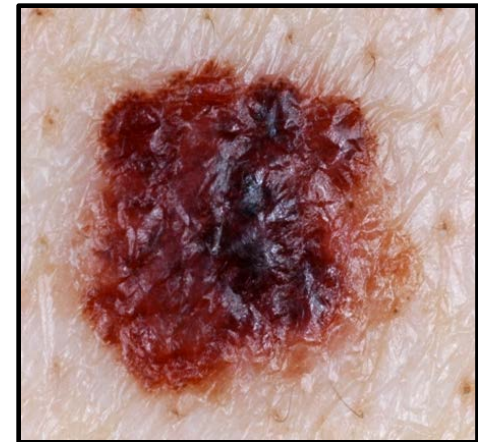
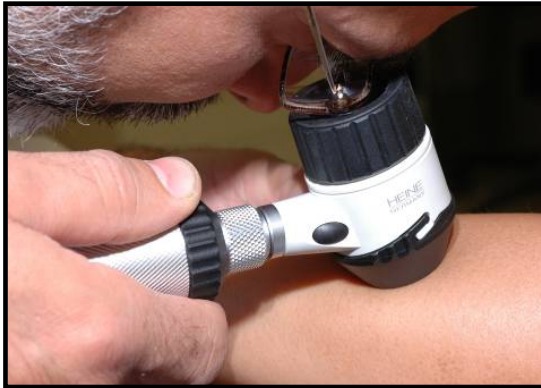


Technology can augment melanoma screening performed with naked-eye examination alone



Michael A. Marchetti, MD

Assistant Attending, Dermatology Service

Memorial Sloan Kettering Cancer Center

New York, NY

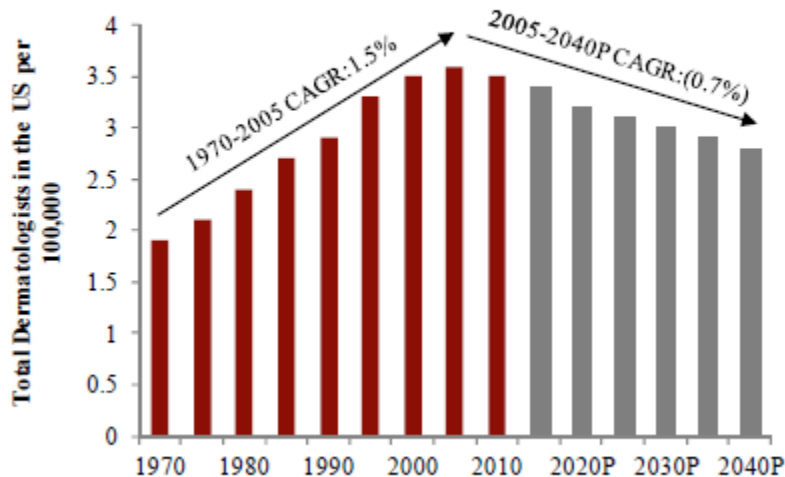
marchetm@mskcc.org

I have no relevant financial disclosures

Consider: (a) dermatologists cannot screen alone, and
 (b) PPV has been low in screening programs

U.S. Dermatologists per 100,000 People

For the Years Ended and Ending December 31, 1970 -2040P

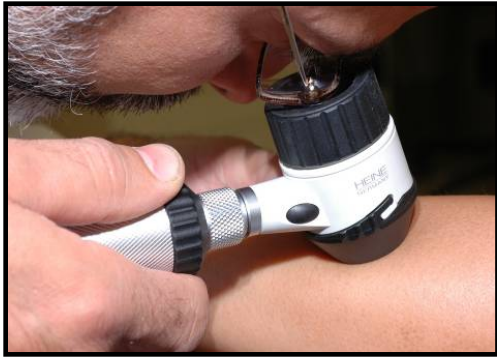


Source: US Census Bureau & AMA.

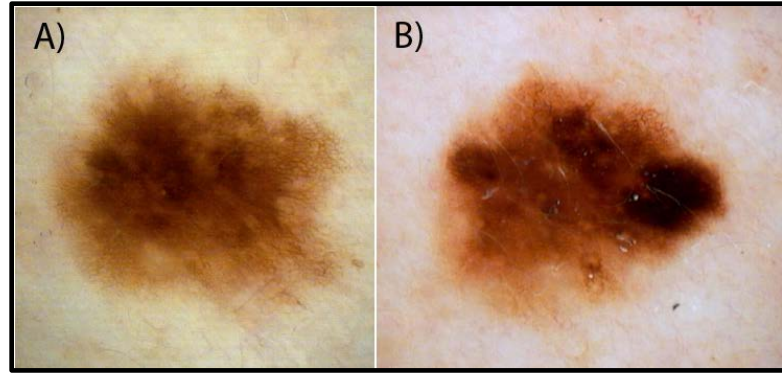
Table 2. Malignant Melanoma (MM) Findings

Sex and Age, y	Yield-S, 1 MM per X Screenees ^a	Yield-E, 1 MM per X Excisions ^b
Women		
20-34	1/1027	1/41
35-49	1/732	1/30
50-64	1/644	1/24
≥65	1/567	1/22
Subtotal	1/714	1/28
Men		
20-34	1/670	1/52
35-49	1/1048	1/55
50-64	1/414	1/22
≥65	1/284	1/20
Subtotal	1/453	1/28
Total	1/620	1/28

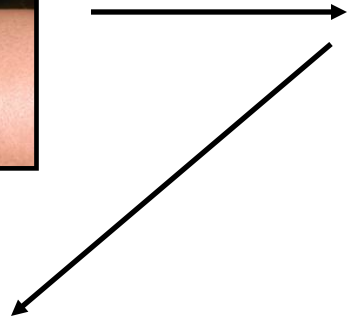
Waldmann et al, JAMA Dermatology, 2012



Dermoscopy



Sequential dermoscopy imaging



Total body photography comparison



Emerging

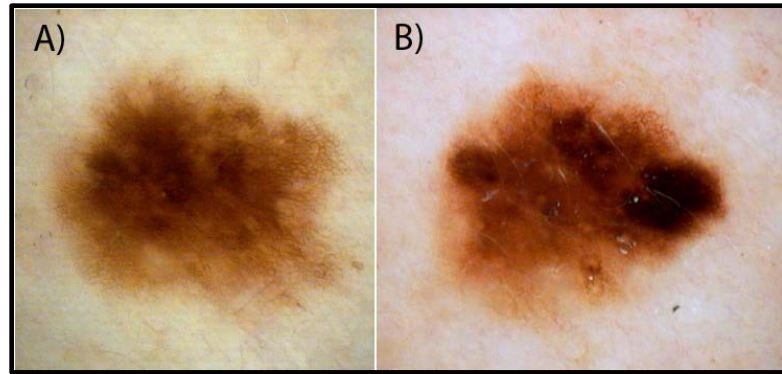


Overdiagnosis





Dermoscopy



Sequential dermoscopy imaging

Total body photography comparison

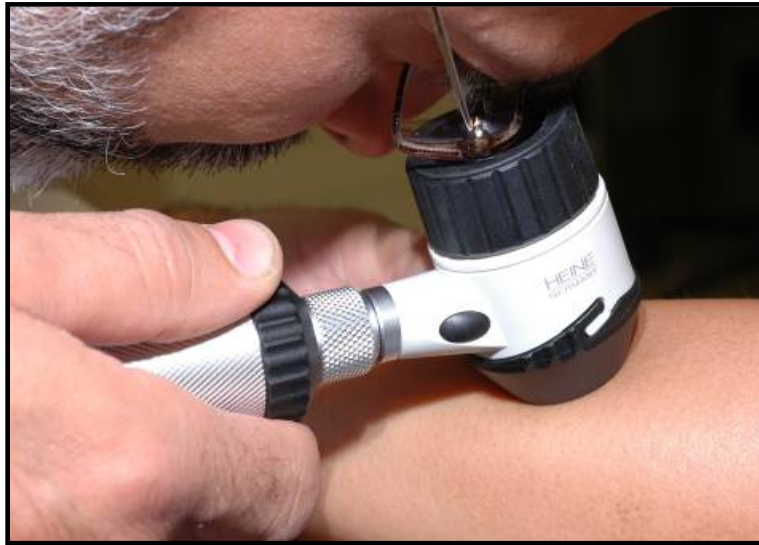


Emerging



Overdiagnosis

A dermatoscope is a handheld device that permits visualization of subsurface features in skin lesions



Contact



Non-contact

Use of dermoscopy improves diagnostic accuracy for melanoma over naked-eye examination alone

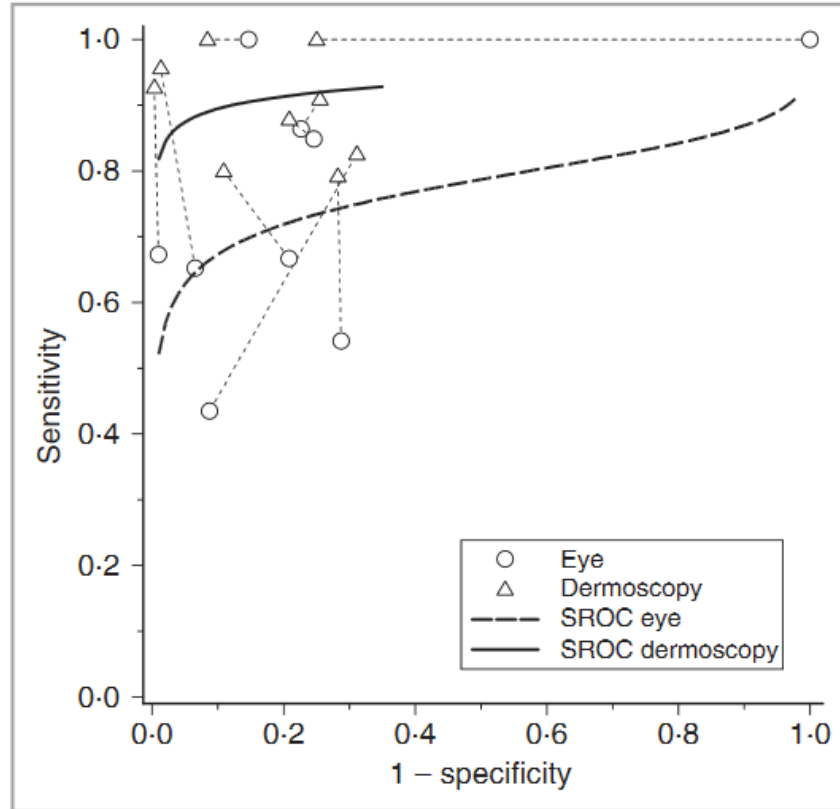
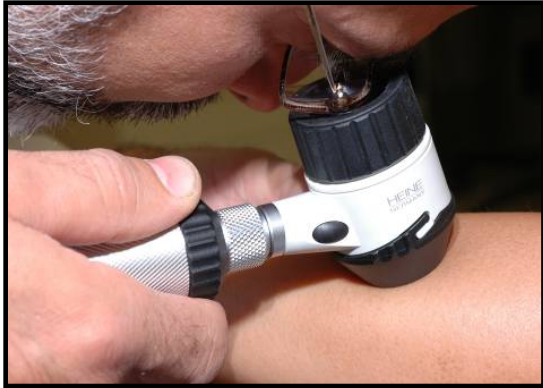


Fig 2. Plot of sensitivity against 1 - specificity for each study and each test with the summary receiver operator curve (SROC) for each test superimposed. The two estimates for each study are joined by a line.

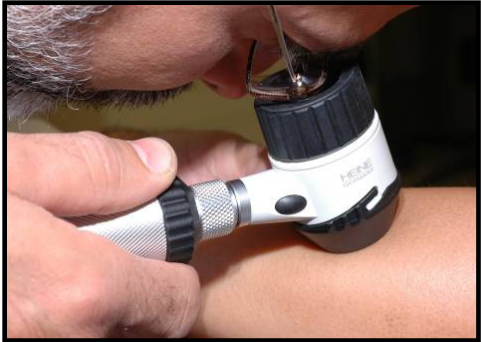
Use of dermoscopy in examining pigmented skin lesions is recommended by national guidelines (grade A, level 1)

SYSTEMATIC REVIEW

BJD
British Journal of Dermatology

Clinical practice guidelines for identification, screening and follow-up of individuals at high risk of primary cutaneous melanoma: a systematic review*

C.G. Watts,¹ M. Dieng,¹ R.L. Morton,^{2,3} G.J. Mann,⁴ S.W. Menzies⁵ and A.E. Cust¹



Item being described	Oxford level of evidence ³	Summary of guideline recommendations
Screening management	1–2	Training and utilization of dermoscopy is recommended for clinicians routinely examining pigmented skin lesions

³Oxford levels of evidence: 1–2, high level of evidence; 3–4, lower levels of evidence; 5, consensus-based decisions (lowest level of evidence).

