# Anatomy of a Delayed Diagnosis of Cancer Lawsuit

## 2016 DermFoot MidWest

American Society of Foot and Ankle Dermatology


**Bryan C. Markinson, DPM**

The Leni and Peter W. May Department of Orthopedics
Department of Dermatololgic Surgery
Melanoma and Skin Cancer Program-Tisch Cancer Institute
Icahn School of Medicine at Mount Sinai
Consultant – Bako Integrative Podiatric Solutions


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# Definition of delayed diagnosis of cancer

Delayed diagnosis in cancer is when someone who has cancer:

- is not investigated or referred for investigation; *or*
- having been investigated, is not diagnosed at the time of the investigation; *or*
- is diagnosed incorrectly; *or*
- where a positive test result or diagnosis is not communicated effectively to a clinician with the ability to act on the information; *or*
- where a positive test result or diagnosis is not acted upon and treatment commenced as appropriate.

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# Time from noticing to reporting symptoms:

- Including breast, lung, upper GI, colorectal and prostate, Melanoma had the longest average time delay in patient reporting of symptoms of just under 80 days!!
- But time from reporting symptoms to primary care physician to appropriate referral, for melanoma, along with breast was the quickest

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- **The effect of misdiagnosis and delay in diagnosis on clinical outcome in melanomas of the foot.**

J Am Coll Surg. 1994 Sep;179(3):279-84.

- Bridgeport Hospital and Connecticut tumor registry – 1980 -89 : 168 cases
- Significant delay in 68% of hospital cases, 16% from state tumor registry
- Regardless of stage, melanoma of the foot had a worse prognosis than melanoma of the thigh and lower leg.
- **Delays in diagnosis had no demonstrable effect on clinical outcome.**
- It is the inherent aggressiveness of the tumor rather than the delay in diagnosis that accounts for the poor clinical outcome.
- Misdiagnosis was common.

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- Thomas Jarrad Matzke; Andrew K. Bean; Tanya Ackerman: **Avoiding Delayed Diagnosis of Malignant Melanoma**
- Journal for Nurse Practitioners. 2009;5(1):42-46. © 2009 Elsevier Science, Inc.
- **“Delayed diagnosis of melanoma directly impacts patient survival.“** *not referenced*
- Misdiagnosis of melanoma involving partial biopsy samples is major source of malpractice claims
- Advocate complete removal/shave, punch or excision

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# Benign versus Malignant

- Risk management principles apply regardless of the potential for malignancy as benign conditions can cause considerable symptomatology, cosmetic issues, scarring, and other complications or sequelae long term.
- Malignant conditions however are the main thrust of our efforts at early diagnosis and eradication, appropriate initial evaluation and local treatment, and appropriate referral for systemic care.

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# Benign versus Malignant

- In most cases, for podiatry, the skin biopsy becomes the central issue regarding whether standard of care is met.
- Was the biopsy:
  - Done?
  - Correct type?
  - Done on a timely basis?

**Allegations of failure to biopsy are difficult to defend!**

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# Potential issues in podiatric dermatology malpractice:

- DELAYED DIAGNOSIS
- NO BIOPSY
- BIOPSY DONE, UNEXPECTED MALIGNANT RESULT, NO REVIEW OR PATHOLOGY COMMUNICATION, RESULTING IN TREATMENT FOR MALIGNANCY
- PATHOLOGY ERROR
- DELAY OR FAILURE TO TELL PATIENT (NO PROCEDURE TO INSURE NOTIFICATION)
- RE-EXCISION OF WRONG LESION (MORE COMMON ON TORSO)
- LOST SPECIMEN (WHAT DO YOU DO?)
- SCAR

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# Plaintiff Allegations

- Lack of consent (Weak case if first allegation)
- Lack of informed consent (Weak)
- Delayed diagnosis (no testing, biopsy, consult)
- Lack of timely referral or consultation
- Failure to document results of referral or consultation or test and biopsy results
- Failure to inform patient of biopsy or test results (failure to follow-up)

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# Defendant's Defense

- Lost patient (hospital clinic case, no-show, cancelled appointments)
- Insurance verification after first visit
- Never received biopsy report
- Patient refused biopsy !!!!
- Relied on pathologist for diagnosis
- "I thought the dermatologist was taking care of it."

