MoleMax™

Digital Epiluminescence Microscopy With MoleMax

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Objective

- Early recognition of melanoma
  - Epidemiology of melanoma
  - Treatment of early melanoma
  - Methods for improved detection
    - Epiluminescence Microscopy (ELM)
    - Digital Epiluminescence Microscopy
  - Computer aided tracking of changing lesions

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Introduction

- "To make an impact on cutaneous melanoma mortality in the U.S., All physicians –– not just dermatologists –– must be encouraged to take the initiative to seek out patients at perceived high risk for developing melanoma.
- Such high-risk persons need to be offered periodic surveillance examinations to detect melanoma in a premetastatic phase of development..."

Arthur R. Rhodes, MD, MPH
The Melanoma Letter,17,1,1999

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Facts - Burden of Disease

- 41,600 cases of cutaneous melanoma have been diagnosed in 1998 in the U.S. alone
- 7,300 people died of melanoma in 1999
- Approximately 50% of all melanomas occur in individuals younger than 55 years of age

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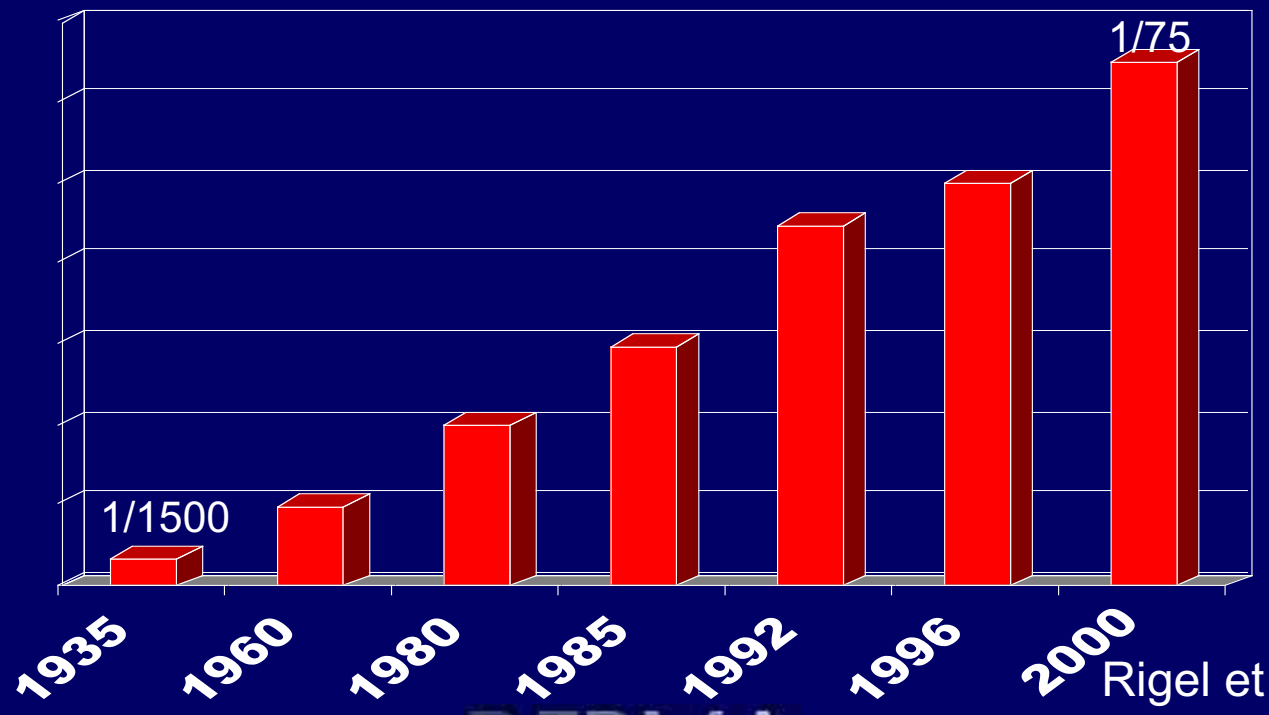
Facts - Burden of Disease

- In the 1930's, the lifetime risk for melanoma was 1:1500
- By the year 2000, the lifetime risk was already 1:75



Rigel et al. JAAD 34:5, 84

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Facts - Epidemiology

- Incidence of melanoma in Caucasians has increased by 52% over the past 15 years

- Caucasians have a 10 times higher risk to develop melanoma than African-Americans and a two to four times higher risk than Hispanics

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Early Recognition of Melanoma

- When melanoma is detected early, the chance for complete cure is excellent
- 5 – year survival rates after very early melanoma detection are greater than 95%
- Early recognition and treatment can turn a potentially fatal disease into an almost curable condition

