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Retrospective evaluation of the performance of the electrical impedance spectroscopy system Nevisense in detecting keratinocyte cancers

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Abstract

Background: Keratinocyte cancers, also referred to as non-melanoma skin cancers (NMSCs), are one of the most common malignant skin tumors. We performed a retrospective analysis of lesions from patients of a private dermatology practice to evaluate the use of electrical impedance spectroscopy (EIS) in detecting keratinocyte malignancies. The aim of the study is to assess the accuracy of the technique and to rate its use as supportive tool in NMSC diagnosis.

Material and Methods: The period evaluated ranges from September 2015 to November 2019. In total, 1712 lesions from 951 patients were included. All lesions suspicious for malignancy were gauged with the Nevisense device. Excised lesions were sent in for histopathological classification, and the results were compared to the Nevisense score.

Results: A total of 767 lesions (44.8%) received a negative score (0-3) from the Nevisense system and 945 lesions (55.2%) a positive score (4-10). The combination of the dermatologist's visual assessment plus the technical determined Neviscore resulted in the excision of 52.5% of all 1712 suspicious lesions whereof 15% were found to be malignant. The sensitivity of Nevisense was 98.4% for NMSC detection.

Conclusion: Electrical impedance spectroscopy was found to be a valuable adjunct support tool in clinical decisions for cases with suspicion for NMSC.

KEYWORDS

early detection, electrical impedance spectroscopy, keratinocyte cancer, Nevisense, Non-melanoma Skin Cancers

1 | INTRODUCTION

Keratinocyte cancers, also referred to as non-melanoma skin cancers (NMSCs), arise in keratinocytes, the most common type of skin cells in the epidermis. The term keratinocyte cancer includes basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and actinic keratosis as a precancerous state. They are the most commonly occurring cancers in humans with a rapidly increasing incidence worldwide.[1-3] The annual increase over the past few decades was 2%-4% in men and 3%-9% in women for BCC and 1%-2% in men and 3%-4% in women for SCC.[1] Exact epidemiological data are sparse because NMSCs are still often excluded from

or listed incompletely in cancer registries. In the United States, for example, an estimated 1Mio cases of SCC[4] and 4Mio cases of BCC[5] are diagnosed every year. In Germany, according to the Robert Koch Institute, an estimated 264 700 new cases of NMSC will be diagnosed in 2020, with BCC accounting for 75% and SCC for 25% of these cases.[6] The long-term prognosis is pessimistic, expecting a continuous increase of NMSC incidence with no tendency for leveling off. By 2030, the current NMSC in Germany is expected to have doubled.[7] The term "skin cancer epidemic" was coined to illustrate this phenomenon.

With advanced age, the incidence of keratinocyte cancer increases. In 2001, a survey in the UK revealed that 80% of all recorded NMSC cases were diagnosed in people aged 55 years or older.[8] In Germany, a cohort of 90 800 employees was assessed and the rate increased with age (11.5% in the group 60-70 years) and was higher in men.[9] Taking the demographic development into account, we have to expect a dramatic increase in the occurrence of all cancer types but especially in age-related diseases.

Risk factors are numerous, but Caucasian skin type and exposure to UV radiation are the key factors predisposing for the development of keratinocyte cancers, which are also referred to as "solar keratoses." It is not surprising that the most sun-exposed parts of the body such as head and neck are the most common sites.[10,11] Interestingly, the cumulative lifelong sun exposure seems to be driving the pathogenesis of SCC and AK, and intermitted sun exposure (eg, sun burns) plays a major role in the development of BCC.[12] Persons with occupational or recreational outdoor exposure, as well as those living at latitudes closer to the equator, have higher incidence rates.[2] Therefore, avoiding the sun at peak hours, wearing protective clothing, regularly applying sunscreen, and other sun-protective behaviors have been identified to decrease the incidence of keratinocyte cancers.[13]

While keratinocyte cancers are rarely fatal, they can cause significant morbidity and, if not treated early, these lesions may regularly recur and can become not only disfiguring but also life-threatening. Early diagnosis is the key to successful therapy. Once diagnosed, a variety of modalities and guidelines for the management have been published. Clinical diagnosis is based on adspection in combination with dermatoscopy. Is the lesion suspicious for malignancy, biopsy and histopathological analysis is performed to determine it's veritable malignant potential. While electrical impedance spectroscopy (EIS; Nevisense, SciBase AB, Stockholm, Sweden) is a new technique for accurate and safe risk assessment in conjunction with clinical examination for patients with suspicion for malignant melanoma, this technique is not used in the detection on non-melanocytic cancers until now.

