

The Impact of Multispectral Digital Skin Lesion Analysis on German Dermatologist Decisions to Biopsy Atypical Pigmented Lesions with Clinical Characteristics of Melanoma

^aRICHARD R. WINKELMANN, DO; ^bAXEL HAUSCHILD, MD; ^cNATALIE TUCKER, BS;
^dRICHARD WHITE, MS; ^eDARRELL S. RIGEL, MD, MS

^aMelanoma Clinical Research Fellow, National Society for Cutaneous Medicine, New York, New York; ^bDepartment of Dermatology, Allergology, and Venerology, University of Kiel, Kiel, Germany; ^cMELA Sciences Inc, Irvington, New York; ^dIris Interactive Systems, Cody, Wyoming; ^eDepartment of Dermatology, New York University School of Medicine, New York, New York

ABSTRACT

Objective: To determine the impact of multispectral digital skin lesion analysis on German dermatologist biopsy decisions of atypical pigmented skin lesions. **Design:** Participants were shown high-resolution clinical images of 12 atypical pigmented skin lesions previously analyzed by multispectral digital skin lesion analysis. Participants were asked if they would biopsy the lesion based on clinical images and high-resolution dermoscopy images and again when subsequently shown multispectral digital skin lesion analysis probability information. **Setting/participants:** Forty-one dermatologists at a skin cancer conference in Germany in September 2014. **Measurements:** Sensitivity, specificity, diagnostic accuracy, percent biopsying all melanomas, and overall biopsy rates. **Results:** Sensitivity for the detection of melanoma following clinical evaluation was 64 percent. After receipt of multispectral digital skin lesion analysis probability information, sensitivity decreased nonsignificantly to 62 percent. Specificity with clinical evaluation was 57 percent and increased to 73 percent using multispectral digital skin lesion analysis. Overall biopsy accuracy increased from 60 percent with clinical evaluation to 68 percent with multispectral digital skin lesion analysis. The percentage of low-grade dysplastic nevi chosen for biopsy decreased from 43 percent after clinical evaluation to 27 percent with multispectral digital skin lesion analysis. Finally, the overall percentage of lesions biopsied decreased from 52 percent with clinical evaluation to 42 percent after multispectral digital skin lesion analysis. **Conclusion:** Multispectral digital skin lesion analysis can be used reliably to detect melanoma as well as clinical evaluation. Dermatologists can confidently use multispectral digital skin lesion analysis to significantly improve specificity and reduce their overall number of biopsies while increasing overall diagnostic accuracy. (*J Clin Aesthet Dermatol.* 2015;8(10):27–29.)

The use of technology has dramatically altered the landscape of clinical practice in the last few decades giving the opportunity to enhance cost-effective, quality care. Within the field of dermatology, early diagnosis of melanoma is critical to survival.¹ Therefore

interventions to enhance timely diagnosis are needed. multispectral digital skin lesion analysis (MSDSL A)^{2,3} is currently being studied in the United States⁴ and Germany⁵ for its use in noninvasively augmenting dermatologist decisions to biopsy suspicious pigmented lesions.

DISCLOSURE: Dr. Winkelmann's clinical research fellowship is funded in part by MelaSciences Inc. Ms. Tucker is employed by MelaSciences Inc. Mr. White received compensation for the collection of audience response data. Drs. Rigel and Hauschild are consultants to MelaSciences Inc. This study was funded in part by a grant from MelaSciences, Inc.

