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Review Article

Screening and Non-Invasive Evaluative Devices for Melanoma Detection: A Comparison of Commercially Available Devices and Dermoscopic Evaluation

Matthew Hand[1], Andy Chien[3] and Douglas Grossman[1,2]*

[1]*Department of Dermatology, University of Utah Health Sciences Center, Salt Lake City, Utah, USA*

[2]*Huntsman Cancer Institute, University of Utah Health Sciences Center, Salt Lake City, Utah, USA*

[3]*Department of Medicine, Division of Dermatology, University of Washington, WA, USA*

Abstract

A number of commercially available devices have been developed to help dermatologists distinguish benign pigmented lesions from malignant melanoma, but it is unclear if and how these technologies should be adopted into clinical practice. This review summarizes the reported diagnostic accuracies of these devices and compares them to clinical exam and dermoscopy. Screening devices appear to have the highest utility in patient populations with a high prevalence of melanoma. However, even in high-risk patients the diagnostic accuracy of evaluative devices is not clearly superior to dermatologists skilled with dermoscopy, potentially limiting their cost effectiveness. General practitioners not skilled with dermoscopy are likely to have larger improvements in diagnostic accuracy when using evaluative devices, however further investigation into the best way to employ them is needed.

Keywords: Dermoscopy; Melafind; Melanoma; Molemate; Nevisense; Spectroscopy; Total Body Photography

Abbreviations

TBP: Total Body Photography; SDDI: Sequential Digital Dermoscopic Imaging; CAD: Computer-Assisted Diagnostic; SIA: Spectrophotometric Intracutaneous Analysis; CSLM: Confocal Scanning Laser Microscopy; ADD: Automated Dermoscopic Diagnostic; PSL: Pigmented Skin Lesion

***Corresponding author:** Douglas Grossman, Department of Dermatology and Huntsman Cancer Institute, University of Utah Health Sciences Center, Salt Lake City, Suite 5262, 2000 Circle of Hope, UT 84112, USA, Tel: +1 8015814682; E-mail: doug.grossman@hci.utah.edu

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Introduction

Population-wide screening for melanoma may lead to long-term decreases in melanoma-specific mortality [1]. Additionally, detection of melanoma at earlier stages reduces morbidity and mortality and curtails healthcare costs [2]. Despite these benefits the US Preventive Services Task Force doesn't endorse regular screening exams for melanoma in the general population due to the relatively rare incidence [3]. Barriers to screening also exist in the form of limited patient access as well as the ability to quickly and objectively determine whether a nevus is new or changing [4].

Further complications in diagnosing melanoma arise when there is uncertainty as to whether a lesion is benign or malignant, as tissue must be procured by biopsy to secure the diagnosis through histological review. While skin biopsies are fairly low risk, morbidity exists in the form of pain, scarring, bleeding and infection [5,6]. Patients with numerous atypical nevi pose a particular dilemma, as there is increased morbidity and risk of complications as the number of biopsies performed increases. Considering that melanoma has the one of the highest propensities for mortality among skin cancers, most physicians would choose to biopsy any lesions in which melanoma enter the differential.

The difficulties in screening and diagnosing melanoma have led to the development of devices that assist with detection of melanoma. These devices have the potential to improve the diagnostic accuracy of physicians by offering objective review on screening as well as providing information not otherwise available to the non-equipped eye. This article aims to provide an overview of these devices with comparison to current standard methods of detection.

Methods

Devices for inclusion were identified through PubMed database search and review of prominent related articles. Additional information on cost and device availability was garnered through review of manufacturer's websites and direct telephone contact. Widely available or soon to be commercially available devices with reported diagnostic accuracy were included for comparison. Sensitivity and specificity (and biopsy ratios when available) for each device was reported. Geometric means were used to calculate the average biopsy ratios as well as sensitivities and specificities since it is more accurate than the traditional mean when averaging normalized results.

For ease of review, devices have been separated into two main categories: 1) screening devices which are used to identify and monitor new or concerning lesions; 2) evaluative devices which are intended to assist the clinician with the appraisal of a previously identified atypical or concerning nevus.

