Introduction and Panel Overview

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Food and Drug Administration

General and Plastic Surgery Devices Panel Meeting

July 28, 2022

Welcome!

Two Independent Panel Meetings

TODAY: General Issues Meeting

- Discuss **future devices** that analyze skin lesions
- Questions to be discussed:
  - Accuracy
  - Ground truth
  - Populations

Two Independent Panel Meetings

<u>Tomorrow: Reclassification Meeting</u>

- Discuss **two approved devices** (MelaFind and Nevisense)
- Approved for adjunctive use by dermatologists in assessing possible melanoma
- Currently Class III (high risk)
- Propose regulation as Class II (moderate-high risk)

Today's Agenda

- Skin cancer
- Skin lesion analyzers (SLA)
- Use contexts
- Public speaker presentations
- Panel questions

Skin Cancer

- Skin cancer: 20% of individuals
- Early melanoma diagnosis critical
- Limited access to specialist care
- SLA may provide early detection

Skin Lesion Analyzers

- AI/ML-based devices to support lesion identification:
  - Assess visual appearance (photographs)
  - Assess physiological or biochemical changes

SLA Users

- Different users:
  - Dermatologists
  - Non-dermatologist healthcare provider
  - Lay persons

SLA Applications

- Different uses:
  - Specific lesion:
    - Is this lesion cancerous?
    - Is this lesion melanoma or BCC ?
  - Screening: are any of my lesions suspicious?

Questions for General Issues Panel Meeting

1. Options for determining ground truth
   - Histology
   - Visual diagnosis by single or multiple dermatologists
   - Other means
2. Acceptable thresholds for sensitivity and specificity, based on
   - Target diagnosis (melanoma, BCC, SCC)
   - Intended user (dermatologist, primary care physician, lay person)
3. Health equity considerations
   - Variable incidence in different populations
   - Variable lesion appearance in different skin types

Thank you


FDA
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ADMINISTRATION

Overview of Skin Lesions

Jennifer Bai, M.D.

Medical Officer
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration

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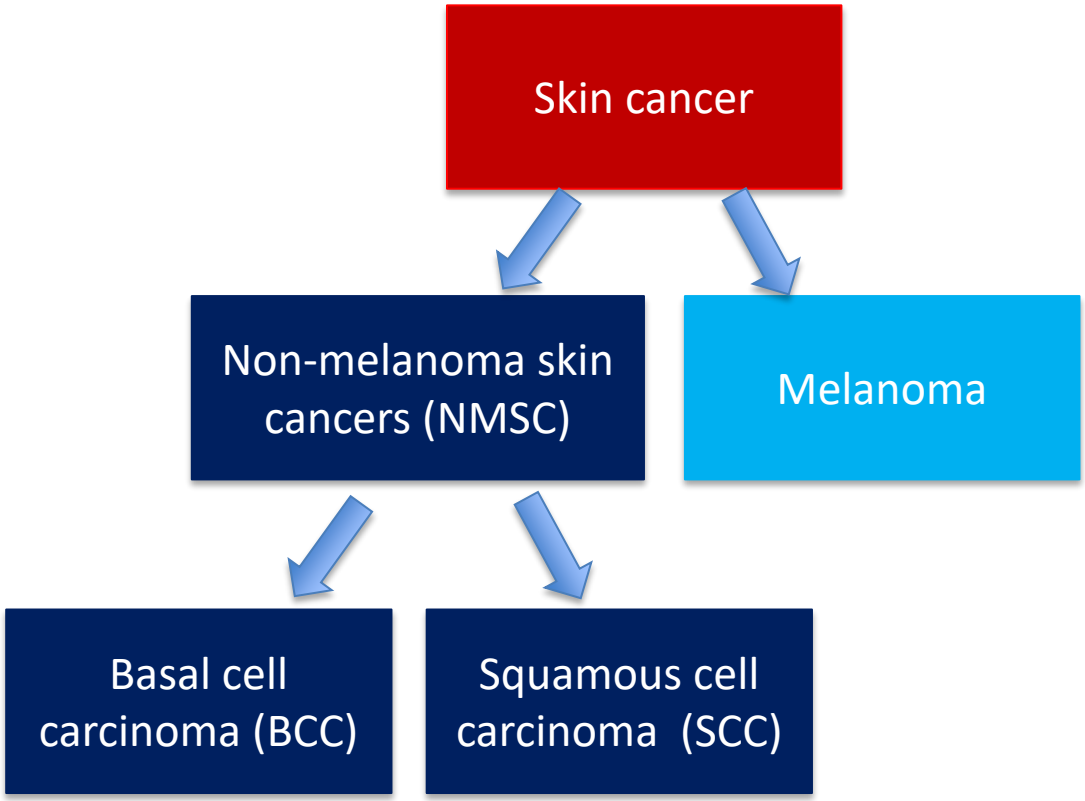
Overview

- Skin Cancer
  - Epidemiology
  - Natural history and management of the most common skin cancers
- Typical workflow
  - Current practice
  - Skin lesion analyzers (SLA)
  - Clinical Considerations

Types of Skin Cancer



Epidemiology of Skin Cancers

Skin Cancer	Estimated Cases Annually in US	Estimated Deaths Annually in US
BCC	3.6 million	Uncommon
SCC	1.8 million	Uncommon*
Melanoma	**99,780**	**7,650**

*Except in immunosuppressed patients (i.e., after organ transplant)

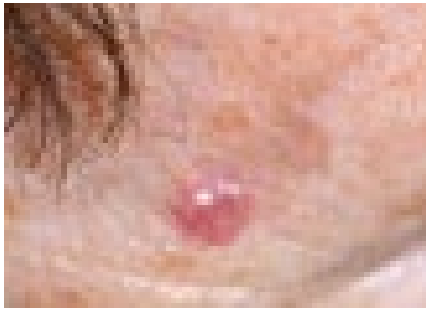
Skin Cancer Foundation, Skin Cancer Facts & Statistics: What You Need to Know. 2022. https://www.skincancer.org/skin-cancer-information/skin-cancer-facts/

National Cancer Institute, S. Epidemiology and End Results Program (SEER). *Cancer Stat Facts: Melanoma of the Skin.* 2021 https://seer.cancer.gov/statfacts/html/melan.html

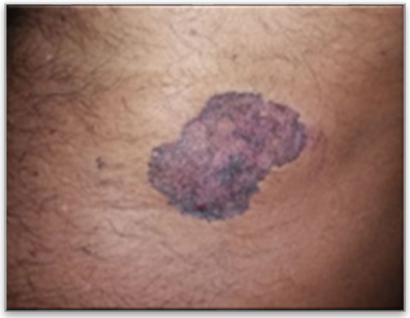
American Cancer Society. Key Statistics for Basal and Squamous Cell Skin Cancers. 2022. https://www.cancer.org/cancer/basal-and-squamous-cell-skin-cancer/about/key-statistics.html

Basal Cell Carcinoma (BCC)

- Most common type of skin cancer
- Related to sun exposure
- Skin-colored papule with a pearly appearance
- Slow-growing, most often curable



BCC



BCC in skin of color

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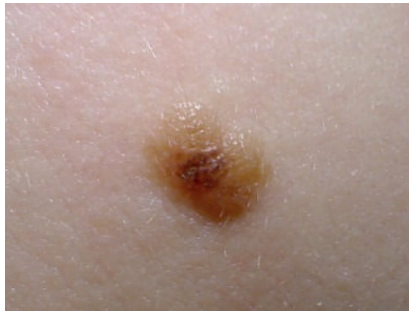
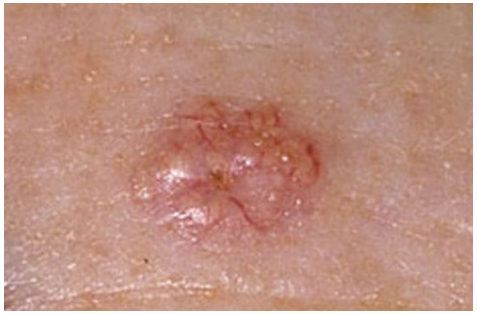
Basal Cell Carcinoma (BCC)

