The nomela® test in secondary care: a novel screening photographic image analysis system to discriminate benign pigmented skin lesions from melanoma skin cancers

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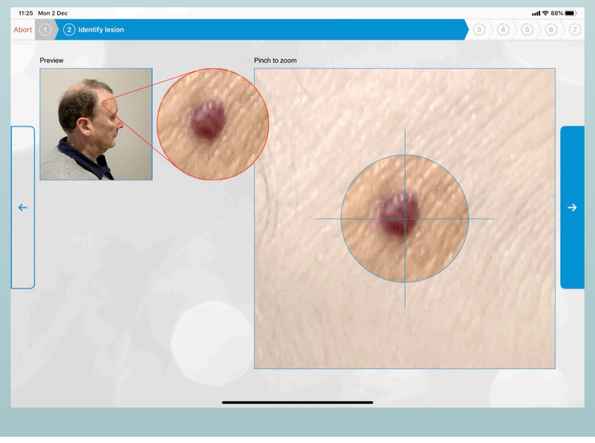
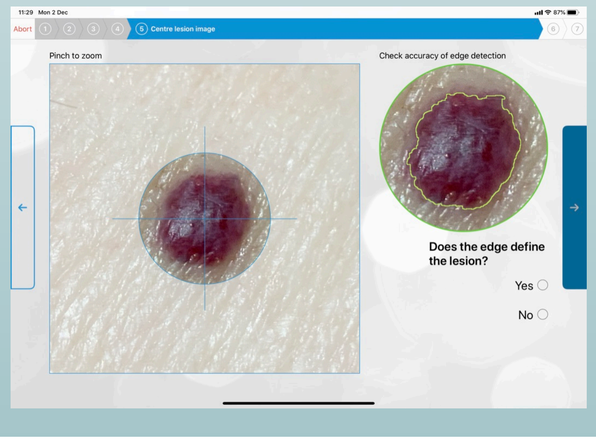
The nomela® Test

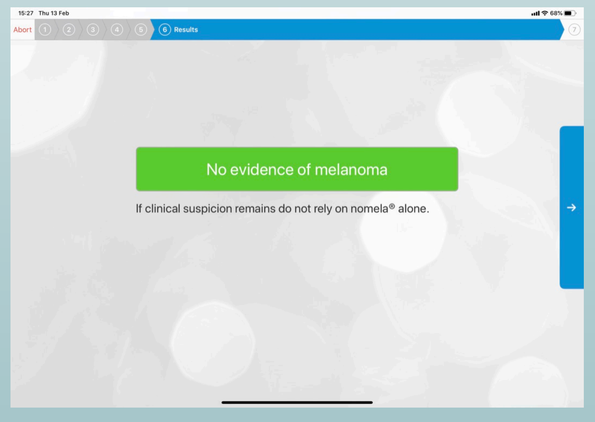
The nomela® test, a dermatological differential diagnostic aid Class I Device (Medical Devices Regulations 2002:19) for professional medical use, is in development to assist exclusion of cutaneous melanoma in suspicious lesions. The nomela® device is a single-application iOS tablet (in this study the iPad Air 2) loaded under licence with the nomela® test software. All other functions are disabled except those needed for the nomela® test namely image capture and analysis.

The perimeter of a skin lesion is recognised by nomela® prior to image analysis. Readings are made for certain defined characteristics of the image, some not apparent to the naked eye, using five proprietary signal processing measurements ("texture", "asymmetry", "colour", "average gradient" and "edge irregularity") from which scores are obtained using non-scalar metrics. Signal processing provides consistent performance.
For a particular lesion, the values of the five measurements are compared to the respective ranges in sequence and if one measurement is found to fall outside then the result is "not at risk" of melanoma. When applied to suspicious pigmented naevi the test provides a binary result which is shown as either "No evidence of melanoma" or "Melanoma not excluded".

nomela® is not suitable for lesions which are: pigmented moles smaller than 5mm diameter; moles obscured by hair, tattoos or scars; moles in the mouth, eyelid, nailbed, genital and perianal areas; ulcerated lesions; non-pigmented moles which may be the amelanotic form of melanoma or lesions likely to be basal cell carcinoma, squamous cell carcinoma, Merkel cell tumours, lymphoma or metastatic carcinoma.







The Study - the objective was to acquire images of lesions with known diagnosis and further define the ranges for the five measurements.