ADDRESS CORRESPONDENCE TO: Richard R. Winkelmann, DO; E-mail: rrwink@gmail.com

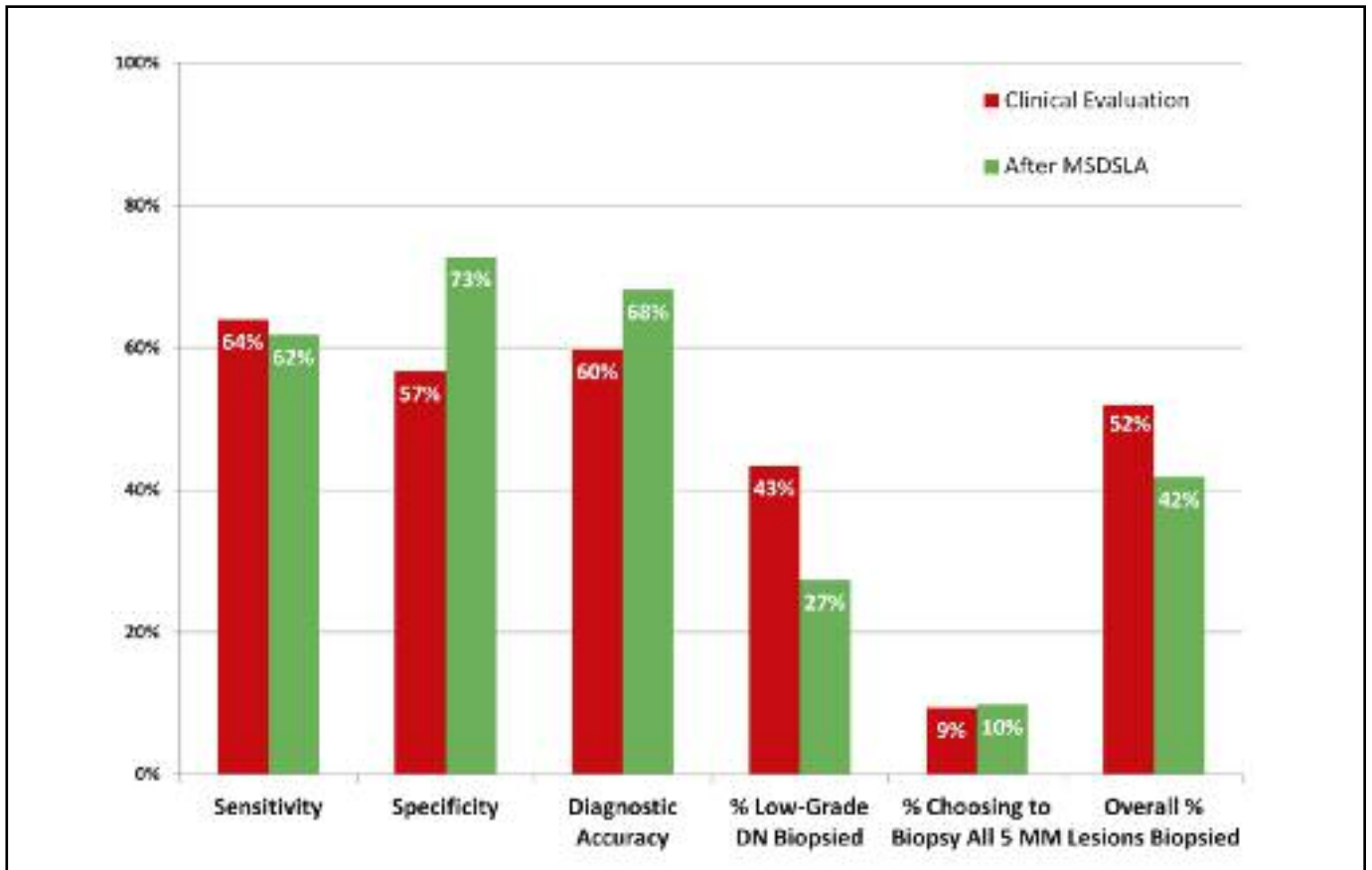


Figure 1. Summary of standard diagnostic accuracy evaluation metrics for MSDSLA.

MSDSLA employs visible and near-infrared 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, MSDSLA also provides the probability of an analyzed lesion being melanoma and melanoma, atypical melanocytic hyperplasia (AMH) or a high-grade dysplastic nevus (DN) to the clinician.⁴

The MSDSLA device is available for purchase commercially. Following some training on how to properly acquire an image immersed in isopropyl alcohol, the hand-held device takes approximately 30 seconds to image and analyze each pigmented lesion per patient sitting. The additional objective information provided by MSDSLA about a suspicious pigmented lesion is then integrated into a dermatologist’s biopsy decision. MSDSLA is not meant to be followed blindly. For example, if the additional probability information suggests a low probability of melanoma, AMH, or high-grade DN, the final biopsy decision is still up to the experienced dermatologist evaluating the entire clinical picture. The purpose of this study was to determine how physicians’ biopsy decisions are affected by integration of this objective data.