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# Refused Biopsy

- This is a weak defense in cases where treatment for other problems continues
- “Refused biopsy” written in large bold letters different from surrounding writing is highly suspect
- Treat this refusal the same as a non-compliant diabetic ulcer patient

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## The effect of misdiagnosis and delay in diagnosis on clinical outcome in melanomas of the foot.

Bennett DR, Wasson D, MacArthur JD, McMillen MA

J Am Coll Surg. 1994 Sep;179(3):279-84

- RESULTS: 166 cases. ***Significant delay in diagnosis occurred in 68 percent of the cases from the hospital and at least 16 percent of the cases in the state tumor registry.***
- Regardless of stage, melanoma of the foot had a worse prognosis than melanoma of the thigh and lower leg. ***Delays in diagnosis had no demonstrable effect on clinical outcome.***

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# The effect of misdiagnosis and delay in diagnosis on clinical outcome in melanomas of the foot.

Bennett DR, Wasson D, MacArthur JD, McMillen MA

J Am Coll Surg. 1994 Sep;179(3):279-84

- **CONCLUSIONS: Melanoma of the foot constituted 3 percent of the 4,562 melanomas reported in the state tumor registry for the nine-year period. The majority were in fair-skinned individuals, and misdiagnosis was common.**
- ***It is the inherent aggressiveness of the tumor rather than the delay in diagnosis that accounts for the poor clinical outcome.***

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# Delay in the diagnosis of cutaneous melanoma: an analysis of 233 patients: M. H. Schmid-Wendtner , et al, Dept. of Dermatology and Allergology, Ludwig-Maximilians-University, Frauenlobstr.

Melanoma Research 2002, 12, pp. 389–394

Between January 1999 and January 2001, 233 patients (124 women and 109 men; mean age 55 years, median age 56 years; range 20–88 years) with histologically proven primary cutaneous melanomas diagnosed were interviewed.

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Delay in the diagnosis of cutaneous melanoma: an analysis of 233 patients: M. H. Schmid-Wendtner , et al, Dept. of Dermatology and Allergology, Ludwig-Maximilians-University, Frauenlobstr.
Melanoma Research 2002, 12, pp. 389–394

Superficial spreading melanoma (56.7%)
Nodular melanoma (17.2%)
Unspecified melanoma (10.7%)
Melanoma in situ (6.9%)
Acral lentiginous melanoma (4.7%)
Lentigo maligna melanoma (3.9%)

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Delay in the diagnosis of cutaneous melanoma: an analysis of 233 patients: M. H. Schmid-Wendtner , et al, Dept. of Dermatology and Allergology, Ludwig-Maximilians-University, Frauenlobstr.
Melanoma Research 2002, 12, pp. 389–394

Histopathological examination revealed that:

42.1% of the patients had a **tumor thickness < 0.75 mm**

**26.6% of the patients had a tumor thickness 0.75–1.5 mm**

**12.0% of the patients had a tumor thickness 1.5–3.0 mm**

**12.5% of the patients had a tumor thickness > 3.0 mm.**

**The trunk was the most common tumour site (43.3%), followed by the legs and feet (32.6%), arms (13.7%), and head and neck (10.3%)**

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Delay in the diagnosis of cutaneous melanoma: an analysis of 233 patients: M. H. Schmid-Wendtner , et al, Dept. of Dermatology and Allergology, Ludwig-Maximilians-University, Frauenlobstr.
Melanoma Research 2002, 12, pp. 389–394

- **No correlation between delay and tumor thickness**
- **30% of patients waited one year to present lesion to a physician**
- **Professional delay (> I month delay in physician treatment) averages 12 – 25% across several studies.**
- **Only 15% of patients recognizing possibility of melanoma consulted a physician within one month.**