Prospective part
1200 participants recruited (1382 eligible lesions) in two blocks.
Gender ratio: 60.2% female, 39.8% male.
Skin type distribution: 1=11.2%, 2=25.6%, 3=18.9%, 4=35.1%, 5= 8.9%, 6=0.1% and missing 0.3% (no participants with African/African-Caribbean skin type).

First block: used to improve technical aspects of image capture using nomela® without altering the underlying algorithm and to establish the usefulness of the five proprietary signal processing measurements.

Second block: 795 participants with 911 eligible lesions (less 196 image exclusions: images unsuitable [95], unmatched images [19], incomplete measurements [35], unavailable clinical diagnosis [48], unreturned biopsy results [6]), providing 715 lesions suitable for final analysis [547 (76.5%) benign, 91 (12.7%) dysplasia, 25 (3.5%) melanoma, 52 (7.5%) non-melanoma malignancy].

Using the five signal processing parameters to analyse these lesions with three different range-sets (D1, D2, D3):

D1 (placed all 25 melanoma in the "at risk" group) assigned 437 lesions (61.1%) to the "not at risk" category of which 346 [79.2%] were benign, 59 [13.5%] dysplasia and 32 [7.3%] other malignancies; of the 278 lesions (38.9% of the total) assigned to the "at risk" group 201 were benign.

D2 (placed all malignancies in the "at risk" group) assigned 171 lesions (23.9%) to the "not at risk" category of which 140 [81.9%] were benign and 31 [18.1%] dysplasia; of the 559 lesions (78.1% of the total) assigned to the "at risk" group 420 were benign.

D3 (placed all melanoma, other malignancies and most dysplasia in the "at risk" group) assigned 129 lesions (18.3%) to the "not at risk" category of which 113 [87.6%] were benign and 16 [12.4%] dysplasia.

Retrospective part
99 (of which superficial spreading melanoma [66] and melanoma-in-situ [22], other melanoma [11]) confirmed malignant melanoma lesion images (1 participant with two distinct melanomas) were available.

Combined data-set
Automatic cropping and edge detection, using images from both parts of the study, were employed to filter out those with poor quality (8 melanoma and 123 non-melanoma) so that for the final analysis 116 melanoma and 424 non-melanoma images were analysed.

The 'auto-crop' facility used with enhanced edge detection demonstrated that nomela® is capable of differentiating up to 53% (table below) of the non-melanoma images to 'no evidence of melanoma'.

Distribution of allocation in prospective study second block (total lesions allocated =715)

	Perfect		D1		D2		D3	
	n	%	*n*	%	*n*	%	*n*	%
"At risk"	168	23.4	278	38.9	544	76.1	586	82.0
Correctly assigned	168	100.0	77	27.7	137	25.2	152	25.9
Mis-assigned	0	0.0	201#	72.3#	407#	74.8#	434#	74.1#
"Not at risk"	547	76.5	437	61.1	171	23.9	129	18.0
Correctly assigned	547	100.0	346	79.2	140	81.9	113	87.6
Mis-assigned	0	0.0	91**	20.8**	31*	18.1*	16*	12.4*

**dysplasia (59;13.5%) and other malignancies (32;7.3%) *dysplasia #benign

Conclusion

Ranges were defined in the nomela® test to exclude all melanoma (i.e. setting for 100% sensitivity for melanoma) with the result that 53% of all non-melanoma lesions may be identified as "no evidence of melanoma".

Re-evaluation New Edge Irregularity (n= 116 Melanoma, 424 Non-Melanoma)

Measurement ranges for melanoma set at 100% sensitivity	Minimum (values without units)	Maximum (values without units)	Lesions outside of range (individual measurement)	Performance of individual measurement	Lesions outside of range (cumulative)	Cumulative performance
Texture	0.3841	0.9000	19	4%	19	4%
Asymmetry	0.0000	0.0800	141	33%	155	37%
Colour	0.1900	1.0000	6	1%	156	37%
Average Gradient	3.6500	18.0000	77	18%	196	46%
Edge Irregularity	0.0000	0.0073	166	39%	224	53%

Overall=53%

Research Ethics

Approval was obtained from Cambridge South and from West of Scotland 5.

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Conflict of interest disclosures

Dr Peter Freedman is Medical Director, Mr Bruce Murray is Technical Director, Mr Ross Milligan is Head of Medical Illustration, and Mr Nick Ager is Head of I.T, all of Moletest (Scotland) Ltd.

Further information

British Association of Dermatologists 100th Annual Meeting (Virtual): Submission number 288
Further information on nomela® can be obtained from ***www.nomela.com***

nomela
Melanoma risk-assessment technology