Screening Technologies

Screening devices use image modalities to evaluate or monitor the temporal evolution of lesions and provide objective data for comparison. Sensitivity measures have not been calculated for many of the devices as it often takes long periods of follow up to determine whether melanomas were missed using the screening method.

Screening devices are helpful for monitoring lesions in patients likely to follow up as mildly suspicious lesions can be monitored with short term follow up for signs of evolution.

Total Body Photography

Total Body Photography (TBP) is designed to screen for the emergence of *de novo* lesions or the evolution of existing lesions by imaging the entire body in sections, permitting comparison to a photographed baseline at subsequent visits. In contrast to Full Skin Exam (FSE) or other methods of comparison imaging where only existing nevi are noted, TBP offers the ability to objectively determine whether a lesion is new by imaging areas where nevi are absent at baseline. This particular strength is evidenced by 25-75% of melanomas detected using TBP which presented as *de novo* pigmented lesions, many of which had gone undetected by the patients themselves [7-11]. However, these advantages remain somewhat theoretical since no studies used control groups for comparison of detection rates with FSE and none of the studies presented *de novo* detection rates on FSE prior to TBP image comparison.

Another potential advantage of TBP is enhanced specificity by enabling the clinician to make more informed decisions about which lesions to biopsy. By objectively identifying changes in nevi, clinicians are able to better determine which changes necessitate biopsy and which changes are benign and amenable to continued monitoring. Biopsy ratios, presented as the number of benign nevi excised for every melanoma excised, provide a helpful comparison between detection methods. Unfortunately, the interdependence of both sensitivity and specificity make diagnostic accuracy indeterminable without knowing both, thus isolated biopsy ratios are of limited value. The challenges of prolonged monitoring necessary to detect false-negatives and the uncertainty whether melanoma was actually present at the time of exam (true false-negative) or had evolved post-screening (*de novo* melanoma arising in a nevus) makes the determination of sensitivity extremely challenging, and has consequently limited the number of studies available for comparison. If sensitivity could be standardized then reductions in biopsy ratios would be useful, but unfortunately determining a cutoff in sensitivity will remain an academic debate.

TBP has been primarily used to screen patients at high risk for developing melanoma (variably defined as patients with greater than 100 nevi, more than ten atypical nevi, personal history of melanoma, history of melanoma in two primary family members, history of severe dysplastic nevi, or a genetic condition that enhances melanoma risk) resulting in a mean benign-to-malignant biopsy ratio of 6.1:1 (range from 2.8:1 to 17:1 [7,8,10,12,13] see also (Table 1). One retrospective study compared TBP with a control group and found no significant difference in the number of biopsies performed per patient (0.82 without TBP versus 0.80 with TBP p=0.43) [9]. However, interpretation of this retrospective study is limited by the small sample size (n=53 per arm) and the lack of any melanomas detected in the TBP group. Another challenge that arises when comparing biopsy ratios between trials is the variability in biopsy ratios according to melanoma prevalence in the sample. This effect is most pronounced when trying to interpret the biopsy ratio from Fiet et al., which yielded the lowest benign-to-malignant biopsy ratio (2.8:1) out of all screening devices [10]. The 100% prevalence created by inclusion of only patients who had melanoma detected on at least one biopsy makes comparisons to prospective trials impossible, even in the extremely high-risk groups. Unfortunately better methods of comparison are lacking given the challenges of prolonged monitoring necessary to detect false-negatives and the uncertainty whether melanoma was actually present at the time of exam (true false-negative) or had evolved post-screening (*de novo* or melanoma arising in a nevus). Another notable finding was the low benign-to-malignant biopsy ratios (3:1) reported in the trial by Banky et al., [3], which incorporated additional dermoscopic examination of suspicious Pigmented Skin Lesions (PSL) identified by TBP. Comparison to results from Kelly et al., [7], which used TBP alone in the same clinic and yielded a benign-to-malignant biopsy ratio of 9.5:1, suggests that follow-up dermoscopy in conjunction with TBP may reduce biopsy ratios. In summary, it is clear that TBP could play a role in enhancing melanoma detection in patients with at least one risk factor, but determining the cost effectiveness of this approach requires larger, prospective trials.

