Enhanced Melanoma Diagnosis With Multispectral Digital Skin Lesion Analysis

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PRACTICE **POINTS**

- Multispectral digital skin lesion analysis (MSDSLA) can be a valuable tool in the evaluation of pigmented skin lesions (PSLs).
- MSDSLA may help to better identify high-risk PSLs and improve cost of care.

Multispectral digital skin lesion analysis (MSDSLA) is both sensitive and specific in the detection of malignant melanoma by dermatologists and nondermatologists, and data have shown that MSDSLA can be a valuable tool in the evaluation of pigmented skin lesions (PSLs). This study aimed to aggregate data from 7 prior studies to provide a comprehensive overview and evaluate the consistency of the effects of MSDSLA when used in conjunction with clinical examination and dermoscopy to evaluate PSLs.

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Early detection of melanoma, which is known to improve survival rates, remains a challenge for dermatologists. Suspicious pigmented lesions typically are evaluated via clinical examination and dermoscopy; however, new technologies are being developed to provide additional objective information for clinicians to incorporate into their biopsy decisions.

Multispectral digital skin lesion analysis (MSDSLA) uses 10 bands of visible and near-infrared light (430–950 nm) to image and analyze pigmented skin lesions (PSLs) down to 2.5 mm below the skin surface and measures the distribution of melanin using 75 unique algorithms to determine the degree of the morphologic disorder. Using a logical regression model previously validated on a set of 1632 PSLs, the probability of melanoma and probability of being a melanoma/PSL of high-risk malignant potential are then provided to the clinician.[1]

In this study, we analyzed aggregate data from 7 prior studies[2-8] to better determine how MSDSLA impacts the biopsy decisions of dermatologists and nondermatologists following clinical examination and dermoscopic evaluation of PSLs.

Methods

A total of 855 practitioners (657 dermatologists, 126 dermatology residents, 72 nondermatologists [ie, primary care physicians, physician assistants, nurse practitioners]) in 7 prior reader studies (Table)[2-8] were shown a total of 62 clinical (distant and close-up) and dermoscopic images of PSLs (13 invasive melanomas, 10 melanomas in situ, 7 high-grade dysplastic nevi, 32 benign skin lesions including low-grade dysplastic nevi) previously analyzed by MSDSLA.[2-8] For each lesion evaluated, the practitioners were first asked if they would biopsy based on their review of the clinical and dermoscopic images and were asked again when given the associated MSDSLA information. Data were aggregated across all participants for the individual lesions presented in each reader study. Biopsy decisions were compared overall after evaluation of clinical and dermoscopic findings and then after evaluation of MSDSLA findings. Statistical analyses were

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Meta-Analysis of Prior Studies Evaluating the Impact of Multispectral Digital Skin Lesion Analysis on Melanoma Diagnosis

Reference (Year)	Study Population, N[a]	Sensitivity, %		Specificity, %		Biopsy Accuracy, %	
		Clinical Evaluation	MSDSLA Evaluation	Clinical Evaluation	MSDSLA Evaluation	Clinical Evaluation	MSDSLA Evaluation
Rigel et al[2] (2012)	179	69	94	54	40	-	-
Yoo et al[3] (2013)	126	52	77	54	40	-	-
Winkelmann et al[4] (2015)	67	67	92	37	57	49	71
Winkelmann et al[5] (2015)	41	64	62	57	73	60	68
Winkelmann et al[6] (2015)	212	65	83	40	76	52	80
Winkelmann et al[7] (2016)	70	59	74	51	61	54	67
Farberg et al[8] (2017)	160	76	92	52	79	64	86

Abbreviation: MSDSLA, multispectral digital skin lesion analysis.
[a]The meta-analysis included all participants in each study, including those who did not evaluate the complete set of lesions.

performed using *t*-test and χ^2 analysis for proportions where appropriate.

Results

Overall sensitivity for the detection of melanoma or other high-grade PSLs improved from 70% on clinical and dermoscopic evaluation to 88% after MSDSLA information was provided ($P<.0001$), and specificity increased from 52% to 58% ($P<.001$). Diagnostic accuracy also improved from 59% on clinical evaluation to 69% after review of MSDSLA findings ($P<.0001$). The positive predictive value of biopsy decisions was 47% following clinical evaluation, which improved to 56% after evaluation of MSDSLA findings ($P<.001$), and the negative predictive value increased from 74% to 89% ($P<.0001$). The overall percentage of lesions selected for biopsy did not significantly change following MSDSLA data integration (57% vs 60%)(Figure). Given that similar numbers of lesions were biopsied with improved sensitivity and specificity, the integration of MSDSLA data into the biopsy decision led to an improved biopsy ratio (ratio of melanomas biopsied to total biopsies) and fewer unnecessary biopsies.