- Most occur spontaneously
- Distinguished from similar appearing lesions by biopsy
- Treatment
  - Excision
  - 95-99% cure rates
- Rarely metastasizes (<0.1%)

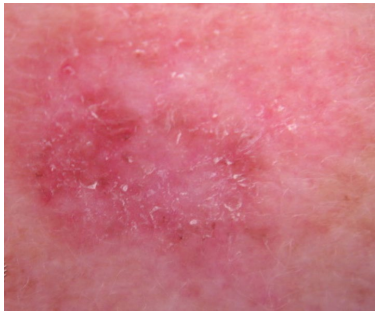
BCC Mimics



Nevus



Sebaceous hyperplasia



Amelanotic melanoma

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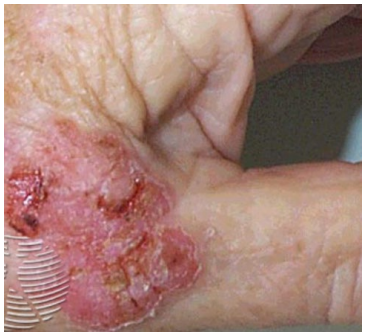
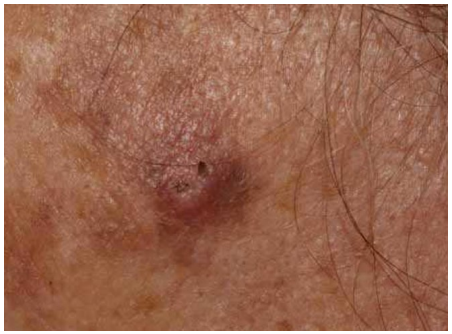
dermnetnz.org/assets/Uploads/amelanotic-melanoma-016__WatermarkedWyJXYXRlcm1hcmtlZCJd.JPG

Squamous Cell Carcinoma (SCC)

- 2nd most common skin cancer
- Scaly, thin erythematous lesion
- Often in sun-exposed areas
- Originates from epidermal keratinocytes



SCC



SCC in skin of color

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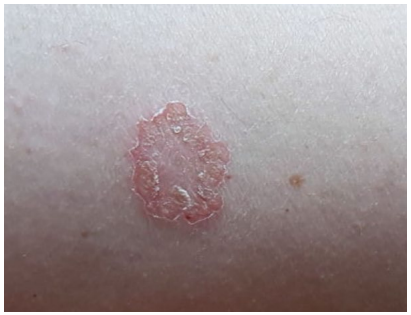
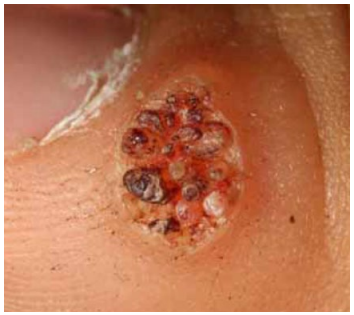
SCC

- Precursor: actinic keratosis
- Diagnosis confirmed by biopsy
- Treatment:
  - Excision: 95-99% cure rates
- Metastasis:
  - 2-6% rate
  - 5-year survival rate is 34%
  - Higher risk if immunosuppressed

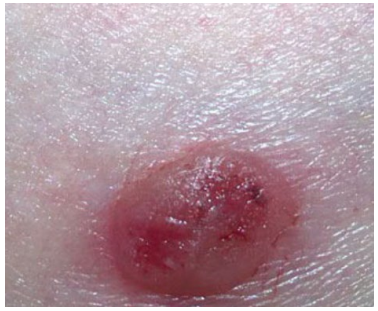
SCC Mimics



Eczema



Wart



Inflamed seborrheic keratosis

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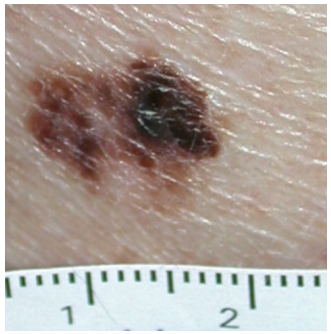
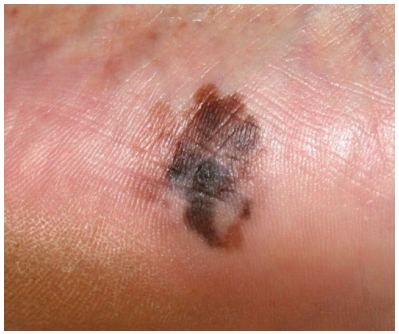
Melanoma

- Arises from melanocytes
- Can develop from nevi or normal skin
- Clinical exam:
  - **ABCD** (**a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter >6mm)
  - **E**: evolution
  - **F**: funny looking
  - **U**: “ugly duckling”



Melanoma



Melanoma in skin of color

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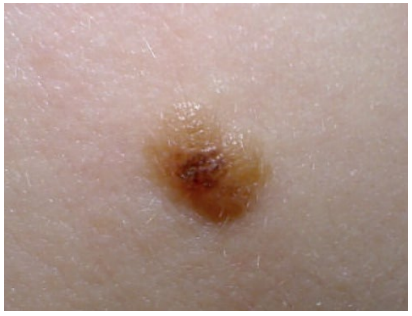
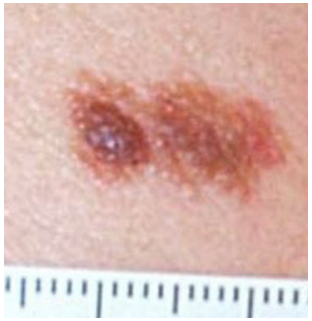
Melanoma

- Diagnosis confirmed by biopsy
- Thickness is critical for prognosis
- Treatment:
  - Localized: excision +/- lymph node biopsy
  - Metastatic: requires oncologic care
- High risk of metastasis and death

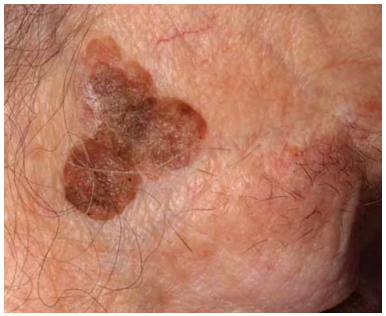
Melanoma Mimics



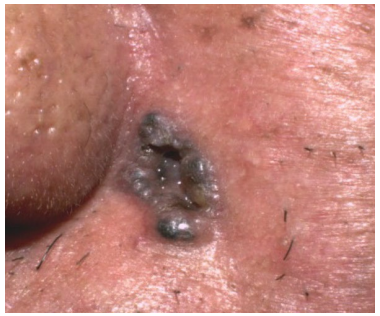
Benign nevus



Dysplastic nevus



Seborrheic keratosis



Pigmented BCC

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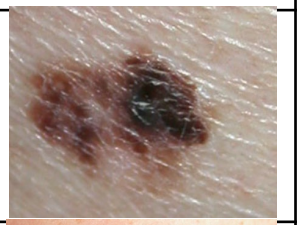
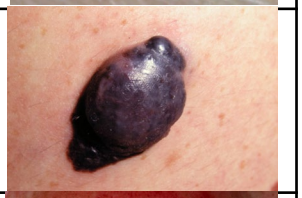
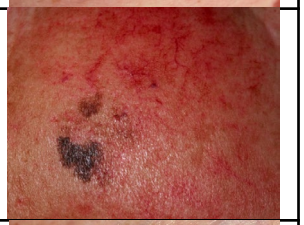
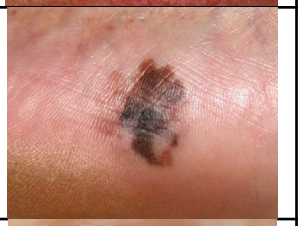
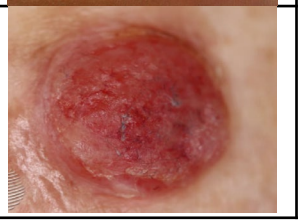
Melanoma Stage and Survival