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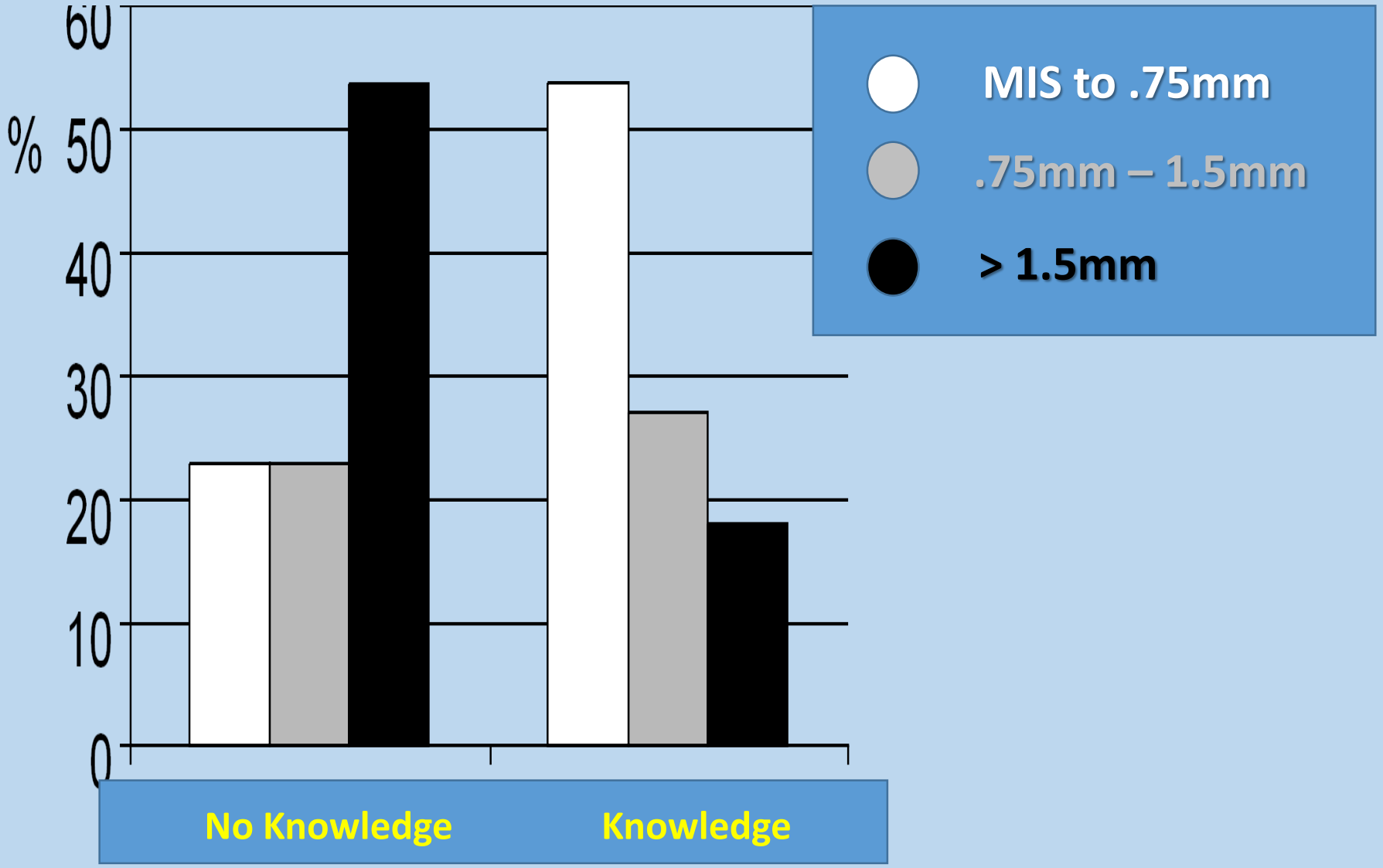
# Melanoma Research 2002, 12, pp. 389–394, CTD.

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# 404 subjects with invasive melanomas

- **International public health efforts tout the ABCD rule as a way to help people identify potentially harmful skin growths.**
- **Rapidly growing melanomas do not look like a mole and do not fit the description encoded by the ABCD rule (asymmetry, border irregularity, color irregularity, large diameter)**
- ***Faster rates of growth were associated with faster mitotic rates***
- **Characteristics that were *not* associated with the rate of growth were age spots and liver spots, history of sun damage or blistering sunburns, family history of melanoma, and eye color.**
- **One third of the melanomas grew less than 0.1 mm per month; one third grew between 0.1 and 0.49 mm; and one third grew by 0.5 mm or more per month.**

Wendy Liu of the Victorian Melanoma Service at the Alfred Hospital in Melbourne, Australia – Archives of Dermatology December 2006

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# 404 subjects with invasive melanomas

- ***rapidly growing melanomas tended to be symmetrical, have even borders, and to occur in people who didn't have a lot of freckles or moles . "These are things that we as doctors associate with benignness"***
- **Liu's research doesn't contest the ABCD rule but suggests a need for awareness about other kinds of deadly lesions and growths**
- ***We've got to raise the level of suspicion."***