Screening method First Author	Number of Lesions examined (patients)	Biopsy ratio (benign: malignant)	Median follow up in months
TBP			
Kelly [12]	(278)	9.5:1	42
Lucas [13]	(169)	6:1	28
Risser [9]	(64)	53:0	NR
Banky [8]	(309)	2.8:1	34
Feit [10]	(12)	3:1	18
Goodson [7]	(467)	17:1	24
Geometric Mean		6.1:1	
SDDI			
Fuller [14]	5945 (297)	44.5:1	22
Bauer [15]	2015 (196)	15.5:1	25
Haenssle [16]	2939 (212)	6.5:1	18
Argenziano [17]	600 (405)	3.4:1	23
Robinson [18]	3482 (100)	47.3:1	36
Kittler [19]	1862 (202)	8.4:1	12
Menzies [20]	318 (245)	7.7:1	3
Altamura [21]	2602 (1859)	4:1	2.5
Geometric Mean		10.8:1	
TBP + SDDI			
Haenssle [22]	7001 (530)	18.4:1	32
Haenssle [23]	11,137 (688)	8.5:1	46
Kovalyshyn [24]	(394)	5.4:1	NR
Geometric Mean		9.5:1	
TBP + SDDI			
Salerni [25]	11,396 (618)	10.7:1	96
Malvehy [11]	3170 (290)	4.2:1	17
Geometric Mean		6.7:1	
Dermoscopy			
Haenssle [22]	NR	7.5:1	32
Haenssle [23]	NR	6.4:1	46
Sidhu [26]	4691	6.3:1	NR
Chia [27]	686	4:1	NR
Argenziano [28]	300,215	8.7:1	NR
Geometric Mean		6.4:1	
Naked eye			
Risser [9]	(64)	16:1	NR
Marks [29]	11,365	11.7:1	NR
Geometric Mean		13.7	

Table 1: Summary comparison of screening modalities.

NR: Not Reported

Sequential Digital Dermoscopic Imaging (SDDI)

SDDI represents another screening method that employs digitized dermoscopic images for objective comparison overtime. Individual lesions for SDDI are identified by the clinician on a screening examination and subsequently photographed in isolation. The ability to capture detailed images for comparing interval changes makes SDDI more sensitive than traditional photographic methods or dermoscopy alone. A large observational study found that a third of all

melanomas detected using SDDI were not detected by other methods of screening, providing strong support for the utility of this approach [22]. Furthermore, in patients at high risk for melanoma, SDDI detected invasive melanomas with a significantly lower mean Breslow depth (0.41 for SDDI versus 0.62 mm using other methods; p=0.04) [23]. While these results appear promising, another study comparing SDDI to TBP found that SDDI resulted in a significantly higher number of biopsies per patient (1.1 with SDDI versus 0.59 for TBP; p <0.001), possible lower melanoma detection rates (2.2% with SDDI versus 5.5% with TBP; p = 0.088) and longer estimated times for clinic appointments [7]. Two studies examining the use of SDDI in patients without at least one risk factor for melanoma (representing a low-risk population) failed to identify any malignancies despite median follow up durations of 6 and 24 months [30,31]. These results, in conjunction with the high biopsy ratio of 79:1 in the low risk arm of the Haenssle et al., trial; suggest that SDDI is of most utility in the high-risk groups [23]. Currently, it is unclear whether the improvements in diagnosis by SDDI would offset potential increases in healthcare costs from additional biopsies and longer clinic visits.

Combination Screening with both TBP and SDDI

TBP has also been used in conjunction with SDDI for more detailed evaluation and comparison of identified lesions. Studies using TBP once for baseline images, dermoscopy for *de novo* interval lesions, and SDDI for monitoring suspicious lesions between visits have yielded benign-to-malignant ratios ranging from 5.4:1 to 18.4:1[22-24]. Two studies examining sequential TBP with SDDI (TBP and SDDI on each visit) yielded ratios of 4.2:1[11] and 10.7:1[25]. The geometric mean of benign-to-malignant biopsy ratios for TBP without SDDI is 6.1:1 vs. 8.2:1 for combined TBP and SDDI (including TBP for baseline imaging). However the limited number of trials, variability in prevalence, and study designs make meaningful comparison very difficult without data from prospective comparative trials.

