

Clinical Utility of an Elastic Scattering Spectroscopy Device in Assisting Primary Care Physicians' Detection of Skin Cancers

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Background and Objective

Access to a dermatologist for diagnosis and management of skin cancer is challenging, as around 40% of the United States population live in areas that have limited access to a dermatologist [1]. This puts primary care physicians (PCPs) in an integral role for early detection of skin cancers, as early detection of these malignancies is imperative to decreasing morbidity, mortality, and cost to the patient [2].

Elastic Scattering Spectroscopy (ESS), an optical tissue sampling technique, distinguishes between normal and abnormal tissue in vivo without the need to remove tissue.

A handheld device that employs ESS and artificial intelligence was developed as an adjunctive tool for PCPs, to aid in their management of lesions suspicious for skin cancer. The technology has been shown to have skin cancer sensitivity over 90% in various prospective, multi-center studies when compared to gold-standard dermatopathology results [3-5].

The aim of this study was to assess and compare the diagnosis and management performance of PCPs with and without the use of the handheld ESS device in detecting skin cancer.

Materials & Methods

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 degree of spectral similarity a lesion has to malignant lesions in studies, with 10 representing the highest degree.

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 derma ologists.

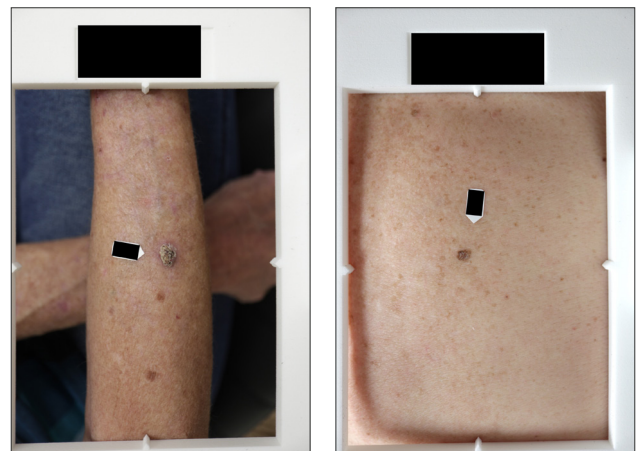
An accompanying clinical validation study was performed in which 1579 lesions from 1005 patients were assessed with the ESS device [6].

In this clinical utility study, 108 PCPs evaluated 50 skin lesions (25 malignant, 25 benign), with and without ESS device output. For each case, high resolution digital clinical images (Figure 2A and 2B), the patient's clinical information, including prior skin cancer history, risk factors, and physical examination results were provided. The PCPs completed a questionnaire about their diagnosis of the lesion, their recommended management decision and their confidence level on their management decision for each case.

Sensitivity and specificity of PCP diagnostic and management with and without the device output were calculated.



Fig 1. Handheld ESS Device



Figures 2A and 2B. Two example clinical photographs provided to PCP evaluators



PCP Participants

PCP participants (Table 1) included U.S. board-certified internal and family medicine physicians with an even distribution of years in practice (range: 1-21+ years). PCPs were recruited from across the U.S., including urban and rural areas.

Table 1: Description of PCP Participants (N=108)

Characteristics	N (%)
Gender	
Male	71 (65.7%)
Female	37 (34.3%)
Area of Board Certification and Active Practice	
Internal Medicine	52 (48.1%)
Family Medicine	56 (51.9%)
Years Practicing Medicine	
1-5	21 (19.4%)
6-10	19 (17.6%)
11-15	19 (17.6%)
16-20	15 (13.9%)
21+	34 (31.5%)
Type of Area of Practice Location	
Urban area (population > 50,000)	67 (62.0%)
Urban cluster (population > 2,500 and < 50,000)	36 (33.3%)
Rural (population 2,500)	5 (4.6%)

Lesion Characteristics

The 50 lesions (Table 2) evaluated by PCPs were dispersed across the body (22.0% head, 26.0% upper and 10.0% lower extremities, 32.0% trunk) had a mixture of surfaces (66.0% elevated vs. 34.0% flat), textures (46.0% smooth vs. 54.0% rough), and pigmentation (48.0% light vs. 52.0% dark). Pathology of lesions were matched to the clinical study prevalence.

