Impact of Guidance Provided by a Multispectral Digital Skin Lesion Analysis Device Following Dermoscopy on Decisions to Biopsy Atypical Melanocytic Lesions

^aRICHARD R. WINKELMANN, DO; ^bJANE YOO, MD, MPH; ^cNATALIE TUCKER, BS; ^dRICHARD WHITE, MS; ^cDARRELL S. RIGEL MD, MS

^aMelanoma Clinical Research Fellow, Rigel Dermatology, New York, New York; ^bMohs Surgery Fellow, Department of Dermatology, Yale School of Medicine, New Haven, Connecticut; ^cMELA Sciences Inc., Irvington, New York; ^dIris Interactive System, Cody, Wyoming; ^cClinical Professor of Dermatology, NYU School of Medicine, New York, New York

ABSTRACT

Objective: To determine how a multispectral digital skin lesion analysis (MSDSLA) device data affects the biopsy performance of dermatologists and non-dermatologist practitioners following clinical and dermoscopic pigmented lesion evaluation. **Design:** MSDSLA employs near infrared light to image and analyze pigmented skin lesions. MSDSLA generates a "classifier score" based on morphological disorganization. Using a logistical regression model, 1) a probability of being melanoma and, 2) a probability of being melanoma, atypical melanocytic hyperplasia, or a high grade dysplastic nevus is computed. Participants were shown clinical images of 12 lesions (2 melanomas *in situ*, 3 invasive melanomas, and 7 low grade DNs). They were asked first if they would biopsy the lesion based on clinical images, again after observing dermoscopy images, and once more when presented with MSDSLA probability information. Setting: National dermoscopy conference. Participants: Sixty-four healthcare providers; 30 dermatologists and 34 non-dermatologist practitioners. **Measurements:** Sensitivity, specificity, diagnostic accuracy, biopsy rates **Results:** For the 30 dermatologists, sensitivity was 65 percent after clinical evaluation (C) and 65% post-dermoscopy (D) but improved to 91% after MSDSLA. For the 34 non-dermatologist practitioners, sensitivity improved from 66 percent (C) to 70 percent (D) to 95 percent after MSDSLA. With MSDSLA information, dermatologist specificity increased from 40 percent (D) to 58 percent while non-dermatologist practitioners specificity increased from 34 percent (D) to 55 percent. Diagnostic accuracy of malignant and benign lesions decreased for both groups 55 percent (C) to 51 percent (D) for dermatologists and 54 percent (C) to 49 percent (D) for non-dermatologist practitioners. However, diagnostic accuracy increased to 72 percent for dermatologists and 72 percent for non-dermatologist practitioners with MSDSLA data. Non-melanoma biopsy percentages by dermatologists increased from 53 percent (C) to 60 percent (D), but decreased to 42 percent when provided with MSDSLA data. Similarly, non-dermatologist practitioners' biopsy percentages of nonmelanomas increased from 55 percent (C) to 66 percent (D) and decreased to 45 percent with MSDSLA. **Conclusion:** Decisions to biopsy atypical melanocytic lesions were more sensitive and specific when MSDSLA information was provided for both dermatologists and nondermatologist practitioners. Both groups were also less likely to biopsy nonmelanomas after MSDSLA evaluation. The authors' results suggest providing practitioners with MSDSLA data leads to improved biopsy accuracy decreasing the number of nonessential biopsies for nonmelanocytic lesions even after dermoscopic evaluation. (J Clin Aesthet Dermatol. 2015;8(9):21-24.)