The aim of this study is to evaluate if EIS can be used as a supportive tool in the diagnosis of keratinocyte cancer. We compare the Neviscore (NS), the output of the Nevisense, with histopathological findings to assess the accuracy and reliability in detecting keratinocyte cancer, primarily BCC. However, it should be noted that EIS should only be used in combination with the clinical assessment.

2 | MATERIALS AND METHODS

2.1 | Study population

The study did not involve any invasive or potentially dangerous methods, was reviewed by the ethical committee of Bayerische Landesärztekammer, and was deemed not to require ethical approval. A total of 1055 participants were recruited among patients of a dermatological private practice in Munich who presented with 2038 lesions. After excluding 326 (16%) lesions from 104 patients because of missing information, for example missing pathohistological diagnosis or EIS measurement, the study population considered for further analysis consisted of 951 participants with a total of 1712 lesions. The study population comprised 571 males (60%) and 361 females (38%) as well as 19 patients of unknown sex. The participants were between 7 and 87 years old, with a mean age of 49 years (M = 49, SD = 13.35 years).

2.2 | Study design

A retrospective analysis was performed on 1712 lesions examined with the EIS system Nevisense between September 2015 until November 2019. Firstly, a thorough visual examination of the patient's lesion was performed by the dermatologist, followed by dermoscopy to identify suspicious lesions for skin cancer. If suspicion for malignancy existed, the lesion was examined with the EIS system Nevisense. The aim here is to generate additional information on the degree of aberration of the physiological cell structure to obtain an objective, automated, and unbiased "second opinion" in order to make an informed decision on whether to excise the lesion or not.

Electrical impedance spectroscopy is a painless and noninvasive technology based on the measurement of the overall resistance within the tissue. Skin tissue has different electrical properties under different medical conditions. By applying an alternating potential using frequencies in the range between 1 kHz and 2.5 MHz, the changed impedance characteristics typical for cancerous vs non-cancerous cells can be detected. The frequencies used by EIS relate to clinically relevant properties, such as composition of intra- and extracellular environments, cell shape and size, and cell membrane composition, all of which are similar to those used by histopathologists to diagnose skin cancer. The output from the system is a score from 0 to 10. A Nevisense score (NS) of 0-3 is considered negative, indicating that a lesion is benign and the patient was thus possibly spared this excision of the skin. A NS of 4-10 is considered positive, indicating that the properties of the cell issue are altered. These scores reflect present dysplasia of the tissue and potential malignancy. Thus, a NS of 4-10 supported the decision to excise the lesion.

The NS is then combined with the dermatologist's clinical judgment to come to a final decision on whether a lesion should be excised or not. Lesions were screened for features of malignancy. Nevisense uses an algorithm to classify the lesions based on reference values.

To confirm this assumption, a histopathological analysis of the excised lesions was performed and the histopathological diagnosis was compared to the NS. All excised samples were interpreted by the same expert histopathologist.

Since Nevisense was upgraded to a newer version (Nevisense 3.0) in June 2018 with a new measurement procedure and an updated classifier with higher accuracy, all lesions were reanalyzed with the updated classifier for consistency.