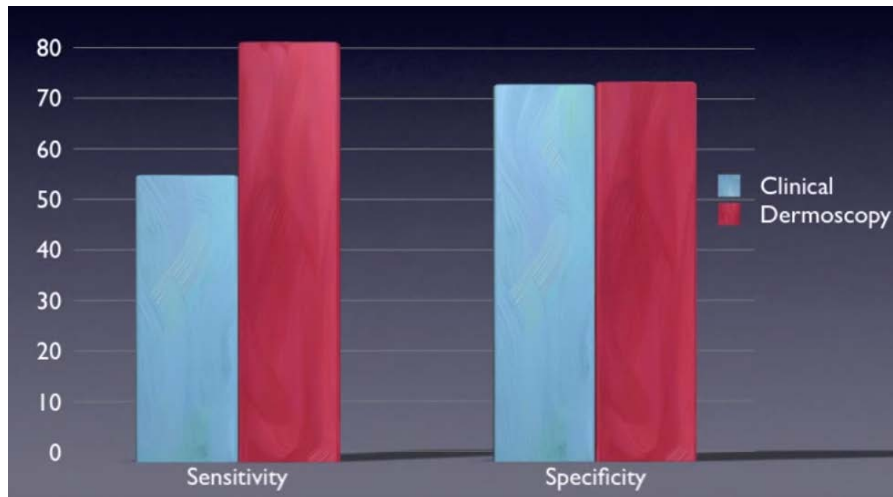
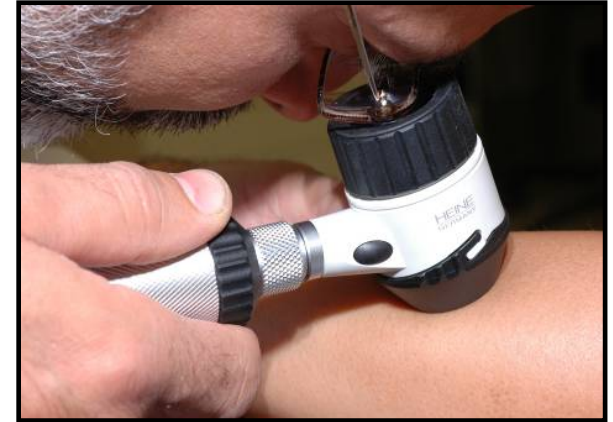
Dermoscopy improves evaluation of pigmented skin lesions in the primary care setting

VOLUME 24 · NUMBER 12 · APRIL 20 2006

JOURNAL OF CLINICAL ONCOLOGY

Dermoscopy Improves Accuracy of Primary Care Physicians to Triage Lesions Suggestive of Skin Cancer

Giuseppe Argenziano, Susana Puig, Iris Zalaudek, Francesco Sera, Rosamaria Corona, Mercè Alsina, Filomena Barbato, Cristina Carrera, Gerardo Ferrara, Antonio Guilabert, Daniela Massi, Juan A. Moreno-Romero, Carlos Muñoz-Santos, Gianluca Petrillo, Sonia Segura, H. Peter Soyer, Renato Zanchini, and Josep Malvehy



Improve sensitivity:
54.1% → 79.2% (p=0.002)

No change in specificity:
71.3% → 71.8% (p=0.915)

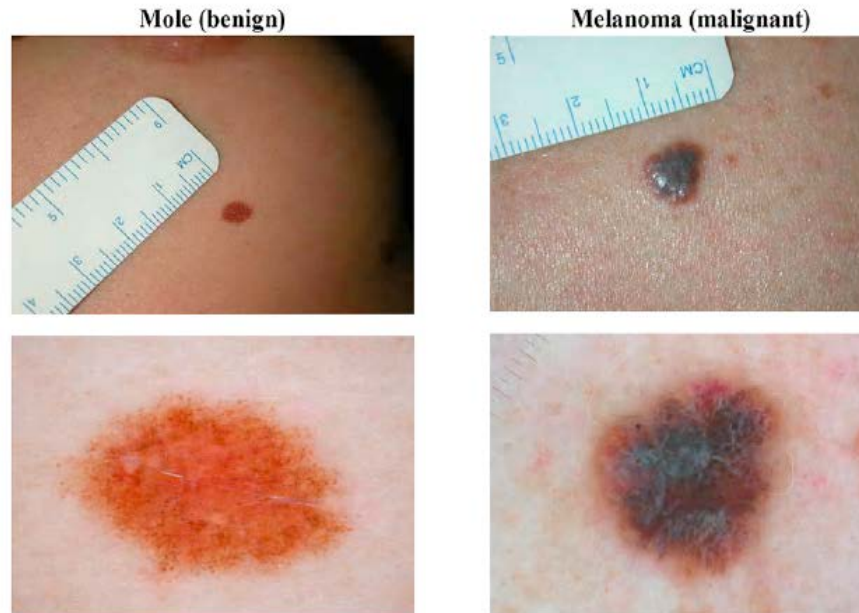
25% better triage overall
reference standard: dermatologist

Simplified dermoscopic algorithms help laypersons recognize melanoma

A **mole** is a brown coloured spot on the skin composed of normal melanocytes (pigment producing cells). Moles tend to be **symmetrical** and uniform in **colour**.

A **melanoma** is a malignant cancer of melanocytes, wherein cells grow independently of the body's control mechanisms. Melanomas tend to be **asymmetrical** and have multiple colours within the lesion. Dark black or blue-grey colour is very suggestive of melanoma.

This is the basis for the **AC Rule** (Asymmetry, Colour variation).
Unfortunately, not all melanomas follow the rules!



Lesions which are suspicious of a melanoma should be shown **immediately** to a doctor.
NB. It must be remembered that in nature, nothing is perfectly symmetrical and regular.

Fig 1. The AC Rule for melanoma educational brochure.

Patients can self-detect melanoma with dermoscopy

Dermoscopy in Skin Self-examination

A Useful Tool for Select Patients

*Jacqueline M. Goulart, BA; Josep Malvehy, MD; Susana Puig, MD;
George Martin, MD; Ashfaq A. Marghoob, MD*

June 2015 saw introduction of 1st generation low-cost dermatoscopes marketed specifically for laypersons



MoleScope™ by MetaOptima is designed to help you track and monitor your moles over time to ensure they are receiving the attention they need. [\[Learn More\]](#)

* Please note that MoleScope is not a diagnostic or a therapeutic device. It is intended for imaging, archiving and communication only.



\$120



\$80

June 2015 saw introduction of 1st generation low-cost dermatoscopes marketed specifically for laypersons



 **MoleScope™**

MoleScope™ by MetaOptima is designed to help you track and monitor your moles over time to ensure they are receiving the attention they need. [\[Learn More\]](#)

* Please note that MoleScope is not a diagnostic or a therapeutic device. It is intended for imaging, archiving and communication only.



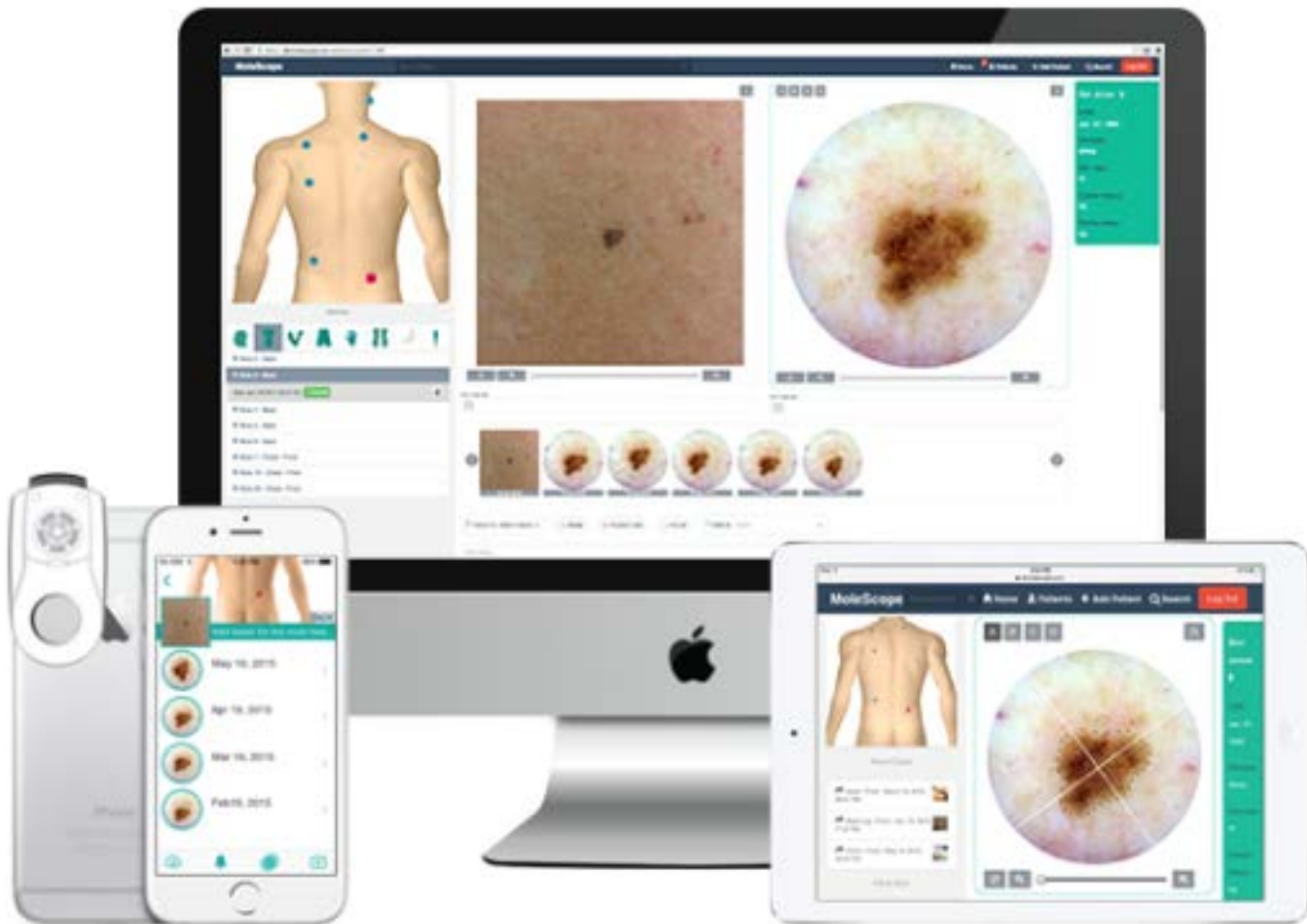
\$120



 **dermLite®**

\$80

MoleScope™ software permits tagging to 3D body, sequential imaging over time for change, and simplified dermoscopy algorithm teaching



Mobile, patient-performed teledermoscopy studies are underway

EPIDEMIOLOGY AND HEALTH SERVICES RESEARCH

BJD
British Journal of Dermatology

A pilot trial of mobile, patient-performed teledermoscopy*

M.N. Manahan,^{1,2} H.P. Soyer,³ L.J. Loescher,⁴ C. Horsham,¹ D. Vagenas,⁵ D.C. Whiteman,^{1,6} C.M. Olsen⁶ and M. Janda¹

Research Letter | June 2014

Lesion Selection by Melanoma High-Risk Consumers During Skin Self-examination Using Mobile Teledermoscopy **FREE**

Monika Janda, PhD¹; Lois J. Loescher, PhD²; Parastoo Banan, MD³; Caitlin Horsham, BHlthSc¹; H. Peter Soyer, MD³

Research Letters | February 2013

Enhanced Skin Self-examination: A Novel Approach to Skin Cancer Monitoring and Follow-up **FREE**

Monika Janda, PhD; Lois J. Loescher, PhD; H. Peter Soyer, MD, FACD

July 2014 – 39 “apps” for melanoma detection

Table 1 Properties of smartphone applications for melanoma detection by nonspecialist users including previously unaffected individuals, patients previously diagnosed with skin cancer, and generalist clinicians