DISCLOSURE: Dr. Winkelmann is a clinical research fellow funded in part by MelaSciences Inc, Dr. Yoo has worked as a consultant for MelaSciences Inc., Ms. Tucker is employed by MelaSciences Inc, Mr. White has no conflicts of interest to disclose, and Dr. Rigel is a consultant to MelaSciences Inc. **ADDRESS CORRESPONDENCE TO:** Richard R. Winkelmann, DO, Melanoma Clinical Research Fellow, Rigel Dermatology, 35 E 35th St. Ste. 208, New York, NY 10016; E-mail: rrwink@gmail.com

Clinical.Aesthetic

21

TABLE 1. Pigmented lesion biopsy decision data for dermatologists vs. non-dermatologist practitioners following clinical evaluation, subsequent dermoscopy, and subsequent MSDSLA

DERMATOLOGISTS (N = 30)	CLINICAL EVALUATION	AFTER DERMOSCOPY (<i>P</i>)	AFTER MSDSLA (<i>P</i>)
Sensitivity	65%	65% (NS)	91% (<0.0001)
Specificity	47%	40% (NS)	58% (0.0002)
Diagnostic accuracy	55%	51% (NS)	72% (<0.0001)
% Low grade dysplastic nevus biopsies	53%	60% (NS)	42% (0.0002)
% All lesions biopsied	58%	62% (NS)	62% (<0.0001)
% Biopsying all 5 malignant melanomas	4%	10% (NS)	72% (0.002)
NON-DERMATOLOGIST PRACTITIONERS (N = 34)	CLINICAL EVALUATION	AFTER DERMOSCOPY (<i>P</i>)	AFTER MSDSLA (<i>P</i>)
Sensitivity	66%	70% (NS)	95% (<0.0001)
Sensitivity Specificity	66% 46%	70% (NS) 34% (0.01)	95% (<0.0001) 55% (<0.0001)
· ·	46%	34% (0.01)	55% (<0.0001)
Specificity Diagnostic accuracy	46%	34% (0.01) 49% (NS)	55% (<0.0001) 72% (<0.0001)

arly detection of melanoma improves survival.¹ Suspicious pigmented lesions are typically evaluated by clinical examination and sometimes dermoscopy.² New technologies may provide additional clinically significant information to augment accurate biopsy decisions.^{3,4}

This study was designed to determine how information provided by a multispectral digital skin lesion analysis (MSDSLA) device (MelaFind, MELASciences Inc, Irvington, New York)^{4,5} affects the biopsy decisions of dermatologists and non-dermatologist practitioners (NDPs) following clinical and dermoscopic pigmented skin lesion evaluation. MSDSLA employs visible and nearinfrared light (430–950nm) to image lesions up to 2.5mm below the skin surface. MSDSLA then analyzes pigmented lesions across 10 spectral bands using 75 unique analytical algorithms to determine a "classifier score" based on the degree of morphological disorganization. Validated on a database of 1,632 pigmented lesions,⁵ MSDSLA also provides the probability of an analyzed lesion being

22

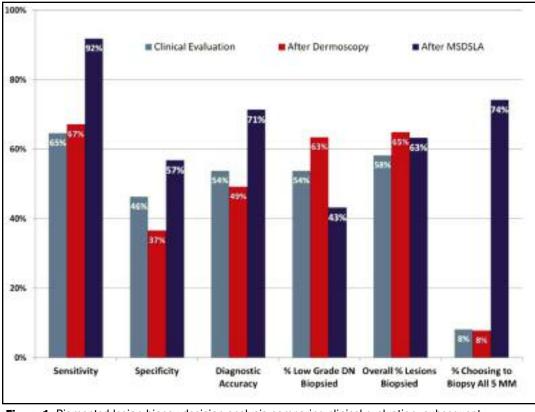


Figure 1. Pigmented lesion biopsy decision analysis comparing clinical evaluation, subsequent dermoscopy, and subsequent MSDSLA for entire study group.

melanoma and melanoma, atypical melanocytic hyperplasia (AMH) or a high-grade dysplastic nevus (DN) to the clinician.

