Abstract

The Safety and Effectiveness of Elastic Scattering Spectroscopy and Machine Learning in the Evaluation of Skin Lesions for Cancer

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Abstract

Background: Elastic scattering spectroscopy (ESS) is an optical biopsy technique that can distinguish between a normal and abnormal tissue in vivo without the need to remove it. The handheld device measures ESS spectra of skin lesions and classifies lesions as either malignant or benign with an output of “Investigate Further” or “Monitor,” respectively, with positive results accompanied by a spectral score output from 1 to 10, indicating how similar the lesion is to the malignant lesions the device was trained on. The algorithm was trained and validated with over 11,000 spectral scans from over 3500 skin lesions.

Objective: The purpose of this study was to evaluate the safety and effectiveness of the handheld ESS device in detecting the most common types of skin cancer.

Methods: A prospective, single-arm, investigator-blinded, multicenter study conducted at 4 investigational sites in the United States was performed. Patients who presented with skin lesions suggestive of melanoma, basal cell carcinoma, squamous cell carcinoma, and other highly atypical lesions were evaluated with the handheld ESS device. A validation performance analysis was performed with 553 lesions from 350 subjects with algorithm version 2.0. An independent test set of 281 lesions was selected and used to evaluate device performance in the detection of melanoma, basal cell carcinoma (BCC), and squamous cell carcinoma (SCC). Statistical analyses included overall effectiveness analyses for sensitivity and specificity as well as subgroup analyses for lesion diagnoses.

Results: The overall sensitivity of the device was 92.3% (95% CI: 87.1 to 95.5%). The sensitivity for subgroups of lesions was 95% (95% CI 75.1% to 99.9%) for melanomas, 94.4% (95% CI 86.3% to 98.4%) for BCCs, and 92.5% (95% CI 83.4% to 97.5%) for SCCs. The overall device specificity was 36.6% (95% CI 29.3% to 44.6%). There was no statistically significant difference between the dermatologist performance and the ESS device (P=.2520). The specificity of the device was highest for benign melanocytic nevi (62.5%) and seborrheic keratoses (78.2%). The overall positive predictive value (PPV) was 59.8%, and the negative predictive value (NPV) was 81.9% with the study’s malignancy prevalence rate of 51%. For a prevalence rate of 5%, the PPV was estimated to be 7.1%, and the NPV was estimated to be 98.9%. For a prevalence rate of 7%, the PPV was estimated to be 9.8%, and the NPV was estimated to be 98.4%. For a prevalence rate of 15%, the PPV was estimated to be 20.3%, and the NPV was 96.4%.

Conclusions: The handheld ESS device has a high sensitivity for the detection of melanoma, BCC, and SCC. Coupled with clinical exam findings, this device can aid physicians in detecting a variety of skin malignancies. The device output can aid teledermatology evaluations by helping frontline providers determine which lesions to share for teledermatologist evaluation as well as potentially benefitting teledermatologists’ virtual evaluation, especially in instances of suboptimal photo quality.

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Conflicts of Interest: None declared.

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KEYWORDS

melanoma sensitivity; elastic scattering spectroscopy (ESS) device; malignancy detection; machine learning; skin lesions; cancer

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