MATERIALS AND METHODS

Forty-seven German dermatologists were enrolled in a cross-sectional reader study at a skin cancer conference in September 2014. Data were analyzed from 41 participants who completed at least 90 percent (>22/24) of the study questions. 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. Participants were first asked if they would biopsy the lesion based on clinical photographs and high-resolution 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 with dermoscopy and then after the additional MSDSLA information was provided. Results before and after MSDSLA integration were analyzed for statistical significance ($p < 0.05$) using the chi-square method for proportions.

RESULTS

Calculations for several of the standard diagnostic accuracy evaluation metrics are summarized in Figure 1. Sensitivity for the detection of melanoma following clinical

evaluation (C) was 64 percent. After receipt of MSDSLA probability information, sensitivity decreased non-significantly (NS) to 62 percent. Specificity with (C) was 57% and increased to 73 percent using MSDSLA ($p<0.001$). Overall biopsy accuracy increased from 60 percent (C) to 68 percent with MSDSLA ($p<0.001$). The percent change of intervention with MSDSLA after (C) among German dermatologists choosing to biopsy low-grade DN was -16 percent (43–27%, $p<0.001$). The proportion of dermatologists choosing to biopsy all five melanomas (C) was relatively unchanged with receipt of MSDSLA data (9–10%, NS). Finally, the overall percentage of lesions biopsied decreased from 52 percent (C) to 42 percent after MSDSLA ($p=0.002$).

DISCUSSION

Sensitivity for the detection of melanoma did not change significantly following receipt of MSDSLA probability information. This is in contrast to a previous study of German dermatologists (n= 211) in which sensitivity increased from 70 percent (C) to 97 percent with MSDSLA ($p<0.00001$)⁵ and an American study (n= 179) with an identical protocol in which sensitivity increased from 69 percent (C) to 94 percent after MSDSLA ($p<0.001$).⁶ The present data suggest, as compared to the US dermatologists, German dermatologists rely more strongly on their own clinical judgment to detect melanomas and are more inclined to use MSDSLA when deciding which pigmented lesions do not require a biopsy. This finding is supported by the marked increase in specificity obtained using MSDSLA as well as the reduction in the number of low-grade DN biopsies and overall biopsy rate. Most importantly, the overall biopsy accuracy significantly increased with a concomitant reduction in the total number of lesions selected for biopsy.

Potential limitations of this study include lack of opportunity for *in vivo* lesion evaluation, small number of

participants, and practitioners with a particular expertise in skin cancer or technology may self-select themselves to take part in the study.

CONCLUSION

MSDSLA can be used reliably to enhance melanoma detection and to help rule out the necessity for biopsy while increasing diagnostic overall accuracy. German dermatologists were more likely to integrate MSDSLA into their biopsy decisions through ruling out lesions that did not require biopsy (enhancing specificity) versus US dermatologist using MSDSLA to rule in lesions for biopsy (enhancing sensitivity).

REFERENCES

1. Rigel DS, Russak J, Friedman R. The evolution of melanoma diagnosis: 25 years beyond the ABCDs. *CA Cancer J Clin.* 2010;60(5):301–316.
2. Elbaum M, Kopf AW, Rabinovitz HS, et al. Automatic differentiation of melanoma and melanocytic nevi with multispectral digital dermoscopy: a feasibility study. *J Am Acad Dermatol.* 2001;44(2):207–218.
3. Gutkowitz-Krusin D, Elbaum M, Jacobs A, et al. Precision of automatic measurements of pigmented skin lesion parameters with a MelaFind(TM) multispectral digital dermoscope. *Melanoma Res.* 2000;10(6):563–570.
4. Monheit G, Cognetta AB, Ferris L, et al. The performance of MelaFind: a prospective multicenter study. *Arch Dermatol.* 2011;147(2):188–194.
5. Hauschild A, Chen SC, Weichenthal M, et al. To excise or not: impact of MelaFind on German dermatologists' decisions to biopsy atypical lesions. *J Dtsch Dermatol Ges.* 2014;12(7): 606–614.
6. Rigel DS, Roy M, Yoo J, et al. Impact of guidance from a computer-aided multispectral digital skin lesion analysis device on decision to biopsy lesions clinically suggestive of melanoma. *Arch Dermatol.* 2012;148:541–543. ●