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Performance of an automated total body mapping algorithm to detect melanocytic lesions of clinical relevance

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ABSTRACT

Importance: Total body photography for skin cancer screening is a well-established tool allowing documentation and follow-up of the entire skin surface. Artificial intelligence-based systems are increasingly applied for automated lesion detection and diagnosis.

Design and patients: In this prospective observational international multicentre study experienced dermatologists performed skin cancer screenings and identified clinically relevant melanocytic lesions (CRML, requiring biopsy or observation). Additionally, patients received 2D automated total body mapping (ATBM) with automated lesion detection (ATBM master, Fotofinder Systems GmbH). Primary endpoint was the percentage of CRML detected by the bodyscan software. Secondary endpoints included the percentage of correctly identified "new" and "changed" lesions during follow-up examinations.

Results: At baseline, dermatologists identified 1075 CRML in 236 patients and 999 CRML (92.9%) were also detected by the automated software. During follow-up examinations dermatologists identified 334 CRMLs in 55 patients, with 323 (96.7%) also being detected by ATBM with automated lesions detection. Moreover, all new (n = 13) or changed CRML (n = 24) during follow-up were detected by the software. Average time requirements per baseline examination was 14.1 min (95% CI [12.8–15.5]). Subgroup analysis of undetected lesions revealed either technical (e.g. covering by clothing, hair) or lesion-specific reasons (e.g. hypopigmentation, palmoplantar sites).

Conclusions: ATBM with lesion detection software correctly detected the vast majority of CRML and new or changed CRML during follow-up examinations in a favourable amount of time. Our prospective international study underlines that automated lesion detection in TBP images is feasible, which is of relevance for developing AI-based skin cancer screenings.

1. Background

Incidence rates of melanoma are further increasing and mortality rates remain high [1]. Early detection is of utmost importance, since thin melanomas may be cured by surgery, while more advanced melanomas tend to progress and metastasize [1,2]. Skin cancer screening programs worldwide have been implemented to support melanoma detection [3]. Surveillance programs in patients at increased melanoma risk have been shown to be both less expensive and more effective than melanoma treatment [4]. Established screening procedures include the examination of the total body skin with the unaided eye and dermoscopy [5]. Total body photography (TBP) was shown to support melanoma detection by unmasking new or changing lesions in patients with multiple nevi [6–9]. TBP reduced the number of benign nevus biopsies in patients at risk for melanoma [10]. The "two-step method" was designed to combine benefits of TBP and sequential digital dermoscopy (SDD) into

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one examination schedule [11,12]. Here, TBP is performed repeatedly to detect changing or new skin lesions, whereas SDD is applied to detect subtle changes or architectural atypia of single lesions [13]. During recent years, partly automated imaging systems for TBP, providing a 2D or 3D reconstruction of the skin surface, and SDD supported by artificial intelligence (AI) have attracted great attention. Deep learning convolution neural networks (CNN) analyzing close-up images or dermoscopic images of skin lesions may already achieve a diagnostic accuracy comparable to experienced dermatologists [14,15]. Nevertheless, Australian data suggest that detection rate of melanomas by CNN in primary care centres demand further improvement.

Hence, it is of interest to further develop total body imaging in combination with automated lesion detection for future artificial intelligence-based diagnostics. The aim of the study was to investigate the performance of an automated total body mapping algorithm to detect clinically relevant melanocytic lesions in a first international real-world analysis.

2. Methods

This study was approved by local ethics committees (approval no. S-836/2020) and performed in accordance with the Declaration of Helsinki principles. All patients gave written informed consent before study related procedures.

2.1. Study settings

We conducted a prospective, observational, international, multicentre study assessing the performance of ATBM in combination with automated lesion detection (Fotofinder Systems GmbH, Bad Birnbach, Germany; version 3.3.1.0). The study was carried out at four sites, i.e. at the Department of Dermatology at the Hospital Provincial del Centenario de Rosario (Argentina), North Queensland Skin Centre Townsville (Australia), University Department of Dermatology Heidelberg (Germany) and the University Department of Dermatology Basel (Switzerland).