Wendy Liu of the Victorian Melanoma Service at the Alfred Hospital in Melbourne, Australia – Archives of Dermatology December 2006

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## Avoiding Delayed Diagnosis of Malignant Melanoma

Thomas Jarrad Matzke; Andrew K. Bean; Tanya Ackerman

Journal for Nurse Practitioners. 2009;5(1):42-46

- ***Delayed diagnosis of melanoma directly impacts patient survival.***

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# Melanoma and Tumor Thickness – Challenges of early diagnosis Richard, Grob, et al, Arch Dermatol, March 1999

- **Cassileth 1982, Temoshok 1984,, Krige 1991, Baccard 1997**
- **Poor prognosis can be accounted for by aggressive rapidly growing tumors *RATHER THAN BY DELAYS***
- ***No correlation is found between melanoma thickness and physician delays!***

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# Common method of assessing delay by obtaining series of dates

- D1 – day patient first noticed lesion on site diagnosed
- D2 – when patient first believed lesion was curious or could be dangerous
- D3 – when lesion examined by physician for the first time
- D4 – when physician first recommended biopsy or removal
- D5 – when melanoma resection was performed
- Intervals are then D1-D2, D2-D3,D3-D4, D4-D5
- An interval may become irrelevant as in when a physician is first to notice the lesion, therefore D1-D2 is irrelevant.

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Betti, Vergani, et al, **Factors of delay in the diagnosis of melanoma**, European Journal of Dermatololgy, March –April 2003; 183-8

As regards our data on *physician delay*, only three types of significant correlations are shown: namely**, pigmentation, age and site.**

-Amelanotic lesions have **longer** delay

-Elderly patients have **less** delay

-The back has **less** delay than other areas

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# Other factors in delay

- Sex
- Knowledge of patient
- Body site
- Age
- Modality of detection (self or family member)
- Physician response
- Insurance issues in United States?

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# Staging of Melanoma

- **Mortality/Morbidity: If detected early, melanoma can be cured with surgical excision. Clinically, lesions are classified as thin if they are 1 mm or less in depth; moderate if 1-4 mm; and thick if more than 4 mm in depth.**
- **Stage IA: Lesions less than or equal to 1 mm thick with no evidence of ulceration or metastases (T1aN0M0) are associated with a 5-year survival rate of 95%.**
- **Stage IB: Lesions less than or equal to 1 mm thick with ulceration noted but without lymph node involvement (T1bN0M0) or lesions 1.01-2 mm thick without ulceration or lymph node involvement (T2aN0M0) are associated with a 5-year survival rate of approximately 91%.**

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# Staging of Melanoma

- **Stage IIA : Melanomas greater than 1 mm but less than 2.01 mm in thickness with no evidence of metastases but with evidence of ulceration (T2bN0M0) or lesions 2.01-4.0 mm without ulceration or lymph node involvement (T3aN0M0) are associated with an overall 5-year survival rate of 77-79%.**
- **Stage IIB : Melanomas 2.01-4 mm thick with ulceration but no lymph node involvement (T3bN0M0) or lesions greater than 4 mm without ulceration or lymph node involvement (T4aN0M0) are associated with a 5-year survival rate of 63-67%.**
- **Stage IIC: Lesions greater than 4 mm with ulceration but no lymph node involvement (T4bN0M0) are associated with a 5-year survival rate of 45%.**

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# Staging of Melanoma

- Stage IIIA: Patients with any depth lesion, no ulceration and 1 positive (micrometastatic) lymph node (T1-4a,N1a,M0) have a 5-year survival rate of 70%. T1-4a,N2a,M0 lesions (any depth lesion, no ulceration but 2-3 nodes positive for micrometastasis) are associated with a 5-year survival rate of 63%.
- Stage IIIB : Patients with any depth lesion, positive ulceration and 1 lymph node positive for micrometastasis (T1-4b,N1a,M0) or 2-3 nodes positive for micrometastasis (T1-4b,N2a,M0) have a 5-year survival rate of 50-53%. Patients with any depth lesion, no ulceration and 1 lymph node positive for macrometastasis (T1-4a,N1b,M0) or 2-3 nodes positive for macrometastasis (T1-4a,N2b,M0) have a 5-year survival rate of 46-59%.
- Stage IIIC : Patients with any depth lesion, positive ulceration and 1 lymph node positive for macrometastasis (T1-4b,N1b,M0) or 2-3 nodes positive for macrometastasis (T1-4b,N2b,M0) or 4 or more metastatic lymph nodes, matted lymph nodes, or in transit met(s)/satellite(s) have a 5-year survival rate of 24-29%.

