
Abstract

The Clinical Utility of a Handheld Elastic Scattering Spectroscopy Tool and Machine Learning in the Diagnosis and Referral Management of Skin Cancer by Primary Care Physicians

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Abstract

Background: Elastic scattering spectroscopy (ESS) is a noninvasive optical biopsy technique that can distinguish between normal and abnormal tissue in vivo. The handheld device measures ESS spectra of skin lesions and classifies lesions with an output of “Investigate Further” or “Monitor.” The algorithm was trained and validated with over 11,000 spectral scans from over 3500 skin lesions. The device performance was also evaluated in an associated clinical study.

Objective: The aim of this paper was to establish whether the use of a handheld ESS tool can improve the detection of skin malignancies by evaluating clinical performance while emulating a real-world telemedicine clinical care setting.

Methods: The associated clinical study examined an independent test set of 332 lesions in a prospective multicenter study that compared algorithm performance to biopsy results for diagnosing malignant lesions. A total of 50 cases were randomly selected from the study data base (25 malignant and 25 benign lesions). Device performance on these lesions had a 96% sensitivity. High-resolution digital images and the patient’s clinical information including prior skin cancer history, risk factors, and physical examination results were available for evaluation. A total of 57 primary care physicians participated in this study in 2 phases, the first phase with their standard-of-care diagnostic and the second phase regarding their evaluation with the device output. The physicians were educated on the ESS device before evaluating the cases in a random order. Case evaluation included the physician reporting their diagnosis, management decision, and confidence level without the device output in the first phase and with the device output in the second phase. The results were evaluated for sensitivity and specificity with confidence intervals.

Results: The diagnostic sensitivity of the readers without and with the use of the handheld ESS device increased significantly from 67% to 88% ($P<.001$). There was no significant difference in specificity at 40% and 53% ($P=.05$). The management sensitivity of the readers increased significantly with and without the use of the device, which, respectively, was 94% (91%-96%) and 81% (77%-85%) ($P<.001$), suggesting that the use of the device may reduce false negatives by 68%. Specificity was comparable for management decisions ($P=.36$) at 31% compared to 36% without the device.

Conclusions: The use of the handheld ESS device significantly improved diagnostic and management sensitivity over standard-of-care, with comparable specificity. While telemedicine has shown promise in many fields, studies have shown that in-person skin evaluation is superior to telemedicine evaluations; however, integration with this type of tool has the potential to improve early detection.

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KEYWORDS

artificial intelligence; melanoma detection; skin cancer; spectroscopy

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