Lesions included in this study had to meet certain criteria to be considered suitable for evaluation with EIS. Conversely, the exclusion criteria for the use of EIS based on the manufacturer's specifications for the device and in accordance with previous studies are as follows: (a) metastases from an existing malignancy; (b) a diameter of <2 mm or more than 20 mm; (c) lesions on skin that is obviously not intact, for example, in the form of eczema, psoriasis, scars, sunburn, or ulcerations; (d) previous injuries, trauma, surgical interventions, or biopsies; (e) lesions on very hairy skin such as the scalp or beard; (f) lesions in the genital area or other mucosal locations; (g) lesions on tattoos, in the presence of other foreign bodies or unphysiologic disruptive factors; and (h) pedunculated lesions. In contrast to previous studies, underage patients were also included in the study. According to the manufacturer, there is an evidence of a limited ability to assess the skin of minors through the device.

3 | RESULTS

3.1 | Neviscore classification

After a thorough visual examination in combination with dermatoscopy, suspicious lesions were examined with EIS. Out of 1712 lesions included in the retrospective analysis, 767 lesions (44.8%) received a negative score (NS 0-3) from the Nevisense system and 945 lesions (55.2%) received a positive score (NS 4-10) (Figure 1). Of the

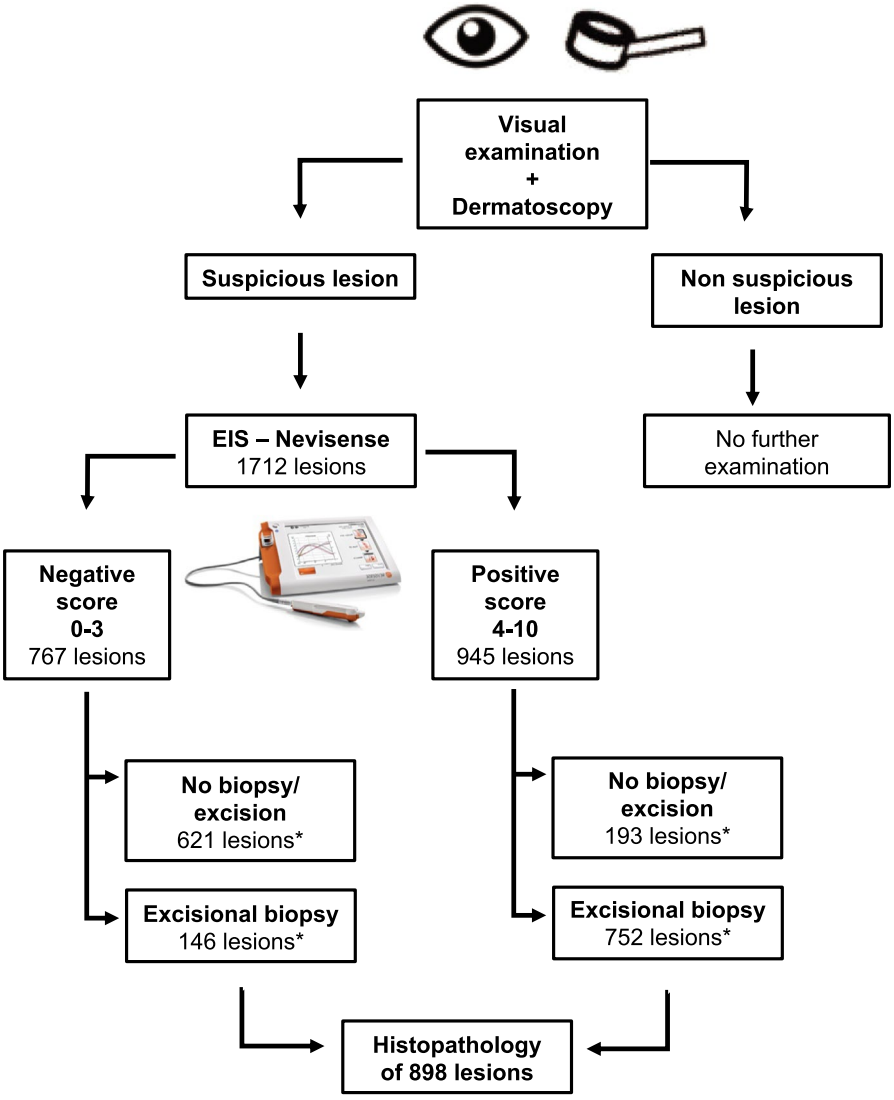

FIGURE 1 Flowchart of the practical approach of lesion evaluation including number of lesions affiliated to each decisional step. * Final decision for or against excisional biopsy depended on the dermatologist's judgement