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# Staging of Melanoma

- **Stage IV: Melanoma metastatic to skin, subcutaneous tissue, or lymph nodes with normal LDH (M1a) is associated with a 5-year survival rate of 19%. M1b disease (metastatic disease to lungs with normal LDH) has a 5-year survival rate of 7%. M1c disease (metastatic disease to all other visceral organs and normal LDH or any distant disease with elevated LDH) is associated with a 5-year survival rate of 10%.**

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# In Office Skin Cancer Screening for Every Patient

- **It is easy not to realize what you cannot see if you do not properly examine the skin.**

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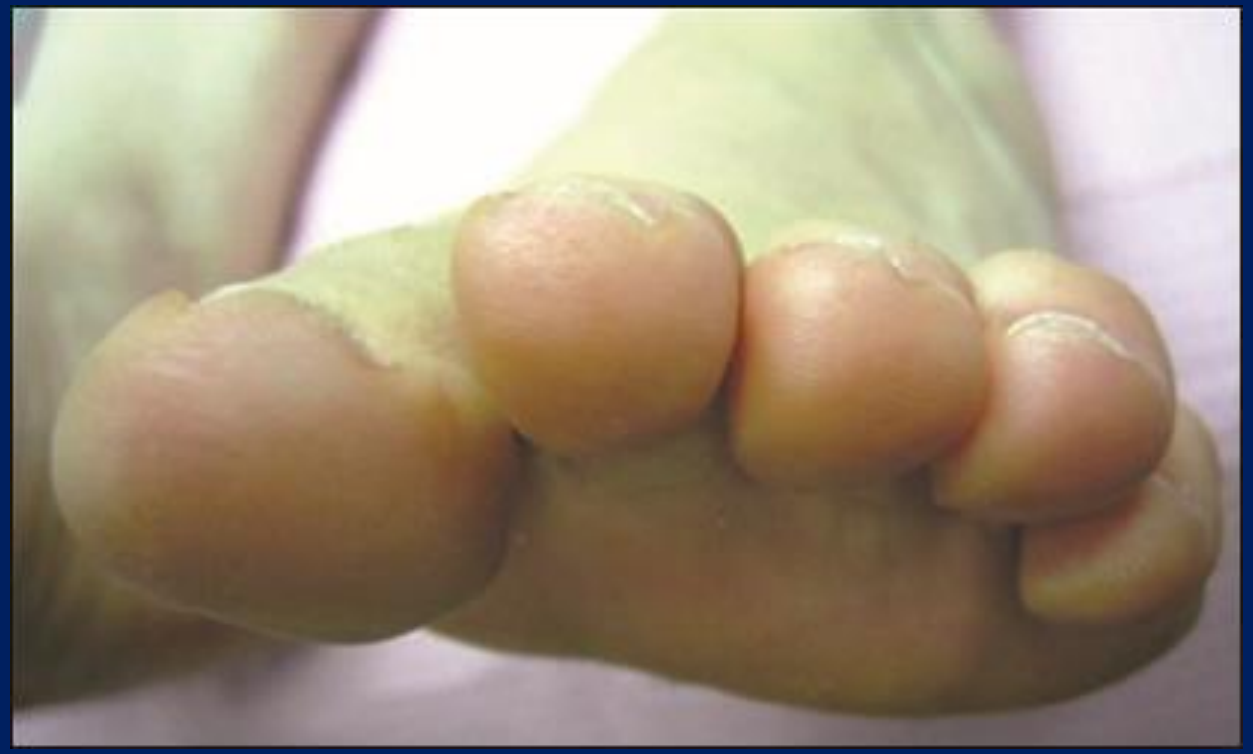
# Typical position of foot with patient in treatment chair



