Clinical Registry Case Study: Assessing the Impact of Integrating DermaSensor™ into Primary Care for Skin Cancer Management

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The DermaSensor Device

DermaSensor is a validated, FDA-cleared handheld device that non-invasively evaluates skin lesions for cancer. It captures spectral samples of a lesion and, using a proprietary algorithm, classifies the lesion's spectral properties against those of known malignant and benign lesions.

- Validated to detect melanoma, basal cell carcinoma, and squamous cell carcinoma.
- Assesses skin lesions between 2.5 and 15 mm in diameter immediately at the point of care.
- Classifies lesions as “Investigate Further” or “Monitor.”
- A positive “Investigate Further” result is accompanied by a spectral score of 1 to 10, with higher scores indicating greater similarity to malignant lesions; a negative “Monitor” result indicates no signs of malignancy.
- Published studies found that the device detects 96% of malignant lesions and that use of the device in clinical decisions reduces mismanaged skin cancers by half.

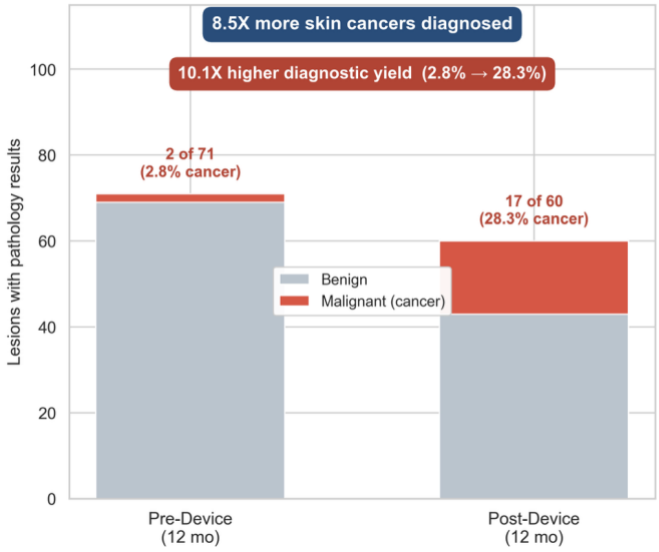
Real-World Impact: More Cancers Detected, with Greater Diagnostic Efficiency

Drs. Goisse and Thomas reviewed skin-lesion data and metrics for the 12 months prior to implementing DermaSensor into their practice, compared with a subsequent 12-month period of device use.

- **Skin cancers diagnosed** increased 8.5X (from 2 to 17). Diagnoses were determined by pathology following further investigation of the lesions.
- **Diagnostic yield** improved 10.1X: the share of further investigated lesions confirmed as cancer rose from 2.8% to 28.3%; thus, far fewer benign lesions were investigated for each diagnosed cancer.
- **Dermatology referrals** decreased 33%, from an average of 1.5 to 1.0 per month.

More skin cancers were identified while dermatology referrals decreased, indicating the additional cancers reflect much improved lesion management and skin-examination frequency rather than increased dermatology referrals. These findings demonstrate that device use can increase skin cancer detection while also decreasing unnecessary dermatology care.

Pre-Device vs. Post-Device Lesion Pathology Results



8.5 times more skin cancers were diagnosed in the device-use period even though fewer lesions were further evaluated.

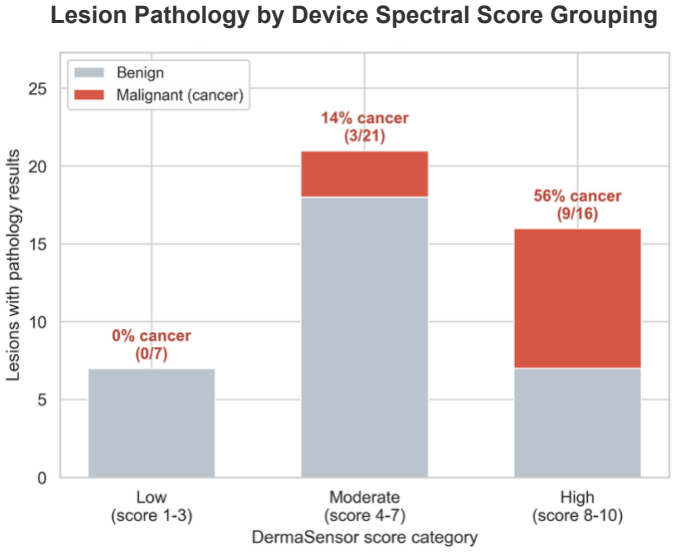
How the Device Was Used and What It Found

Over the device-use period, the practice evaluated 125 lesions with DermaSensor in a predominantly older, fair-skinned patient population (mean age 63 years; 90% aged 40 or older), consistent with the device's cleared indication.

- **The device returned** an “Investigate Further” result for 92% of lesions and a “Monitor” result for 8%.
- **No lesion classified as “Monitor”** was subsequently found to be malignant, consistent with the device's high published sensitivity of 96%[2].
- **Among lesions with pathology results,** confirmed diagnoses included squamous cell and basal cell carcinoma, the most common skin cancers in this patient population.

Higher Device Scores Signaled Higher Cancer Risk

The DermaSensor spectral score demonstrated increasing likelihood of malignancy, consistent with findings of the two large validation studies that supported FDA De Novo clearance[1,2]. The cancer rate was 0% for low scores (1 to 3), 14% for moderate scores (4 to 7), and 56% for high scores (8 to 10). Clinicians' decisions to further investigate tracked the score as well, with further investigation pursued in 14%, 61%, and 68% of low-, moderate-, and high-score lesions, respectively. Together, these management patterns and malignancy rates indicate the score meaningfully and effectively informed management rather than overriding users’ clinical judgment.



The proportion of malignant lesions increased greatly with increasing DermaSensor scores.

Indications for Use

The DermaSensor device is indicated for use to evaluate skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma in patients aged 40 and above to assist in the decision regarding referral of the patient to a dermatologist. The device should be used in conjunction with the totality of clinically relevant information from the clinical assessment, including visual analysis of the lesion, by physicians who are not already expertly trained in the diagnosis and management of skin cancer.

Disclosures

Funding for this registry was provided by DermaSensor Inc. This report analyzed retrospective medical-record data as well as prospective medical-record data following IRB review of the clinical registry.

References: 1. Hartman RI, et al. Multicenter prospective blinded melanoma detection study with a handheld elastic scattering spectroscopy device. JAAD Int. 2023;15:24-31. 2. Merry SP, et al. DERM-SUCCESS: Clinical validation of an ESS device in assisting primary care physicians' detection of skin cancer. J Clin Aesthet Dermatol. 2023;16(4 suppl):S16. 3. Seiverling EV, et al. Clinical utility of an ESS device in assisting primary care physicians' detection of skin cancers. J Clin Aesthet Dermatol. 2023;16(4 suppl):S16-17. 4. Ferris LK, et al. DERM-SUCCESS FDA Pivotal Study. J Prim Care Community Health. 2025;16:21501319251342106.