Adult patients with multiple common and/or atypical nevi and/or a personal history of previous melanoma(s) were included in the study. Hence, the study focussed on including patients at increased risk for developing melanoma. Patients not able to follow study procedures or to assume predefined body postures in a standing position for ATBM were excluded.

Study participants received skin cancer screenings by trained dermatologists identifying melanocytic lesions of clinically relevant melanocytic lesions (CRML), i.e. lesions requiring excision or observation. The entire skin surface was imaged using a market-approved medical device for ATBM and lesion detection.

Patients were offered follow-up examinations at 3 to 12-month intervals according to their individual skin cancer risk such as previously detected skin cancer, number of atypical nevi or immunosuppression. Baseline examinations were performed between January 13th and November 29th 2021 and follow-up examinations between May 17th 2021 and June 3rd 2022.

Primary endpoint was the percentage of CRML detected by the combination of ATBM and automated lesion detection. During follow-up examinations dermatologists determined “new” or “changed” lesions. Secondary endpoints included the percentage of correctly identified “new” and/or “changed lesions” by ATBM with automated lesion detection. Time requirements and feasibility were additional endpoints. Patients’ acceptance was evaluated by using a validated “trust in medical technology” instrument [16,17]. CRML failing automated lesion detection were further investigated (review of dermoscopy and/or histopathology reports) in patients from the Heidelberg study centre.

A sample of at least 236 patients was considered as sufficient to detect a sensitivity of software-based CRML detection of above 85% with a power of 90% at a level of significance of 5%, taking into account 20% of loss to follow up [18].

2.2. Statistical analysis

All endpoints were analyzed descriptively by tabulation. Depending on variables, means, standard deviations (SD) or percentages were reported. Exact 95% confidence intervals (95%-CI) for binomial proportions were calculated applying the method of Clopper-Pearson. Data analysis was performed with SPSS Version 29 (SPSS, Chicago, IL, U.S.A.).

3. Results

3.1. Patients’ characteristics

In this study 236 patients from 4 sites were included: Argentina (n = 50, 21.2%), Australia (n = 40, 16.9%), Germany (n = 95, 40.3%), Switzerland (n = 51, 21.6%). Mean age (range) was 50.1 years (19–89 years), and data demonstrated near-balanced sex distribution (112 females, 47.5%; 124 males, 52.5%) (Table 1). Most patients had skin type (Fitzpatrick classification) II (47.9%) or III (45.3%). The total body nevus count was > 100 in 132 patients (55.9%), and more than 5 atypical nevi were documented in 82 patients (34.7%). Almost half of the patients had previously been diagnosed with melanoma (n = 112, 47.5%) and 38 patients (16.1%) with non-melanoma skin cancer. Sixty patients stated that melanoma had occurred in their family (25.4%). Hence, a high-risk population for melanoma was included. Almost a third of patients reported previous monitoring with SDD (n = 67, 28.4%) and/or ATBM (n = 38, 16.1%).

3.2. Performance of ATBM with automated lesion detection

A total of 300 examinations were carried out on the 236 patients. All 236 patients received a baseline examination, of which 55 patients (23.3%) were considered to require additional follow-up examinations

Table 1
Characteristics of the 236 patients included in the study.

	Number of patients (n)	Percentage (%)
Gender		
Male	124	52.5%
Female	112	47.5%
Skin type (Fitzpatrick)		
Type 1	14	5.9%
Type 2	113	47.9%
Type 3	107	45.3%
Type 4	2	0.8%
Type 5	0	0%
Type 6	0	0%
Number of nevi		
0-15 nevi	14	5.9%
16-50 nevi	47	19.9%
51-100 nevi	43	18.2%
> 100 nevi	132	55.9%
Number of atypical nevi		
0 nevi	80	33.9%
1 nevus	25	10.6%
2 nevi	25	10.6%
3 nevi	16	6.8%
4 nevi	5	2.1%
5 nevi	3	1.3%
> 5 nevi	82	34.7%
Personal/family history		
Previous melanoma	112	47.5%
Previous non-melanoma skin cancer	38	16.1%
Family history of melanoma	60	25.4%
Previous monitoring		
by sequential digital dermoscopy	67	28.4%
by ATBM	38	16.1%

(n = 64). Most of them received one follow-up examinations (47 patients, 85.5%), whereas 7 patients received two (12.7%) and one patient three follow-up examinations (1.8%). The mean interval between follow-up examinations was 8.6 months (range 3–17 months).

