User experience case:
Dr. Hjalmar Kurzen, Freising, Germany

Nevisense® – An innovative, accurate and secure new method of diagnosing malignant melanoma

Even today, the exact diagnosis of malignant melanoma remains a challenge for dermatologists. Although dermoscopy offers support during the visual clinical assessment, unclear cases still leave physicians and patients with a degree of uncertainty – and ultimately the risk of misdiagnosis. Nevisense® makes it possible to use an additional objective measurement method to increase diagnostic accuracy.

As a doctor, one of my goals is to provide early skin cancer detection, especially of malignant melanoma (MM), in order to improve the patient's prognosis.

Due to numerous factors including changing leisure habits, the incidence of MM is continually increasing. Despite this, the mortality rate remains constant because of a growing risk awareness and especially due to the unique preventive and specialized medical care structures in Germany.

A Diagnostic Challenge

While diagnostic capabilities have improved over time, a doctor's clinical experience and his or her trained eye are still the most important diagnostic tools. Dermatoscopy has established itself as an important tool in confirming a suspicion or examining the unclear presentation of a nevus. For deeper optical structure analysis and the documentation of changes over time, digital tools such as video dermatoscopy have become available. Essentially, technical aids for the assessment of suspicious pigment structures are based on optical support.

Uncertainty - suspect cases in the "gray area"

Despite the aid provided in the analysis of suspicious pigment structures through technical means, in many cases an uncertainty remains. An unambiguous assessment is particularly difficult in early, usually treatable stages. A clear diagnostic decision is also often difficult in the case of atypical, dysplastic nevi. Even the use of optical aids can often not completely eliminate the uncertainty of a misdiagnosis, i.e. overlooking a malignant structure or unnecessarily surgically removing a benign lesion. Often the self-assessment and mindset of the physician play a large role in the decision of whether to opt for or against an immediate excision or, rather, to opt for close observation and further diagnostic measures.

The psyche of the patient and family

The psychological state of the patient should not be disregarded within the context of any medical treatment. Patients who are given an unclear diagnosis are left very stressed. This is particularly true for the parents of children. They want immediate certainty and clarity. In uncertain cases, it is particularly important to explore all diagnostic routes in order to relieve the worries of those affected and their loved ones.

> Despite their experience and the diagnostic aids availble, the accurate detection of malignant melanoma remains a challenge for dermatologists.
>
> – Dr. Hjalmar Kurzen

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"Overall, there is only a narrow corridor of uncertain cases in skin cancer diagnosis. However, this makes it even more important to exhaust all diagnostic possibilities in order to exclude false-negative diagnoses as well as unnecessary surgery. It is also important to ensure as much clarity as possible – for the relief of the unsettled patient."

My clinical experience with Nevisense®

A patient with an unclear birthmark can be offered a Nevisense® check as an alternative to immediate excision and histological diagnosis. Experience shows that the additional diagnosis with Nevisense® is usually preferred. This generally leads to a clearer decision.

According to studies, benign lesions are recognized as such with about 98% certainty (a Nevisense® score of 1-3). The incidence of identification for non-malignant skin changes is significantly increased, and many unnecessary excisions performed simply to clarify the diagnosis can be avoided.

Should the analysis of a malignancy be corroborated (Nevisense® score of 4-10), a decision for or against an immediate excision can be made in a doctor-patient consultation.

Nevisense® is particularly helpful in cases where doctor and patient are uncertain and a third "objective party" is required. The attitude and feelings of the patient are of highest importance. If the patient demands clarity quickly, Nevisense® provides robust additional objective evaluation criteria. For many patients, the ability of this "neutral party" to provide an additional measure of security is of great importance.

It is particularly advantageous that the device is approved for use on children. A quick decision contributes decisively in calming worried parents. Parents receive clarity and certainty quickly, and unnecessary additional visits to other doctors for a second opinion can be avoided. An additional advantage is its use on skin type IV or colored skin. Other diagnostic methods are of limited significance with more pigmented skin. Here the impedance measurement through Nevisense® can provide crucial information.

Objective overview of the Nevisense® technology

- Literature shows that the Electrical Impedance Spectroscopy (EIS) method used by Nevisense is documented as a reliable diagnostic tool that allows the discrimination of benign and malignant lesions (1, 2).
- In comparison to normal tissue, atypical tissue has a different orientation, size, and shape of cells as well as a different density and structure in cell membranes. The changes affect the ability of cells to conduct and store electricity. This electronically measurable property is called impedance.
- The frequencies used in Nevisense® (1 KHz - 2.5 MHz) are particularly suitable for the detection of clinically relevant intra-and extracellular conditions and the composition of the cell membrane; these structures are also used in histopathology for diagnosis of skin cancer.
- To detect the entire extent of a lesion, measurement is carried out with 35 frequencies and 4 depth settings in a total of 10 permutations.
- Using an algorithm, Nevisense® classifies the lesions in comparison to a reference. As a result, a value is supplied that corresponds to the degree of atypia found.
- The patented Nevisense device was developed during 20 years of research at Karolinska Institutet Stockholm.

(1)Peter Mohr et al. Skin Research and Technology 2013;19: 75-83.
(2)Peter Åberg et al. Experimental Dermatology, 2011, 20: 648-652. DOI:10.1111/j. 1600-0625.2011.01285.
(3) Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multi-centre, prospective and blinded clinical trial on efficacy and safety. Malvehy J, Hauschild A, Curiel-Lewandrowski C, et al. British Journal of Dermatology. 2014 Oct 19. DOI: 10.1111/bjd.13121.

"In our practice, Nevisense® quickly conveys security and reassurance for both the physician and the patient in uncertain cases. It is a valuable diagnostic tool." -Dr Kurzen

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