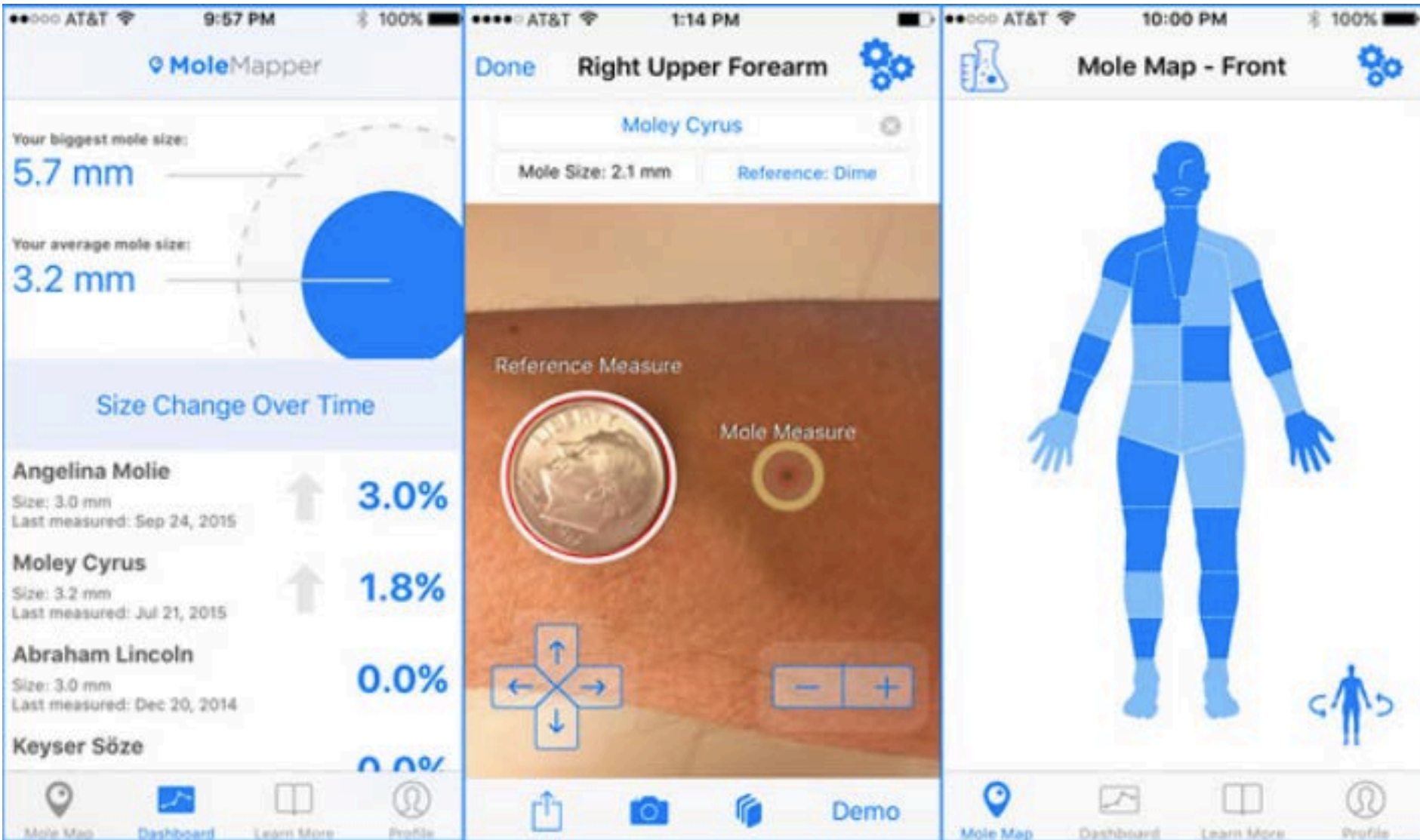
Name	Information and/or education			Cataloging/classifying			
	Melanoma/skin cancer	UVR/sun exposure advice	Skin self-examination	Risk factor assessment	Image analysis ^a	Dermatologists review	Monitoring/tracking
1 ABCDEs of melanoma	•		•				
2 Dermatology Planet	•						
3 DermLink.md						•	
4 Doctor Mole – Skin Cancer App ^b	•		•	•	•		•
5 Embarrassing Bodies – My MoleChecker ^b	•		•		•		•
6 Embarrassing Bodies – My SelfChecker	•		•				•
7 FotoSkin	•	•	•		•		•
8 iDoc24 – Ask the dermatologist today!	•					•	
9 iSkin				•			
10 LoveMySkin – Mole map for skin cancer prevention	•		•				•
11 Melanoma (ABCD rule)	•		•				
12 Melanoma Visual Risk Calculator ^c				•	•		
13 Melanoma Watch ^b	•		•		•		
14 Mole Check App						•	
15 Mole Checker (by Strotka) ^d	•		•		•		
16 Mole Checker (by Harry Arden)	•		•		•		
17 Mole Detective ^b					•		•
18 Mole Monitor ^b					•		•
19 MoleQuest						•	
20 MoleTrac							•
21 Mollie's Fund	•	•	•				
22 nevus	•	•					•
23 OnlineDermClinic						•	
24 Skin Analytics							•
25 Skin Cancer	•						
26 Skin Cancer Information	•						
27 Skin Doctor ^b					•		•
28 Skin Mole Analysis ^c	•		•		•	•	
29 Skin of Mine ^c					•	•	•
30 Skin Prevention – Photo Body Map for Melanoma and Skin Cancer Early Detection ^c					•		•
31 Skin Scanner ^c					•	•	•
32 SkinTagger	•						•
33 Skin Vision ^b	•	•			•		
34 SkinXM ^c					•		•
35 SpotCheck 1 ^c	•		•			•	
36 SpotMole ^c					•		
37 Track-A-Mole	•		•				•
38 UMSkinCheck ^c	•	•	•	•	•		•
39 YourSkinDiary ^c		•			•		•
Total	21	6	15	4	18	9	19

A B C D E F G



- a. Skin cancer education**
- b. UVR exposure education**
- c. SSE education**
- d. Risk factor assessment**
- e. Image analysis**
- f. Dermatologist review**
- g. Monitoring/tracking**

Apple – OHSU recently made a splash



WIKI WORLD®

by Greg Williams

HELICOPTER PARENT

is a term for a person who pays extremely close attention

to his or her child or children, particularly at educational institutions. They are so named because, like a helicopter, they hover closely, rarely out of reach — whether their children need them or not.



1,000 moles are removed for every melanoma in individuals ≤ 19 years in US, 2009-2013

RESEARCH LETTER

Biopsies of Nevi in Children and Adolescents in the United States, 2009 Through 2013

We estimated that 2 007 423 biopsies of nevi occurred in individuals 19 years or younger, along with 1940 melanomas and an overall NNB of 1035 during 2009 through 2013 in the United States, on the basis of HIRD and 2010 US Census data.



Susan A. Oliveria, ScD, MPH
Nandini Selvam, PhD, MPH
Darius Mehregan, MD
Michael A. Marchetti, MD
Hozefa A. Divan, PhD
Bahar Dasgeb, MD
Allan C. Halpern, MD, MS

“Apps” for melanoma detection – we aren’t there yet

Smartphone diagnosis of skin cancer: there’s not yet an app for that

A. FINNANE¹
H.P. SOYER^{1,2}

DOI: 10.1111/bjd.13842

Considering the majority of melanomas are found by patients or their partners,³ any technology that can improve the ability of the general population to identify suspicious or changing lesions early could have enormous benefits. However, until these apps have been rigorously tested and found to have high sensitivity and specificity, it remains inappropriate to support their use. It is possible that such apps could contribute to dangerous, false reassurance in patients and/or increases in unnecessary excisions.



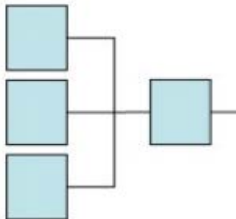
**“Screening” is not just the physician skin exam,
it should also empower population at large**



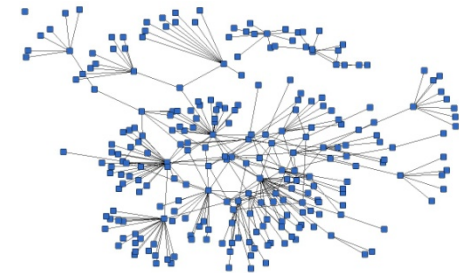
Traditional: physician-directed care



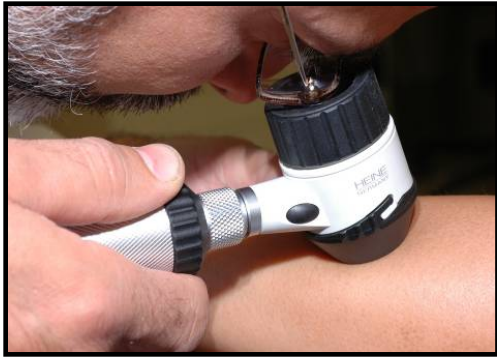
Today/future: patient-directed care



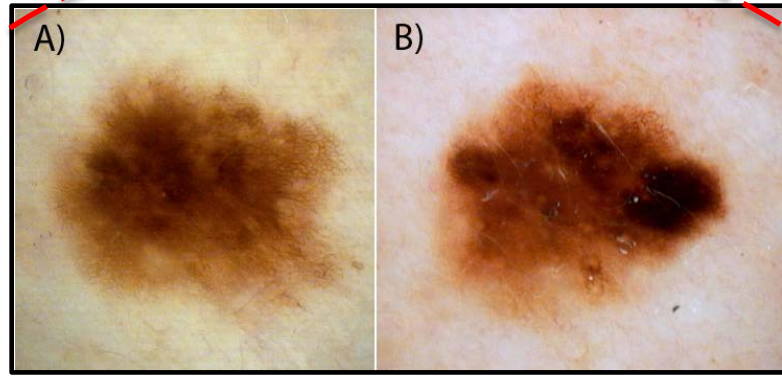
Screeener is bottleneck



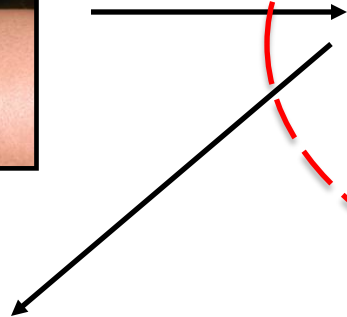
Integrated network



Dermoscopy



Sequential dermoscopy imaging



Total body photography comparison



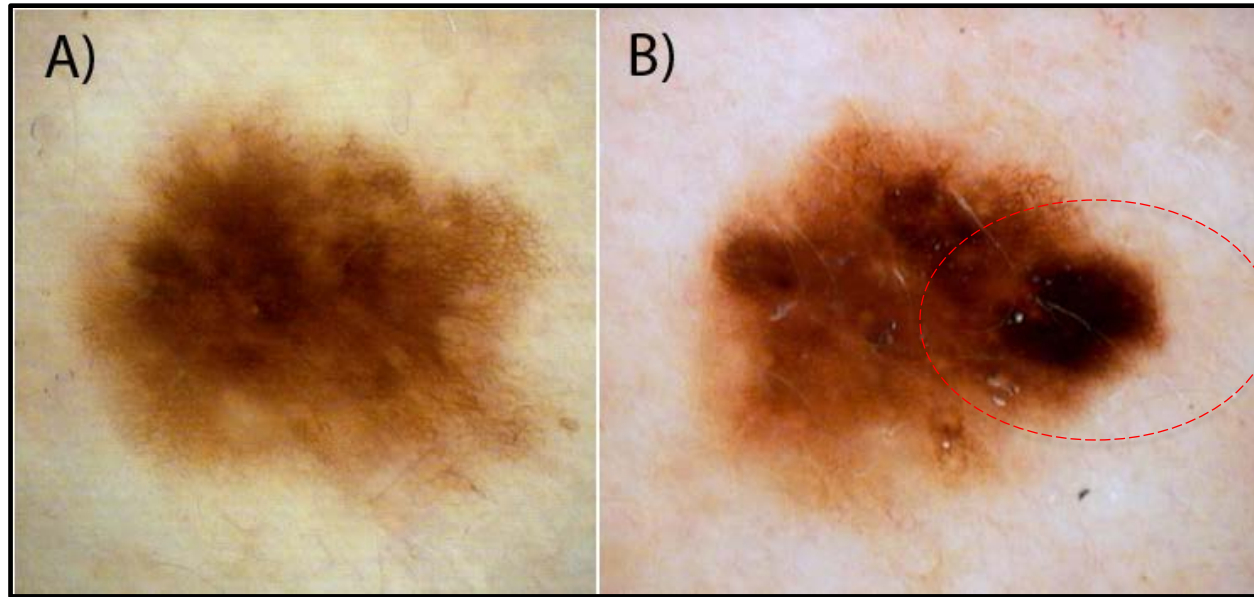
Emerging



Overdiagnosis



Sequential dermoscopy imaging (SDI) involves repeating dermoscopy images* over time to detect change

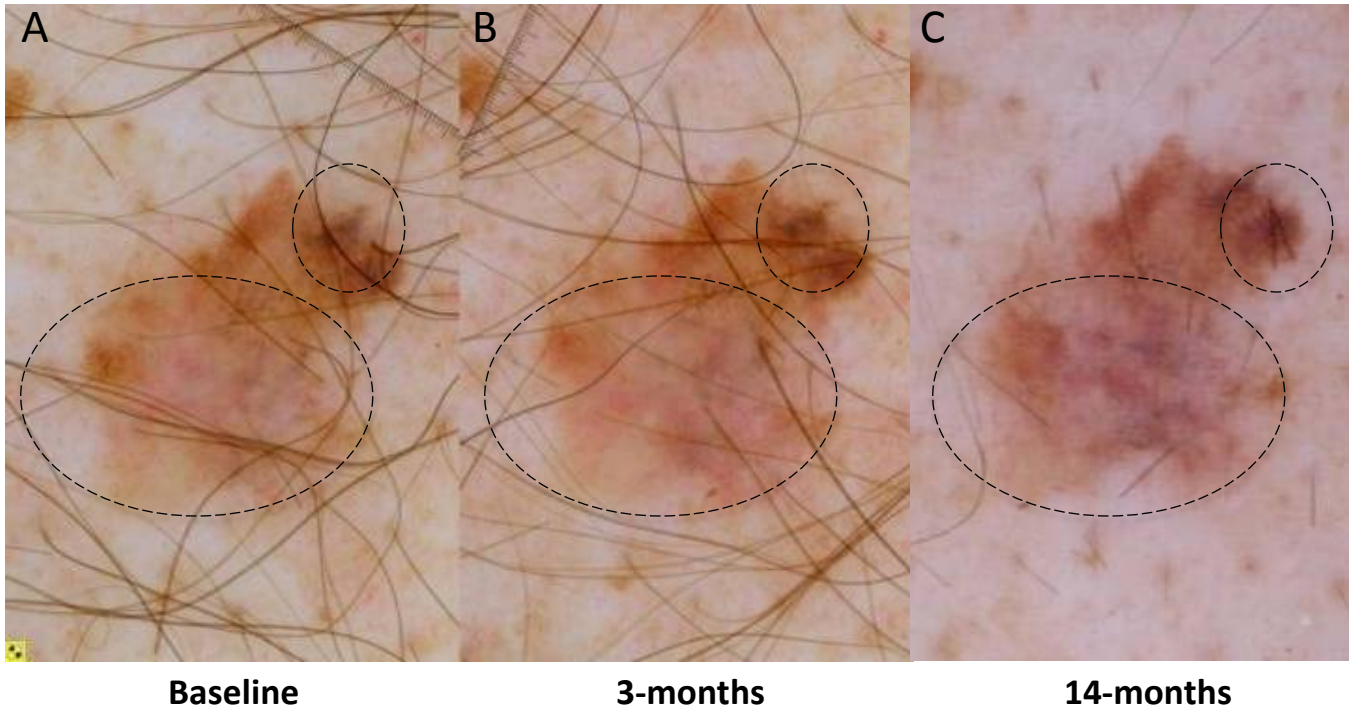


Baseline

3-months later

***Must examine side-by-side on monitor**

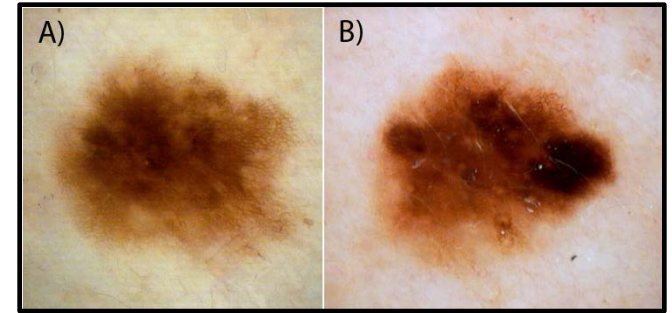
SDI can detect melanomas with subtle changes