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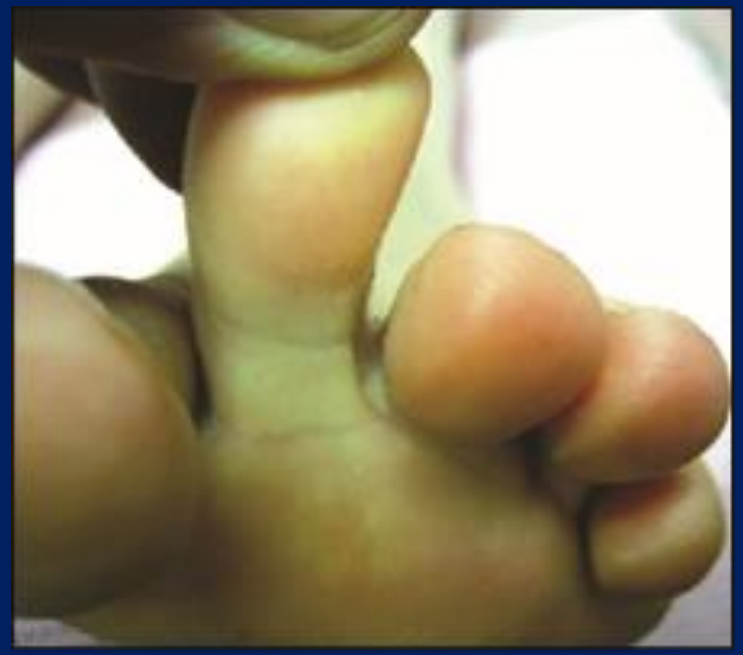
You cannot adequately see the plantar surface of the toes or sulcus area without extending the digit.



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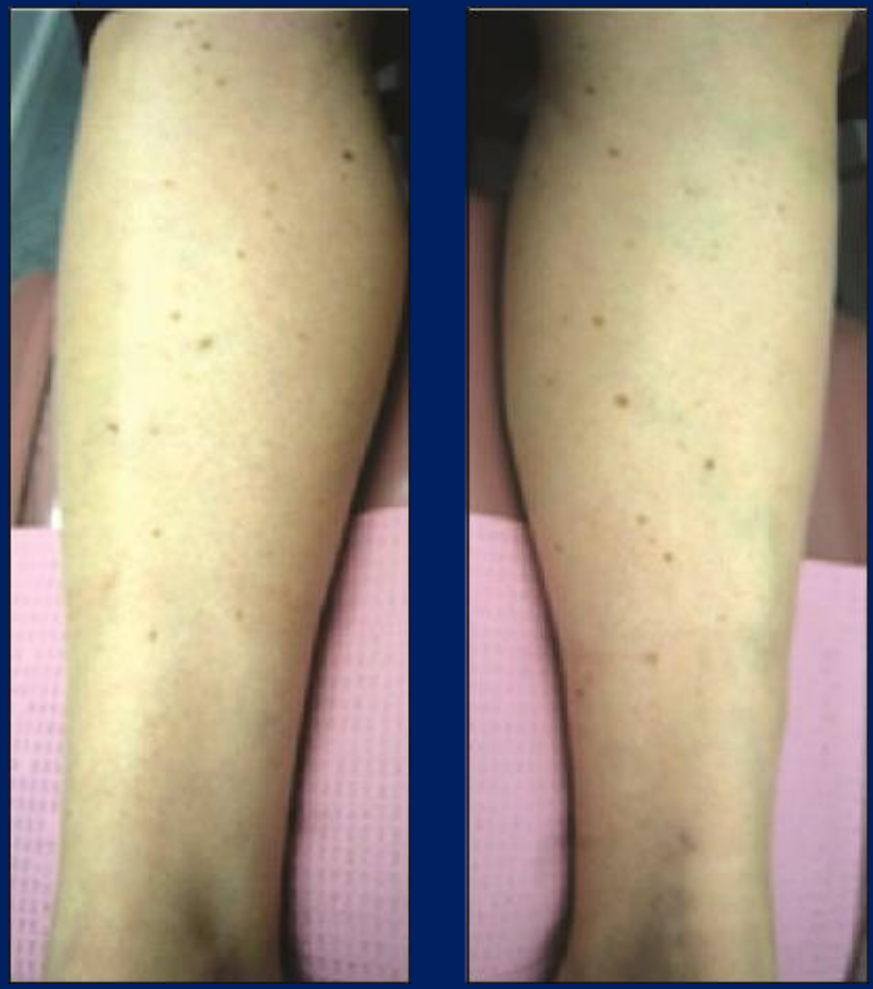
# Typical position with legs externally rotated blocks the lateral leg surface from view