Summary of the Clinical Utility of Screening

Screening devices have demonstrated utility in the ability to provide objective evidence of lesion evolution or novelty and are most valuable in screening patients with numerous nevi that are at higher risk for melanoma. Some of the largest limitations of the devices include the cost of use, patient modesty while obtaining images, as well as the time needed to gather and compare images. Due to the time constraints and cost it seems unlikely that population wide screening would be practical using these methods. Another limitation that originates from the provider using the device rather than the device itself is the subjectivity of the clinician's decision to biopsy or monitor a lesion once detected. Further research should be aimed at determining what criteria would enable safe monitoring while limiting unnecessary biopsies.

Evaluative Technologies

Evaluative devices provide diagnostic information not available to the clinician by examination with the unaided eye. Methods of obtaining this information include use of higher levels of magnification, using polarized and different wavelengths of light to highlight features associated with malignancy, as well as analysis of genetic material for aberrations associated with melanoma. The intended use of the evaluative device is as an adjunct to assist with the decision to biopsy, as histological examination of tissue remains the gold standard for diagnosis.

Dermoscopy

Multiple studies have shown that dermatologists trained in dermoscopy with two or more years of clinical experience with the device had superior diagnostic accuracy compared to unaided visual examination [32-34]. Dermoscopy (also called epiluminescence microscopy) improves biopsy ratios by enhancing the diagnostic confidence of providers, and has been extensively reviewed in the literature [35,36]. Melanoma diagnosis with dermoscopy is subjective and varies with provider experience [30,37,38]. Consequently, Automated Dermoscopic Diagnostic (ADD) programs have been applied to dermoscopy images in an attempt to reduce subjective analysis. In general, ADD programs analyze an imaged lesion for malignancy-associated features that are weighted, summed and then compared to a predetermined (usually experimentally-obtained) cut-off score to differentiate between benign and malignant lesions. Two meta-analyses comparing the accuracy of 'expert-implemented' dermoscopy to ADD found no significant difference between the two [39,40]. While sensitivity for melanoma between expert dermoscopists and ADD was equivalent, dermoscopy specificity was significantly better than ADD (86% compared to 78% P < 0.001) [40]. In-clinic comparison of three different ADD devices revealed an inability of all devices to reliably discriminate dysplastic nevi from early melanoma, resulting in a greater number of unnecessary biopsies.

MelaFind

MelaFind (Electro-Optical Sciences Inc., Irvington, NY) is an FDA-approved device (limited to use by dermatologists only) that analyzes ten images from different spectra and then provides a recommendation to biopsy or monitor the lesion. The use of multispectral digital dermoscopy by Melafind enables the characterization of certain morphologies otherwise imperceptible on dermoscopic exam. In addition to melanoma, MelaFind also recommends severely atypical nevi for biopsy. MelaFind's reported sensitivity and specificity for melanoma are 92-100% and 9.9-85%, respectively (Table 2) [41-43]. Comparison of MelaFind to experienced dermoscopists yielded a biopsy sensitivity and specificity for melanoma of 98% and 44% for MelaFind compared to 71% and 49% for dermoscopy [43]. The accuracy for dermoscopy in this study was notably lower than in prior meta-analyses, and the authors postulated that the lower specificities might be due to the inclusion of a greater proportion of smaller melanomas (<6mm). Another multi-center, prospective RCT found a biopsy sensitivity of 98.4% and specificity of 9.9% for MelaFind [42]. Study authors explained the low rates of specificity as a product of utilizing lesions pre-selected by clinical exam for biopsy. By comparison, trial data generated estimates of 98% sensitivity and 7% specificity for melanoma diagnosis by participating dermatologists. In another study where dermatologists blinded to the results of MelaFind scans were asked to evaluate PSLs, sensitivities for melanoma were 96% for MelaFind and 80% for dermatologists, while specificities were 8% and 43%, respectively [44]. MelaFind was found to increase biopsy sensitivity for melanoma from 69% to 94% if providers integrated the results of their clinical exam with a MelaFind scan, while biopsy specificity for melanoma decreased from 54% to 40% [45]. Unfortunately, the generalizability of findings from the studies on MelaFind remains limited, as all participating clinicians were asked to make a diagnosis based on images of lesions previously biopsied. Consequently real-life sensitivities and specificities for use in the