SDI helps detection of so-called “featureless” melanomas

Results from an Observational Trial: Digital Epiluminescence Microscopy Follow-Up of Atypical Nevi Increases the Sensitivity and the Chance of Success of Conventional Dermoscopy in Detecting Melanoma

Holger A. Haenssle¹, Ullrich Krueger¹, Claudia Vente¹, Kai-Martin Thoms¹, Hans P. Bertsch¹, Markus Zutt¹, Albert Rosenberger², Christine Neumann¹ and Steffen Emmert¹



530 patients, prospective, median f/u ~3 years

7,000 atypical nevi

18/53 “follow-up” melanomas detected exclusively with SDI

Table 2. Chance of success for the detection of cutaneous melanoma at first visits and follow-up examinations according to the different examination techniques

Technique of examination	Excisions performed to identify one melanoma (percentage of melanomas among excised lesions, absolute numbers)	
	At first visit	During follow-up
Patient apprehension alone	12 Excisions (8.3%, 84 excisions, 7 melanomas)	14 Excisions (7.1%, 84 excisions, 6 melanomas)
ELM criteria alone	5 Excisions (19.6%, 153 excisions, 30 melanomas)	9 Excisions (11.8%, 110 excisions, 13 melanomas)
DELM criteria alone	Not available at first visit	19 Excisions (5.2%, 349 excisions, 18 melanomas)
ELM plus DELM criteria	Not available at first visit	6 Excisions (17.0%, 94 excisions, 16 melanomas)
OVERALL	6 Excisions (15.6%, 237 excisions, 37 melanomas)	12 Excisions (8.3%, 637 excisions, 53 melanomas)

SDI's larger impact is reducing unnecessary biopsies of equivocal lesions by documenting lack of change

Baseline

Baseline

3-months

6-months

Ugly duckling – outlier

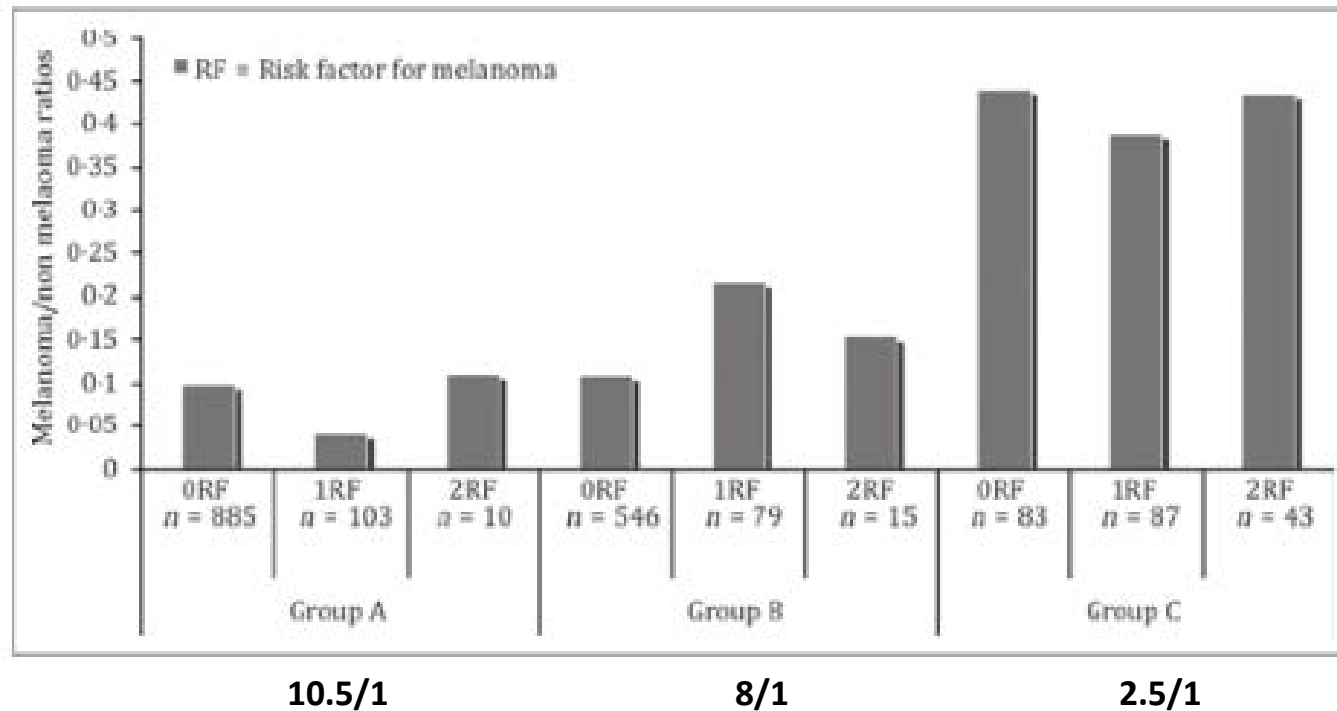
No biopsy needed

SDI reduces unnecessary biopsies of moles by 75%

46 dermatologists, 1-year study

Availability of digital dermoscopy in daily practice dramatically reduces the number of excised melanocytic lesions: results from an observational study

I. Tromme,^{1*} L. Sacré,^{1*} F. Hammouch,² C. Legrand,³ L. Marot,¹ P. Vereecken,¹ I. Theate,¹ P. van Eeckhout,¹ P. Richez,¹ J.F. Baurain,² L. Thomas⁴ and N. Speybroeck⁵ on behalf of the DEPIMELA study group



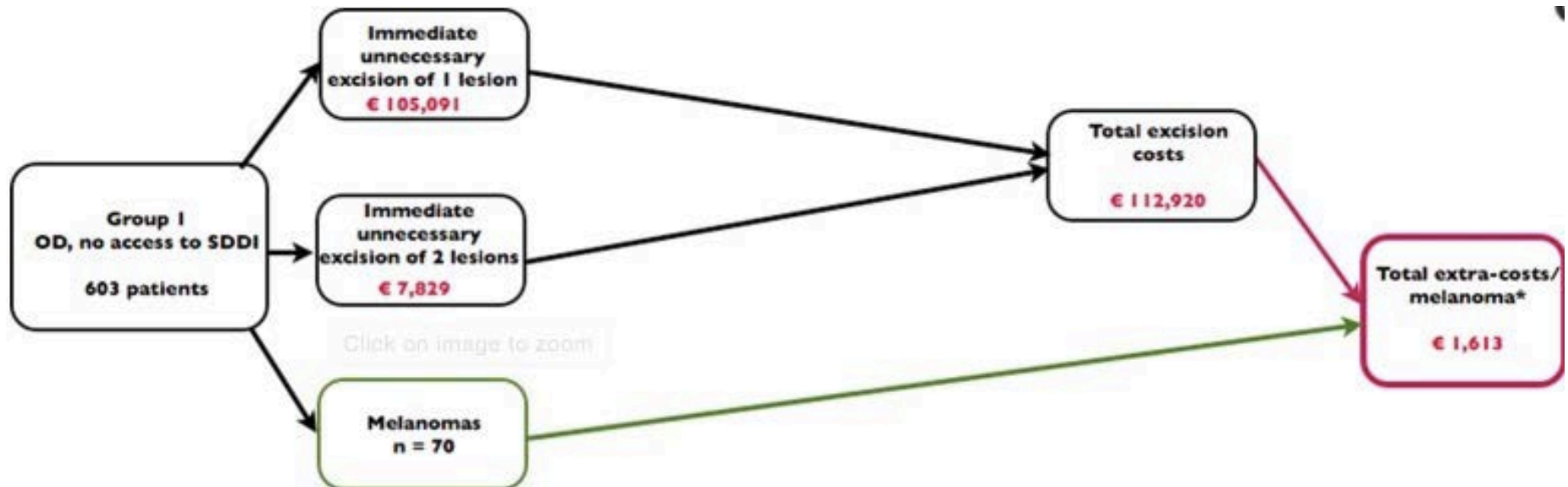
SDI reduces costs per melanoma found by ~40%

PLoS One. 2014; 9(10): e109339.

PMCID: PMC4196852

Published online 2014 Oct 14. doi: [10.1371/journal.pone.0109339](https://doi.org/10.1371/journal.pone.0109339)

Selective Use of Sequential Digital Dermoscopy Imaging Allows a Cost Reduction in the Melanoma Detection Process: A Belgian Study of Patients with a Single or a Small Number of Atypical Nevi



Traditional care

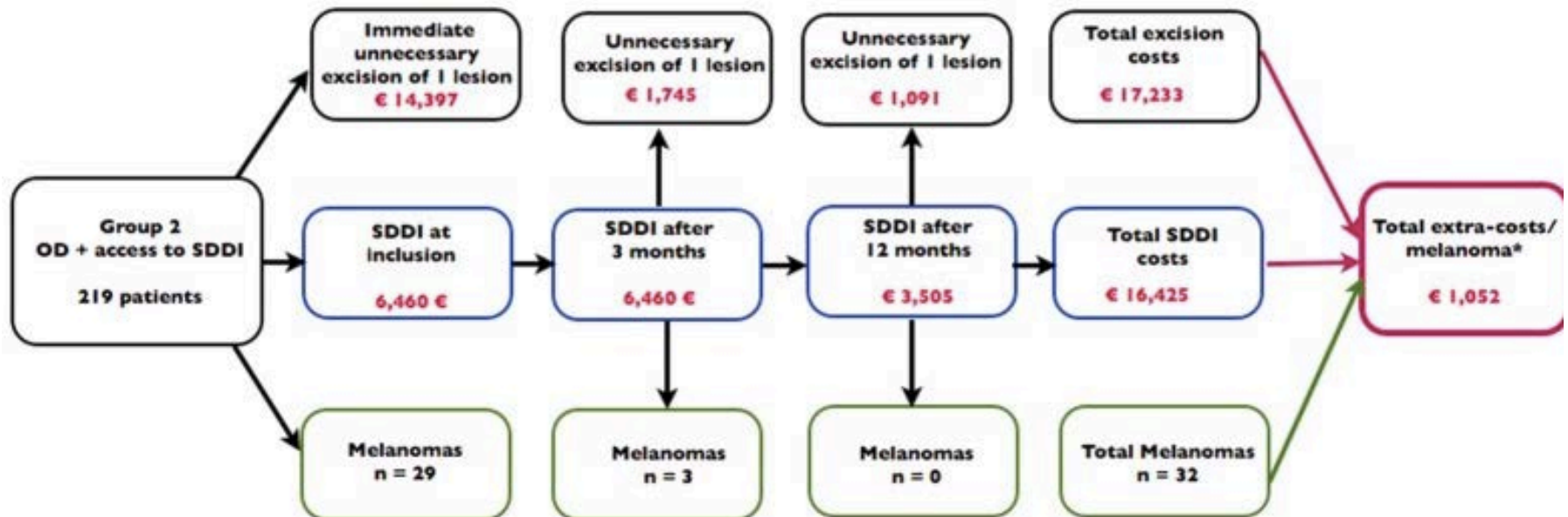
SDI reduces costs per melanoma found by ~40%

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PMCID: PMC4196852

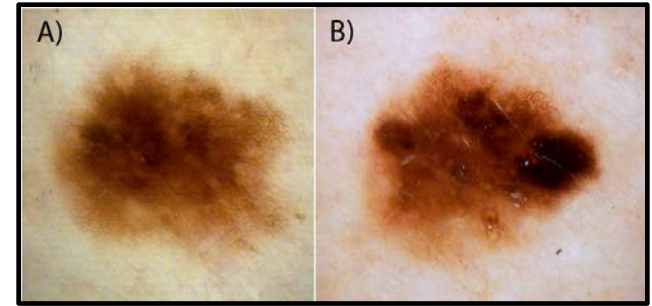
Published online 2014 Oct 14. doi: [10.1371/journal.pone.0109339](https://doi.org/10.1371/journal.pone.0109339)

Selective Use of Sequential Digital Dermoscopy Imaging Allows a Cost Reduction in the Melanoma Detection Process: A Belgian Study of Patients with a Single or a Small Number of Atypical Nevi