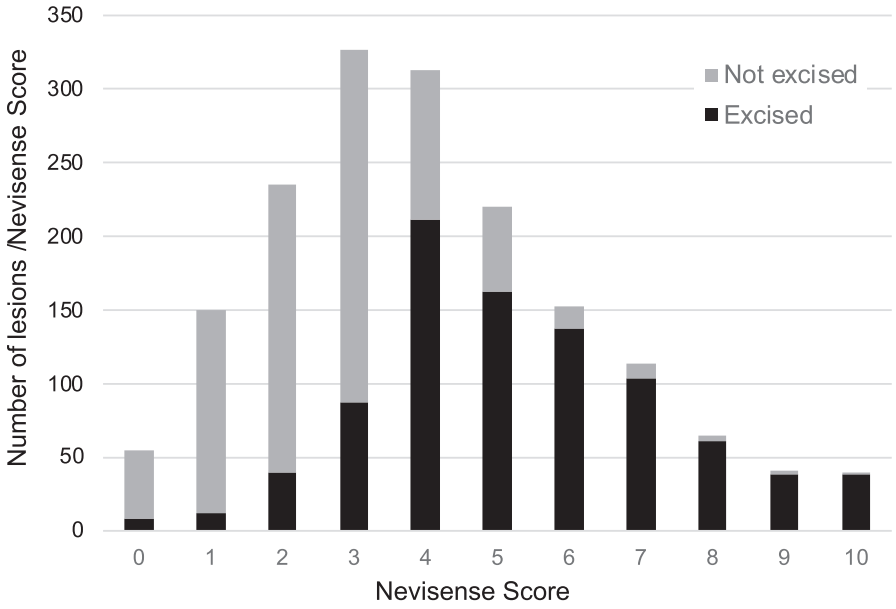

FIGURE 2 Number of lesions excised and not excised corresponding to the respective Nevisense Score

767 negative scored lesions (NS 0-3), a total of 146 (19%) were excised. Of the 945 positive scored lesions (NS 4-10) 752 lesions (80%) were excised, whereas 193 lesions (20%) were not excised (Figure 1). Consequently, combining the NS with the dermatologist's clinical evaluation resulted in the decision to excise 898 (52.5%) lesions, 814 lesions (47.5%) were not excised. The number of excised lesions per NS was analyzed (Figure 2).

3.2 | Histopathological examination

The excised tissue was sent in for histopathological analysis to define the nature of the suspicious lesion. According to the histopathological results, the lesions were affiliated to the following subtypes: nodular (36%), superficial (8%), sclerodermiform (0%), pigmented (2%), and ulcerative (2%). For several lesions, more than one subtype was identified. 39% were classified as nodular-superficial, 6% as nodular-sclerodermiform, 0.8% as nodular-pigmented, and 0.8% as nodular-superficial-sclerodermiform (Figure 3A). The number for each lesion type per NS was analyzed (Figure 3B).

A histopathological diagnosis was then assigned. Of 898 excised lesions, 131 (15%) were found to be malignant, or premalignant. Regarding the malignant lesions, histopathological diagnosis showed 82 basal cell carcinomas (BCC), 13 squamous cell carcinomas (SCC), 11 Bowen's disease, and one basosquamous carcinoma as well as six melanomas. Eighteen lesions were classified as precancerous actinic keratosis (AK; Table 1).

3.3 | Analysis of basal cell carcinoma (BCC)

In a next step, we focused on BCC, the most prevalent form of NMSC. Eighty-two BCC lesions were diagnosed, originating from n = 82 participants, 64 males and 18 females between 44 and 84 years of age (M = 63 years, SD = 13.05). The number of lesions per NS was analyzed (Figure 4). All BCC received a NS of 4 or higher, indicating a potentially malignant state. The positive predictive value as well as the sensitivity for BCC detection using the Nevisense system was 100%.

