

Paired comparison of the sensitivity and specificity of multispectral digital skin lesion analysis and reflectance confocal microscopy in the detection of melanoma in vivo: A cross-sectional study

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Background: Several technologies have been developed to aid dermatologists in the detection of melanoma in vivo including dermoscopy, multispectral digital skin lesion analysis (MDSLA), and reflectance confocal microscopy (RCM). To our knowledge, there have been no studies directly comparing MDSLA and RCM.

Objective: We conducted a repeated measures analysis comparing the sensitivity and specificity of MDSLA and RCM in the detection of melanoma (n = 55 lesions from 36 patients).

Methods: Study patients (n = 36) with atypical-appearing pigmented lesions (n = 55) underwent imaging by both RCM and MDSLA. Lesions were biopsied and analyzed by histopathology.

Results: RCM exhibited superior test metrics ($P = .001$, McNemar test) compared with MDSLA. Respectively, sensitivity measures were 85.7% and 71.4%, and specificity rates were 66.7% and 25.0%.

Limitations: The sample size was relatively small and was collected from only one dermatologist's patient base; there was some degree of dermatopathologist interobserver variability; and only one confocalist performed the RCM image evaluations.

Conclusion: RCM is a useful adjunct during clinical assessment of in vivo lesions suspicious for melanoma or those requiring re-excision because of high level of dysplasia or having features consistent with an atypical melanocytic nevus with severe cytologic atypia. (J Am Acad Dermatol <http://dx.doi.org/10.1016/j.jaad.2016.07.022>.)

Key words: dermoscopy; melanoma; multispectral digital skin lesion analysis; noninvasive imaging; reflectance confocal microscopy.

Early detection of malignant melanoma (MM) is paramount in improving the prognosis of patients given a diagnosis of MM. In recent

years, new technologies have been developed to evaluate pigmented lesions for the detection of melanoma in vivo. MelaFind (STRATA Skin Sciences,

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Horsham, PA) is a multispectral diagnostic device (MSDD) that uses multispectral digital skin lesion analysis (MDSLA) to evaluate pigmented lesions to a depth of 2.5 mm. MSDD analyzes the lesion for asymmetry, color variation, border irregularity, and texture to generate a classifier score (CS) that categorizes lesions as having high or low levels of disorganization.¹ The initial study evaluating the efficacy of MSDD observed scores ranging from -5.2 to 9.² Reflectance confocal microscopy (RCM) uses the reflectance properties of structures in the skin to allow cellular visualization of the epidermis to the papillary dermis to a depth of 200 μm .³ Evaluation of RCM images requires training and, similar to MDSLA, performance is dependent on experience.⁴

Several studies have evaluated the diagnostic accuracy of MDSLA and RCM, independently, in the detection of melanoma. The initial study evaluating the performance of MSDD reported a sensitivity and specificity of 98.4% and 10.5%, respectively, among 1632 pigmented lesions.⁵ Subsequent studies have reported nearly equally high sensitivity and low specificity.^{6,7} Several studies also report the use of MSDD as a clinical adjunct increases the overall sensitivity of dermatologists in the detection of melanoma. The sensitivity of dermatologists using MSDD ranges from 78% to 94% and specificity ranges from 40% to 54.1%.⁷⁻⁹ These investigations were reader studies in which dermatologists viewed images of pigmented lesions both without and with MSDD analysis and were asked whether or not they would biopsy the lesion.⁶⁻⁹ All images used in these reader studies originated from the repository of 1632 images of pigmented lesions amassed during the initial MSDD study by Monheit et al.⁵

Regarding RCM, several algorithms have been proposed for detecting MM in vivo. Segura et al¹⁰ proposed a 2-step method that demonstrated a sensitivity of either 86.1% or 100% and specificity of 95.3% or 57% depending on the scoring method used. Guitera et al¹¹ proposed another 2-step algorithm that produced a sensitivity of 87.6% and specificity of 70.8% in detecting melanoma. Both RCM and MDSLA have the potential to lower the rate of unnecessary biopsies, but their use in clinical practice is limited by time, cost, availability, and dermatologist unfamiliarity with the diagnostic accuracy of the technologies. The

current cost of MelaFind (STRATA Skin Sciences) is \$29,000 and of a VivaScope 1500 (Caliber Imaging and Diagnostics, Rochester, NY) is \$98,000. Furthermore, data are lacking comparing the performance of the 2 technologies when assessing the same lesions. The study herein, therefore, performed a repeated measures comparison of MDSLA and RCM in the detection of melanoma in vivo.

CAPSULE SUMMARY

- Multispectral digital skin lesion analysis and reflectance confocal microscopy may be useful adjuncts for dermatologists in the detection of melanoma in vivo.
- This study compares the sensitivity and specificity of the technologies in detecting melanoma using a repeated measurements analysis.
- Reflectance confocal microscopy is superior to multispectral digital skin lesion analysis in both sensitivity and specificity ($P = .001$).

METHODS

Study population

Patients were recruited between October 2014 and March 2016 at the Department of Dermatology, University of Connecticut Health. Atypical-appearing pigmented lesions were identified by a dermatologist via clinical and dermoscopic exam as lesions that were not obvious melanomas, but melanoma, could not be excluded. Atypical-appearing lesions were lesions that did not conform to the

classic ABCDE (asymmetry, border irregularity, color variegation, changing diameter, evolving or changing lesion) signs of melanoma, but demonstrated enough clinical or dermoscopic atypia or a history of change to warrant concern by the dermatologists as a potential melanoma. Patients with at least 1 atypical-appearing pigmented lesion were invited to participate in the study. Participation did not affect patient treatment. After enrollment, lesions underwent evaluation by both MDSLA and RCM. Exclusion criteria included patients younger than 18 years, lesions on acral or mucosal surfaces, lesions smaller than 2 mm or larger than 8 mm, and lesions that could otherwise not be imaged according to manufacturer's guidelines. Patient age, gender, personal and family history of skin cancer, and location of lesion were recorded. The institutional review board approved the study protocols. All institutional rules regarding clinical investigation of human subjects were strictly followed. The Declaration of Helsinki protocols were followed and all study participants gave written informed consent.

Multispectral digital skin lesions analysis

MDSLA was performed with MSDD (MelaFind, STRATA Skin Sciences). One individual, trained by MelaFind representatives, performed imaging of all pigmented lesions. MSDD analyzes lesions at 10 different spectra of light (430-950 nm). The MSDD automatically generates the CS. Lesions with a CS of

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