SDI care

SDI improves evaluation of pigmented skin lesions in the primary care setting



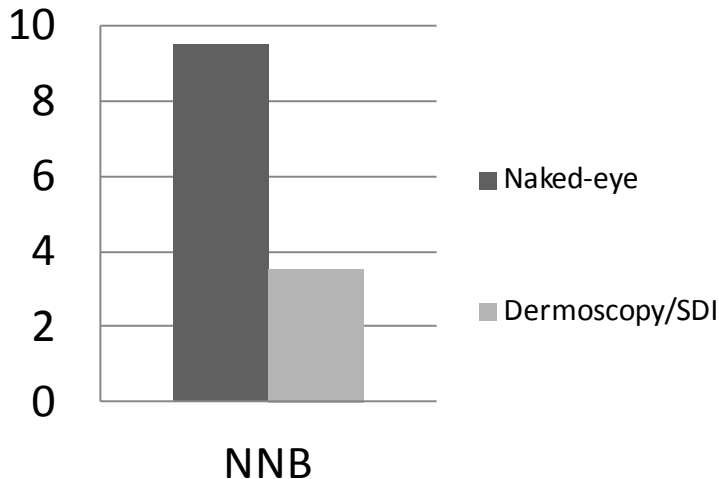
CLINICAL AND LABORATORY INVESTIGATIONS

BJD British Journal of Dermatology

Impact of dermoscopy and short-term sequential digital dermoscopy imaging for the management of pigmented lesions in primary care: a sequential intervention trial

S.W. Menzies,*† J. Emery,‡ M. Staples,§ S. Davies,‡ B. McAvoy,¶ J. Fletcher,** K.R. Shahid,†† G. Reid,‡ M. Avramidis,* A.M. Ward,‡‡ R.C. Burton§§ and J.M. Elwood¶¶

Journal Compilation © 2009 British Association of Dermatologists • British Journal of Dermatology 2009 161, pp1270–1277



a. 63.5% reduction in benign lesions biopsied

b. 42 malignant lesions

1 incorrectly managed (melanoma in situ)

97.1% melanomas correctly managed

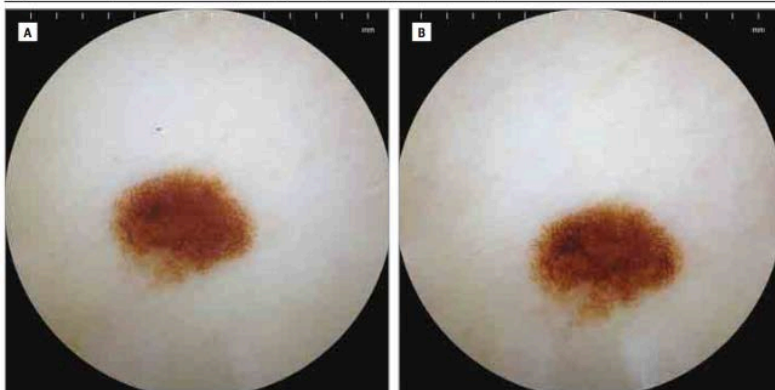
Patients can successfully perform imaging needed for SDI

Feasibility and Efficacy of Patient-Initiated Mobile Teledermoscopy for Short-term Monitoring of Clinically Atypical Nevi

Xinyuan Wu, BA; Susan A. Oliveria, ScD; Sarah Yagerman, MD; Lucy Chen, MD; Jennifer DeFazio, MD; Ralph Braun, MD; Ashfaq A. Marghoob, MD

RESULTS Of the 29 patients who completed the study, 28 (97%) were able to acquire baseline and follow-up images that were subsequently deemed evaluable by the teledermatologist. The diagnostic concordance between conventional office-based visits and teledermoscopy encounters was 0.87 (SE, 0.13) (κ statistic). In addition, patients reported high receptivity to teledermoscopy for short-term monitoring of nevi.

Figure 2. Examples of Dermoscopic Images Captured by Patients Using the Mobile Dermatoscope



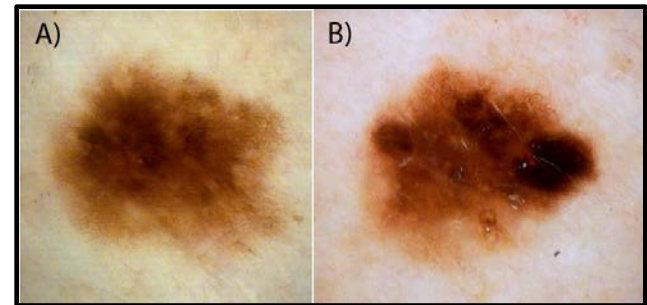
Use of SDI in examining pigmented skin lesions is recommended by national guidelines (grade A, level 1)

SYSTEMATIC REVIEW

BJD
British Journal of Dermatology

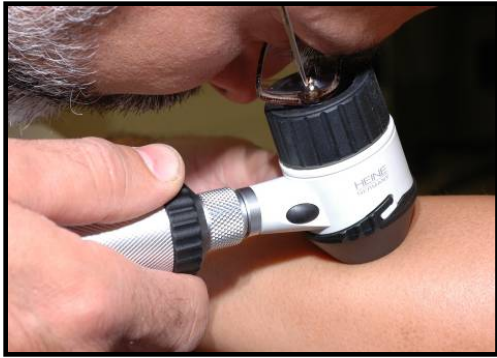
Clinical practice guidelines for identification, screening and follow-up of individuals at high risk of primary cutaneous melanoma: a systematic review*

C.G. Watts,¹ M. Dieng,¹ R.L. Morton,^{2,3} G.J. Mann,⁴ S.W. Menzies⁵ and A.E. Cust¹

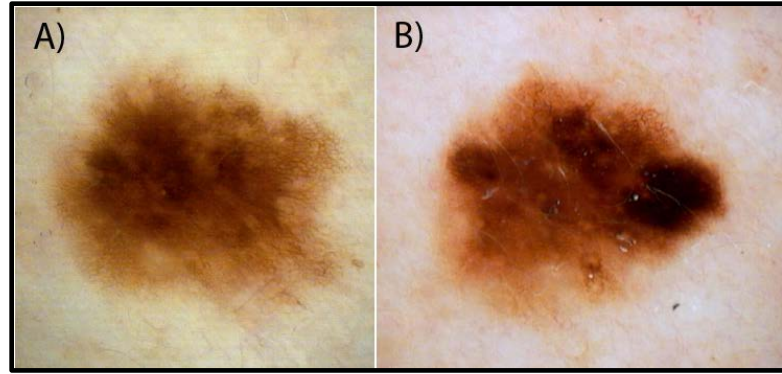


Item being described	Oxford level of evidence ³	Summary of guideline recommendations
Screening management	1–2	Consider recording dermoscopic images of lesions over time so changes in the lesion can be identified (sequential digital dermoscopy imaging, SDDI)

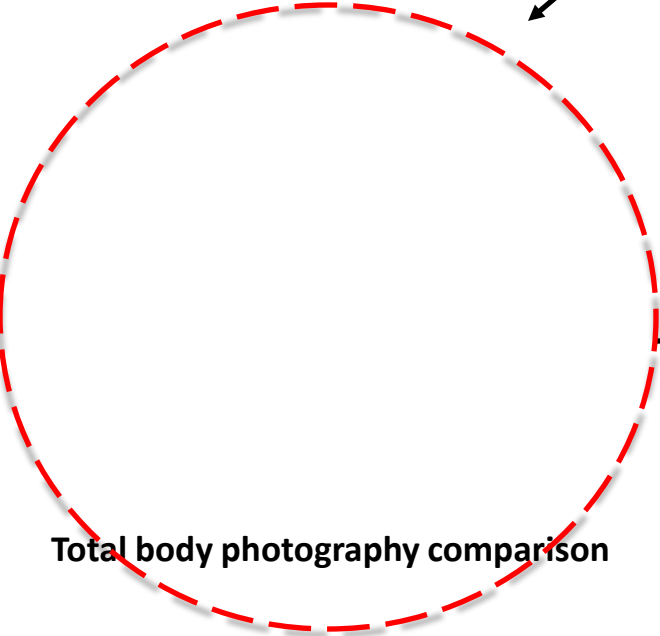
³Oxford levels of evidence: 1–2, high level of evidence; 3–4, lower levels of evidence; 5, consensus-based decisions (lowest level of evidence).



Dermoscopy



Sequential dermoscopy imaging



Total body photography comparison

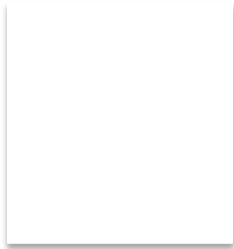


Emerging



Overdiagnosis

Total body photography catalogues skin surface



Use of TBP in high-risk individuals associated with detection of thin melanomas

- Prospective, cohort study
- 278 pts with ≥ 5 DN, mean f/u 42 m
- 20 melanomas (16 patients)
- MM diagnosed at early stages
 - 45% of MM were in-situ (vs. 33% for population)
 - 0.4mm median thickness (vs. 1.4 mm for population)
- 55% (n=11) found with aid of TBP (change detected)

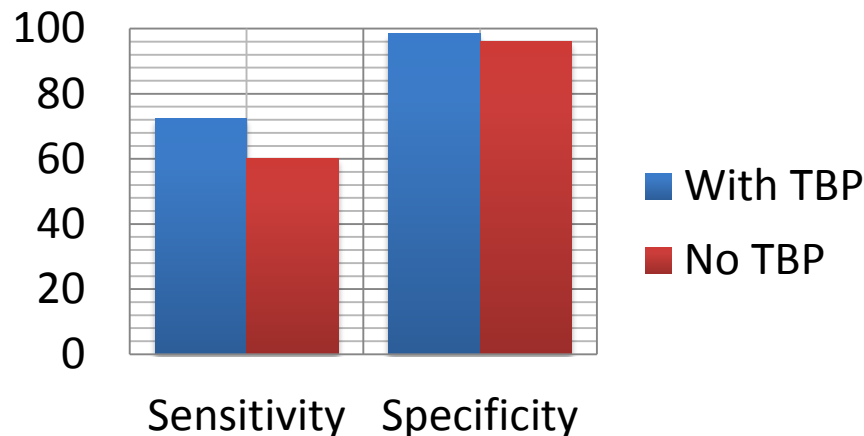
TBP improves sensitivity of SSEs in detecting new and changing moles

STUDY

Diagnostic Accuracy of Patients in Performing Skin Self-examination and the Impact of Photography

Susan A. Oliveria, ScD; Dorothy Chau, MD; Paul J. Christos, MPH;
Carlos A. Charles, MD; Alvin I. Mushlin, MD; Allan C. Halpern, MD

Results The sensitivity and specificity of SSE for detection of both altered and new moles without photography were 60.2% and 96.2%, respectively. Skin self-examination with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively. The findings were similar when stratified by site (back vs chest or abdomen). The sensitivity and specificity for new moles were higher compared with altered moles.



Holy grail of automatic change detection – not yet realized

A New Total Body Scanning System for Automatic Change Detection in Multiple Pigmented Skin Lesions

Konstantin Korotkov, Josep Quintana, Susana Puig, Josep Malvehy, Rafael Garcia

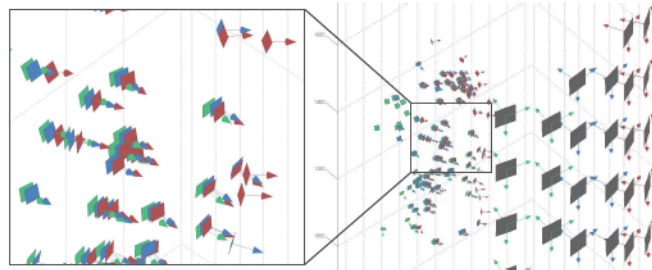
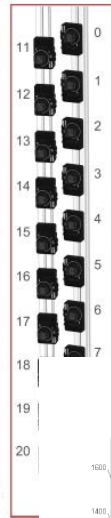
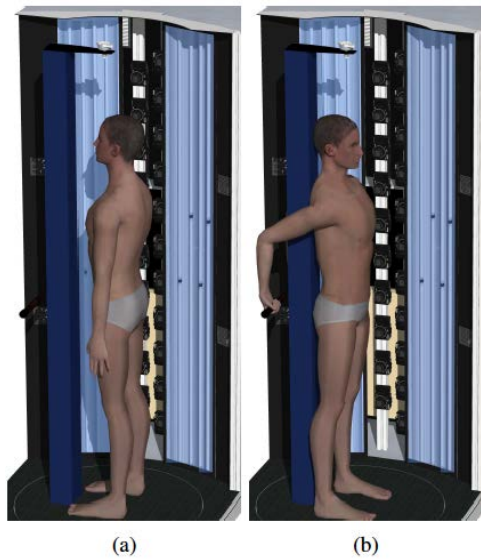
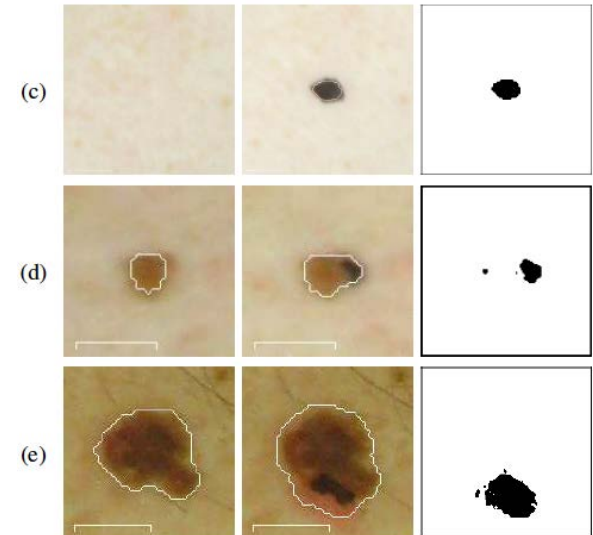
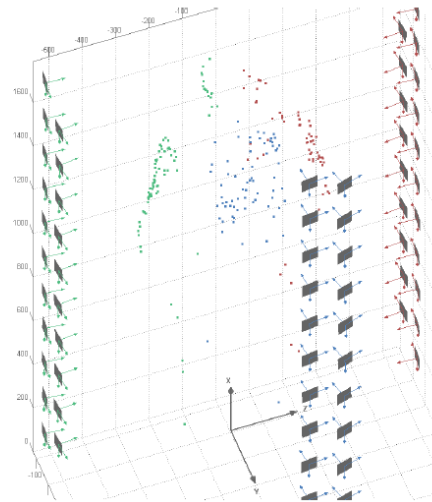


Fig. 28: A 3D component of overlapping mole sets. Mole sets computed at turntable positions 3 (red), 4 (blue), and 5 (green). The smaller arrows denote normals to the local planes of the moles which are marked by square patches of the color.

