

The Q-Clear™ laser system provides a new laser technology that is safer and often effective in treating dystrophic nails, particularly those due to fungal infections (onychomycosis). In early clinical studies* some degree of improvement has been demonstrated in the majority of patients without any significant side effects and without causing pain. In some cases substantial or complete improvement was achieved after only a single treatment. The most dramatic results were achieved using a simple treatment protocol in cases with mild to moderate involvement, generally performed without the application of adjunctive topical therapies or use of any anesthetic agents and taking less than 5 minutes to treat 10 toenails. With very severe involvement simple avulsion of the nail plate with subsequent laser treatment of the nail bed and matrix has shown to be promising in obtaining a much improved nail in the more difficult cases. Due to the efficacy, speed, and lack of disposables, treatment costs have been substantially reduced, helping to expand treatment availability.

The Q-Clear™ is a Nd:YAG laser system with certain unique properties that differentiate it from lasers that have been used previously in podiatry. Nd:YAG lasers themselves are relatively new in podiatry and have been cleared by the FDA only within the last year for “the temporary increase of clear nail in patients with onychomycosis”. The Q-Clear™ laser system from Light Age, Inc. was the third such laser system to be FDA cleared for this application, however, it has been FDA cleared for use in many other medical procedures, primarily in dermatology, since 2005. Previously, its principal uses have been for tattoo removal, treatment of age spots, birthmarks, spider veins and other pigmented and vascular lesions, as well as for general incision, excision and ablation of soft tissues including treatment of keloids and warts. Due to its broad scope of use, the Q-Clear™ laser system has been one of the most widely employed medical laser systems over the last 5 years. It has been safely used in an estimated one million treatments.

Nd:YAG laser systems provide fundamental light output in the near infrared region of the spectrum. Most commonly the output is at a wavelength of 1064 nm, a wavelength slightly outside of the range of visible light (nominally 400 – 800 nm, violet to deep red). The output of these laser systems can be provided in either a continuous stream (called cw, for “continuous wave”) or in a pulsed format and is sometimes “frequency doubled”, by the nonlinear process called second harmonic generation, to the green wavelength of 532 nm. Of the pulsed format lasers, there are several types, distinguished by the duration of the laser pulses; the most common of these being long pulsed lasers, having pulse durations typically in the millisecond (10^{-3} s) to microsecond (10^{-6} s) range, and Q-switched lasers, having pulse durations in the nanosecond (10^{-9}) range. For a given pulse energy, generally expressed in units of millijoules or joules, the shorter the pulse duration, the higher is the laser’s peak power. Although there may be other important factors, the way a laser interacts with tissue depends critically on its wavelength, pulse energy, peak power as well as on its average power (pulse energy times repetition rate). The way that light interacts with biological materials (tissue, pigments, infectious organisms, etc.) also depends upon the areal extent of the material exposed to the laser beam,

therefore the laser energy per illuminated area is often referred to as the “light dosage” or fluence and is usually expressed in units of joules per square centimeter (J/cm^2). cw and long-pulse lasers interact with biological materials (“biomatter”) dominantly through photothermal means; that is, the energy in the light absorbed is rapidly converted into heat causing a temperature rise in the material illuminated. Q-switched laser pulses additionally can interact more disruptively, causing photoacoustic, photoablative, and other photomechanical effects.

The goal of all medical therapies, and laser therapies in particular, is to have a selective effect on various tissues and organisms. Selectivity is key, as the anti-targeting of its surroundings can be every bit as important targeting a specific bio-entity. Selective photothermolysis, a process that uses differential light absorption to selectively heat and kill a targeted cell type, can be used to effect when a wavelength can be found at which the bio-target has stronger specific absorption than the surrounding tissue and when the absorbed energy can be confined within the target for times long enough for thermal necrosis to occur in the target. This process is abetted by poor thermal transport between the target and its surrounding and by good cooling of the anti-targeted tissue due to blood circulation or, when possible, by external means.

Onychomycosis has been an historical problem because fungi are hardy and robust organisms, whose spores and hyphae can survive under conditions and at temperatures more extreme than most human cells can tolerate. Many species are anaerobic or require little oxygen and most flourish under conditions of warm temperature and high moisture. Regions beneath the nail plate and within the nail bed and matrix form a nearly ideal environment providing fungal colonies with nutrients and protection from external assault. Topical anti-fungal agents have a hard time getting through and maintaining presence long enough to be effective. Systemic antifungal medications, such as Terbinafine (Lamisil), can attack the colony from below but comes with sometimes serious side effects. Most thermal therapies, including many laser therapies, are ineffective because dermal cells and pain sensors under the nail plate are more sensitive to temperature rise than the fungi.

Light in the near infrared, and specifically at wavelengths around $1\ \mu\text{m}$ are well transmitted through the nail plate, even when reasonably compromised by infection, and are only weakly absorbed by most dermal tissues – the penetration depth of $1064\ \text{nm}$ light in dermis is greater than $1\ \text{cm}$. These wavelengths are more strongly absorbed by the fungi colonizing the nail. The Q-Clear™ laser system delivers sufficiently high pulse energies in spatial and temporal pulse formats that were designed to provide the heating and photomechanical disruption needed to penetrate and kill the fungal colonies without causing pain or adversely affecting the surrounding tissue. It is this combination of pulse energy, spot size, spatial and temporal pulse formats that make the Q-Clear™ laser system so uniquely effective. Additional considerations, such as its speed (repetition rate and spot size), its absence of disposables, and low cost of consumables, have reduced the treatment

time to under 5 minutes and the cost of treatment (for everything related to the laser system) to under \$5 per fully treated foot. Because laser treatment for onychomycosis is not a reimbursable procedure for most patients having a reduced cost treatment modality is necessary to provide relief to the many millions who suffer from this malady.

*These studies of the Q-Clear™ laser system for treatment of nails with clinically apparent diagnosis of onychomycosis was conducted at Southwest Foot and Ankle Associates, Inc., Southwest General Health Center, University Hospitals Health System of Cleveland, by James Holfinger, DPM and associates.