Skin Cancer in the Medicare Population: Can an Elastic Scattering Spectroscopy device help improve PCPs' detection?

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Background and Objective

Skin cancer is by far the most common type of cancer in the United States [1]. The most common types of skin cancer are basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) followed by melanoma [1,2]. In the United States, it is estimated that there will be 5.4 million new cases of nonmelanoma skin cancer (NMSC), 97,610 new cases of invasive melanoma and another 89,070 cases of melanoma in situ diagnosed annually [1,2].

The risk for developing skin cancer increases with age, with most cases found in people 65 years of age and older [3]. As older adults are living longer, the need for public health efforts to promote life-long skin health is more critical than ever. Primary care providers (PCPs) have demonstrable difficulty in identifying skin lesions in need of further evaluation [4] Leveraging technology may aid physicians in improving early detection, potentially reducing associated mortality and morbidity. Elastic scattering spectroscopy (ESS) technology utilizes visual light and detects the backscatter of the light by subcellular structures to differentiate between benign and malignant cells [5]. A handheld ESS device has been developed to aid primary care physicians (PCP) in their clinical assessment of concerning skin lesions. Measuring the ESS spectra of skin lesions, a novel handheld device classifies lesions as either high risk or low risk for malignancy with an output of "Investigate Further" or "Monitor".

This study aimed to assess the sensitivity and specificity of a handheld ESS device in evaluating skin lesions suspicious for skin cancer while controlling for the confounder of age. To address age, we compared patients eligible for Medicare (Medicare Group) to those patients in the younger population (Non-Medicare Group).

Materials

The handheld ESS device (Figure 1) measures spectra of skin lesions and uses an algorithm to classify the lesion's scanned properties against those of known malignant and benign lesions, providing an output of "Investigate Further" or "Monitor", respectively. Additionally, for "Investigate Further" classified lesions, a score from 1 to 10 is provided which corresponds to the amount of spectral similarity a lesion has to malignant lesions in studies, with 10 representing the highest amount. The algorithm has been trained and validated with over 20,000 spectral scans from over 4,500 skin lesions, including histologically confirmed melanoma, BCC, SCC and benign lesions as well as unbiopsied benign lesions diagnosed by board-certified dermatologists.

Figure 1. Handheld ESS device

Methods

DERM-SUCCESS was a blinded, prospective, multi-center study was conducted at 22 primary care study sites across the United States (18 sites) and Australia (4 sites) [6]. In this sub-analysis, patients were stratified and compared by age groups for those eligible for Medicare and those not yet eligible. Patients with lesions suggestive of skin cancer were clinically assessed by PCPs and then evaluated by the ESS device. Patients and PCPs were blinded to device output. All lesions enrolled were biopsied per physician assessments and standard of care. Each lesion's diagnosis involved 2-5 dermatopathologists, dependent on pathology and discordance. Statistical analyses after study unblinding included standard diagnostic test parameters of the device for detecting skin cancer as well as the influence of lesion and patient factors on device performance.

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Patient Enrollment

During study enrollment, five lesions (0.3%) were excluded due to device data capture issues and five lesions (0.3%) due to lack of dermatopathology consensus (Figure 2).

There were no adverse events related to device use.

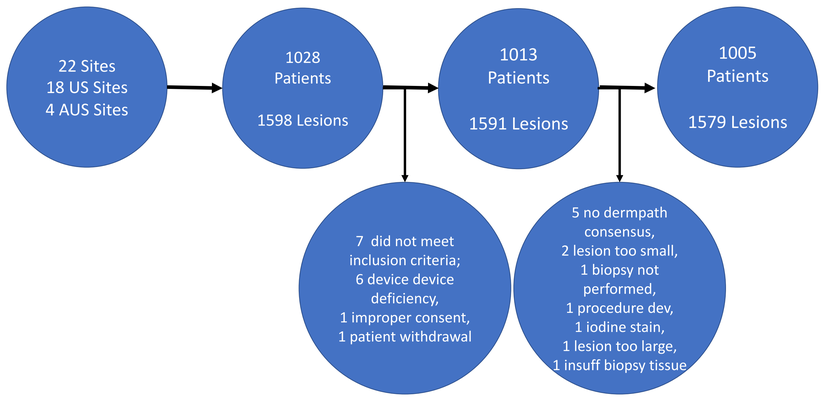

Figure 2. Consort diagram of the study participant flow

Table 1: Description of patient characteristics (N=1005)