IEEE transactions on medical imaging 34: 317-38, no. 1 (2015)



Use of TBP in examining pigmented skin lesions (grades B-C, levels 3-4)

SYSTEMATIC REVIEW

BJD
British Journal of Dermatology

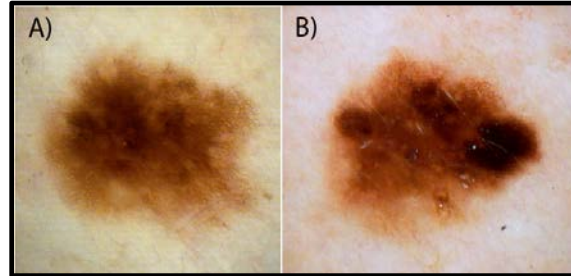
Clinical practice guidelines for identification, screening and follow-up of individuals at high risk of primary cutaneous melanoma: a systematic review*

C.G. Watts,¹ M. Dieng,¹ R.L. Morton,^{2,3} G.J. Mann,⁴ S.W. Menzies⁵ and A.E. Cust¹

Item being described	Oxford level of evidence ³	Summary of guideline recommendations
Screening management	3–4	Consider the use of baseline total-body photography in conjunction with dermoscopy as a tool for the early detection of melanoma in patients who are at high risk for developing primary melanoma

³Oxford levels of evidence: 1–2, high level of evidence; 3–4, lower levels of evidence; 5, consensus-based decisions (lowest level of evidence).

Use of dermoscopy, SDI, TBP together is complementary and effective in monitoring those at high-risk for melanoma



Original Investigation

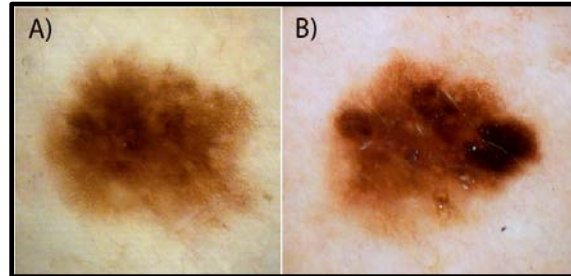
Detection of Primary Melanoma in Individuals at Extreme High Risk

A Prospective 5-Year Follow-up Study

Fergal J. Moloney, MD; Pascale Guitera, MD, PhD; Elliot Coates, MB, BS; Nikolas K. Haass, MD, PhD; Kenneth Ho, MB, BS; Ritta Khoury, BMedSci; Rachel L. O'Connell, PhD; Leo Raudonikis; Helen Schmid, MPH; Graham J. Mann, MB, BS, PhD; Scott W. Menzies, MB, BS, PhD

311 patients, median f/u 3.5 years
75 melanomas detected (14 baseline)
postbaseline median thickness was in situ
38% TBP; 39% SDI
5 > 1mm thickness (desmo/nodular types)
NNB of 4.4 to 1 (melanocytic lesions)

Use of dermoscopy, SDI, TBP q6months in examining high-risk individuals (grade C, level 5)



SYSTEMATIC REVIEW

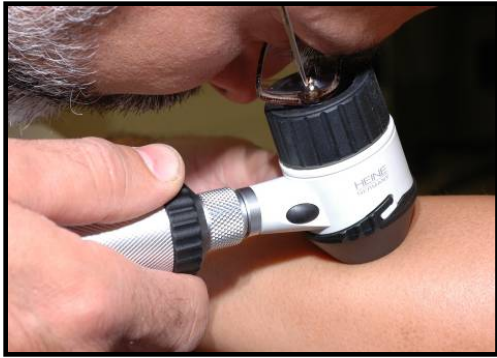
BJD
British Journal of Dermatology

Clinical practice guidelines for identification, screening and follow-up of individuals at high risk of primary cutaneous melanoma: a systematic review*

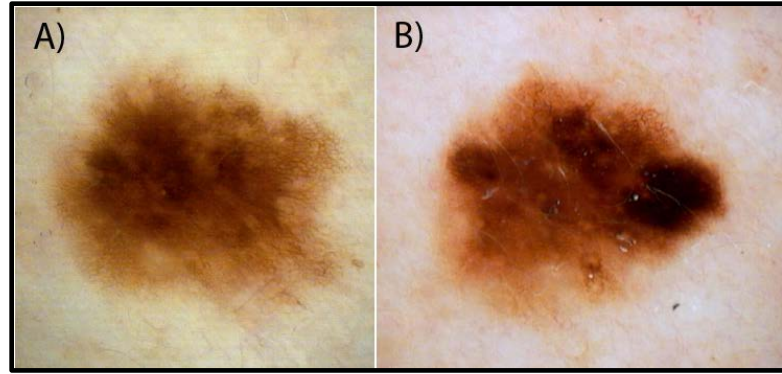
C.G. Watts,¹ M. Dieng,¹ R.L. Morton,^{2,3} G.J. Mann,⁴ S.W. Menzies⁵ and A.E. Cust¹

Item being described	Oxford level of evidence ^a	Summary of guideline recommendations
Screening management	5	High-risk individuals may benefit from 6-monthly surveillance with a full-body examination supported by total-body photography and sequential dermoscopy as required

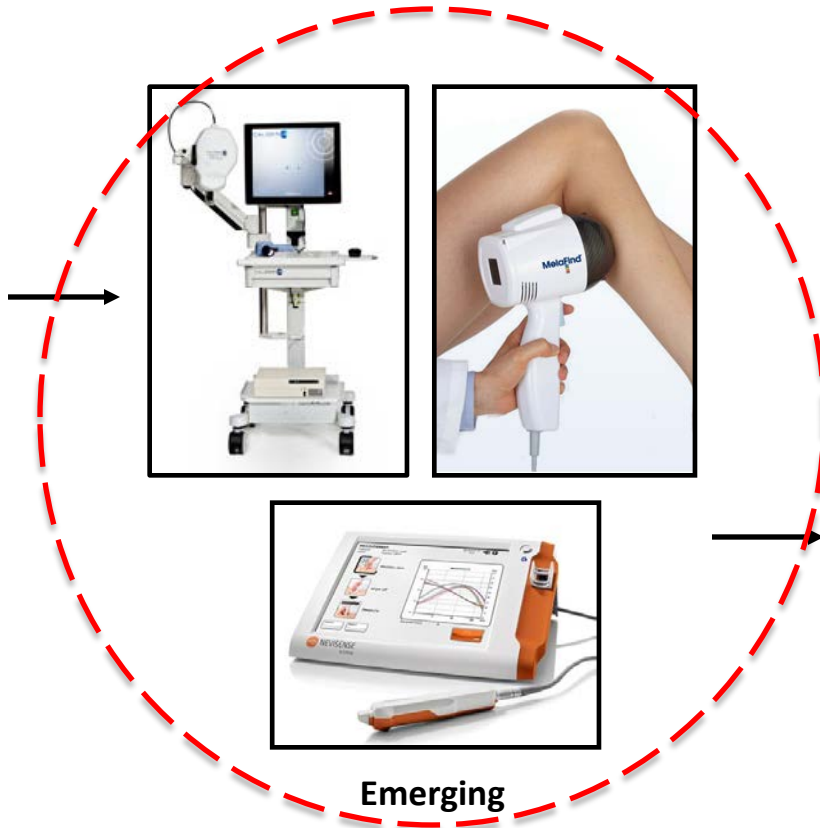
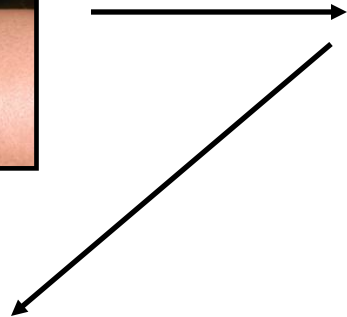
*Oxford levels of evidence: 1–2, high level of evidence; 3–4, lower levels of evidence; 5, consensus-based decisions (lowest level of evidence).



Dermoscopy



Sequential dermoscopy imaging



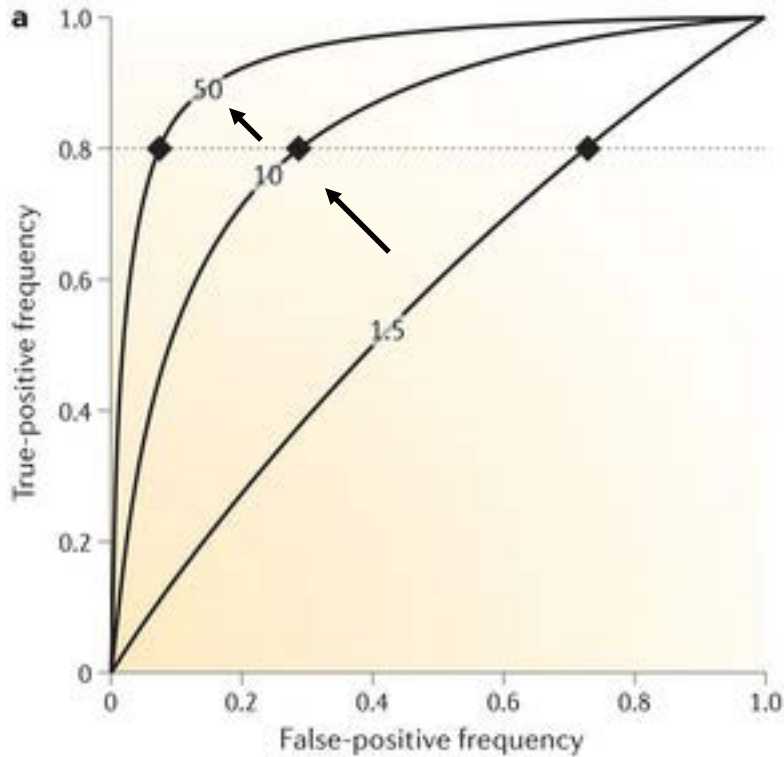
Total body photography comparison

Emerging

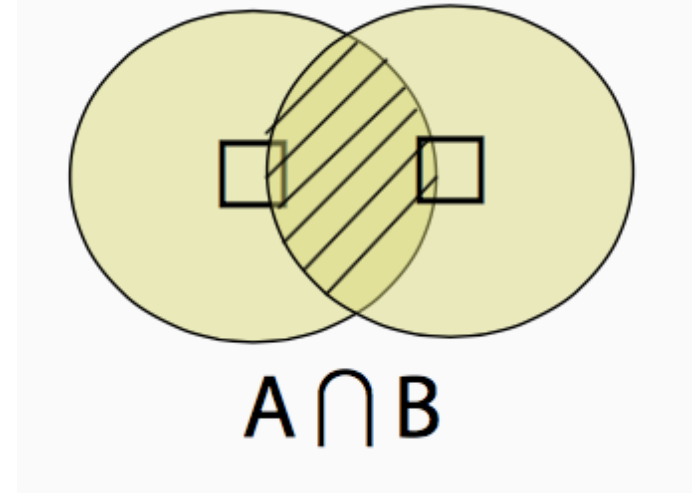


Overdiagnosis

Dermoscopy, SDI, & TBP improve PPV of lesions selected to undergo skin biopsy by dermatologist

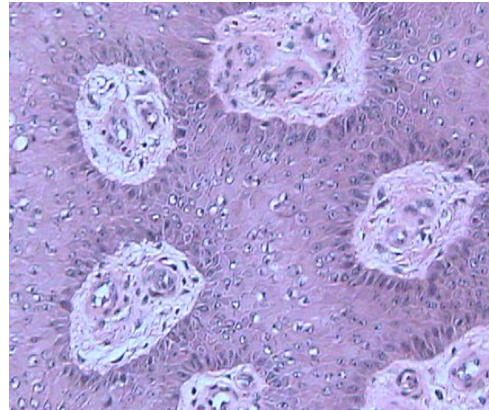
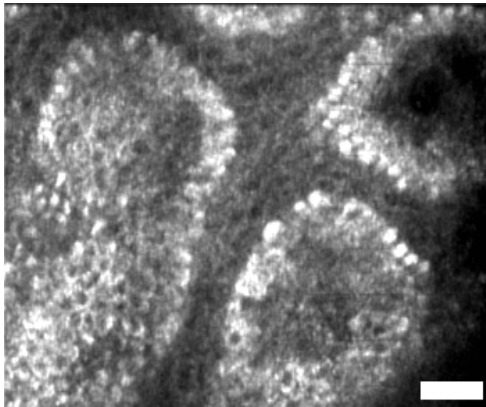


Fundamentally improves sensitivity and specificity of skin exams



Sequential screening improves specificity

Reflectance confocal microscopy creates images of skin that approach histological detail



Disadvantages:

- Cost of device
- Time required for imaging
- Training

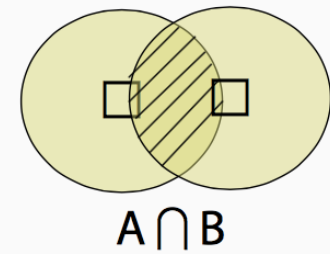


A black and white microscopic image of tissue. A yellow arrow points from the text to a cluster of cells in the lower-left quadrant. The cells in the cluster are large and have prominent, dark nuclei. The surrounding tissue is dark and has a granular texture.