Table 2: Characteristics of Evaluated Lesions (N=50)

Characteristics	N (%)
Anatomic Location	
Head	11 (22.0%)
Arm	13 (26.0%)
Leg	10 (20.0%)
Trunk	16 (32.0%)
Length (mm) Mean (min, max)	8.7 (2.5, 15.0)
Width (mm) Mean (min, max)	6.6 (2.5, 15.0)
Flat or Elevated	
Flat	17 (34.0%)
Elevated	33 (66.0%)
Smooth or Rough	
Smooth	23 (46.0%)
Rough	27 (54.0%)
Light or Dark	
Light	24 (48.0%)
Dark	26 (52.0%)
Characteristics	N (%)
Pathology	
High Risk	
Basal Cell Carcinoma (BCC)	10 (20.0%)
Melanoma ¹	6 (12.0%)
Squamous Cell Carcinoma (SCC)	9 (18.0%)
Low Risk	
Benign melanocytic nevi (BMN)	9 (18.0%)
Seborrheic Keratosis (SK)	9 (18.0%)
Benign other ²	7 (14.0%)

¹Includes all high risk melanocytic lesions that require re-excision, i.e. invasive and in situ melanoma, atypical junctional melanocytic proliferations, highly atypical nevi

²Benign other category includes all benign lesions that are not benign melanocytic nevi or seborrheic keratosis

Results

Management sensitivity increased significantly from 82.0% to 91.4% (p=0.003) with device output (Table 3). Diagnostic sensitivity increased significantly from 71.1% to 81.7% with device output (p=0.008) (Table 4).

Table 3: Management Sensitivity and Specificity With and Without the Device

Management	Estimate (%) and 95% Confidence Interval ²		
	Without Device	With Device	p-value ²
Sensitivity¹	82.0% (76.4%-87.6%)	91.4% (85.7%-97.1%)	0.003
Specificity¹	44.2% (36.0%-52.4%)	32.4% (20.7%-44.1%)	0.026

¹For sensitivity analyses, only true positive (malignant lesion cases) are included; for specificity analyses, only true negative (benign lesion cases) are included

²MRMC analysis of variance (ANOVA) method of Obuchowski and Rockette (1995)

Table 4: Diagnostic Sensitivity and Specificity With and Without the Device

Diagnosis	Estimate (%) and 95% Confidence Interval ²		
	Without Device	With Device	p-value ²
Sensitivity¹	71.1% (63.4%-78.8%)	81.7% (72.4%-90.9%)	0.008
Specificity¹	60.9% (52.5%-69.3%)	54.7% (42.3%-67.1%)	0.190

¹For sensitivity analyses, only true positive (malignant lesion cases) are included; for specificity analyses, only true negative (benign lesion cases) are included

²MRMC analysis of variance (ANOVA) method of Obuchowski and Rockette (1995)

Specificities decreased from 60.9% to 54.7% (p=0.190) for diagnosis and 44.2% to 32.4% (p=0.026) for referrals. Overall diagnostic performance (i.e. AUC) increased from 0.685 to 0.727. Physicians reporting high confidence in their assessments increased from 73.0% to 81.6% (<0.0001) with device output (Table 5).



Table 5: Shifts in Level of Confidence of PCPs in Their Management Decision

Level of Confidence			
Without the Device	With the Device		
	Low	High	Total
Low	476 (8.8%)	983 (18.2%)	1459 (27.0%)
High	515 (9.5%)	3426 (63.4%)	3941 (73.0%)
Total	991 (18.4%)	4409 (81.6%)	5400 (100.0%)

Kappa statistic 0.314; OR (95% CI) 1.99 (1.55-2.54); p<0.0001

Conclusion

Use of the ESS device by PCPs significantly improved both diagnostic sensitivity (from 71% to 82%) and management sensitivity (from 82% to 91%). There were clinically acceptable decreases in associated specificities. Additionally, the effectiveness analyses observed an increase in PCPs' overall diagnostic performance (i.e. AUC) and confidence level in their management decisions with the use of the handheld ESS device. The findings suggest the use of the ESS device output improves PCP skin cancer detection and confidence in skin lesion evaluation and management.

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Disclosures

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