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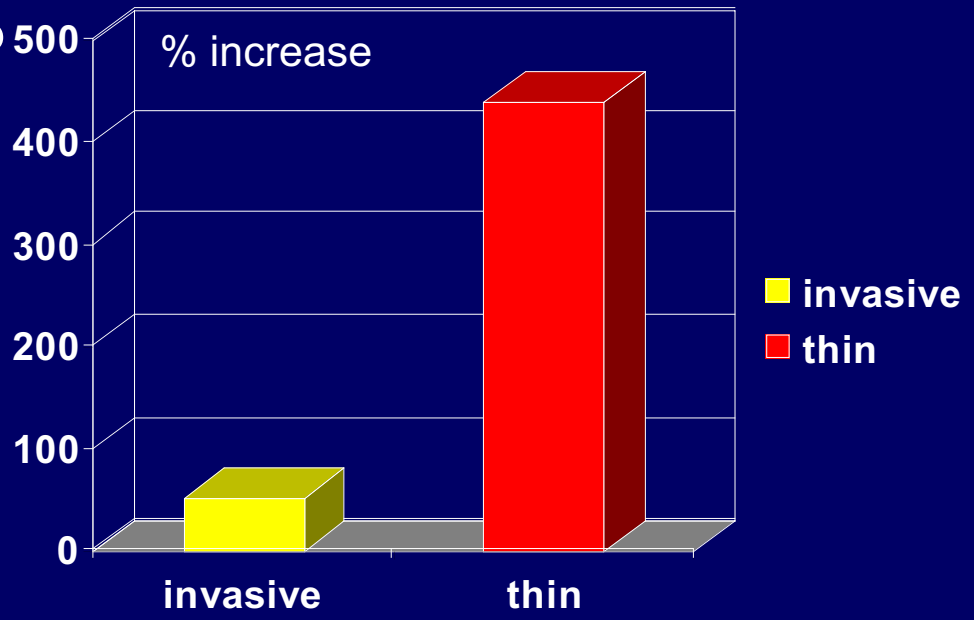
Facts - Early Detection

- Recently, the incidence of *in situ* melanomas has increased by about 400 % in Caucasians



Elder et al. Cancer 1995

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When Is Melanoma *Thin* or *Early* ?

- Invasion thickness is the most important single risk factor for melanoma
- Breslow's invasion thickness measures in millimeters the distance between the top layer of the epidermis and the deepest point of tumor penetration
  - Very thin tumors are 0.75 mm or less
  - Thin tumors are 0.76 mm to 1.5 mm

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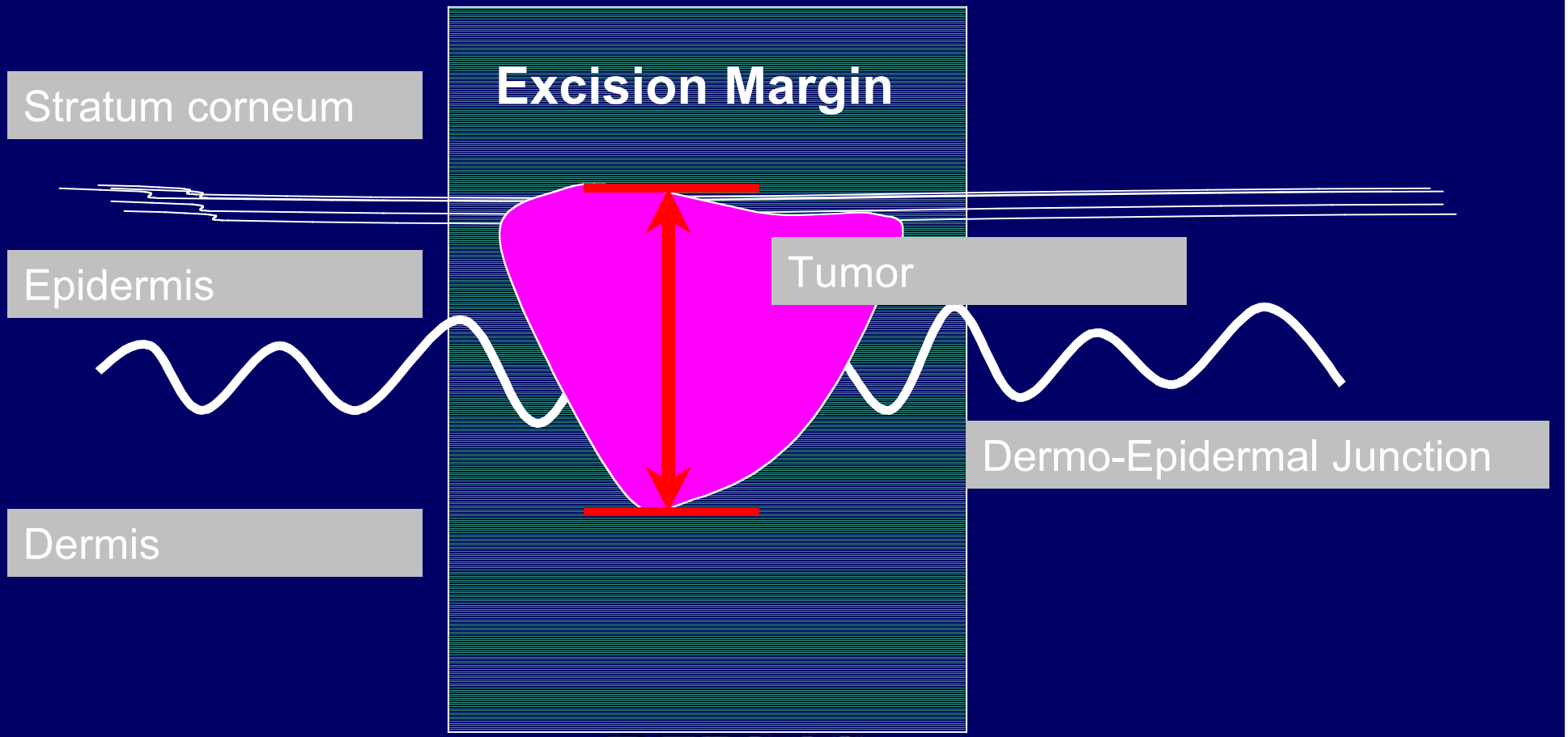
Breslow's Invasion Thickness