Large round nucleated
cells = malignant
melanocytes

CELLULAR INFORMATION

RCM reduces unnecessary biopsies of moles



CLINICAL AND LABORATORY INVESTIGATIONS

BJD
British Journal of Dermatology

Reflectance confocal microscopy as a second-level examination in skin oncology improves diagnostic accuracy and saves unnecessary excisions: a longitudinal prospective study*

G. Pellacani,¹ P. Pepe,¹ A. Casari¹ and C. Longo²

CLINICAL AND LABORATORY INVESTIGATIONS

BJD
British Journal of Dermatology

Integration of reflectance confocal microscopy in sequential dermoscopy follow-up improves melanoma detection accuracy

I. Stanganelli,¹ C. Longo,² L. Mazzoni,^{1,3} S. Magi,^{1,3} M. Medri,¹ G. Lanzanova,⁴ F. Farnetani⁵ and G. Pellacani⁵



Reduce benign excisions 50%
Sensitivity >95%

Siascope™ device and MelaFind® handheld scanner both use multispectral imaging



FDA 510k clearance
5 images
User interprets



FDA approval
10 images
75 features
Automated analysis

MelaFind[®] device is FDA approved but not widely used

- MelaFind[®] device (binary outcome)
 - Prospective study, 1632 pigmented lesions selected to undergo biopsy by dermatologist
 - Sensitivity = 98.4% (same as clinicians)
 - Specificity = 9.9% (superior to clinicians 3.7%)
- Unanswered questions?
 - Validation study
 - Application to pigmented lesions not selected to undergo biopsy...
 - Sufficiently cost-effective?

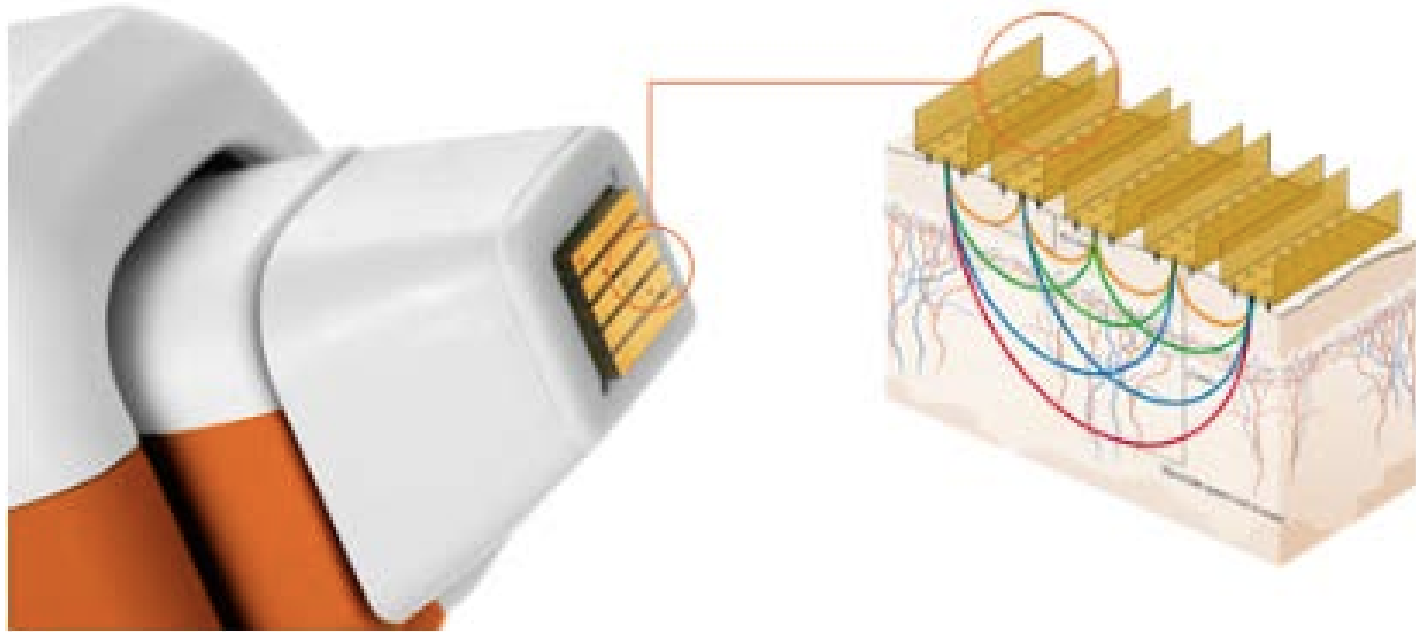


**If you remove dermatologist pre-screening, imaging device's
is much harder**



**Very low prevalence of disease
35,000 (200 atypical) nevi per melanoma**

Nevisense measures resistance within skin tissue (electrical impedance spectroscopy)



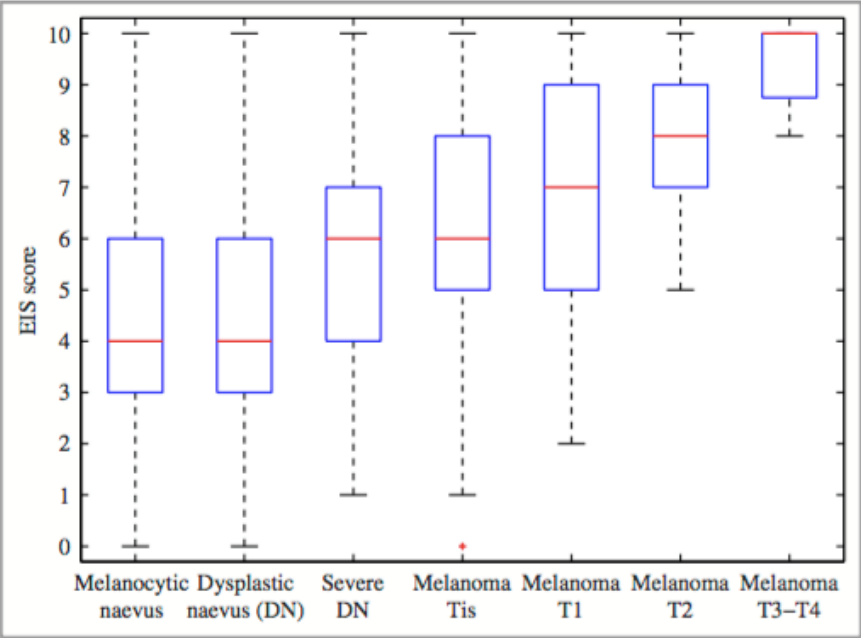
Commercially available in Belgium, Great Britain, Germany, Australia, Austria and Nordic markets.

FDA – pending submission end of 2015

Nevisense has high sensitivity for melanoma and may have value as sequential screening test

Clinical performance of the Nevisense system in cutaneous melanoma detection: an international, multicentre, prospective and blinded clinical trial on efficacy and safety*

J. Malveyh,¹ A. Hauschild,² C. Curiel-Lewandrowski,³ P. Mohr,⁴ R. Hofmann-Wellenhof,⁵ R. Motley,⁶ C. Berking,⁷ D. Grossman,⁸ J. Paoli,⁹ C. Loquai,¹⁰ J. Olah,¹¹ U. Reinhold,¹² H. Wenger,¹³ T. Dirschka,¹⁴ S. Davis,¹⁵ C. Henderson,¹⁶ H. Rabinovitz,¹⁷ J. Welzel,¹⁸ D. Schadendorf¹⁹ and U. Birgersson^{20,21}



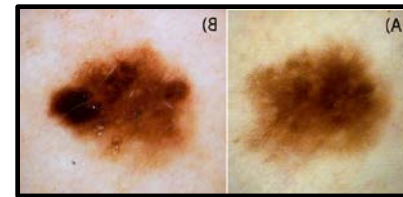
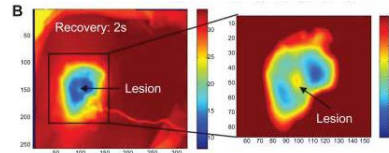
	Malignancy grading ^a	Investigational site's histopathology	Nevisense
Melanoma sensitivity	70.6	84.5	97.1
Overall specificity	81.4	98.0	35.8

Aug 2015: US Reader study with 41 dermatologists showed "improved" diagnostic accuracy