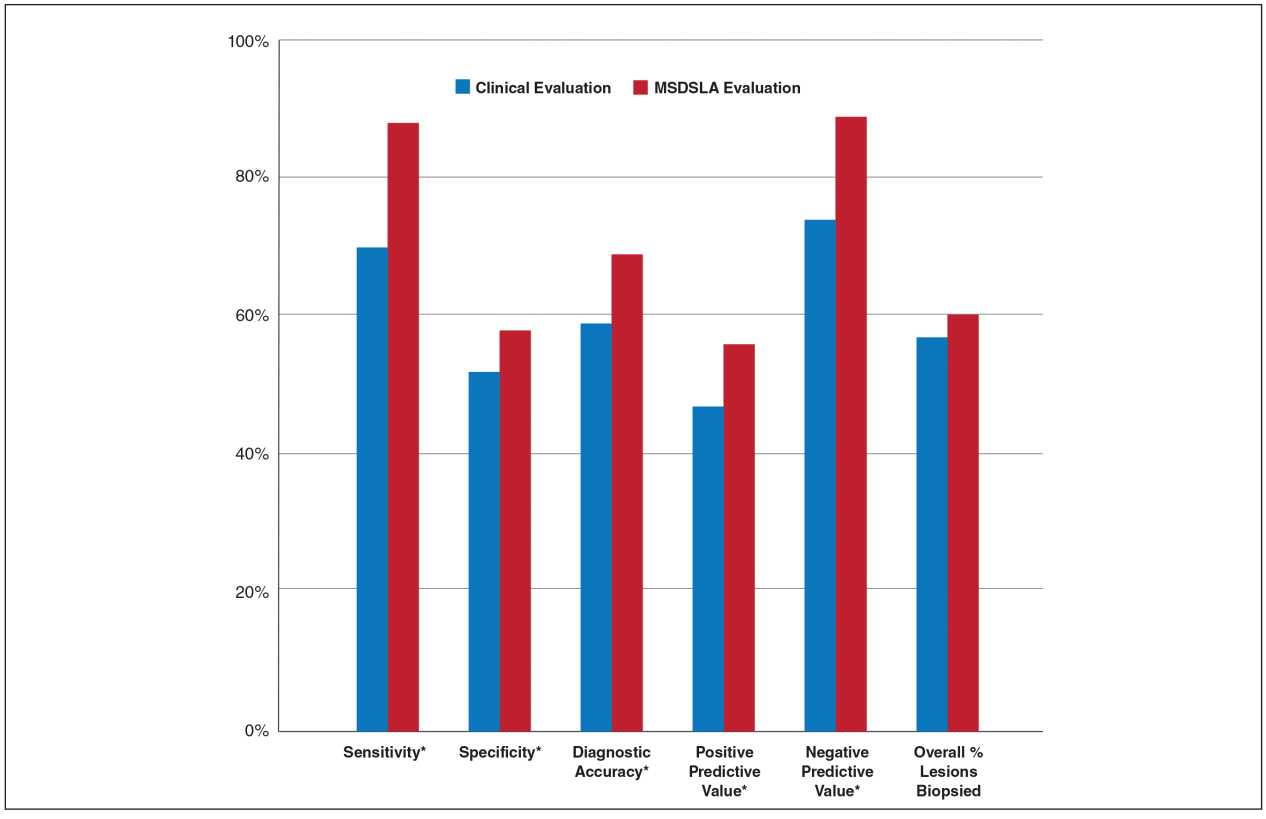
Comment

Our broad analysis further supported the findings of prior studies that decisions to biopsy clinically suspicious PSLs are more sensitive, specific, and accurate when practitioners are provided MSDSLA information following clinical examination.[2-8] With no significant increase in the number of biopsies performed, the fact that all 5 of the standard diagnostic evaluation metrics (sensitivity, specificity, diagnostic accuracy, positive predictive value, negative predictive value) were improved after MSDSLA information was provided additionally supported this conclusion.

Given the evolution in health care economics, it is clear that greater emphasis will continue to be placed on superior, evidence-based, effective care. The reported diagnostic sensitivities and specificities of clinical evaluation and dermoscopy for melanoma detection vary widely throughout the literature, with sensitivities ranging from 58% to over 90% and specificities ranging from 77% to 99%.[9-11] Diagnostic performance generally has been found to be higher among dermatologists than nondermatologists and is highest in specialized pigmented lesion clinics.[12]

Our study had several limitations. For this analysis to be more representative of lesion biopsy selection in the clinical setting, biopsy sensitivity (correctly identifying lesions appropriate for biopsy) vs melanoma sensitivity (identifying a lesion as melanoma) was used.[13] The overall sensitivity found was within the range of prior studies,[2-8] but this approach may have potentially led to a lower specificity due to an increased number of lesions biopsied. Additionally, the melanomas selected for these studies were early (malignant melanoma in situ or mean thickness of invasive malignant melanoma of 0.3 mm), and the nonmelanomas (including low-grade dysplastic nevi) were not necessarily diagnostically straightforward. This may have led to the clinical and dermoscopic sensitivity and specificity noted being lower than in some prior studies.[9-11]

The risk of missing a melanoma with MSDSLA devices has led manufacturers to strive for a high sensitivity for their devices, leading to lower specificity as a consequence. For this reason and other ambiguous practical



Standard statistical metrics evaluating the impact of multispectral digital skin lesion analysis on pigmented lesion diagnosis. All 5 of the standard metrics for diagnostic tests improved following the provision of multispectral digital skin lesion analysis data to the health care providers (N=855). Asterisk indicates statiscally significant improvement ($P<.05$).

considerations (eg, device and patient costs, difficulty with insurance reimbursement), the adoption of this technology into routine clinical practice has remained relatively static; however, using enhanced diagnostic technologies such as MSDSLA may help with more accurate identification of high-risk PSLs, thereby leading to earlier detection and overall less expensive, more cost-effective treatment of melanoma.

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