- Cancer stage at time of melanoma diagnosis is critical, strong correlation to overall survival
- Average overall 5-year survival in US is 93.7%

Stage	Diagnosed at Stage	5-Year Relative Survival
Localized	82%	99%
Regional	9%	71%
Distant	4%	32%

32%

National Cancer Institute, S. Epidemiology and End Results Program (SEER). *Cancer Stat Facts: Melanoma of the Skin.* 2021; https://seer.cancer.gov/statfacts/html/melan.html

Subtypes	% of Melanoma	Anatomic Site	
Superficial Spreading Melanoma	70%	Any site, typically trunk or extremities	
Nodular Melanoma	15-30%	Any site	
Lentigo Maligna Melanoma	5%	Chronically sun-exposed sites	
Acral Lentiginous Melanoma	2-3%	Palms, soles, under nails	
Amelanotic Malignant Melanoma	0.4%	Any site, little/no pigment	

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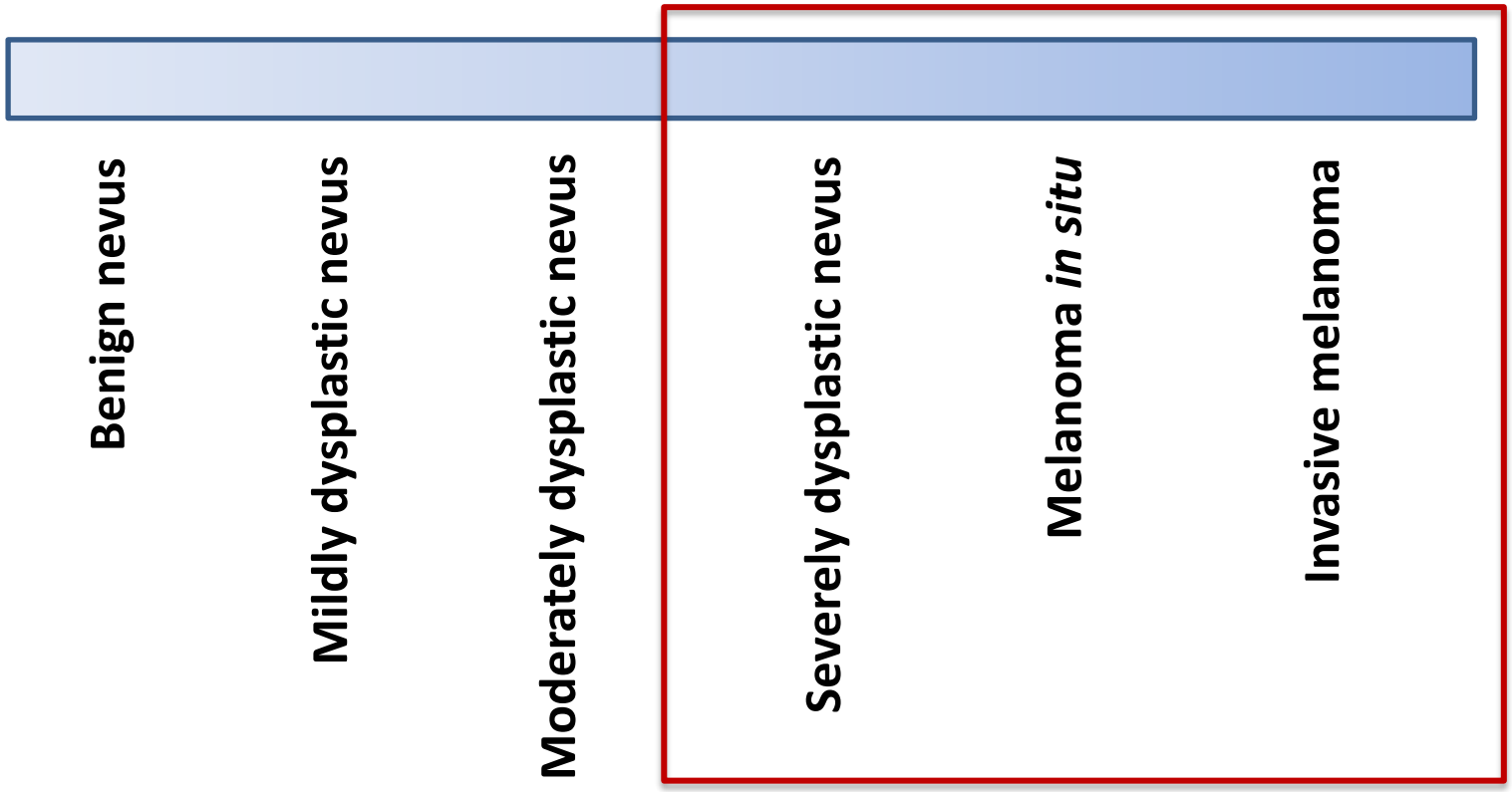
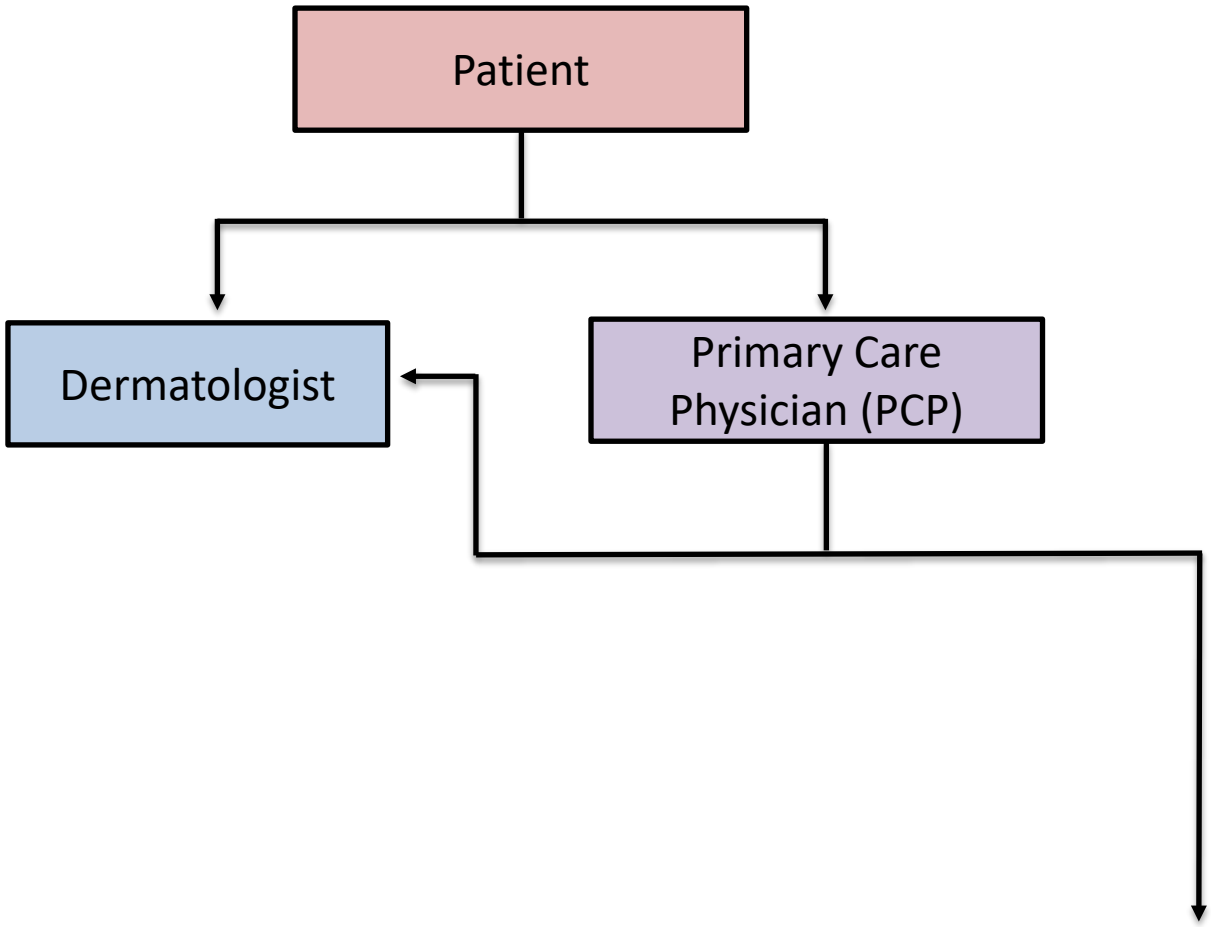
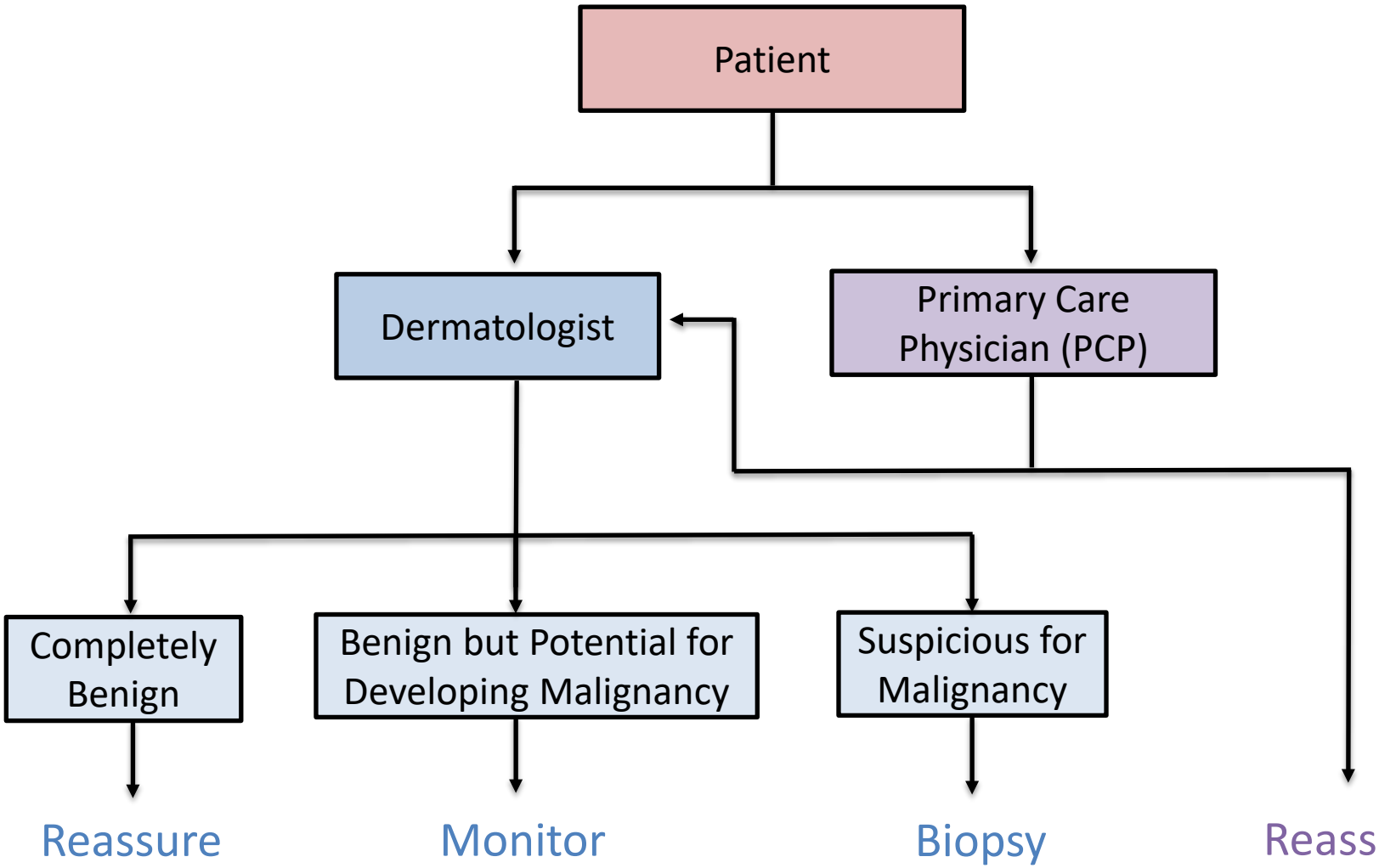
Spectrum of Melanocytic Lesions