Technology	Number of lesions (melanomas)	Sensitivity in percent		Specificity in percent		Positive LR*		Negative LR	
		Device	Dermoscopy	Device	Dermoscopy	Device	Dermoscopy	Device	Dermoscopy
Naked eye									
Vestergaard [33]	8,487	69	87	88	91	5.8	9.7	0.35	0.14
CAD									
Rajpara [40]	9,784	91	88	79	86	4.3	6.3	0.11	0.14
MelaFind									
Elbaum [41]	246(63)	95		68		3.2		0.07	
Friedman [43]	99(49)	98	71	44	49	1.8	1.4	0.05	0.59
Wells [44]	47(23)	96	80	8	43	1.0	1.4	0.5	0.47
Monheit [42]	1612(114)	98	98	0	7	1.1	1.1	0.2	0.29
Geometric Mean		97	82	29	25	1.59	1.29	0.14	0.43
SIAscopy									
Haniffa [46]	881(31)	87		91		9.7		0.14	
Moncrieff [47]	348(52)	83	94	80	91	4.1	10.4	0.21	0.07
Glud [48]	83(12)	1		59		2.4		0	
Tomatis [49]	347(41)	81	92	77	81	3.5	4.8	0.25	0.1
Carrera [50]	1198(72)	88		80		4.4		0.15	
Geometric Mean		90		77		4.3	7.06	0.26	0.08
Raman Spectroscopy									
Lui [51]	518(44)	90,95,99		68,44,15		2.8,1.7,1.2		0.15,0.11,0.07	
Gniadecka [52]	223(22)	85		99		85		0.15	
Geometric Mean		90		66		12		1.28	
CSLM									
Gerger [53]	117(27)	88		98		44		0.12	
Pellacani [54]	102(37)	97		72		3.5		0.04	
Pallacani [55]	351(136)	92		69		3.0		0.12	
Langley [56]	125(37)	97	89	84	86	6.1	6.4	0.04	0.13
Geometric Mean		93		80		7.29		0.07	
Tape stripping									
Wachsman [57]	128(39)	100		88		8.3			0

Table 2: Sensitivity and Specificity for evaluative devices.

*LR: Likelihood Ratio

clinic are difficult to extrapolate from existing studies. More trials with in-clinic use comparing the diagnostic accuracy of MelaFind with existing techniques are necessary before a full recommendation can be made for its regular use.

SIAscopy and MoleMate/SIMSYS

SIAscopy (Astron Clinica, Lake Success, NY) is another FDA-approved device that uses spectral data to gather information regarding collagen, hemoglobin content, melanin, and melanin distribution in the dermis and epidermis. While MelaFind provides recommendations to biopsy or monitor, SIAscopic data is presented in graphs that the provider interprets and incorporates in his/her decision to biopsy or monitor. Software (MoleMate or SIMSYS, MedX corp.) can be added to SIAscopic information to assist the provider with interpretation of images by providing an interactive decision tree to guide lesion management. The SIMSYS system also provides the capability of scoring lesions according to a 7-point dermoscopy checklist and saving the data for later comparison. Sensitivity and specificity for melanoma with SIAscopy ranges from 81-100% and 59-91% respectively [46-50,58]. A prospective study comparing SIAscopy to dermoscopy found no significant difference between sensitivity of the two methods for melanoma diagnosis, although calculated positive likelihood ratios were higher for dermoscopy (5 compared to 2.45 with SIAscopy) suggesting it is overall a more accurate diagnostic test than SIAscopy [48]. In light of two other studies that also found no significant difference in melanoma diagnosis between an experienced dermoscopist and SIAscopy [46,58], the utility of SIAscopy in dermatologic practice appears to be limited given its subjectivity and the absence of significant improvements in diagnostic accuracy. Another potential limitation of SIAscopy is that hyperkeratosis has been interpreted as dermal melanin, yielding false positive results [59].