Characteristics	Non-Medicare N (%)	Medicare-Eligible N(%)
Gender		
Male	277 (44.2%)	210 (55.5%)
Female	350 (55.8%)	168 (44.4%)
Age (years)		
Mean (SD)	49.6 (11.5)	73.3 (6.2)
Ethnicity		
Hispanic or Latino	66 (10.5%)	13 (3.4%)
Not Hispanic or Latino	555 (88.5%)	358 (94.7%)
Unknown	6 (1.0%)	7 (1.9%)
Race		
White	603 (96.2%%)	373 (98.6%)
Other/Multiracial	24 (3.8%)	5 (1.3%)
Fitzpatrick skin type		
I-III	466(74.3%)	263 (69.6%)
IV-VI	161(25.7%)	115 (30.4%)
Common Risk Factors		
UV Exposure	276 (44.0%)	179 (47.4%)
History of Skin Cancer	107 (17.1%)	126 (33.3%)
New or Changing Lesion	449 (71.6%)	276 (73.0%)
Fair skin, freckling, light hair	221 (35.2%)	141 (37.3%)
Other risk factors (e.g. Xeroderma pigmentosa)	22 (3.5%)	11 (2.9%)

Results

Dermatopathology evaluation confirmed 224 high risk lesions: 48 melanomas (including highly atypical nevi), 90 BCCs and 86 SCCs. The prevalence of high-risk lesions was higher in the Medicare group (21.6%) compared to the younger group (9.5%). The Non-Medicare and Medicare groups had similar distributions of BCC and melanoma, but the Medicare group had more SCCs, as expected clinically

Table 2: Dermatopathology Diagnosis (n=1579)

Risk Classification and Diagnosis	Non Medicare n (% prevalence)	Medicare n (% prevalence)
Malignant lesions	93 (9.5%)	131 (21.7%)
Basal cell carcinoma	48 (4.9%)	42 (7.0%)
Squamous cell carcinoma	18 (1.8%)	68 (11.2%)
Melanoma	27 (2.7%)	21 (3.5%)
Benign lesions	882 (90.5%)	473 (78.3%)

Results Continued

The ESS device had an overall sensitivity of 95.5% (95% CI: 91.9-97.8%). Device sensitivity was similar in both groups, at 96.9% (95% CI:92.4-99.2%) in the Medicare group and 93.5% (95% CI: 86.5-97.6%) in the Non-Medicare group. Specificity of the device was 20.7% for ruling out benign biopsied lesions. Device specificity was lower in the Medicare group at 15.2% compared to 23.7% in the Non-Medicare group for PCP-biopsied lesions (Table 3 and 4).

Table 3: Concordance between device assessment and biopsy, Non-Medicare Population (n=975)

Device Reading	Biopsy diagnosis	
	Benign	Malignant
Monitor	209 (23.7%)	6 (6.5%)
Investigate Further	673 (76.3%)	87 (93.5%)
Total	882	93

Table 4: Concordance between device assessment and biopsy, Medicare Population (n=604)

Device Reading	Biopsy diagnosis	
	Benign	Malignant
Monitor	72 (15.2%)	4 (3.1%)
Investigate Further	401 (84.8%)	127 (96.9%)
Total	473	131

The overall negative predictive value (NPV) of the device was 96.6%, meaning a for a "Monitor" result has a 3.4% likelihood of being malignant. The device overall positive predictive value (PPV) for an "Investigate Further" result was 16.6%, which correlates to a number needed to biopsy (NNB) of of 6:1. The PPV of the device was higher for the Medicare group at 24.1% (NNB = 4:1) compared to 11.4% (NNB = 9:1) for the Non-Medicare group. Device NPV was similar in the two groups (94.7% for Medicare and 97.2% for Non-Medicare-eligible patients, respectively). Overall device diagnostic performance, as measured by Area Under the Receiver Operating Characteristic Curve (AUROC) was 0.7796. Similarly, device AUROC was 0.7743 for the Medicare group and 0.7548 in the Non-Medicare group.

Conclusion

The novel hand-held ESS device demonstrated high sensitivity in detecting skin cancer when compared to the gold standard of histopathologic examination. Coupled with clinical exam findings, this device may aid PCPs to improve clinical decisions about suspicious skin lesions (i.e., to refer or monitor). These findings suggest use of the ESS device has the potential to improve PCP skin cancer detection in both the Medicare-eligible and younger population with minimal differences in device effectiveness. The lower specificity in the Medicare group may be due to increased underlying damage associated with age-related cutaneous changes.

This highly sensitive, non-invasive, hand-held ESS device may fill a well-recognized void in PCP dermatologic care by providing an objective, point-of-care test for clinical assessment. This device may help increase quality of referrals to dermatology by providing PCPs with an additional instrument to assess lesions for skin cancer risk.

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