Most BCC lesions were classified as "superficial," even though more than one subtype was identified for several lesions. The lesion depth ranged from 0.25 mm up to 2.5 mm with an average depth of 0.74 mm. The lesion diameter ranged from 0.15 to 1.5 cm with an average diameter of 0.59 cm. We examined the correlation between lesion size and NS (Figure S1) as well as lesion depth and NS (Figure S1). Though no significant difference was detected, we observed a slight correlation. With increased depth as well as bigger lesion size, the NS becomes higher.

3.4 | Analysis of spinocellular carcinoma (SCC), actinic keratosis (AK), and Bowen's disease

The analysis of 13 confirmed SCC revealed that they originated from n = 10 male and n = 2 females between 51 and 82 years of age, mean age being 65 years. All SCC received a positive NS of 4 or higher resulting in a calculated sensitivity of 100%.

Of all 18 confirmed AK, n = 11 originated from male participants and n = 7 from female participants between 53 and 80 years of age, mean age was 69 years. One AK lesion (5.6%) received a negative NS whereas 17 lesions (94.4%) received a positive NS. The sensitivity for detecting AK with the EIS system Nevisense is 94.4%.

Bowen's disease was confirmed in n = 11 participants, n = 9 males and n = 2 females. Their age ranged between 37 and 80 years, and the mean age was 57 years. One lesion (9.1%) received a negative NS, and the other 10 lesions (90.9%) received a positive score. The sensitivity for detecting lesions classified as Bowen's disease with the EIS system is 90.9%.