At baseline dermatologists identified 1075 CRMLs. Of these, 999 (92.9%; 95%-CI: 91.2%−94.3%) were also detected by automated lesions detection.

Automated lesion detection correctly identified all CRMLs in approximately 3 of 4 baseline examinations (180 of 236 participants; 76.3%; 95%-CI: 70.5%−81.3%), whereas in 56 participants (23.7%; 95%-CI: 18.8%−29.6%) at least one CRML remained undetected at baseline. In 40 of baseline examinations (16.9%) one, in 14 examinations (5.9%) two, and in two examinations (0.8%) three or more CRML remained undetected.

Altogether, 64 follow-up examinations were performed. Here, dermatologists identified 334 CRMLs, with 323 (96.7%, 95%-CI: 94.2%−98.2%) being detected by ATBM with automated lesions detection.

CRML detected versus undetected at baseline and during follow-up are summarized for the different study centers in Table 2.

Average time requirement [95% CI] for ATBM with automated lesion detection was 14.1 min [12.8–15.5] for baseline examinations and 13.8 min [12.9–14.7] for follow-up examinations.

During follow-up examinations dermatologists found 13 lesions to be new and 24 to be changed (1st follow-up examination (55 patients): 10 new and 18 changed lesions; 2nd follow-up examination (8 patients): 3 new and 6 changed lesions; 3rd follow-up examination (1 patient): no new or changed lesions). All of these new or changed lesions identified by dermatologists were also detected by ATBM with automated lesion detection.

3.3. Subgroup analysis of undetected CRML

In patients from the University Hospital Heidelberg (n = 95) undetected CRML at baseline (n = 48) were investigated in more detail (Table 3, Fig. 1).

The majority (approximately 60%) of these undetected CRML showed lesion-specific features that could be responsible for the failure of automated lesions detection (faint pigmentation (n = 13); lentiginous or large lesions (n = 9); grouped lesions (n = 2); small palmoplantar lesions (n = 2)). All remaining undetected CRML were missed because they did not show on images of ATBM (covered by hair (n = 9), clothes (n = 4); localisation in skin folds or partly invisible due to camera angle (n = 8)). Undetected lesions were mostly localized on trunk (n = 19), followed by face (n = 8), arms (n = 7), head, buttock or lower abdomen (n = 4 each), legs or palmoplantar sites (n = 3 each).

3.4. Histopathology of detected and undetected CRML

In patients examined at the University Hospital Heidelberg (n = 95) histopathology of excised lesions at baseline was evaluated (Table 4). In these 95 patients 306 CRML were detected with automated lesion detection and 49 lesions (16.0%) were excised. Most excised lesions were benign (n = 35, 71.4%), including nevi (n = 29), seborrheic keratoses (n = 4) or collision tumours (n = 2). A smaller percentage of excised lesions was diagnosed as malignant (n = 14, 28.6%) including seven in situ melanomas, five invasive melanomas and two basal cell carcinomas.

Altogether, 48 CRML remained undetected by automated lesion detection at baseline. Out of these, 13 were excised due to suspected malignancy and seven lesions were malignant (two melanomas in situ, three invasive melanomas, two basal cell carcinomas), two were non-melanoma skin cancer precursors, and four lesions were benign (nevus, seborrheic keratosis, other). Figs. 2 and 3 depict representative examples of melanomas detected or undetected by ATBM.

Table 2
CRML detected versus undetected at the different study centers during baseline and follow-up.

Study center	Baseline		Follow-up	
	CRML detected	CRML undetected	CRML detected	CRML undetected
Argentina	274 (98.9%)	3 (1.1%)	148 (100.0%)	0 (0.0%)
Australia	312 (96.3%)	12 (3.7%)	63 (98,4%)	1 (1.6%)
Basel	107 (89.2%)	13 (10.8%)	32 (94,1%)	2 (5.9%)
Heidelberg	306 (86.4%)	48 (13.6%)	80 (90.9%)	8 (9.1%)

Table 3
Characteristics and localization of 48 undetected CRML in a subgroup of 95 patients at baseline examination.