Melanoma detection will be multimodal

- **Imaging**

- Dermoscopy
- SDI
- TBP
- RCM
- Multispectral
- Thermal



- **Mechanical/electrical**

- Electrical impedance spectroscopy



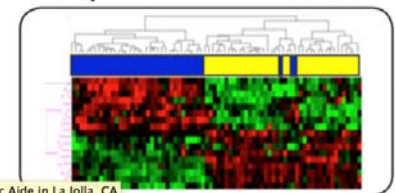
- **Molecular**

- Tape strip for RNA
- Micro-punch biopsy

Adhesive Patch Biopsy

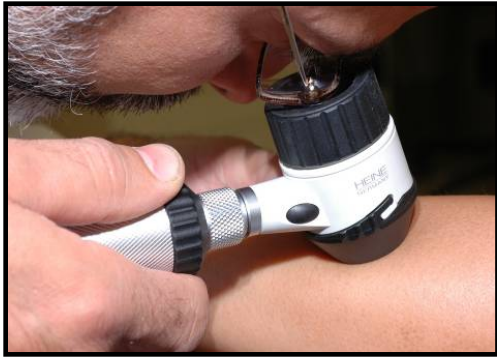


Objective Gene Expression Assessment

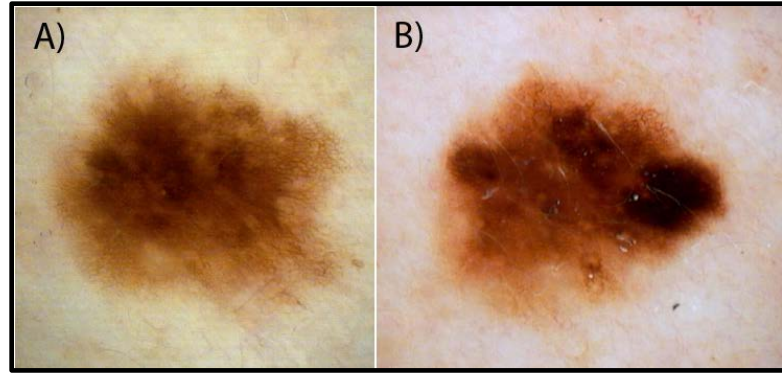


Diagnostic Aide in La Jolla, CA

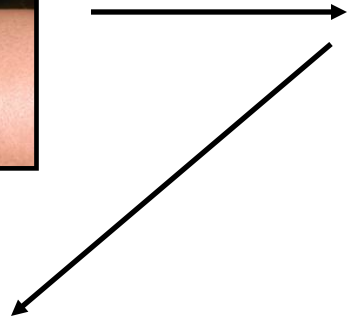
Not skin cancer Skin cancer



Dermoscopy



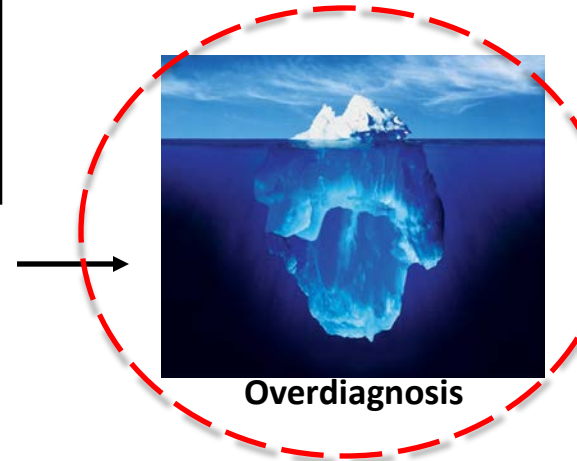
Sequential dermoscopy imaging



Total body photography comparison



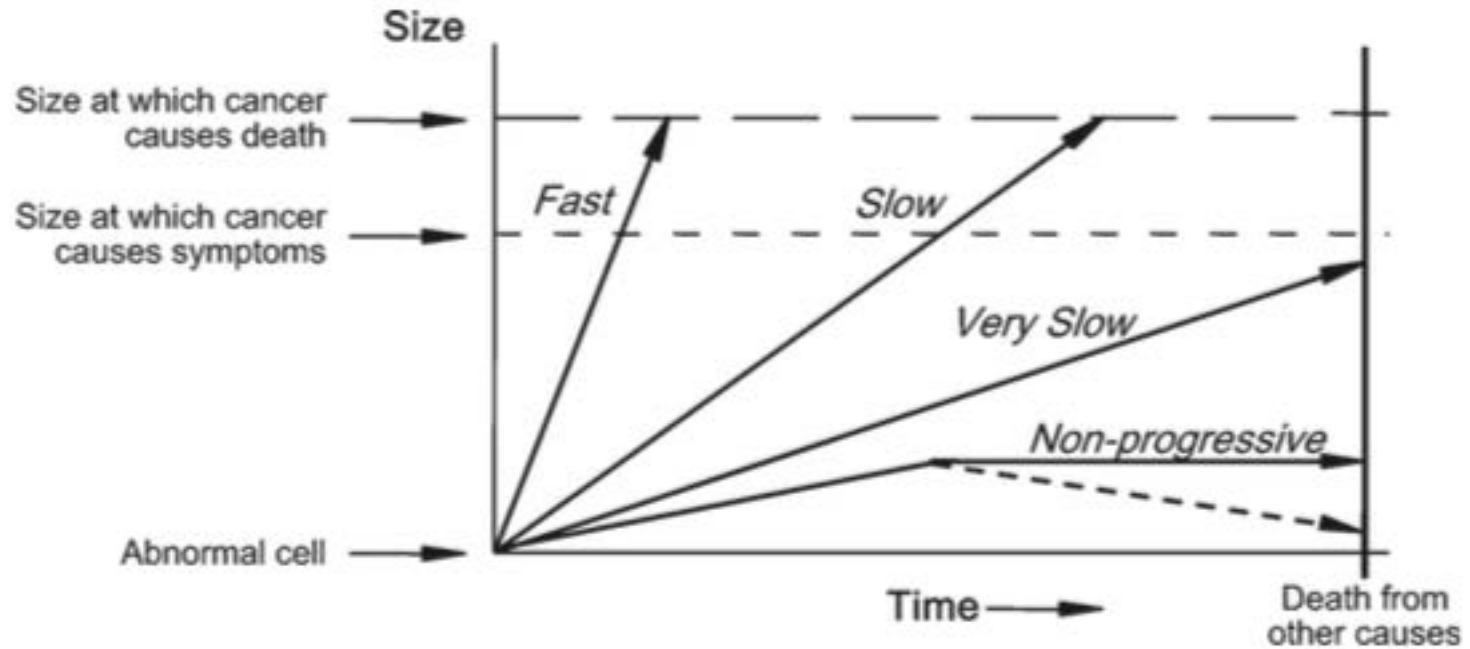
Emerging



Overdiagnosis



There is significant heterogeneity in cancer progression





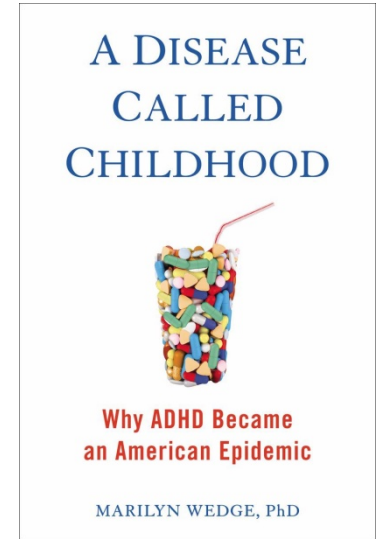
Fatal Cancer



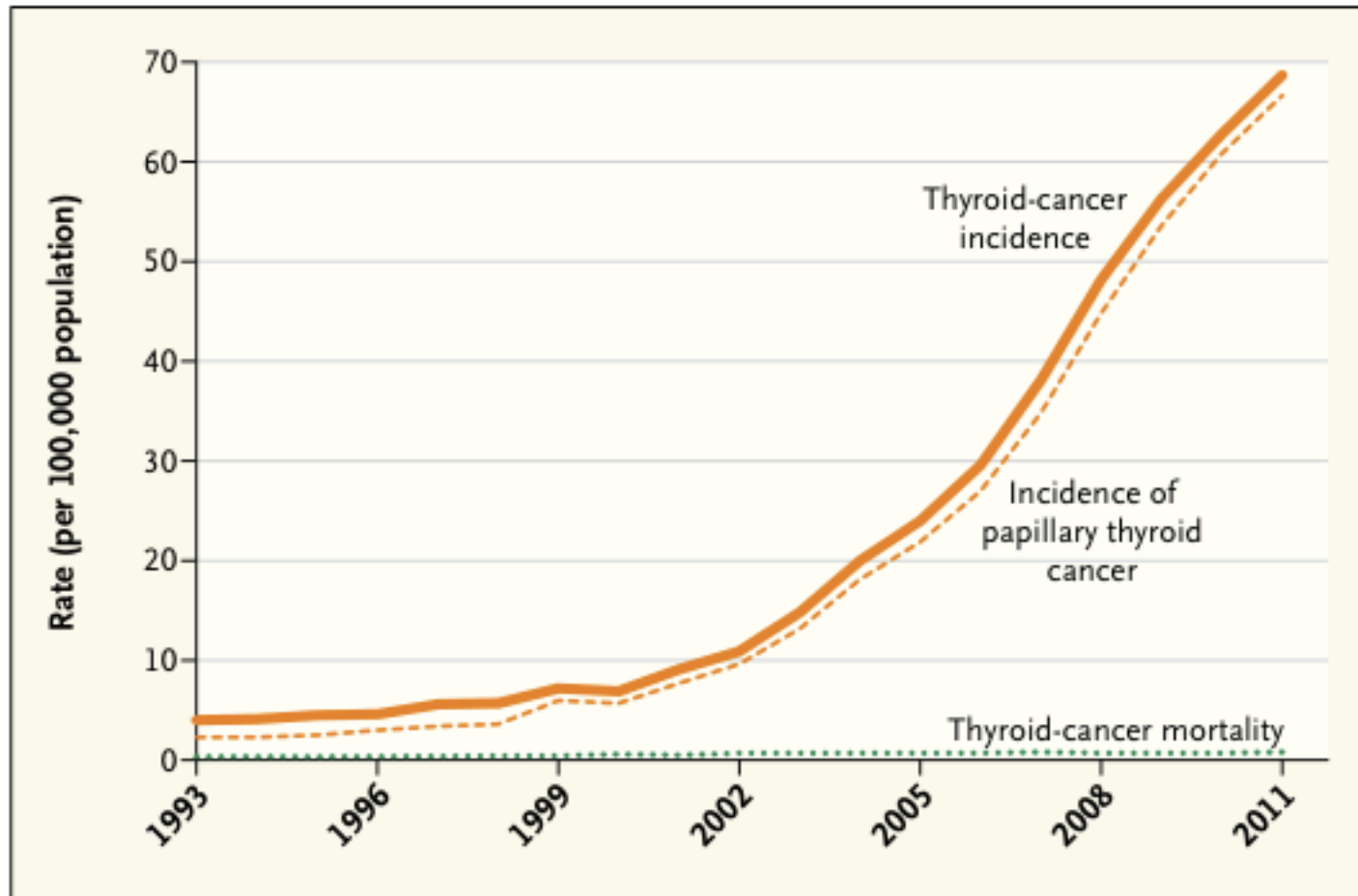
Overdiagnosis is a condition that would otherwise not go on to cause symptoms or death (not misdiagnosis)



Technology is a well-recognized contributor to overdiagnosis



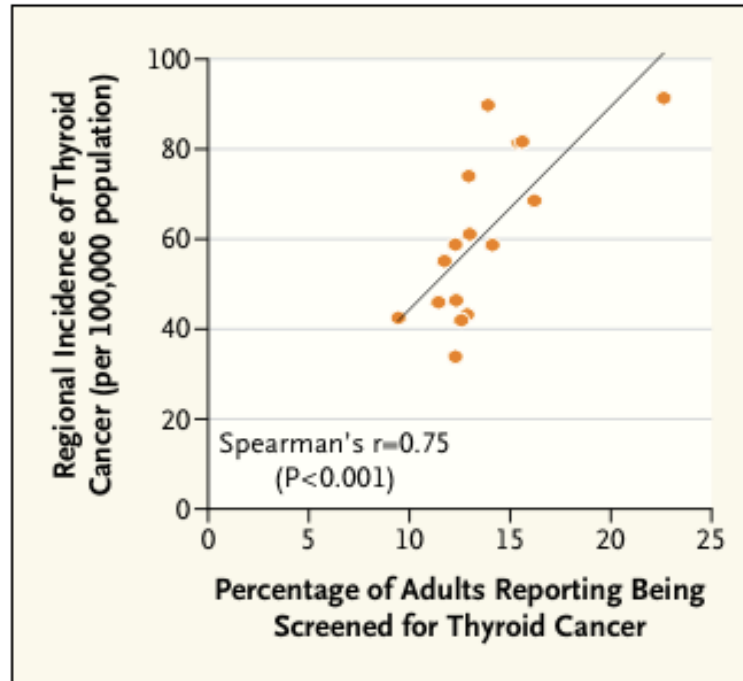
Ultrasound screening led to profound overdiagnosis of thyroid cancer in South Korea



Thyroid-Cancer Incidence and Related Mortality in South Korea, 1993–2011.

Data on incidence are from the Cancer Incidence Database, Korean Central Cancer Registry; data on mortality are from the Cause of Death Database, Statistics Korea. All data are age-adjusted to the South Korean standard population.

Incidence of thyroid cancer associated with penetration of thyroid-cancer screening activities



Penetration of Thyroid-Cancer Screening (2008–2009) and Incidence of Thyroid Cancer (2009) in the 16 Administrative Regions of South Korea.

Data on thyroid-cancer screening are from the Korean Community Health Survey Database, Korea Centers for Disease Control and Prevention; data on incidence are from the Cancer Incidence Database, Korean Central Cancer Registry.

Incidence of melanoma associated with penetration of melanoma-screening activities (rate of skin biopsy)

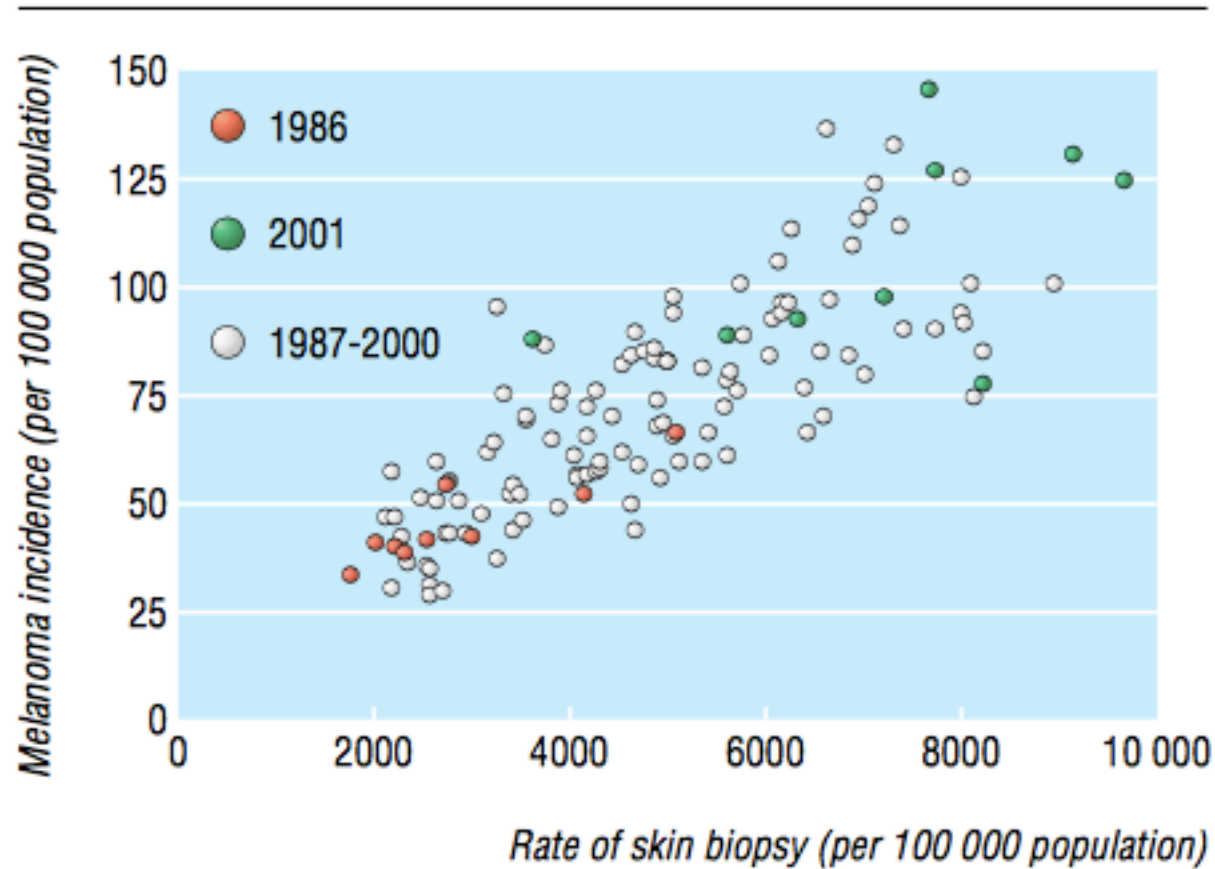


Fig 2 Scatterplot of annual rate of skin biopsy and incidence of melanoma for residents age 65 and older in each of nine US areas participating in Surveillance Epidemiology and End Results programme, 1986-2001

Use of technology in melanoma screening likely to be associated with some degree of overdiagnosis

CLINICAL AND LABORATORY INVESTIGATIONS

BJD
British Journal of Dermatology

Slow-growing melanoma: a dermoscopy follow-up study

G. Argenziano, H. Kittler,* G. Ferrara,† P. Rubegni,‡ J. Malvehy,§ S. Puig,§ L. Cowell,¶ I. Stanganelli,** V. De Giorgi,†† L. Thomas,‡‡ P. Bahadoran,§§ S.W. Menzies,¶¶ D. Piccolo,*** A.A. Marghoob††† and I. Zalaudek‡‡‡



...BUT if we biopsy more dynamic lesions and remove fewer benign lesions I am okay with that

CLINICAL AND LABORATORY INVESTIGATIONS

BJD
British Journal of Dermatology

Slow-growing melanoma: a dermoscopy follow-up study

G. Argenziano, H. Kittler,* G. Ferrara,† P. Rubegni,‡ J. Malvehy,§ S. Puig,§ L. Cowell,¶ I. Stanganelli,** V. De Giorgi,†† L. Thomas,‡‡ P. Bahadoran,§§ S.W. Menzies,¶¶ D. Piccolo,*** A.A. Marghoob††† and I. Zalaudek‡‡‡



Technology can augment melanoma screening performed with naked-eye examination alone

