Small pigmented lesions have long presented a diagnostic challenge to the clinician. On the one hand, the rates at which pigmented lesions under 6mm in diameter are diagnosed as either thin or in situ melanoma are estimated to be quite low. The well-established ABCDE criteria for evaluation of suspicious pigmented lesions emphasizes increased risk in lesions greater than 6mm in diameter. Therefore, clinicians may maintain a lower index of suspicion when evaluating small pigmented lesions. However, early detection and treatment are integral to the successful management of melanoma and can contribute significantly to clearance and good long-term prognosis for affected patients. Failure to detect small melanoma under 6mm in diameter contributes to treatment delays and may be associated with poorer prognosis.

The relatively recent addition of “Evolution” to the evaluation criteria to some extent addressed the challenges of identifying small melanomas, as any change in a lesion under 6mm is thought to indicate an increased risk for malignancy and should increase the clinician’s level of suspicion. New research indicates that use of a computer-vision system can help identify small melanomas and may limit unnecessary biopsies of benign lesions.

Assessment Tools
While detection of small melanomas by clinical evaluation alone has always been difficult, previous studies have demonstrated the benefit of dermoscopy in differentiating small benign lesions from malignant ones. Bono et al subjected 206 pigmented lesions (3mm or less in diameter) from 204 consecutive patients to both clinical and dermoscopic evaluation. While clinical evaluation was associated with a diagnostic sensitivity of 43 percent and specificity of 91 percent, dermoscopy resulted in a sensitivity of 83 percent and specificity of 69 percent.

But dermoscopy has limitations. One retrospective study compared baseline dermoscopic images of 325 pigmented lesions that were observed by digital dermoscopy then ultimately excised due to changes over time. These lesions consisted of 262 melanocytic nevi and 63 early melanomas that were deemed to have uncharacteristic clinical and dermoscopic characteristics. Researchers identified no differences in the patterns of dermoscopic features in baseline images of the two lesion types. Furthermore, neither the ABCD rule of dermoscopy nor the seven-point checklist accurately diagnosed early melanomas.

Computer-aided dermoscopy has emerged as a potential tool to improve the efficacy of dermoscopy in identifying uncharacteristic and small melanomas, since such systems have been suggested to aid diagnosis of melanoma generally. One study of an automated dermoscopy image analysis instrument found that it gave a sensitivity of 91 percent and specificity of 68 percent for melanoma. The sensitivity for dermatologists evaluating the same images was 81 percent, while the specificity was 60 percent. Lesions included for evaluation in the trial were not selected due to any specific criteria.

About the MelaFind System
MelaFind (Electro-Optical Systems or ELOS) uses a hand-held imaging device that emits 10 different specific wavelengths (including near infra-red bands) of light to obtain views of pigmented lesions at multiple depths. Each view is essentially a cross-section of the lesion at a specific depth, down to 2.5mm deep into the skin.

Once these images are obtained, the system’s proprietary algorithms analyze these data against a proprietary database of melanomas and benign lesions (6,000 lesions total) in order to generate a detailed report with an immediate recommendation of whether the lesion should be biopsied.

The overall lesion classifier, Friedman et al explain, “consists of six constrained linear classifiers, each trained to differentiate melanomas with 100 percent sensitivity from a particular type of lesion (low-grade dysplastic nevus, congenital nevus, common nevus, seborrheic keratosis, solar lentigo, and pigmented basal cell carcinoma).” Each lesion analyzed receives six scores and is recommended for biopsy only if all scores fall above the threshold value.
New data for a multispectral imaging and automated evaluation system for pigmented lesions offers support for use of the computer system specifically for small pigmented lesions. Ten dermoscopists independently assessed images and data for 99 pigmented lesions measuring 6mm or less in diameter. Of these, 49 were biopsy-confirmed melanomas and 50 were randomly-selected non-melanomas that served as controls. For each lesion, reviewers received electronic images collected by the MelaFind multispectral imaging system (see sidebar) along with information about patient sex, age, and lesion location. Standard dermoscopic images were provided for some cases, as well. Whereas the computer system recommended biopsy for 98 percent of small melanomas and missed one melanoma in situ, dermoscopists on average would have biopsied only 71 percent of small melanomas, missing 29 percent of melanomas, including both in situ and invasive types.

Dermoscopists’ average diagnostic sensitivity for small melanomas was 39 percent; specificity was 82 percent. They recommended small melanomas for biopsy with a sensitivity of 71 percent and a specificity of 49 percent. The computer-vision system recommended biopsy to rule out melanoma with a sensitivity of 98 percent and a specificity of 44 percent. While these specificities are not statistically significantly different, the sensitivities are. Both dermoscopists and the computer-vision system have higher sensitivity to invasive melanoma than to melanoma in situ. Analysis of the data suggests that approximately 19 percent of small invasive melanoma and 37 percent of small melanomas in situ may not be biopsied, “even by expert physicians.”

Despite the positive findings for the computer-assisted system in this study, there are some limitations to consider. As pointed out in the editorial accompanying the study,7 the computer was asked to evaluate lesions hand-selected by human experts; it was “taught” to assess lesions through the calculated input of specific lesions. By contrast, human physicians in the clinic evaluate thousands of lesions that are not “pre-selected.” Plus, the editorial notes, the dermoscopists’ scores represent an average for the 10 participating experts, each of whom likely has a different threshold for treatment. So while one may have had high sensitivity and low specificity, another may have had low sensitivity and high specificity. Averaging their scores may give a distorted sense of how the computer may perform in clinical practice, where an individual physician evaluator will be selecting the lesions to submit for computer analysis.

**Summary of Study Findings**

<table>
<thead>
<tr>
<th></th>
<th>Expert Readers’ Average</th>
<th>MelaFind System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training Set Biopsy Sensitivity</td>
<td>71%</td>
<td>100%</td>
</tr>
<tr>
<td>Training Set Biopsy Specificity</td>
<td>52%</td>
<td>46%</td>
</tr>
<tr>
<td>Pooled Set Biopsy Sensitivity</td>
<td>71%</td>
<td>98%</td>
</tr>
<tr>
<td>Pooled Set Biopsy Specificity</td>
<td>49%</td>
<td>44%</td>
</tr>
</tbody>
</table>

**Expert Readers’ Score Range**

<table>
<thead>
<tr>
<th></th>
<th>Specificity</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert Readers’ Score Range</td>
<td>37 to 88%</td>
<td>22% to 80%</td>
</tr>
</tbody>
</table>

**Every Bit Helps**

While the current study may to some degree over-represent the computer-vision system’s clinical utility, the fact remains that the system demonstrates the ability to accurately identify small-diameter pigmented lesions that may be melanomas—particularly invasive melanomas. Through the use of multispectral imaging, the computer system is able to “view” and assess characteristics of a pigmented lesion that the dermatologist cannot, even the dermatologist aided by a dermoscope.

Given the benefits of early detection and the importance of accurate diagnosis of small melanomas, any additional benefit provided by the computer-vision system would be welcome in the clinic. Of course, dermatologists and dermoscopists continue to monitor evolution or change in small pigmented lesions so as to arrive at an appropriate level of suspicion for potential malignancy. Further enhancements in the computer imaging system coupled with clinician training and familiarity with it (once commercially distributed in the US) may support more accurate diagnosis and ultimate cure of small melanomas.

Dr. Wolfe has been an investigator for Electro-Optical Systems.