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

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DermaSensor

Introduction and Objectives

Skin cancer is the most common type of cancer in the United States and worldwide[1], and the most common types are Basal cell carcinoma (BCC), Squamous Cell Carcinoma (SCC) and Melanoma [1]. Additionally, skin cancer is a significant financial strain on the healthcare system[3].

Changes to lesion microscopic architecture at the cellular and subcellular level influence the scattering of light[4]. Rodriguez-Diaz et al (2019) assessed Elastic Scattering Spectroscopy (ESS) with a machine learning classifier for discriminating the most common types of skin cancer and showed promising results [4]. This study evaluated the handheld version of the same technology (Figure 1).

The DERM-ASSESS II study was designed to evaluate the safety and effectiveness of a handheld device combining ESS and a machine learning spectroscopy classifier algorithm to evaluate skin lesions suggestive of the most common types of skin cancers.

Materials & Methods

The study was a prospective, single-arm, investigator-blinded, multi-center study conducted at 4 (four) investigational sites in the United States. The study population included patients who presented with skin lesions suggestive of melanoma, basal cell carcinoma, squamous cell carcinoma, and/or other highly atypical lesions at study sites.

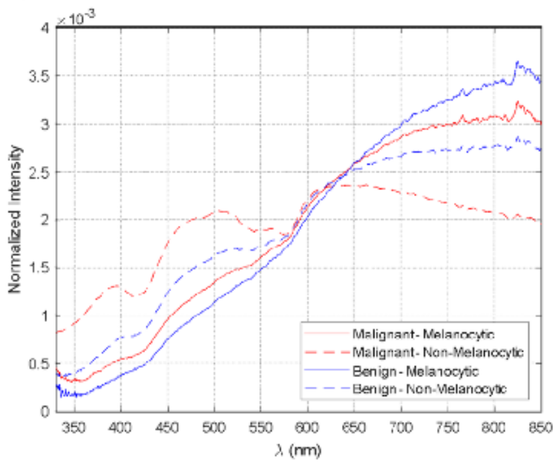
The validation and performance analysis of the algorithm followed a two-step process. First, of all subjects and lesions included through February 28, 2020 (350 subjects with 553 skin lesions) 50% were randomly selected and used as the cross-validation set to validate the machine learning algorithm (175 subjects with 281 skin lesions). Second, the remaining 50% were used as the independent test set on which formal sensitivity estimates, specificity estimates, and their confidence intervals were based (175 subjects with 272 skin lesions). The study is expected to be closed by the end of calendar year 2020.

Figure 1. Handheld ESS device

Data Processing and Machine Learning

Preprocessing and then normalization of spectral data enable analysis based on spectral shape, independent of relative intensities (figure 2)[4]. The development of the algorithms closely followed procedures already laid out in previous ESS studies, such as Rodriguez-Diaz (2019) [4].

Figure 2. Differentiated average spectral signatures for all training dataset lesions grouped by histopathologic assignment Rodriguez-Diaz (2019)



Results

During the period reported in this analysis, no TEAEs were observed in the study. Overall device efficacy analyses for the test group until February 28th 2020 are detailed in Table 1. Efficacy analyses of device and study investigators (dermatologists) for the test group of biopsied lesions are detailed in Tables 2 and 3, respectively. There was no statistically significant difference between the performance of the device and that of dermatologists in terms of overall sensitivity (94.33 vs. 97.16; p=0.1701).

When only biopsied benign lesions were analyzed, there was no statistically significant difference in specificity between the device and dermatologists (27.78 vs. 31.11; p=0.5271). The specificity of the device for unbiopsied lesions (those that dermatologists considered benign, but challenging for less trained healthcare professionals) was 41.46%. Dermatologists' own clinical assessment was the gold standard for such lesions and therefore investigators' specificity results for unbiopsied lesions are biased. Table 4 presents subgroup sensitivity for the testing group of higher risk lesions.

Results (cont.)

Table 1. Device Overall Efficacy Analysis for Testing Group - All Lesions (Biopsied and Unbiopsied)

Total N of Lesions: 272		Adjusted Wilson Score Method 95% CI	Exact Method 95% CI
Sensitivity	94.33 (133/141)	88.27 to 97.35	89.13 to 97.52
Specificity	32.06 (42/131)	24.60 to 40.57	24.18 to 40.77
False Positive Rate	67.94 (89/131)	-	-
False Negative Rate	5.67 (8/141)	-	-

CI: confidence interval, N: number

Table 2. Device Overall Efficacy Analysis for Testing Group - Biopsied Lesions

Total N of Lesions: 231		Adjusted Wilson Score Method 95% CI	Exact Method 95% CI
Sensitivity	94.33 (133/141)	88.27 to 97.35	89.13 to 97.52
Specificity	27.78 (25/90)	19.34 to 38.16	18.85 to 38.22
False Positive Rate	72.22 (65/90)	-	-
False Negative Rate	5.67 (8/141)	-	-

CI: confidence interval, N: number

Table 3. Dermatologist Overall Efficacy Analysis for Testing Group - Biopsied Lesions