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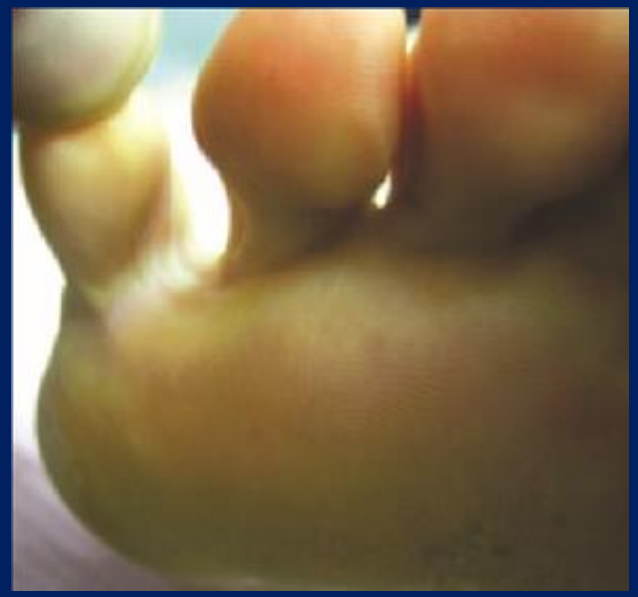
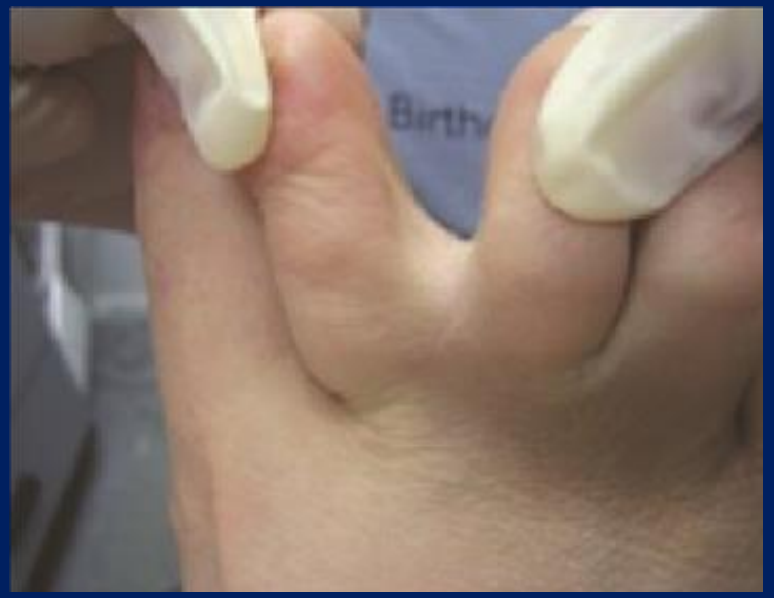
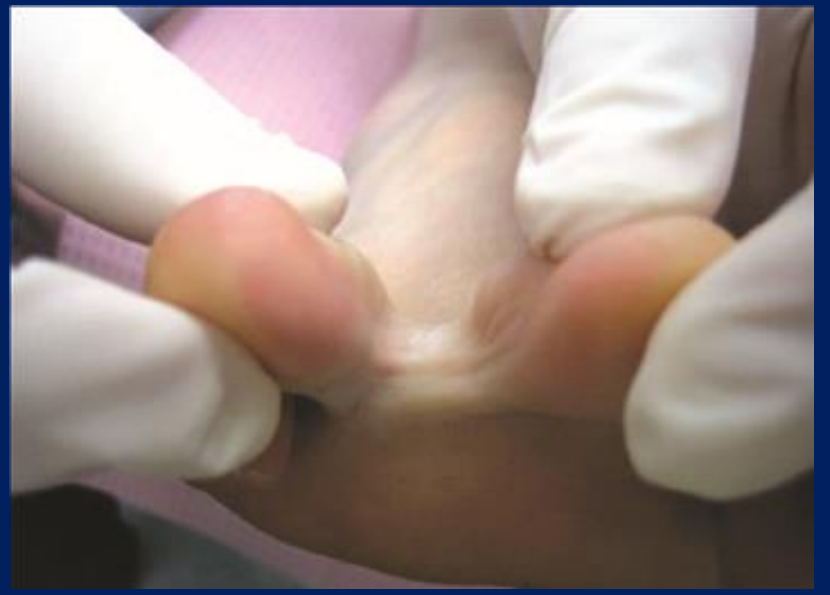
# Note how each view of the toe web has a potential limitation







