellomyces



Trichophyton

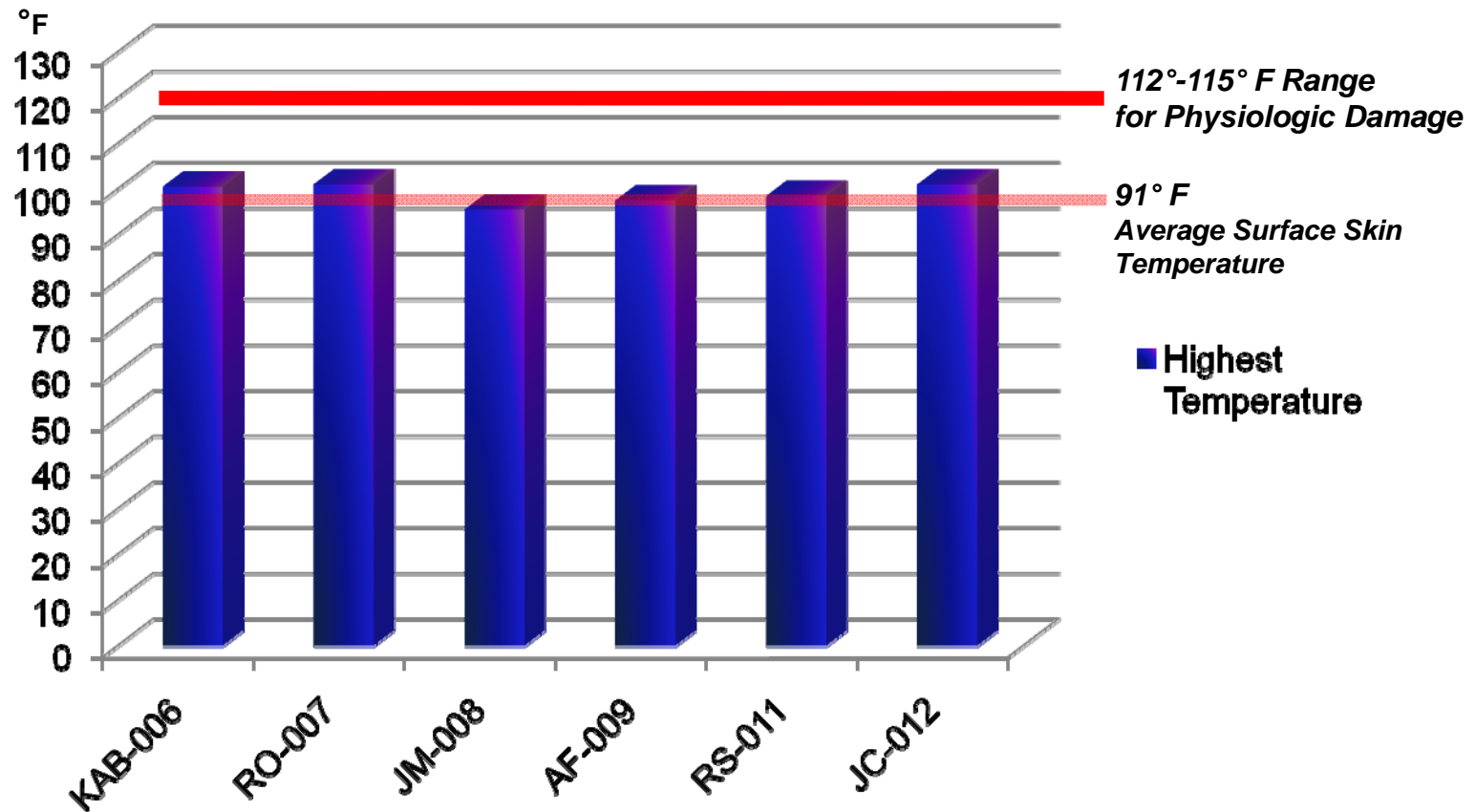


Rhodotorula

MoA: Near Infrared Photodamage

Endogenous *Photobiological Production of ROS* – Not a Thermal Laser/Tissue Interaction

In Vivo Temperatures Well Below Physiologic Damage Threshold



Conclusions:

- **Noveon laser photo-inactivation of the fungi that causes onychomycosis has been accomplished using safe energy densities in vitro and in vivo at physiologic temperatures.**
- **Given the enduring safety issues associated with systemic antifungal therapy, further studies with the Noveon are merited as a possible novel and safe topical phototherapy alternative to systemic treatment.**

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