

Diagnosis and treatment monitoring of toenail onychomycosis by reflectance confocal microscopy: Prospective cohort study in 58 patients

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Background: The clinical presentation of onychomycosis is often nonspecific and can lead to inappropriate antifungal therapy. Available mycologic tests share many drawbacks.

Objective: We sought to evaluate the accuracy of reflectance confocal microscopy (RCM) for the diagnosis of onychomycosis compared with standard mycologic tests.

Methods: In all, 58 patients with suspected onychomycosis were enrolled prospectively. RCM, potassium hydroxide preparation, and fungal culture were performed at baseline and after treatment in patients with confirmed onychomycosis. RCM diagnosis of onychomycosis was based on the presence of filamentous and/or roundish structures in the nail plate, corresponding respectively to septate hyphae and/or arthroconidia.

Results: Of patients, 46 of 58 were correctly classified by RCM, with a diagnosis yield of 79.3%, sensitivity of 52.9%, specificity of 90.2%, positive predictive value of 69.2%, and negative predictive value of 82.2%. The use of a handheld RCM imager permitted a faster examination with the same accuracy. RCM performed after treatment in 9 patients showed a normal nail plate, and healing was confirmed by mycologic tests or by follow-up.

Limitations: Existing RCM scanner heads are not intended for nail examination.

Conclusion: RCM has excellent specificity and can be used as a rapid, office-based test to strengthen the prescription of antifungal therapy and for follow-up. Technical improvement could aid sensitivity. (J Am Acad Dermatol <http://dx.doi.org/10.1016/j.jaad.2014.02.020>.)

Key words: confocal; onychomycosis; reflectance confocal microscopy.

Patients are often bothered by dystrophic nails leading to a visit to the dermatologist. Epidemiologic studies demonstrate that onychomycosis accounts for up to 50% of nail diseases.^{1,2} The clinical findings in onychomycosis are nonspecific and a variety of other conditions demonstrate similar dystrophic features including chronic trauma, psoriasis, lichen planus, peripheral

vascular diseases, and even some skin cancers.³ To avoid unnecessary, potentially toxic antifungal treatments, it is recommended that the diagnosis of onychomycosis be confirmed before a therapeutic trial is initiated. Available tests include potassium hydroxide (KOH) preparation, fungal culture, histopathological examination with periodic acid–Schiff stain, and polymerase chain reaction.^{4,5} KOH

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preparation does not demonstrate viability or causative nature of the isolated fungal elements. On the other hand, fungal culture demonstrates viability and allows the identification of isolated fungi, but it may be associated with a high rate of false-negative results and does not distinguish causative agents from contaminants. Histology is more labor-intensive and costly than KOH and culture. Polymerase chain reaction is more sensitive and produces results more rapidly but it requires expensive specialized equipment. In summary, all these procedures are to a variable extent invasive, are time-consuming to perform, and require a waiting time for results, and none are totally reliable. In accordance with this view, it was reported that a majority of physicians including dermatologists do not use mycologic tests for confirmation of onychomycosis.⁶ Reflectance confocal microscopy (RCM) is a recent, noninvasive, real-time imaging technique of the skin at a near-histologic resolution. RCM is widely used for the diagnosis of melanoma and nonmelanoma skin cancer,^{7,8} and there is increasing interest for the RCM diagnosis of skin infections including onychomycosis.⁹⁻¹² Therefore, RCM could be interesting for a rapid and office-based diagnosis of onychomycosis.

Objective

The primary objective of this prospective cohort study was to evaluate the accuracy of RCM in the diagnosis of onychomycosis in terms of sensitivity, specificity, positive, and negative predictive value in comparison with the combination of the direct microscopy in KOH and fungal culture as the gold standard. Because the patients in our study received treatment for their onychomycosis, this study also evaluated RCM as a method of monitoring treatment success. The time required to perform RCM was measured. Finally, we evaluated the time required for confocal imaging examination of the toenail.

METHODS

Patients

This was a monocentric prospective cohort study conducted in the outpatient clinic of the Dermatology Department of the University Hospital in Nice, France. The inclusion criteria were a

clinically suspected distal and lateral subungual onychomycosis, involving at least one great toenail, and involving 10% to 75% of its surface area. The exclusion criteria were a total dystrophic nail; subjects with psoriasis, lichen planus, or alopecia areata; and subjects who received topical nail antifungal cream or solution during the last 1-month period, antifungal lacquer during the last 3-month period, or systemic antifungal therapy in the last 3-month period. All patients underwent a full general disease history taking and clinical examination. All included patients were subjected to clinical nail photography.

Mycologic tests

Nail sampling direct microscopy in KOH and fungal culture were conducted in the parasitology mycology department at the University Hospital in Nice, France. The diagnosis of onychomycosis

was defined by the association of positive KOH preparation and fungal culture, which is the most widely used diagnosis combination for clinical use and investigation.^{4,5}

Reflectance confocal microscopy

Before nail sampling, clinically suspicious zones of the nail were scanned using two commercially available RCM devices: a standard device (Vivascope 1500, Lucid Technologies, Rochester, NY) and a recently released handheld imager (Vivascope 3000, Lucid). Both devices use the same 830-nm laser in the reflection mode and generate similar horizontal $500 \times 500 \mu$ large sections in different depths from the surface of the nail plate down to the nail bed, but the standard device is supported by an articulated arm and is more difficult to handle. RCM examination was performed with the Vivascope 1500 (Lucid) in the first 38 patients and with the Vivascope 3000 (Lucid) that became available later in the next 20 patients. The RCM diagnosis of onychomycosis was based on the presence on at least three consecutive images of bright filamentous branching structures corresponding to septate hyphae, as described previously.^{13,14} Nine patients with onychomycosis diagnosed by RCM and confirmed by mycologic tests underwent a full course of terbinafine, 250 mg/d for 24 weeks. RCM and mycologic tests were repeated at the end of the treatment

CAPSULE SUMMARY

- Traumatic and inflammatory nail dystrophies mimic onychomycosis and are often inappropriately treated with antifungal drugs.
- Reflectance confocal microscopy is an office-based technique that permits immediate confirmation of onychomycosis with specificity similar to other mycologic tests.
- A positive reflectance confocal microscopy examination result permits clinicians to treat promptly and monitor effects of antifungal therapy.

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