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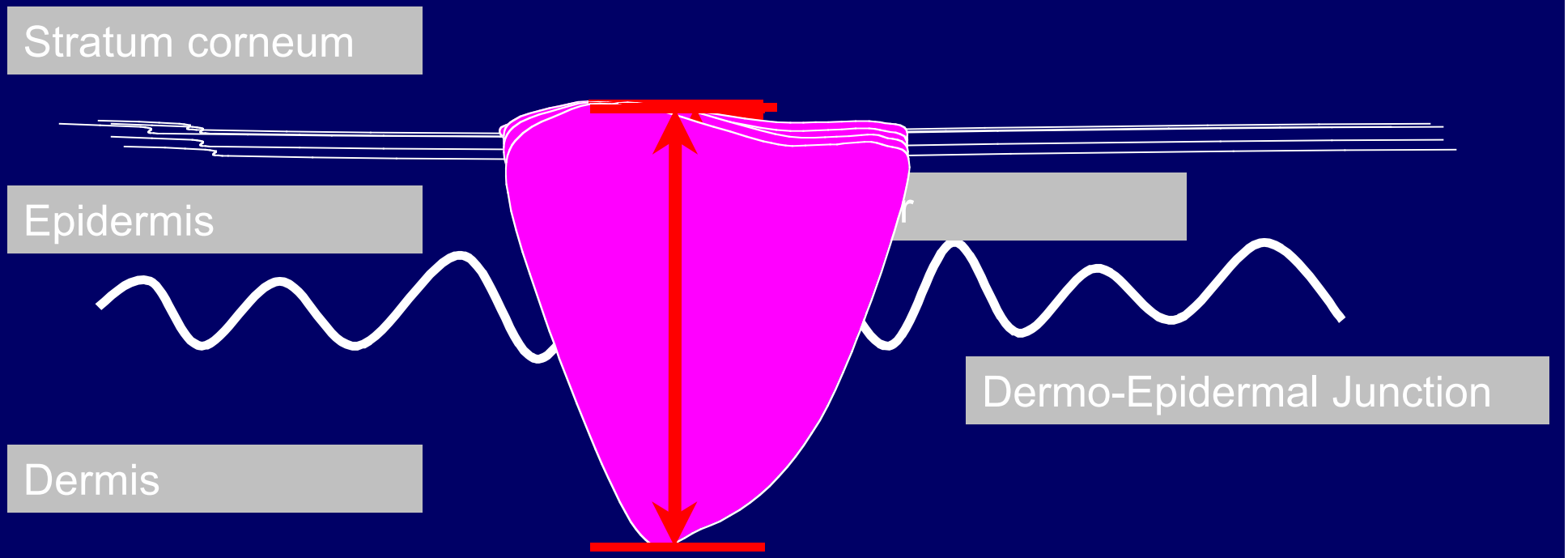
Breslow's Invasion Thickness