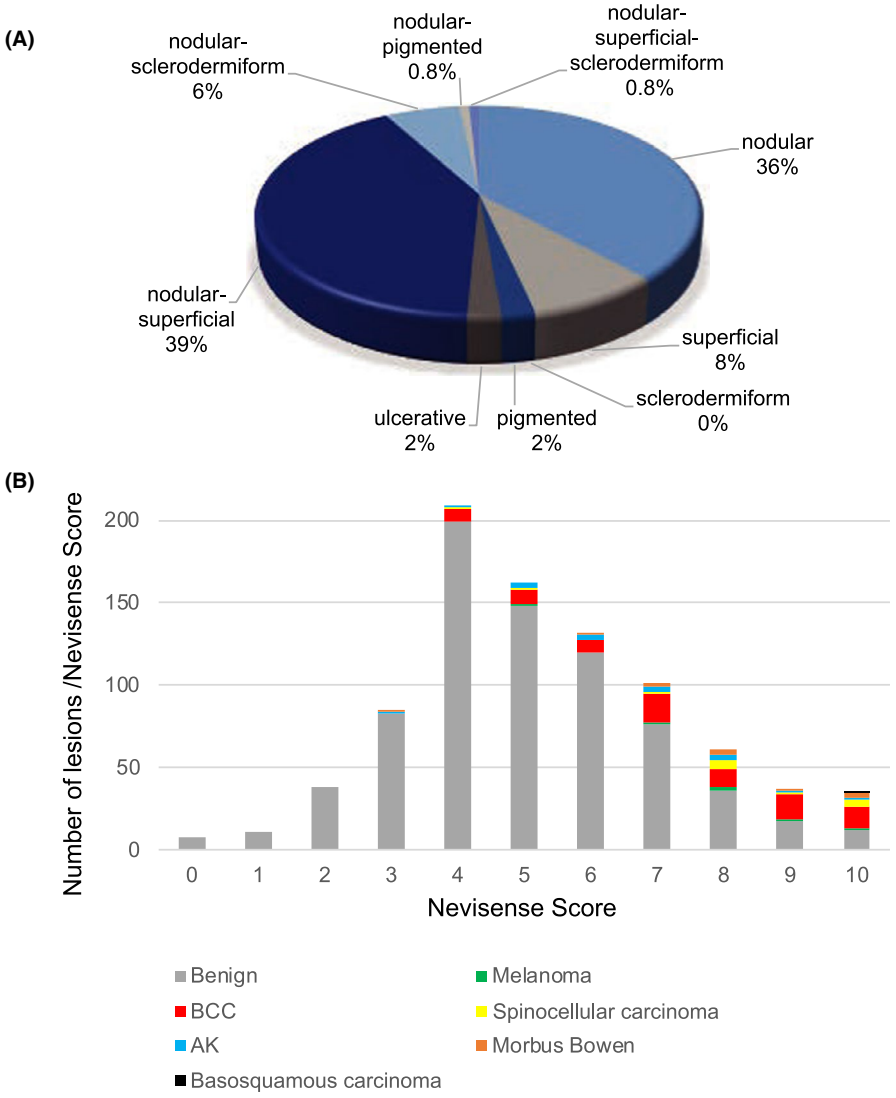

FIGURE 3 A, According to the histopathological results, the lesions were affiliated to the subtypes depicted as percentage of all excised lesions. B, Number of excised and histopathologically classified lesions detected for each Nevisense score

3.5 | Accuracy of the Nevisense device in detecting NMSC

The different types of NMSC included in this study are BCC, SCC, AK, and Bowen's disease. Focusing on the detection of NMSC using the Nevisense, the system assigned a negative NS to two (1.6%) out of 124 diagnosed NMSC lesions but correctly evaluated 122 (98.4%) lesions as suspicious for malignancy. The overall sensitivity for the detection of NMSC was 98.4%.

4 | DISCUSSION

This analysis is based on patients and lesions that were examined in a private dermatology practice and constitutes one example of how electrical impedance spectroscopy and the Nevisense system can impact the clinical management of patients and lesions. The dermatologist's visual assessment combined with the automated EIS score resulted in the excision of 52% of suspicious lesions of which 14.6% were found to be malignant. Once the decision to excise a lesion was made, the sensitivity of EIS was 98.4% for detection of NMSC, including BCC, SCC, AK, and Bowen's disease.

TABLE 1 Histopathological diagnosis of excised lesions

Diagnosis	Number of lesions
Melanoma	6
Basal cell carcinoma	82
Squamous cell carcinoma	13
Bowen's disease	11
Basosquamous carcinoma	1
Actinic keratosis	18
Dysplasia severe	0
Dysplastic nevus	7
Seborrheic keratoses	11
Benign	749
Total	898

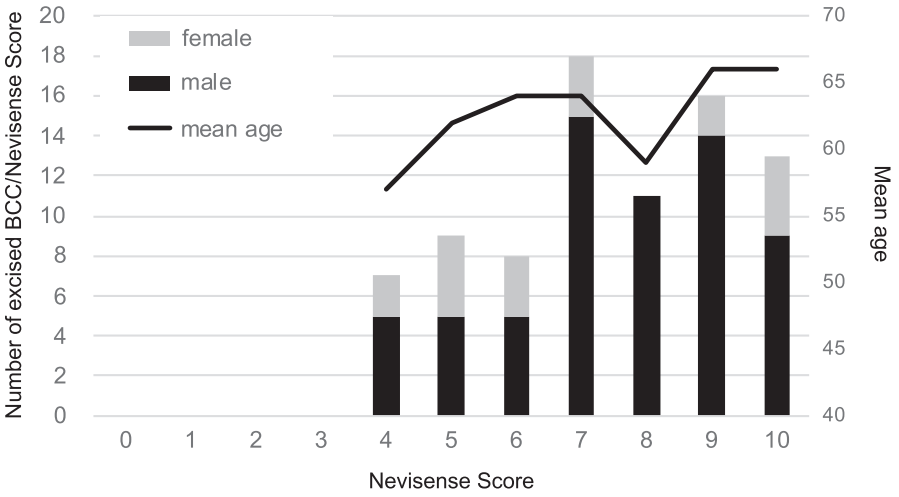

FIGURE 4 Number of basal cell carcinomas (BCC), corresponding to the respective Nevisense score, gender, and median age of patients