Typical Workflow for Skin Lesions



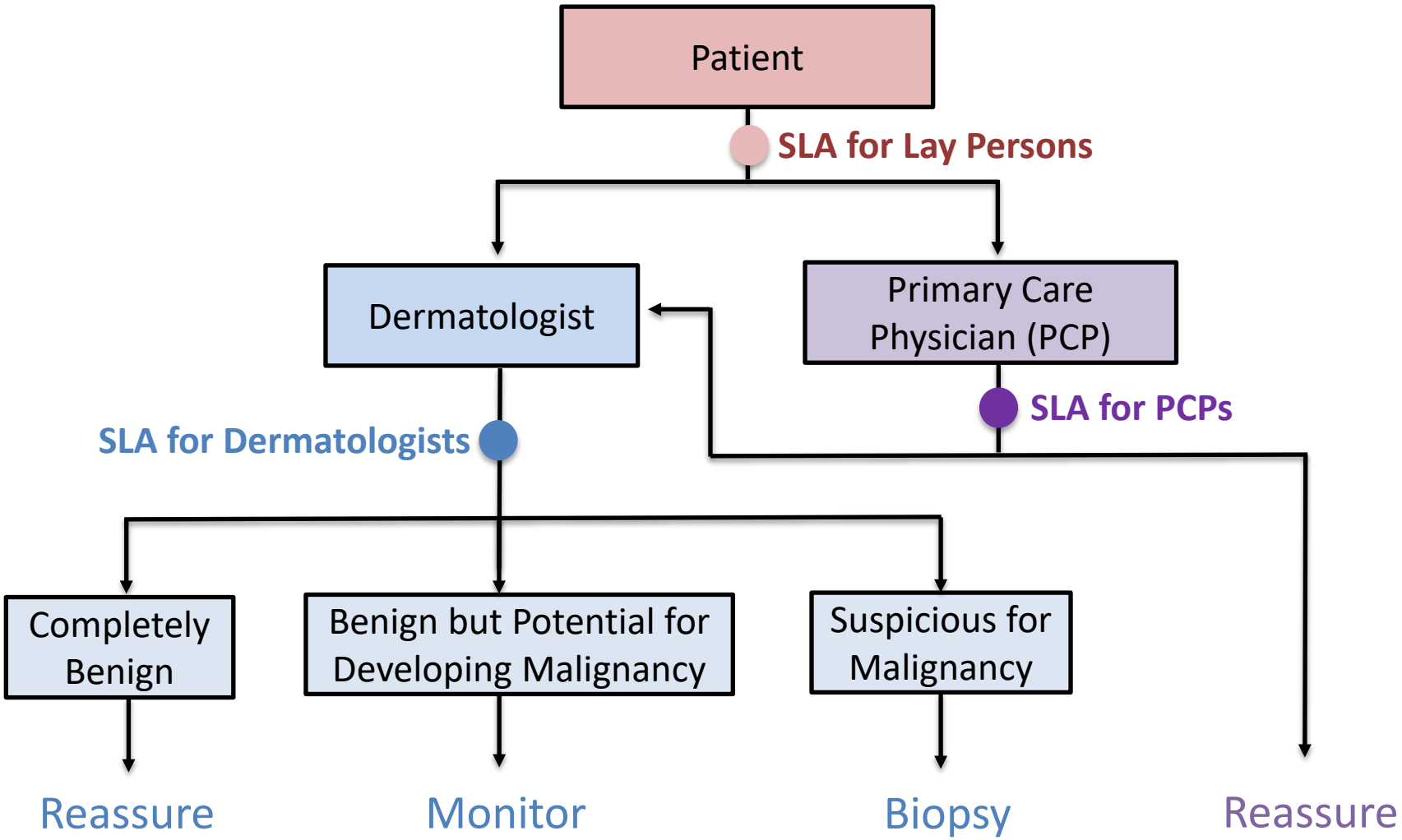
Typical Workflow for Skin Lesions



Approved Devices

- Two approved computer aided devices that utilize AI/ML for assessing pigmented lesions
  - MelaFind
  - Nevisense
- Intended use:
  - Adjunctive
  - For dermatologists only
  - To aid in a decision to biopsy
  - Limited to lesions suspicious for melanoma

Typical Workflow for Skin Lesions with SLAs



Clinical Considerations for SLAs

- Different indications
- Different intended users
- Different outputs
  - Binary (biopsy vs not biopsy)
  - Risk score
  - Diagnosis

Conclusion

- Early detection is important for melanoma
- SLAs may contribute to earlier triage of skin cancers
- Important to consider the accuracy and intended user

Thank you!