As melanoma grows, both the risk and the excision margin grows

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Treatment of Early Melanoma

- Surgical removal is the treatment of choice
- Safety margins (NIH guidelines)
  - In situ melanoma: 0.5 cm of surrounding skin, down to the fat layer
  - Less than 1 mm invasion thickness: 1 cm, down to the fascia
  - 1.1 mm to 3.99 mm: 2 cm margin, down to fascia
  - Larger 4.0 mm: 2 to 4 cm margins, down to

How to Detect Melanoma Early

- The goal is to detect melanoma before it becomes invasive or while it is still minimally invasive
- Epiluminescence microscopy (ELM) or Dermatoscopy is a recognized tool to improve early detection for equivocal pigmented lesions
- ELM allows doctors to visualize structures beneath the skin surface

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Melanoma Detection Using ELM

- ELM is a non-invasive, in vivo imaging method for pigmented skin lesion
- ELM provides additional morphologic criteria
- These criteria are helpful for the differentiation of benign nevi from melanoma

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ELM Facts

- ELM and digital ELM (DELM) improve the diagnostic sensitivity and the diagnostic specificity
- Improvement in sensitivity: 10%–27%
  - Especially in clinically equivocal lesions
  - *Mayer J., Med. J. Aust. 1997*
- Improvement in specificity: ~ 10%
  - *Binder M. Et al., Arch. Derm. 131, 286–291,1995*

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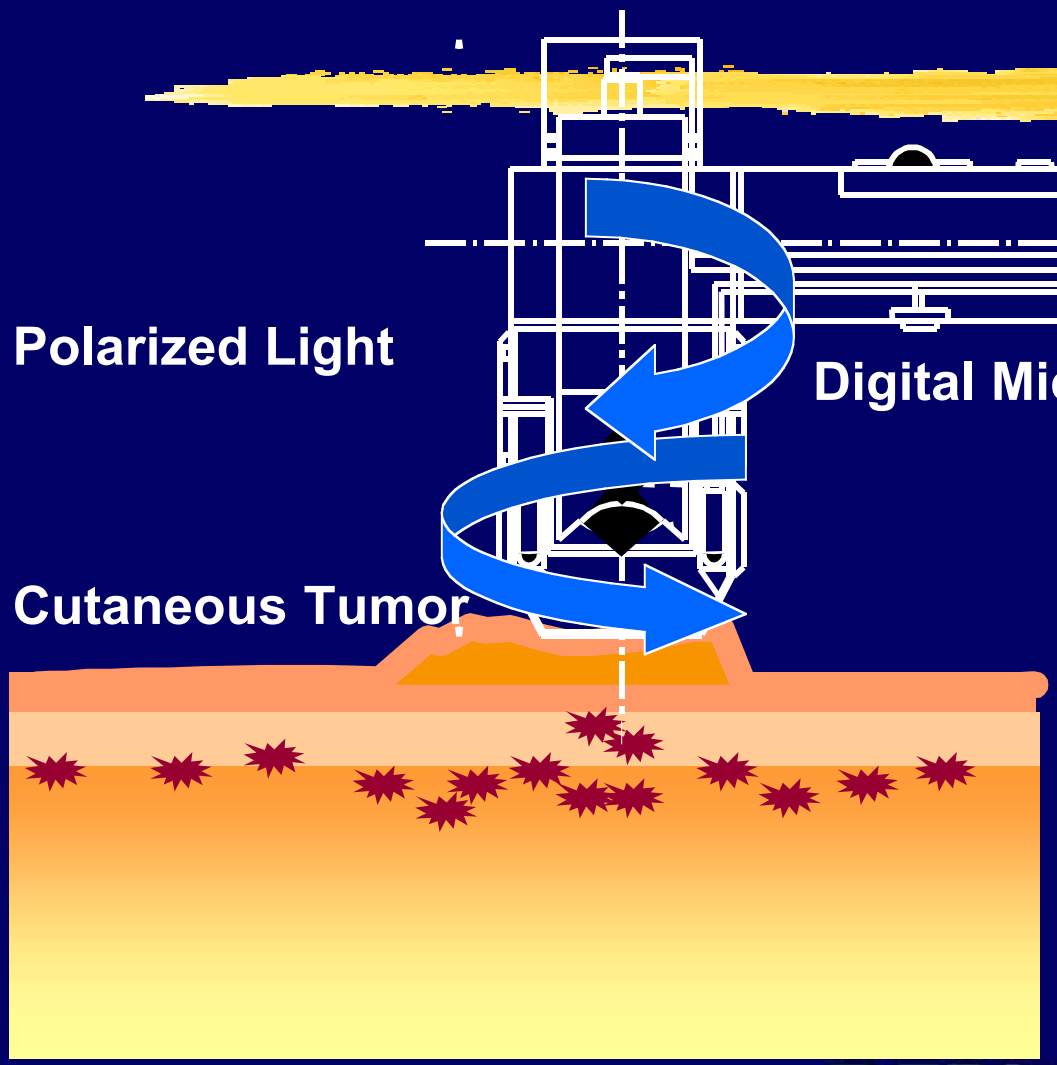
How Digital ELM Works