Raman Spectroscopy and the Verisante Aura

Raman spectroscopy is a rapid, non-invasive, non-destructive technique that uses laser light to characterize tissue composition based on changes in molecular bonds. This technology is based on the theory that melanoma can be differentiated from other types of tissue based on its molecular signature. A study on the *in vivo* use of a handheld Raman spectrographic device (Verisante Aura) for melanoma detection reported specificities ranging from 15-54% depending on selected sensitivities which ranged from 90-99% [51]. No studies directly comparing the accuracy of trained dermatologists to this technique have been published, and consequently it is unclear if spectroscopic diagnosis is any better than dermoscopy. Other limitations that will need to be factored into device utility in the future include a clinician's ability to become facile with interpreting the graphic representation of this type of data. The device has already

been approved for sale in Canada, Europe and Australia with estimated commercial availability in late 2012, and could eventually make its way to the US marketplace.

Reflectance Confocal Microscopy and the Vivascope

Confocal Scanning Laser Microscopy (CSLM) uses lasers and high-resolution optics to visualize tissue morphology on a cellular level *in vivo*, non-invasively, and in real time. The best-known device in this class is the FDA-approved Vivascope (Lucid, Inc, Rochester, NY). CSLM penetrates deep enough to visualize the stratum corneum to the upper papillary dermis with resolution slightly inferior to conventional light microscopy [60-63]. CSLM can be used in two modes, Reflectance (RCM) and fluorescence, with reflectance mode more suitable for clinical use as it visualizes melanin well and fluorescence requires the use of markers [64]. Like other evaluative devices, RCM requires lesion selection and scanning by the clinician. Images can either be interpreted in real-time by a clinician who has undergone training in interpreting images, or can transmitted to specialized dermatopathologist trained to read RCM images with interpretation of images within 24 hours [65]. The reported sensitivity and specificity of RCM for melanoma ranges from 88%-92% and 69%-98%, respectively [53-55]. A direct comparison of dermoscopy to RCM found no significant difference between the sensitivity and specificity for melanoma between these two methods [56]. Attempts have also been made to integrate automated computer analysis with RCM images and have resulted in 93.6% sensitivity and 90.4% specificity for melanoma detection in learning sets [66]. An additional strength of RCM is the ability to identify amelanotic lesions [67] and early melanoma *in situ* with a sensitivity of 85% and specificity of 76% for these tumors [68,69]. Limitations to the clinical use of RCM include a lack of prospective in-clinic assessment as all studies have been retrospective and used pre-selected images (which may have been selected based on ease of identifying morphology). The lowest priced Vivascope costs $70,000, so RCM may be a financially limiting for many clinicians in standard practice (Table 3). Despite these limitations, RCM remains promising, as it could also be useful for delineating tumor borders *in vivo* for excisions, and offers the chance for real-time histologic diagnosis.

Modality	Device	Manufacturer	Purchase price (US dollars)	Caveats
TBP	Mirror TBP MoleMapCD MoleMax 1,2,3, HD, pro	Canfield scientific DigitalDerm Derma Med.	4,500 349-395 per CD 12,700-45,750	Patients must physically go to photo centers which are primarily located in South East USA Capable of SDDI and ADD depending on model and software package
SDDI	DermScope Handyscope PhotoMax	Canfield Fotofinder Derma Med.	895 630 830	iphone attachment iphone attachement Software for macro and micro images
Dermatoscope	Numerous devices DB Dermo-mips/ DDAX3	Numerous Manufacturers biomips	250-1200	Price varies according to optics, polarized light or contact scopes
ADD	MoleExpert MoleScore MoleCount	Datinf Derma Med. Derma Med.	1,670 1,650 1,150	Maps and recognizes new moles
Multi-spectral imaging	Melafind Spectro-Shade	Melasciences MHT	10,000 (2yr rental) 19,000	$50 per Melarecord storage card
			4,999-7,999	
Raman Spectroscopy	Aura	Verisante	60,000	
CSLM	Vivascope 1500 & 3000		69,900-98,500	
EGIR	MelDTect		Not set	

Table 3: Cost comparison of different melanoma detection devices.