Skin Lesion Analyzer Device Landscape

Jianting Wang, Ph.D.

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Light Based Energy Devices Team
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Center for Devices and Radiological Health
Food and Drug Administration

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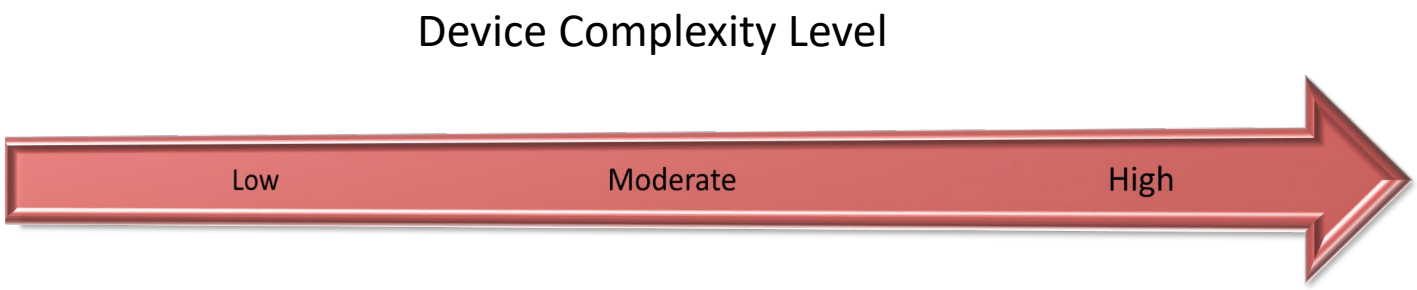
Technologies for Evaluating Skin

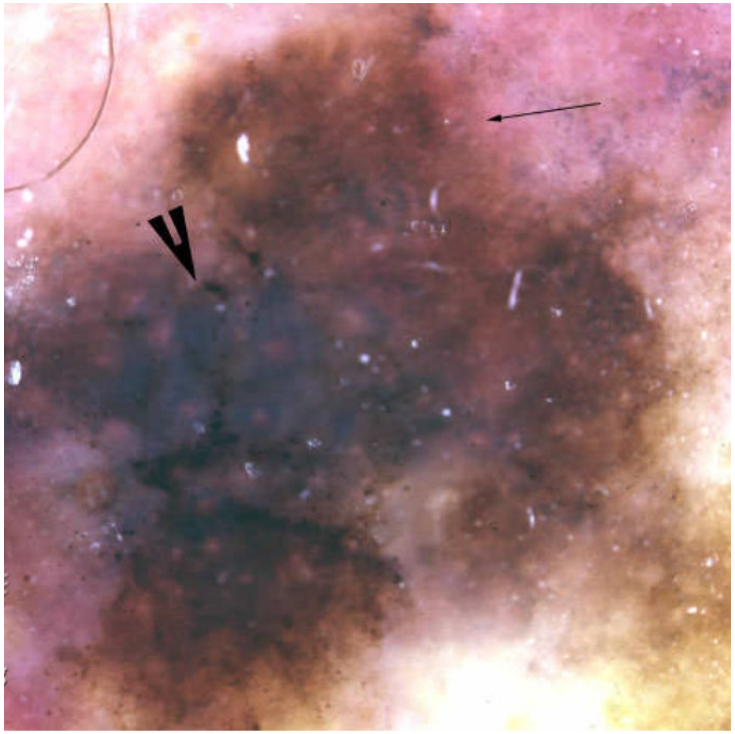
- Physical examination aids
- Optical imaging modalities
- Non-optical modalities
- Skin lesion analyzer software



Physical Examination Aids

Dermatoscope (over the counter)

- Magnification and illumination
- May support image capture/storage
- Provides image for user to assess
- Does not classify lesion or assess risk



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Digital Imaging with Structure Mapping

Advanced dermatoscope (Rx use)

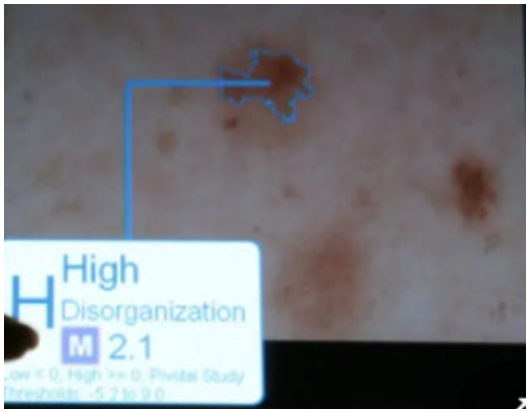
- Multi-spectral light
- Provides image that highlights areas with high melanin, hemoglobin, collagen content
- User must assess image
- Does not classify lesion or assess risk

Multi/Hyper-spectral Imaging

MelaFind

- Optical – light based
- Assesses 3D morphological disorganization
- Artificial Intelligence (AI)/Machine-Learning (ML)-based analysis
- AI-based output: risk score on 10-point scale

- Approved to be used when a dermatologist chooses to obtain additional information for a decision to biopsy.



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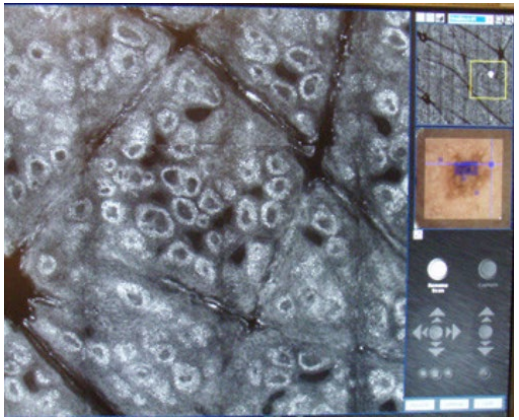
Reflectance Confocal Microscopy (RCM)

- High resolution
- Provides image for user to assess
- Not widely used

- Example: VivaScope, cleared to provide *in vivo* images of tissue in unstained epithelium and supporting stroma

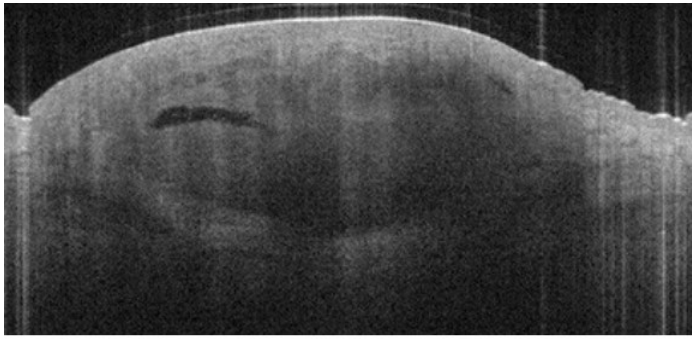
- Cochrane meta-analysis: dermatologists' performance with RCM