METHODS

Sixty-seven practitioners were enrolled in a crosssectional reader study at a national dermoscopy conference. Participants were shown high-resolution clinical images of 12 lesions (2 melanomas *in situ*, 3 invasive melanomas, and 7 low-grade DNs) previously analyzed by MSDSLA.⁵ Participants were first asked if they would biopsy the lesion based on clinical images, again after observing highresolution dermoscopy images, and again when subsequently shown MSDSLA probability information. Each response was input using a wireless keypad. Answers were withheld from participants until all data had been collected to avoid bias. Biopsy decisions were compared for clinical evaluation, after dermoscopy, and then after the additional MSDSLA information was provided.

RESULTS

Data were analyzed from 67 practitioners (Table 1 and Figure 1). Three participants did not identify provider status. For the 30 dermatologists, sensitivity was 65 percent after clinical evaluation (C) and 65 percent post-dermoscopy (D), but 91 percent after MSDSLA (P<0.0001). For the 34 NDPs, sensitivity improved from

66 percent (C) to 70 percent (D) to 95 percent after MSDSLA (P < 0.0001). With MSDSLA, dermatologist specificity increased from 40 percent (D) to 58 percent (P=0.0002) while NDP specificity increased from 34 percent (D) to 55 percent (P < 0.0001). Diagnostic accuracy increased from 51 percent (D) to 72 percent (P < 0.0001) for dermatologists and from 49 percent (D) to 72 percent (P < 0.0001) for NDPs after integrating the MSDSLA data into the biopsy decision. Nonmelanoma biopsy percentages by dermatologists increased from 53 percent (C) to 60 percent (D), but decreased to 42 percent (P=0.0002) with MSDSLA. Similarly, NDP biopsy percentages of nonmelanomas increased from 53 percent (C) to 66 percent (D) (P=0.01) and decreased to 45 percent with MSDSLA (P < 0.0001). The overall number of lesions biopsied did not significantly increase (58-63% post-MSDSLA).

Dermatologists choosing to biopsy all five malignant lesions increased from four percent (C) to 10 percent (D) to 72 percent (P=0.02) after MSDSLA. NDPs biopsying all five melanomas went from 13 percent (C) to six percent (D) to 78 percent (P<0.0001) after MSDSLA. Since both groups were also significantly less likely to biopsy non- malignant melanoma, atypical melanocytic hyperplasia, and high-grade dysplastic nevi lesions after MSDSLA, biopsy ratios improved after the additional information was provided to the clinician. Therefore, more melanomas and fewer low-



grade DNs were subsequently selected for biopsy without a significant concomitant increase in biopsy numbers.

CONCLUSIONS

Decisions to biopsy atypical melanocytic lesions were more sensitive, specific, and accurate after providing MSDSLA probability information to dermatologists and NDPs even after dermoscopic evaluation. Both groups were also less likely to biopsy low grade DN after MSDSLA information was obtained.

The results of this study suggest providing practitioners with MSDSLA data leads to improved diagnostic accuracy, thereby decreasing the number of nonessential biopsies for low grade lesions. Even after dermoscopic evaluation, this study suggests that MSDSLA may significantly further augment the accurate evaluation of suspicious pigmented skin lesions.

REFERENCES

- 1. Gloster HM Jr, Brodland DG. The epidemiology of skin cancer. Dermatol Surg. 1996;22:217-226.
- 2. Wang SQ, Kopf AW, Koenig K, et al. Detection of melanomas in patients followed up with total cutaneous examinations, total cutaneous photography, and dermoscopy. J Am Acad Dermatol. 2004;50:15-20.
- Ruocco E, Argenziano G, Pellacani G, et al. Noninvasive 3. imaging of skin tumors. Dermatol Surg. 2004;30p2: 301-310.
- 4. Gutkowicz-Krusin D, Elbaum M, Jacobs A, et al. Precision of automatic measurements of pigmented skin lesion parameters with a MelaFind multispectral digital dermoscope. Melanoma Res. 2000;10:563-570.
- 5. Monheit G, Cognetta AB, Ferris L, et al. The performance of MelaFind: a prospective multicenter study. Arch Dermatol. 2011;147:188–194.