	Number (n)
Characterization of lesions undetected	
Covered by clothing	4
Lesion not fully depicted (e.g. viewing angle, skin folds)	8
Covered by hair	9
Lentiginous or large lesions	9
Localised within grouped lesions	2
Hypopigmented lesions	13
Palmoplantar localisation	2
Unknown	1
Localisation of lesions undetected	
Head	4
Face	8
Trunk	19
Gluteal	4
Arms	7
Legs	3
Palmoplantar	3

3.5. Patients' perspectives

Written questionnaires on acceptance and confidence in the automated detection of lesions were returned from 233 of the patients (Fig. S1). Most patients consented that ATBM examination gave them a feeling of increased safety (45.2% strongly agree, 47.9% agree). They considered the technology trustworthy (35.5% strongly agree, 57.5% agree) and agreed it might improve performance of dermatologists (44.4% strongly agree, 44.4% agree). Most patients disagreed to completely replace dermatologists' examinations (34.4% strongly disagree, 32.0% disagree) and demanded interpretation of results by an expert (54.8% strongly agree, 43.6% agree). The majority of patients accepted longer examination times for ATBM (26.6% strongly agree, 43.6% agree).

4. Discussion

The "two-step algorithm" comprising TBP and SDD supports dermatologists in facilitating melanoma detection [19–21]. In patients at increased risk for melanoma TBP improves identification of in situ and early invasive melanomas [21]. The number needed to biopsy may be reduced up to 3.7-fold [22,23]. Today, TBP is performed increasingly by automated devices providing a 2D or 3D reconstruction of the skin surface. AI algorithms have promising potential to deliver automated image analysis [21]. Here, automated lesion detection and segmentation are relevant steps on the way supporting augmented intelligence. Various skin lesion detection algorithms for whole body images have been evaluated including deep-learning based approaches [24]. Despite all of these technical advances, prospective studies systematically investigating the performance of imaging devices and lesion detection software are scarce. The general feasibility of automated lesion detection by 3D photography was reported in single reports and small