	Sensitivity	**Specificity**
All lesions	76%	95%
BCC	94%	85%
Melanoma	92%	72%

- **Image permission of DermNet NZ** dermnetnz.org/imagedetail/14188?copyright&label
- Data: Dinnes J et al. Reflectance confocal microscopy for diagnosing cutaneous melanoma in adults. Cochrane Database of Systematic Reviews 2018

Optical Coherence Tomography (OCT)



- High resolution
- Provides image for user to assess
- Not widely used

- Optical “ultrasound”-like images
- Example: VivoSight; cleared for 2D cross-sectional real-time imaging of external tissues

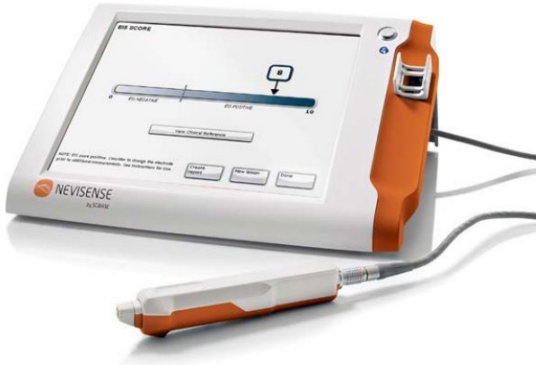
- Cochrane meta-analysis of OCT devices applied to skin cancer:

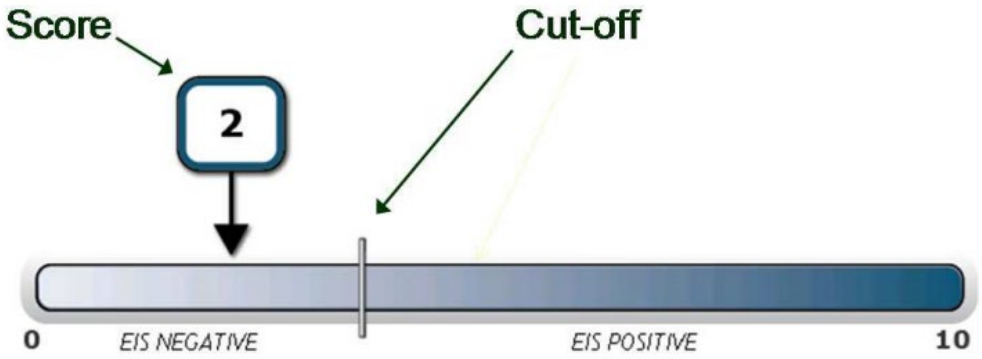
	Sensitivity	**Specificity**
BCC	95% (95% CI 91-97%)	77% (95% CI 69-83%)

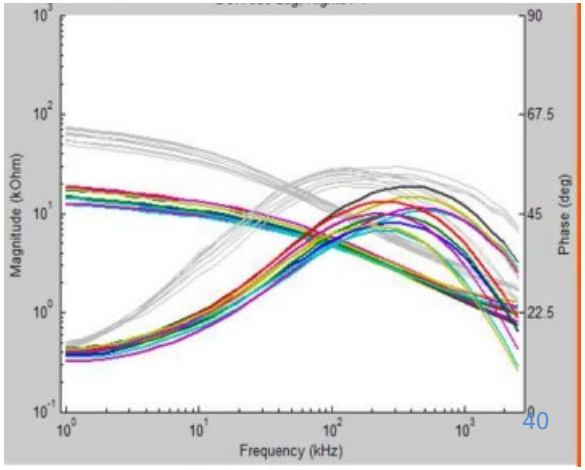
- **Image with permission DermNet NZ**: dermnetnz.org/imagedetail/13870?copyright=&label=+OCT&caption=+OCT
- Data: Ferrante di Ruffano, L., et al., Optical coherence tomography for diagnosing skin cancer in adults. Cochrane Database Syst Rev, 2018. **12**: p. CD013189.

Electrical Impedance Spectroscopy (EIS)

- Nevisense
  - Assesses resistance to current
  - Impedance sampled in normal skin and lesion
  - Assesses difference in EIS signal
  - AI-based output: score on 10-point scale







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Nevisense 3.0 Clinical Reference Guide scibase.com/uk/nevisense3/

Non-Optical Modalities

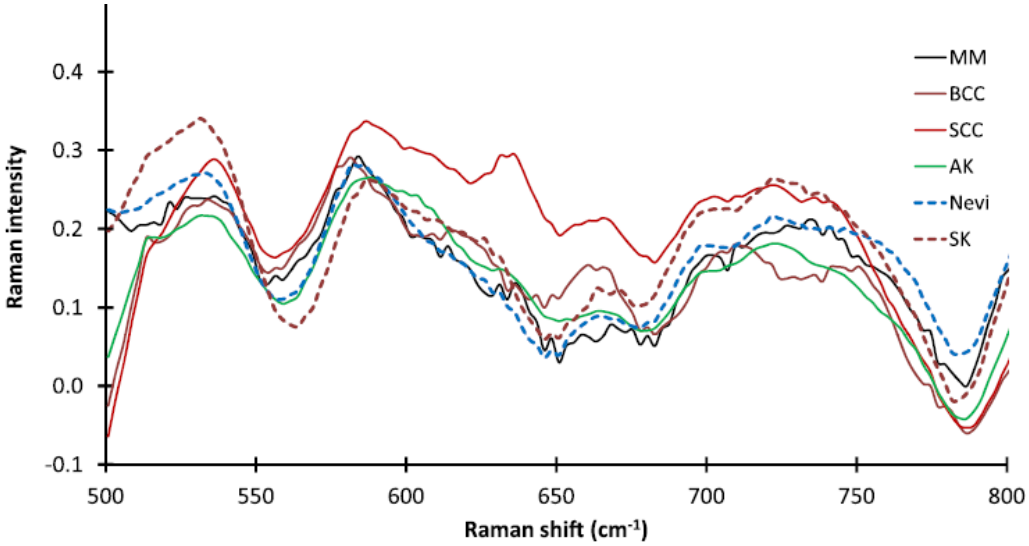
- High frequency ultrasound
  - Provides image to be assessed by user

	Sensitivity	Specificity
Melanoma	83% -100%	33%-73%

Dinnes et al. High-frequency ultrasound for diagnosing skin cancer in adults. *Cochrane Database Syst Rev*. 2018

Non-Optical Modalities

- Raman spectroscopy
  - Assesses light shift induced by molecules
  - Signal requires software for interpretation



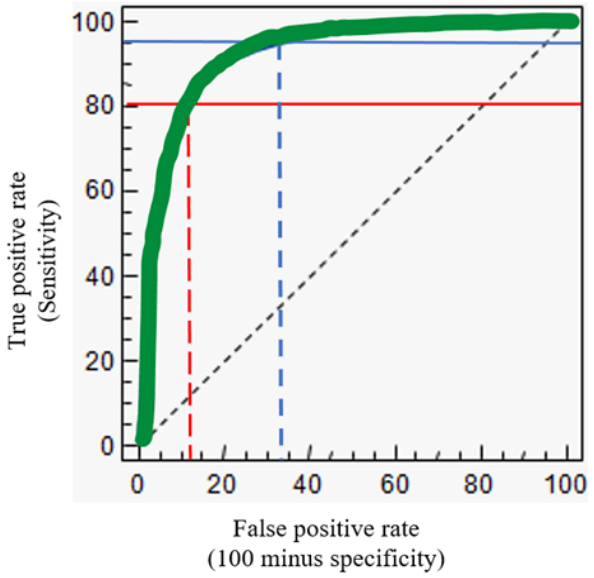
Zhao, J et al. Incorporating patient demographics into Raman spectroscopy algorithm improves in vivo skin cancer diagnostic specificity. Translational Biophotonics. 2019;e201900016.
(Under Creative Commons Attributions License)

