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How AI-powered handheld devices are boosting disease diagnostics - from cancer to dermatology

Nature Medicine explores the latest translational and clinical research news, with FDA approval of an AI-assisted optical reader to help in the diagnosis of skin cancer.

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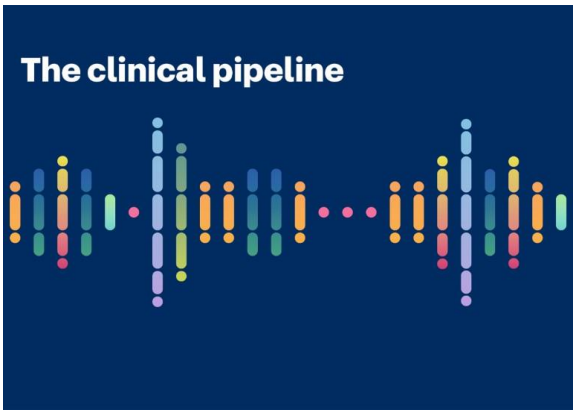

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In the past, artificial intelligence (AI) in healthcare was mostly in the hands of specialists — experts in marrying supercomputers to hefty hospital devices. Now, thanks to a new breed of compact, handheld AI-assisted disease-detection devices, that is changing. Healthcare AI is increasingly in the hands (and the pockets) of non-specialists.

Lightweight, battery-powered handheld healthcare AI devices made a splash in January 2024 with the arrival of a portable device for detecting skin cancer. Approved for marketing by the US Food and Drug Administration (FDA) under the brand name

DermaSensor, the device looks like an oversized cellphone. It is approved for use solely by physicians, and only in patients over 40 years of age, to help in the evaluation of skin lesions suggestive of three types of skin cancer: melanoma, basal cell carcinoma and squamous cell carcinoma.

DermaSensor uses elastic scattering spectroscopy (ESS), an optical tissue-sampling technique that distinguishes between normal tissue and abnormal tissue without requiring any tissue removal. The ESS ability operates through the emission of pulses of light at various wavelengths, ranging from 360 nm to 810 nm, via a compact integrated system that illuminates tissue while the backscattered optical reflectance of the tissue is recorded. The probability of pathology (in this case, skin cancer) correlates with scattered intensity at different wavelengths. To analyze the complex ESS signals, the device has a built in AI-powered analytical ability to evaluate the data from its optical lesion readings. The AI algorithm was developed using a training dataset of more than 10,000 readings from over 2,000 lesions.

Cody Simmons, chief executive officer of DermaSensor, the Miami-based company that developed the device in collaboration with researchers at Boston University, says it promises to "democratize" dermatology. Using the device allows primary care physicians to detect skin cancer without recourse to referrals to dermatologists. Importantly, says Simmons, because background melanin content has minimal effect on ESS efficacy, the device is not affected by skin color.

The interface is user friendly, with a positive result of 'investigate further' accompanied by a spectral score of 1–10 indicating the degree of similarity to malignant lesions. In unpublished clinical trial testing (presented at Maui Derm Hawaii in 2023), the device had an overall sensitivity of 95.5% for high-risk lesions, which was significantly higher than that of primary care physicians. The device sensitivity was 87.5% for melanoma and 97.7% for non-malignant skin cancer. Because the device matched dermatologists' performance in detecting high-risk lesions, Simmons adds, it could help avert large numbers of unnecessary follow-up tests and referrals, bringing down testing costs for organizations that use it, he predicts.

In a statement accompanying DermaSensor's marketing approval on 16 January 2024, the FDA cautioned that it should be used only in conjunction with a clinical assessment, including "visual analysis of the lesion, by physicians who are not dermatologists." The FDA also warned that the device is for use only "on lesions already assessed as suspicious for skin cancer and not as a screening tool." Now that the device is on the market, the FDA wants additional post-market clinical validation performance testing of the device in diverse patient populations, including those with

limited representation of melanomas in the premarket studies, such as people with brown and black skin.