Total N of Lesions: 231		Adjusted Wilson Score Method 95% CI	Exact Method 95% CI	p-value[a]
Sensitivity	97.16 (137/141)	93.12 to 98.86	92.90 to 99.22	0.1701
Specificity	31.11 (28/90)	21.82 to 42.23	21.77 to 41.74	0.5271
False Positive Rate	68.89 (62/90)	-	-	-
False Negative Rate	2.84 (4/141)	-	-	-

CI: confidence interval, N: number; [a]DermaSensor™ vs. Dermatologist Two-Sided P-Value

Table 4. Device Subgroup Sensitivity for Testing Group - All Lesions[a]

Lesion Type	Sensitivity %(n)	Adjusted Wilson Score Method 95% CI	Exact Method 95% CI
Melanoma	100.00 (16/16)	N/A	79.41 to 100.00
BCC	93.75 (60/64)	83.44 to 97.81	84.76 to 98.27
SCC	92.73 (51/55)	80.53 to 97.52	82.41 to 97.98
SAMN	100.00 (6/6)	N/A	54.07 to 100.00
Abnormal Melanocytic	100.00 (22/22)	N/A	84.56 to 100.00
NMSC	93.28 (111/119)	85.43 to 97.04	87.18 to 97.05
Pigmented lesions	91.67 (33/36)	80.40 to 96.72	77.53 to 98.25
Non-pigmented lesions	95.24 (100/105)	87.57 to 98.27	89.24 to 98.44

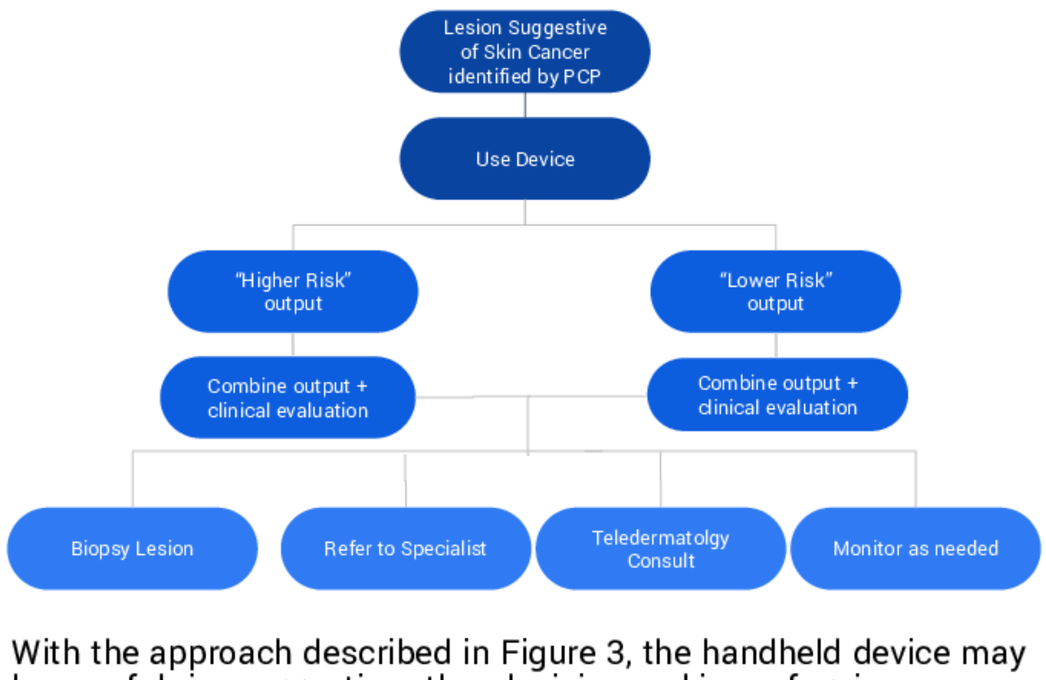
Abnormal Melanocytic: Melanoma + severely atypical melanocytic nevus; BCC: basal cell carcinoma; CI: confidence interval; NMSC: nonmelanoma skin cancer; SAMN: Severely atypical melanocytic nevus; SCC: squamous cell carcinoma; [a]All malignant lesions in the study were biopsied.

Discussion and Conclusion

This report indicates that the handheld combination of ESS and Machine Learning is safe and effective in detecting the most common types of skin cancers.

Although investigators were blinded in the study, real-world use will allow for the device's binary result of "higher risk" or "lower risk" to be used in the clinical evaluation, along with other factors of the patient history and physical examination* (Figure 3).

Figure 3. Proposed device use workflow



With the approach described in Figure 3, the handheld device may be useful in supporting the decision-making of primary care providers. A survey of the literature suggests that primary care physician sensitivity ranges from 54% to 88%[5,6]. Therefore, the device's reported sensitivity of 94% may allow for 6% to 40% additional skin cancer detection in primary care, but additional studies are necessary. Used as an adjunctive tool in the evaluation of skin lesions, ESS may improve primary care selection of lesions that should receive further care or clinical monitoring. Additionally, ESS is not an imaging modality, making it potentially complementary to image-based technologies.

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Disclosures

Benvenuto-Andrade is an employee of DermaSensor Inc; Manolakos and Cognetta declare no conflicts of interest. This study was sponsored by DermaSensor Inc
*The device is commercially available in Europe, Australia, and New Zealand. The device is not currently approved for use in the United States.