SLA: Types, Uses, Users

- Software **in** a device, or Software **as** a Medical Device (SaMD)
- Software input:
  - Image: smartphone camera, dermoscopy
  - Other physical parameter: electrical Impedance, Raman spectroscopy
  - Supporting clinical data, e.g. skin type, history of lesion
- Software output:
  - Binary classifier (e.g., concerning, not concerning)
  - Multiclass classifier (e.g., nevus, melanoma, BCC, SCC)
  - Risk score, probability, etc.
- Intended users:
  - Dermatologists
  - Non-dermatology healthcare providers
  - Lay persons

SLA Software: Algorithm Development

- Artificial intelligence (AI) and machine learning (ML) to develop algorithm
- Three phases of development
  - Training phase
  - Validation/tuning phase
  - Testing phase
    - Device output compared to ground truth
    - Establishes sensitivity and specificity
    - Lock preset sensitivity; specificity follows



Skin Lesion Analysis Software

- Limitations and sources of bias:
  - AI/ML algorithm is only as good as the training provided
  - Datasets used (public or proprietary) may have limited
    - Skin phototype
    - Lesion types/diagnoses included
    - Lesion severity (e.g., lack borderline/challenging cases)

- Therefore, performance may not be generalizable
  - To full population
  - To all lesion types

Summary

- Wide range of technologies
  - Optical imaging
  - Non-imaging technologies
  - AI/ML algorithms

- Device use not limited to dermatologists
  - Dermatologists, non-dermatology providers, lay persons
  - Outputs: risk score, benign/malignant, diagnosis, etc.

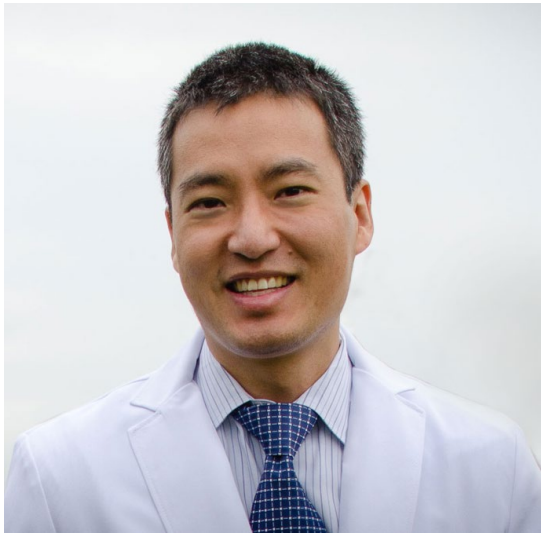
Thank you!

Special Considerations:
Diagnostic Accuracy and Ground Truth

Henry Lee, M.D.

Medical Officer, Light-Based Devices Team

Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration



General and Plastic Surgery Devices Panel Meeting

July 28, 2022

Introduction

- Panel will be asked to comment on
  - Accuracy goals
  - Ground truth
- FDA will provide
  - Context for proposed accuracy
  - Context for proposed ground truth

Performance Benchmarks

- Assessment of output accuracy:
  - ≥ predefined sensitivity and specificity threshold (%)
  - ≥ performance of providers
    - Dermatologists
    - PCPs
- Assessing adjunctive effect on user accuracy:
  - Improves performance of the user

Accuracy of Dermoscopy for Melanoma

	Sensitivity (95% CI)	**Specificity** (95% CI)
Visual examination	76% (66-85%)	75% (57-87%)
Visual examination with dermoscopy	**92%** (87-95%)	**95%** (90-98%)

Dinnes, J., et al., *Dermoscopy, with and without visual inspection, for diagnosing melanoma in adults.* Cochrane Database Syst Rev, 2018. **12**: p. CD011902.

Accuracy of Teledermatology

	Sensitivity (95% CI)	Specificity (95% CI)
Malignant vs. benign	**94.9%** (90.1-97.4%)	**84.3%** (48.5-96.8%)
Melanoma	**Range: 59% to 100%**	**Range: 30% to 100%**

Chuchu, N., et al., *Teledermatology for diagnosing skin cancer in adults.* Cochrane Database Syst Rev, 2018. **12**: p. CD013193.

Accuracy of Lay People

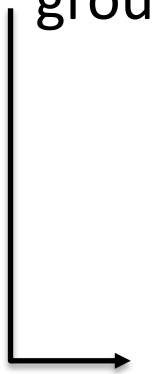
- Limited studies
- No data for US laypeople
- Assume to have limited or no diagnostic skill
- Rely on output at face value

Dermatologists and PCP

Lesion Type	Specialty	Sensitivity	Specificity
Melanoma	Dermatologist	67.2 - 100%	54 - 95.6%
	Primary Care Provider	29 - 98%	49 - 98%
Squamous cell carcinoma (SCC)	Dermatologist	65.8%	95.6%
	Primary Care Provider	42 - 69%	86 - 93%
Basal cell carcinoma (BCC)	Dermatologist	74 - 97%	87 - 98.9%
	Primary Care Provider	79 - 89%	76 - 83%
Binary outcome (e.g. malignant vs. benign; biopsy vs. observation)	Dermatologist	65.8 - 94.8%	59.8 - 95.6%
	Primary Care Provider	87.8 - 95.7%	57 - 90.6%

Ground Truth & Accuracy

- **Accuracy** – sensitivity and specificity compared to ground truth



Ground truth - true diagnosis, as established by a predefined method of assessing the lesion

Ground Truth Options

- **Biopsy** - traditional diagnostic benchmark
- **Non-invasive** - typically used for benign-appearing lesions
  - Clinical diagnosis by specialist (e.g. dermatologist)
  - Consensus diagnosis by panel of dermatologists
  - Stable lesion on follow-up
- **Hybrid model**
  - Biopsy suspicious lesions
  - Clinical diagnosis for benign appearing lesions

Variability and Accuracy of Histopathology

- Braun et al 2012
  - Substantial agreement among expert dermatopathologists: Kappa = 0.80
- Braun et al 2017
  - Local dermatopathologists compared to consensus panel
    - Sensitivity = 84.9%
    - Specificity = 98.1%

Braun, R. P., et al. "Agreement of dermatopathologists in the evaluation of clinically difficult melanocytic lesions: how golden is the 'gold standard'?" *Dermatology* 2012
Braun, R.P., et al. Electrical Impedance Spectroscopy in Skin Cancer Diagnosis. *Dermatologic Clinics*. 2017.

Conclusion

- Clinical accuracy varies by provider, specialty, and lesion type
- Input for regulating SLA:
  - Options for ground truth
  - Appropriate performance goals for accuracy

Thank you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Special Considerations:
Benefit/Risk and Prevalence

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Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices
Panel Meeting

July 29, 2022

Benefit/Risk

Essential to determining reasonable assurance of safety and effectiveness:

1. Evidence of device safety and effectiveness
2. Nature and severity of the condition
3. Benefits and risks of alternatives
4. Risk management

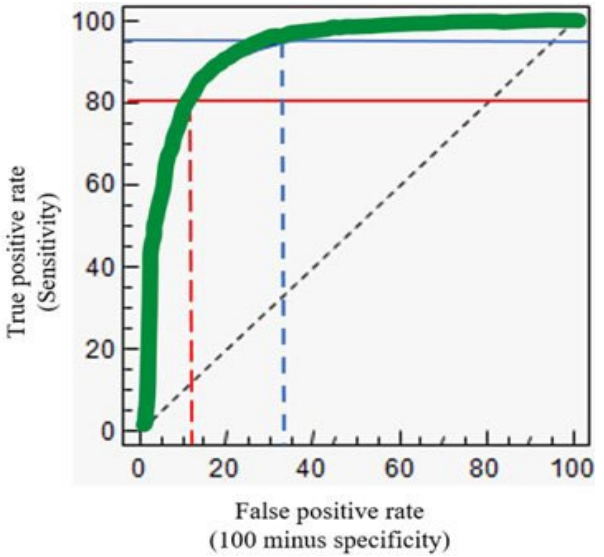
Benefit/Risk Assessment For SLA

Benefits of SLA devices:	Risks of SLA devices:
Greater access to diagnostic information by increasing availability	**Increased healthcare utilization and more skin lesion biopsies** due to false positive results
Earlier testing to improve outcomes in skin cancer, especially melanoma	**Delay in diagnosis** due to false negative results
Enhanced assessment as an additional tool aiding clinical decisions, especially with borderline lesions	**Poor Positive Predictive Value** when skin cancer has low prevalence in a given population