Irving Bigio, a Boston University spectroscopic researcher who helped develop the device, has been probing the potential for medical uses of ESS for decades. He hopes that DermaSensor will help pave the way for other breakthroughs using ESS coupled with AI for other cancer types, including oral, lung and colorectal cancers. Among his current projects is one probing the use of ESS coupled with AI for real-time optical characterization and identification of lung tissue during percutaneous transthoracic needle biopsy. For this research, an ESS-integrated tissue-sampling tool was developed to help lung-cancer investigators determine whether their probe tip location is in a patient's lung tissue or in a lesion. The device software includes an AI algorithm based on training data from more than 1,300 recorded ESS spectra from 83 lung locations in a training set of 50 patients. Early results, which Bigio will present at the Society of Interventional Radiology in March, suggest that ESS-integrated tissue-sampling tools can accurately identify in real time whether the tool is in a lung lesion or not. "Given that location feedback is provided in a fraction of a second," says Bigio, "ESS has the potential to increase tool-in-lesion sensitivity and accuracy."

Carolina Guzman, a kidney specialist who leads an interdisciplinary research group at the Universidad Nacional Autónoma de México in Mexico City, says that specialized optical readers with built-in AI-powered analytical abilities can reduce the need for biopsies altogether. Guzman's 2021 study used optical spectroscopy and AI to assess metabolic-dysfunction-associated steatotic liver disease in mice. Her group found that two types of spectroscopy (diffuse reflectance spectroscopy and endogenous fluorescence spectra), combined with an AI tool, were able to grade mild and moderate liver steatosis with greater accuracy than that of histopathological methods. "The hope is that we can dramatically reduce the need for [liver] tissue biopsies to be taken in … patients," Guzman explains, "because biopsies can sometimes be so dangerous that they kill the patient."

The AI healthcare field is exploding with new innovations, but the idea of harnessing machine learning to medical devices is not new. Since the FDA approval of an automated Pap smear reader in 1995, hundreds of AI-enabled devices have been approved for marketing, mainly in cardiology and radiology. Beyond those two fields, advances range from an AI algorithm for the detection of retinopathy from digital fundus images obtained with an ophthalmic camera to an AI-enabled nasal anemometer used with an endoscope to measure airflow in the nose. Advances have also been made in neurology, with 'Ahead 100' approved for measuring brain trauma, and 'Cognoa ASD Diagnosis Aid' approved as an aid for diagnosing autism.

GE HealthCare leads the commercial field, with 58 FDA-approved AI-assisted healthcare devices on the market. Parminder Bhatia, chief AI officer for GE HealthCare, says the market, currently valued at US $14 billion, is growing about 30% annually. “There’s a huge appetite for AI devices, especially those that help streamline workflow,” he explains. GE is investing in handheld AI-assisted ultrasound devices and pocket-sized remote health-monitoring devices with built in AI-assisted analytical abilities, both of which show great promise, he says.

DermaSensor is unusual, as it is a handheld AI-assisted medical device intended for use by primary care physicians, rather than by dermatology specialists. The FDA has approved only a few such non-specialist devices. One of these is a portable AI-assisted ultrasound device marketed by Boston-based Butterfly Network that, similar to DermaSensor, aims to “democratize medical imaging,” according to the Butterfly Network website. Another similarly portable device is an AI-enabled stethoscope first marketed by Emoryville, California-based Eko Health in 2015. It is currently approved for the detection of atrial fibrillation and structural heart murmurs, but Eko hopes the FDA will soon approve it for the assessment of left ventricular ejection time, a marker of overall heart health.

Eko’s co-founder, Jason Bellet, who is a commercial advisor to DermaSensor, says that although the market for handheld AI-assisted medical devices is in its infancy, it is likely to grow quickly. “Primary care is ripe for AI-assisted tools that work extremely well and are really easy for non-specialists to integrate into their workflows,” he says.

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