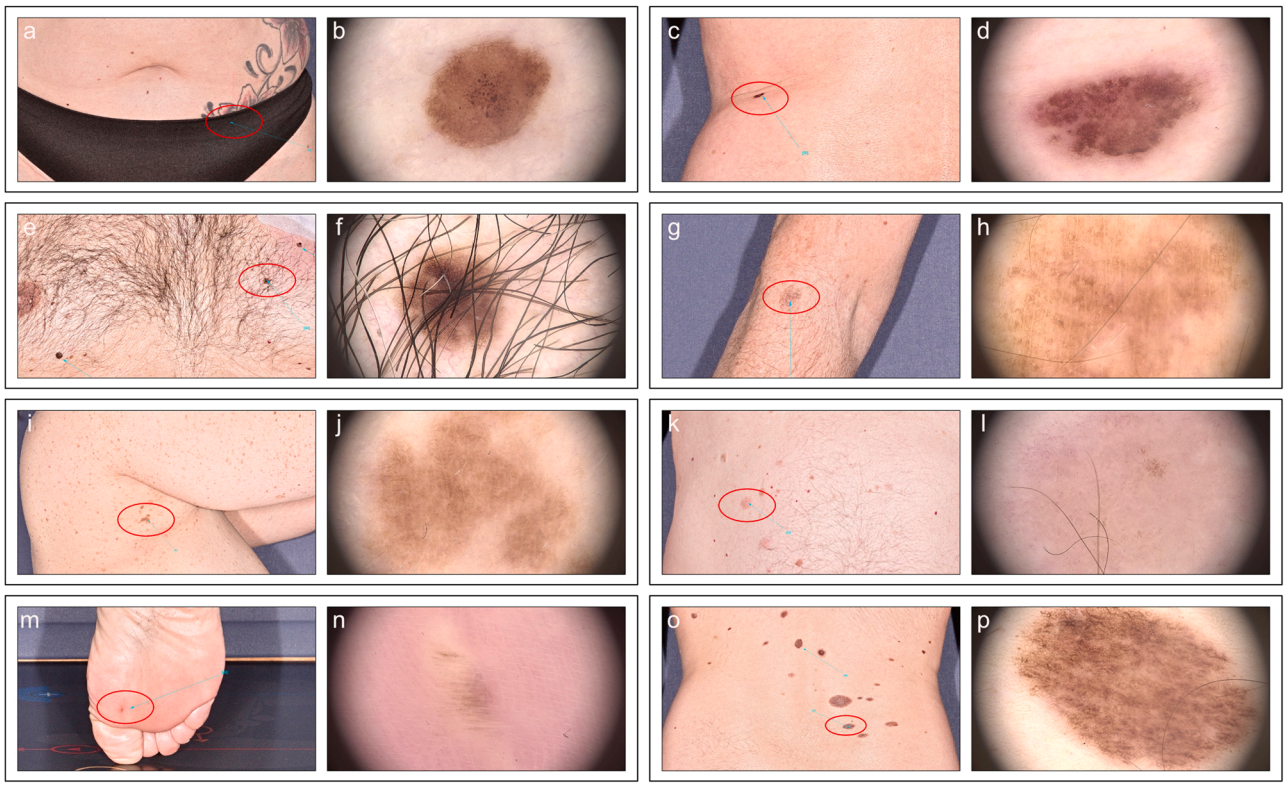


Fig. 1. Representative lesions undetected by the algorithm, including lesions covered by clothing (a, b), partially hidden in skin folds (c, d), covered by hair (e, f), lentiginous lesion on the forearm (g, h), grouped lesion on the lateral thorax (I, j), hypopigmented nevus on the abdomen (k, l), small plantar nevus (m, n) and common nevus on the back (o, p).

Table 4
Histopathology of excised CRML either detected or undetected by ATBM with automated lesion detection in a subgroup of patients (n = 95).

	Number (n)
Detected CRML (n = 306)	
Excised	49
Nevus	29
Collision (Nevus and seborrheic keratosis)	2
Seborrhoic keratosis	4
In situ melanoma	7
Invasive melanoma	5
Basal cell carcinoma	2
Undetected CRML (n = 48)	
Excised	13
Nevus	2
Seborrhoic keratosis	1
Other	1
In situ melanoma	2
Invasive melanoma	3
Basalcellcarcinoma	2
NMSC precursors	2

retrospective studies [25–27]. Prospective randomized controlled studies are currently ongoing [28–30].

We focussed on 2D TBP as 2D photography systems generally require only little physical space within examination rooms and provide image of the total skin surface quite fast, hence they appear more broadly applicable in comparison to 3D systems. We provided data from an international multicentre study accounting for a representative patient spectrum from three continents. Our study population represented a high-risk cohort for melanoma with approximately 50% of the patients reporting one or more previous melanoma(s) and/or > 100 nevi. In the literature, patients at increased risk to develop melanoma were shown to benefit the most from TBP [31].

We found that approximately 93% of baseline and 97% of follow-up CRML were detected by the automated lesion detection software, which provides first evidence regarding the clinical utility of this screening approach. The overall number of undetected CRML at baseline remained modest (76 of 1075, 7.1%). Importantly, undetected lesions were not confined to patients with shared explicit phenotypic traits, e.g. specific skin types or higher level of sun damaged skin. In more than one third of undetected CRML detection failed because lesions were occluded by hair, clothing or skin folds. Most of these cases might be avoided during imaging process. Patients should be encouraged to fully undress and have occluding body hair removed. However, segmentation algorithms need to be improved to avoid CRMLs that are currently not recognised due to lesion-specific characteristics. Some CRML were detected in a specific image only and missed in another view of the same lesion, which additionally underlines that the algorithm demands further improvement.

It has previously been reported, that lesion segmentation is a limiting factor with regard to skin cancer detection in TBP images [27]. Marchetti et al. reported that five out of 44 melanomas were incompletely segmented, while one melanoma was not detected at all [27]. Authors discussed whether segmentation was impaired by training images being limited to benign lesions or rather by insufficient image resolution [27]. Of note, any CRML identified by dermatologists carries an increased risk of being malignant. Therefore, it was not surprising, that of 13 CRML that were excised by clinicians but left undetected by the algorithm 7 were found to be malignant (data of Heidelberg center). Clinicians need to be aware of this limitation to not solely rely on the lesion detection software.