Performance Threshold

BCC/SCC	Sensitivity ≥ 80%
	Specificity ≥ 80%
MM	Sensitivity ≥ 90%
	Specificity ≥ 70%

Potential performance goal



Higher Sensitivity = ↑ Malignancy detection = ↑ Disease Outcome

Higher Specificity = ↓ Unnecessary Biopsies = ↓ Healthcare Resource Strain

Consideration of Target Diagnosis

- Consequences of false negative in cancer diagnosis > false positive

  → Sensitivity may be of greater clinical importance

- Consequences of false negative for melanoma > false negative for BCC/SCC

  → Different sensitivity/specificity thresholds may be appropriate for different target diagnoses

Consideration of User

- Primary care providers (PCPs) assess/treat > 50% of dermatological conditions
  - Diagnostic accuracy varies by training and experience
  - PCPs may have greater reliance on SLA
- Lay persons anticipated to have greater reliance on SLA
  - Not expected to have diagnostic skills

Different sensitivity and specificity thresholds may be appropriate for different users

Prevalence

- Skin cancer is more prevalent in certain populations
  - High prevalence in non-Hispanic white
  - Low prevalence in non-Hispanic black or Asian/Pacific Islander

- Device training/testing may utilize more skin cancer data from high prevalence populations

→ Under-representation of low prevalence populations may affect generalizability of results

Potential Approaches

1. Train and test device using data having an equal representation of skin cancer lesions in both high- and low-prevalence populations
    - Increased time to accrue images → significant delay of device access to those at highest risk

2. Stepwise approach

   Initial training/testing using data sets from high-prevalence populations, followed by that from low-prevalence populations
    - Allows earlier device access to those at highest risk
    - May increase risk of false positive/negative results in lower prevalence populations

Summary

- Weighing of Benefit/Risk
  - Benefits
    - Greater access to diagnostic information
    - Earlier testing
    - Enhanced assessment
  - Risks
    - Increased healthcare resource utilization
    - Unnecessary skin lesion biopsies
    - Delayed diagnosis → poorer disease outcome
    - Poor positive predictive value in low prevalence populations
- Consideration of Disease Prevalence
  - Impact on diagnostic accuracy
  - Influence on device access

Questions for the Panel

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Food and Drug Administration

General and Plastic Surgery Devices Panel Meeting

July 28, 2022

Question Overview

1) Ground truth: options

2) Accuracy: level of sensitivity and specificity

3) Ensuring generalizability to full US population

Definitions for Questions

Ground truth vs accuracy:

Ground truth: "gold standard" that will be used to determine the diagnosis of the lesion

Accuracy: measured sensitivity and specificity of device compared to the selected ground truth

Question 1: Ground Truth

In clinical trials for diagnostic devices, accuracy is assessed by comparing the device output to the ground truth. For skin lesions, particularly when ruling out malignancy, clinical practice has traditionally relied on histology for ground truth.

FDA has requested that histological diagnosis (core specimen processing with a consensus diagnosis from an expert dermatopathologist panel) be used for ground truth because it provides the greatest certainty in the diagnosis.

Device developers, however, cite concerns, both practical and ethical, in requiring biopsy of all lesions, particularly those that appear benign. They have proposed alternate means of defining ground truth, including consensus opinion of experts (of visual or dermoscopic examination of the lesion(s)), opinion of one expert (visual or dermoscopic examination), or other methods.

Question 1: Ground Truth

i. Should histological diagnosis be required for obtaining ground truth diagnosis in all lesions in SLA clinical trials?

ii. Are there scenarios for which alternate means or a combination (e.g., histopathology for suspected malignant lesions and consensus opinion of experts for suspected benign lesions) of ground truth would be acceptable?

Question 2A: Performance Thresholds For **Adjunctive Use**

Some SLA devices may be used for adjunctive use, meaning the output will be adjunctive information, to be used

- by a provider
- in concert with clinical and historical information,
- in reaching a management decision.

The provider may be a dermatologist or a non-dermatologist health care provider.

The table in the following slide provides proposed performance thresholds for sensitivity and specificity for melanoma, BCC, and SCC.

Question 2A: Performance Thresholds For **Adjunctive Use**

i. Should the performance thresholds of SLA devices intended for adjunctive use be a pre-defined sensitivity and specificity across all SLAs e.g., Table 5 (below), or should performance be compared to another metric, such as the performance of the study dermatologists without use of the SLA?
Or, can adjunctive use performance be assessed by whether the SLA output improves the accuracy of the study dermatologists?

ii. If preset thresholds are preferable, are the proposed thresholds for sensitivity and specificity proposed appropriate?
If not, what sensitivity and specificity thresholds do you propose?

BCC/SCC	Sensitivity 80%
	Specificity 80%
MM	Sensitivity 90%
	Specificity 70%

Question 2A: Performance Thresholds For **Adjunctive Use**

iii. Should the performance thresholds differ if the device is intended for use by dermatologists or by non-dermatology healthcare providers?

iv. Should the performance thresholds differ based on the target diagnosis (melanoma, BCC, and SCC)?

BCC/SCC	Sensitivity 80%
	Specificity 80%
MM	Sensitivity 90%
	Specificity 70%

Question 2B: Performance Thresholds
Standalone Device

Other SLA may be used as standalone devices, meaning that the output will be relied upon at face value to guide management.

Devices for lay users will always be standalone.

Question 2B: Performance Thresholds
Standalone Device

i. Should the performance thresholds of SLA devices intended for standalone use be a pre-defined sensitivity and specificity across all SLAs, or should performance be compared to another metric, such as the performance of the study dermatologists without use of the SLA?

ii. If preset thresholds are preferable, are the proposed thresholds for sensitivity and specificity appropriate? If not, what sensitivity and specificity thresholds do you propose?

BCC/SCC	Sensitivity 80%
	Specificity 80%
MM	Sensitivity 90%
	Specificity 70%

Question 2B: Performance Thresholds
Standalone Device

iii. Should the performance thresholds differ if the device is intended for use by lay users versus dermatologists or by non-dermatology healthcare providers? If so, what performance thresholds do you recommend for each?

iv. Should the performance thresholds differ based on the target diagnosis (melanoma, BCC, and SCC)? If so, what sensitivity and specificity thresholds do you propose?

BCC/SCC	Sensitivity 80%
	Specificity 80%
MM	Sensitivity 90%
	Specificity 70%

Question 3: Performance in US Population

Panelists should consider whether these SLA devices must be able to analyze skin lesions with an acceptable sensitivity and specificity in all patients prior to FDA clearance, or whether proof of performance data in higher-prevalence populations (e.g., non-Hispanic white individuals) can be provided to allow these high-prevalence populations access to this technology, followed by clinical studies in lower prevalence populations.

The potential benefit of a stepwise approach is that it may allow for earlier access to this technology for populations at high-risk, but it may increase the risk of false positive and false negative results in lower prevalence populations in whom the device has not been adequately trained and tested.

However, requiring SLA to be tested in patients with lower incidence before entering the market could delay the time to market due to extended enrollment times for statistically relevant numbers of darker skin individuals with skin cancer.

Question 3: Performance in US Population

Should FDA allow SLAs to be marketed based on study data from a limited US demographic (e.g., in higher incidence populations) with subsequent data collection in lower incidence populations to expand the indications for use?

Or, should the FDA require the training of AI/ML-based SLA technologies in all populations regardless of specific cancer incidence?

Question 3: Performance in US Population

Although the previous questions have focused on skin cancer, SLA may also be used for other lesions that have similar prevalence across all US demographics but look different in different Fitzpatrick skin types.

To ensure generalizability across the entire US population, should FDA require all AI/ML-based SLAs indicated for use beyond cancerous lesions to be trained and tested in a representative US population?


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