Costs via website and direct contact with manufactures. Ranges are given as cost and capabilities of devices vary depending on hardware selected and the integration of different software packages.

Tape Stripping mRNA and DermTech

Tape stripping is a non-invasive, relatively painless method for recovering cells that can be examined for gene expression profiles indicative of melanoma. In this method tape is applied to the pigmented lesion and the borders are outlined. Removal of the tape strips a layer of cells from the stratum corneum, providing RNA for genetic analysis. The commercialized version of this technique has been developed by DermTech (LaJolla, CA) and is called the Epidermal Genetic Information Retrieval (EGIR) system. Using EGIR and a 17-gene classification signature, researchers were able to identify melanomas in a 128 lesion test set with 100% sensitivity and 88% specificity [57]. EGIR analysis of control samples taken from normal skin (n=79), solar lentigenies (n=22) and basal cell carcinoma (n=18) was able to identify all but one BCC lesion as non-melanoma. Interestingly, additional review of the 13 false positives by two separate dermatopathologist also identified a superficial spreading melanoma missed on initial reads. The combination of a sensitivity superior to any other examination technique with a specificity equivalent to a skilled dermatopathologist in early trials of EGIR make it a promising modality for evaluating pigmented lesions. Larger clinical trials on diagnostically challenging lesions are necessary to verify its efficacy. Limitations of the technique include a potential inability to accurately test patients who have eczema, photosensitivity, psoriasis, allergies to tape or latex, or used topical steroids on the lesion within the last 30 days as well as the use of lotion or sunscreen in the previous 24 hours. EGIR is not yet on the market but is projected to be available soon. Sample results are expected to be available in 5-7 days, with no cost yet reported.

Summary of The Clinical Utility of Evaluative Devices

Evaluative devices are able to provide additional information about atypical pigmented lesions which can enhance the diagnostic accuracy of the user. The degree of utility however, is highly dependent on the skill of the provider in diagnosing PSL and their proficiency with a dermatoscope. Providers with minimal experience diagnosing PSL stand to benefit the most by using devices to enhance diagnostic accuracy. By contrast, a dermatologist facile with a dermatoscope would receive little enhancement in diagnostic accuracy with their use. Given the relatively low cost, portability of a dermatoscope and equivalent diagnostic accuracy in trained users, such individuals may have less of a need for other evaluative devices.

It should be noted that the lack of a standardized lesion set to compare evaluative devices limits the scope of comparison; however general conclusions can still be made. For instance, it is clear that the majority of evaluative devices sacrifice specificity to enhance overall sensitivity. While the thresholds of sensitivity and specificity in the decision to biopsy an atypical lesion will remain an ongoing debate, providers should be cognizant of this trade-off when employing these devices. Lastly, it will be important to continue to re-examine the utility and cost effectiveness of devices as new technology and algorithms become available.

Conclusion

The use of screening devices enhances the sensitivity of the clinician to detect new and changing lesions, however these devices are most limited by cost and the time constraints required to take images and review them. Selecting patients at highest risk for melanoma will be essential to maximize the utility of screening devices. Similarly, despite recent technical advances and innovations in evaluative devices, these methods have not established significantly improved accuracy compared to a dermatologist experienced with the dermatoscope. In their current state, non-dermoscopic devices perpetuate the existing problem in diagnosing melanoma, and may not warrant the additional costs of implementation. Consequently, greater efforts should be taken to integrate dermoscopy into dermatologic practice.

Alternatively, the high sensitivity of evaluative devices could be useful to the primary care provider trying to screen lesions for referrals. Use of these devices in primary care are already a subject of debate and raise questions regarding the role of the provider in triaging, diagnosing and managing skin lesions. Further investigation of the use of these devices in primary care remains warranted, and energy should be devoted to whether their employment improves dermatologic access to the general population without compromising the quality of care otherwise received from the dermatologist.

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