It seems promising, that the limitations unmasked by our prospective study may subsequently be addressed by selective measures (e.g. allowing for detection of larger lesions, increased training for detection of faintly pigmented lesions).

In our study all lesions defined as “new” or “changed” during follow-



Fig. 2. Detected CRML at baseline examinations that were diagnosed as melanoma by histopathology. Lesions included in situ melanomas on the shoulder (a, b) and lower abdomen (c, d) as well as nodular melanomas on the back (tumor thickness 3.2 mm, e, f) and abdomen (tumor thickness 2.2 mm, g, h).

up examinations were detected by the automated algorithm. It seems especially reassuring that none of these lesions with an implicit high risk of malignancy was missed.

Nevertheless, considering the overall detection rate and especially the relevant number of malignant lesions undetected, the in-person examination by an experienced clinician may currently not be replaced by automated screening.

Feasibility, time requirements, and patient acceptance of ATBM with automated lesion detection were additional endpoints. We found that patients of all ages up to 89 years were motivated and managed to participate in the study. Moreover, the average time of less than 15 min for ATBM and automated lesion detection allows for an effective implementation into routine clinical care. Yet, routine skin cancer screenings by dermatologists may demand less time and may currently not be fully replaced by automated screening. Our evaluation of patient questionnaires indicated favourable attitudes towards automated total body scans, which is in line with previous studies [32–34]. According to a study from Switzerland the vast majority of high-risk patients for developing melanoma preferred a combination of a total body imaging plus a clinical examination by a dermatologist. Obviously, study participants put high confidence in TBP despite a number of identified limitations such as data safety concerns regarding storage of digital images [35]. After all, most patients of our study still favoured the additional opinion of an expert clinician indicating that the largest benefits for more accurate diagnoses may be expected from a human-AI collaboration [32,36].

Our study reveals several limitations. Most patients were fair skinned with a predominance of skin types II-III and only few patients with skin type IV. The majority of patients included were at an increased risk for melanoma. Hence, it is difficult to transfer results to the general population [37]. Total body mapping has especially proven useful for high-risk patients and results in a general patient population with a lower melanoma prevalence may be different. Finally, our more detailed analysis of undetected CRML included only 95 patients. Regarding future studies, a closer investigation of reasons for undetected CRML seems advisable. Due to the design of our prospective study, it was not possible to answer whether ATBM could also detect malignant lesions that are overlooked by experienced dermatologists.

In conclusion, we herein present a first prospective study investigating ATBM with automated lesions detection in 2D TBP to validate this first step towards implementation of an AI-assisted, time-efficient support for dermatologists to detect relevant lesions suspected of being melanoma. Most clinically relevant lesions were correctly identified and segmented by the detection software. The main reasons for CRML left undetected seem amendable by avoiding occlusion of lesions during imaging and by further improving lesion detection and segmentation