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MoleMax™ Digital Dermatoscopy

- MoleMax™ is a computerized imaging system utilizing digital ELM
- It allows doctors to:
  - Examine pigmented skin lesion using digital technology
  - Store and retrieve of images of lesions
  - Detect subtle changes in lesions during follow up
  - Access databases and use on-line diagnostic support

Digital ELM - Examining Lesions

- Digital Epiluminescence microscopy (DELM) allows doctors to look beneath the surface of the skin
- Additional morphologic features are visualized with DELM
- DELM improves the diagnostic accuracy in
  - Benign pigmented skin lesion
  - Early melanoma

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DELM - Junctional Nevus

A benign junctional nevus, scanned with MoleMax

- Nevus is almost symmetrical
- Border is fading towards the periphery
- Light and dark brown are dominating colors
- Pigment network is regular; No suspicious internal structures

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DELM - Atypical Mole

A macular lesion,
scanned with MoleMax

- Lesion is asymmetrical
- In most parts, pigment pattern is fading towards the periphery
- Dark and light brown are dominating colors
- Pigment network is discrete; pseudopods at the periphery

DELM - Early Melanoma

A partially elevated lesion,
scanned with MoleMax

Superficial spreading melanoma,
Breslow´s thickness: 1,2 mm

- Lesion is asymmetrical
- Pigment pattern ends abruptly
- Black, blue and dark brown are dominating colors
- Radial streaming and pseudopods at the periphery

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DELM - Early Melanoma

A macular lesion,
scanned with MoleMax

Superficial spreading melanoma,
Breslow´s thickness: 0, 68 mm

- Lesion is asymmetrical
- Pigment pattern ends abruptly
- Black, dark and light brown are dominating colors
- Radial streaming and pseudopods at the periphery

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DELM - Early Melanoma

A macular lesion,
scanned with MoleMax

Superficial spreading melanoma,
Breslow's thickness: 0, 75 mm

- Lesion is asymmetrical
- Pigment pattern ends abruptly
- Dark and light brown are dominating colors
- Black dots and brown globules are haphazardly distributed
- Radial streaming and pseudopods are present

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Digital ELM - Track of Change

- MoleMax™ facilitates objective comparison of pigmented skin lesions over time
- Pigmented skin lesions may change their
  - Size
  - Shape & appearance
  - Colors
  - Specific structures
- Real time, side by side comparison makes it easy to detect even subtle changes

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Pigmented Lesion, First Exam

A flat, pigmented macula, scanned with MoleMax

Lesion was digitally scanned for follow up

- Lesion is almost symmetrical
- Border is sharply demarcated from surrounding skin
- Light and dark brown are dominating colors
- Pigment network is regular; Brown globules at the periphery

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A Changing Mole, Follow up

First Exam

6 Months later

Detection of a growing lesion

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MoleMax™ - Main Features

- Digital Mole Mapping
- Digital Epiluminescence Microscopy (DELM)
- Patient and Lesion Databases
- Storage and Retrieval of Images
- Follow up
- Printout
- Telecommunication & Diagnostic support

Advantages of MoleMax™

- The innovation of MoleMax™ is based on recognized, international scientific research
- MoleMax™ combines the advantages of computer technology with the power of an established diagnostic technique
- MoleMax™ improves the diagnostic accuracy for equivocal pigmented skin lesions

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Advantages for the Physician

- MoleMax™ supported skin exams
  - Make it easy to use epiluminescence microscopy and therefore improve diagnostic accuracy
  - Help to define objective criteria for decision making due to storage, retrieval and follow up of images lesions
  - Improve the quality of care
  - Help to reassure patients

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Advantages for the Patient

- MoleMax™ supported skin exams
  - Give the confidence a patient needs when they have a serious health problem
  - Improve compliance for
    - Follow up exams in regular intervals
    - Measures of primary prevention

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Summary

- DELM with MoleMax™ is a valuable tool for the early diagnosis of melanoma
- Epiluminescence microscopy has shown to improve the diagnostic performance for pigmented skin lesions
- MoleMax™ helps the physician to apply this technique most efficiently

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