Non-melanoma skin cancers were diagnosed in 124 patients of whom 24% were women and 76% men. The gender distribution in our study cohort corresponds to other reports documenting a significantly higher prevalence of NMSC in men compared to women.[14-17] The main risk factor for developing NMSC is intense sun exposure over many years, and the largest percentage of NMSC is diagnosed in the so called sun terraces — uncovered body sites such as nose, ears, lips, neck, and hands — that are in particular imperiled by intense UV radiation.[14,18] Men pursue outdoor employments more often than women. In addition, due to short hair or early hair loss, the head / neck area of men is largely exposed to the sun which may explain the higher prevalence. However, recent studies suggest a shift in the proportion of female patients. Reasons may be the more frequent use of tanning beds by women as well as an increase in outdoor and therefore photo exposed leisure activities.[19-23]

The age of the study participants affected by NMSC ranged between 44 and 84 years, with a mean age of 63 years for BCC, 65 years for SCC, 69 years for AK, and 57 years for Bowen's disease. We observed a slight correlation between increased age and the prevalence of NMSC. This trend observed coincides with larger epidemiologic studies, which demonstrate the effect of age and therefore the lifelong, chronic intake of UV radiation on the development of NMSC.[3,18] Several studies focusing on NMSC in women report that the age of women affected by NMSC decreases in Europe and the United States. This phenomenon is attributed to the use of tanning beds that became especially popular in women in the 1970s-1990s.[20,21,23-25] Keeping the demographic development in mind, we can expect a constant increase of patients diagnosed with NMSC over the next years and decades.

The Nevisense device has been studied in several previous studies, but primarily for the malignant melanoma indication.[26,27] Still, in other multicenter prospective controlled clinical studies keratinocyte cancers were included. In the IMATS study including in total 1300 lesions, there were 39 BCC and eight SCC included, all receiving an EIS score of 5 or higher.[27] In the pivotal study including in total 1943 lesions, there were 48 BCC and seven SCC, all receiving an EIS score of 5 or higher.[28] This indicates that Nevisense has a high sensitivity for keratinocyte cancers and especially BCC as these were most of the lesions included.

The conclusion of the study presented here is that EIS is a valuable technique which can be used as a supportive tool in the diagnosis of keratinocyte cancer. When integrated in the clinician's diagnostic routine, the output of the EIS system Nevisense interprets dermatologic aberrations and reliably rates lesions with suspicion for malignancy with a positive score. The high sensitivity makes it a valuable tool for the clinician, which helps correctly identifying malignant lesions originating from keratinocytes. In addition to its possible assistant role as an additive diagnostic tool, this method could in future support surgeons intraoperatively in assessing the resection margins. Furthermore, the method optionally can be used in evaluating the success of a specific therapeutic regime in addition to classical dermoscopy and it can serve as a decision-making aid in the event of a questionable change in therapy in the event of a poor response.

Despite increased public awareness campaigns about the effects and dangers of excessive UV exposure, the incidences of actinic keratosis and white skin cancer continue to rise. Therefore, there is a need to continue research in this area with a focus on more precise, less invasive diagnostics, and more effective therapeutic options for keratinocyte cancers and to prevent their occurrence by taking preventive measures.

5 | CONCLUSION

The decision on how to clinically manage skin lesions still depends on the expertise of the physician. Nonetheless, EIS and the Nevisense deliver additional, complementary information about lesions that can support the clinician in taking the appropriate steps. Since EIS is a painless, noninvasive, and fast procedure, the combination of thorough clinical examination and EIS turns out to be powerful setup in evaluating the malignancy of skin lesions. Apart from the detection of melanocytic skin cancer, the Nevisense device was found to reliably detect non-melanocytic skin cancer, too. Therefore, it can be used as a helpful tool in NMSC diagnostic and the appropriate management.

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CONFLICT OF INTEREST

None.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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