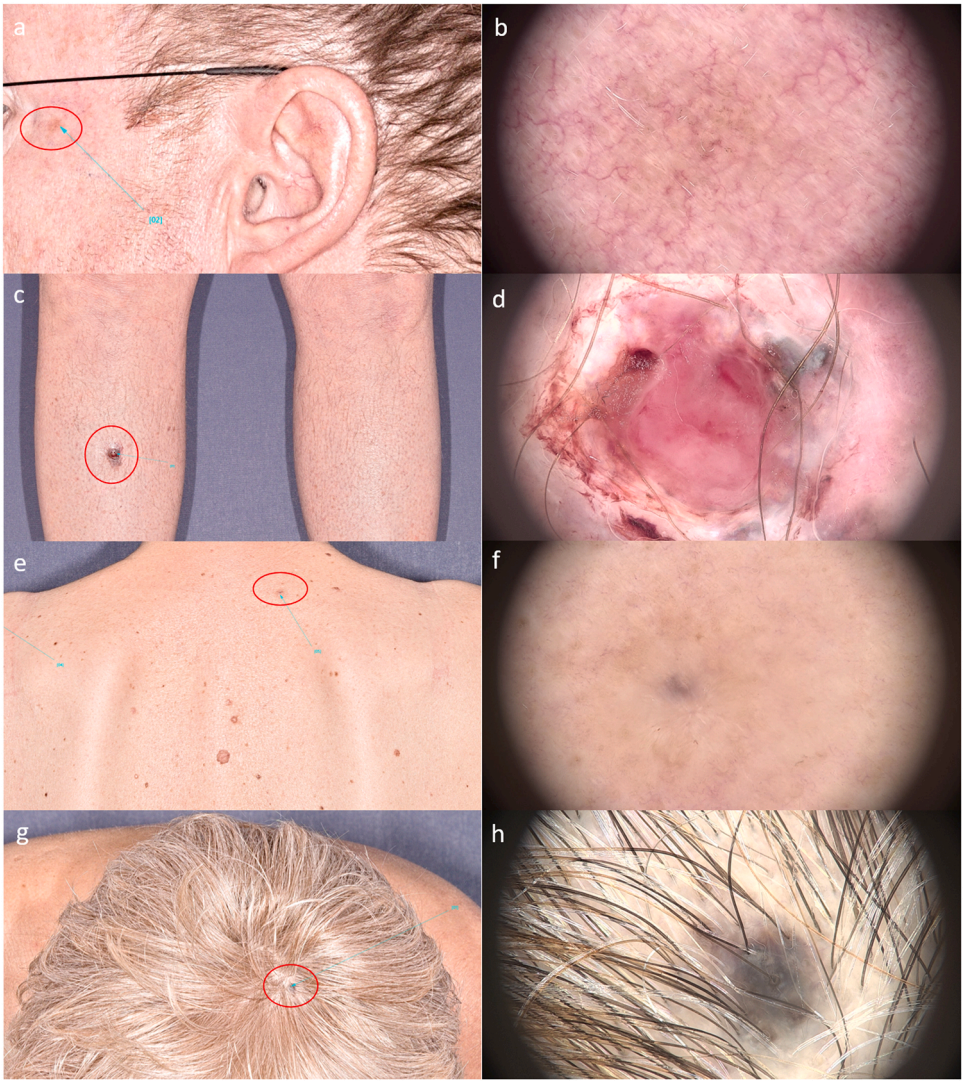


Fig. 3. Undetected CRML that were diagnosed as melanoma by histopathology. Lesions included a lentigo maligna on the lateral face (a, b), invasive melanomas on the lower leg tumor (thickness 2.4 mm, c, d) and back (tumor thickness 1.4 mm, e, f) and a melanoma metastasis on the head covered by hair (g, h).

algorithms. These findings are a key prerequisite before application of deep learning-based algorithms for the diagnostic classification of lesions.

Ethics

Reviewed and approved by the ethic committee of the medical faculty of the University of Heidelberg (Approval number S-836/2020).

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CRediT authorship contribution statement

Laura V. Maul: Writing – review & editing, Investigation, Data curation. **Alexander Enk:** Writing – review & editing. **Ferdinand Toberer:** Writing – review & editing, Methodology. **Katharina S. Kommoss:** Writing – review & editing. **Julia Katharina Winkler:** Writing – original draft, Formal analysis, Data curation. **Holger A. Haenssle:** Writing – original draft, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Albert Rosenberger:** Writing – review & editing, Formal analysis. **Gabriel Salerni:** Writing – review & editing, Investigation, Data curation, Conceptualization. **Jeremy Hudson:** Writing – review & editing, Investigation, Conceptualization. **Alexander A. Navarini:** Writing – review & editing, Data curation.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: HA Haenssle received honoraria and/or travel expenses from companies involved in the development of devices for skin cancer screening: Scibase AB, FotoFinder Systems GmbH, Heine Optotechnik GmbH, Magnosco GmbH.

JK Winkler received honoraria and/or travel expenses from BMS, Fotofinder Systems GmBH, LaRoche Posay, Almirall, Biotest, Amgen, BMS, Leo Pharma, MSD, Philochem and Roche.

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The other authors state no conflict of interest related to the study.

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Access to data and data analysis

HA Haenssle and JK Winkler had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2024.114026.

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