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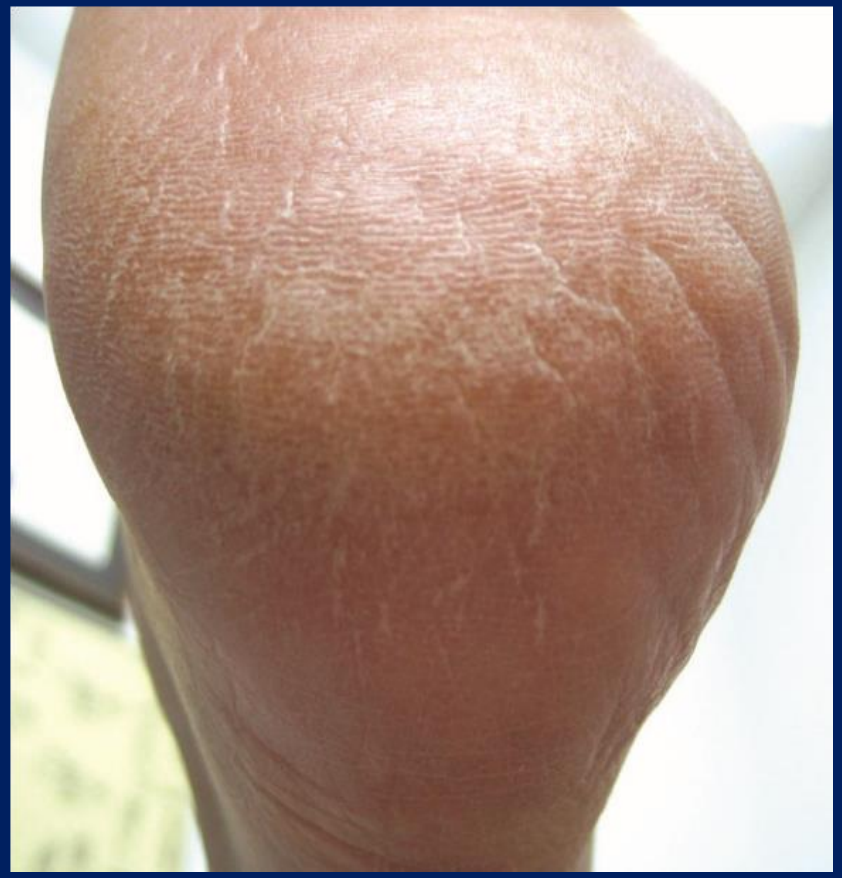
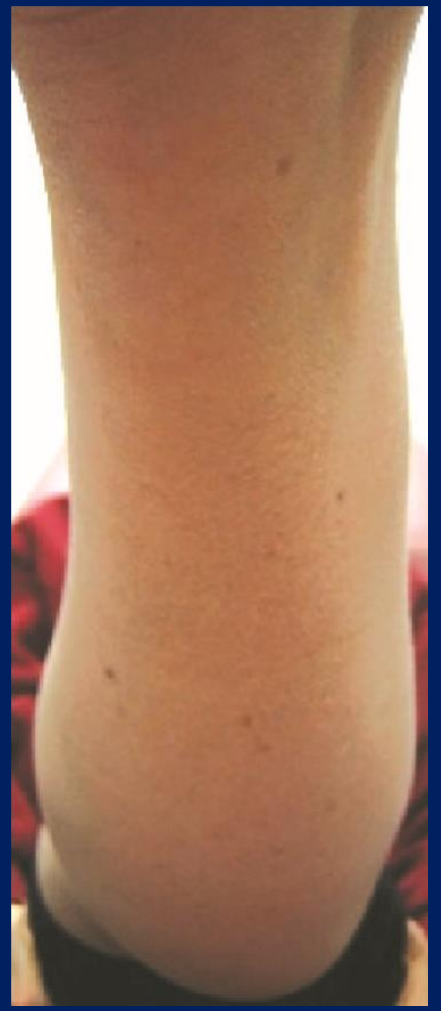
# Heel and posterior leg must be lifted off of exam chair or table to be examined





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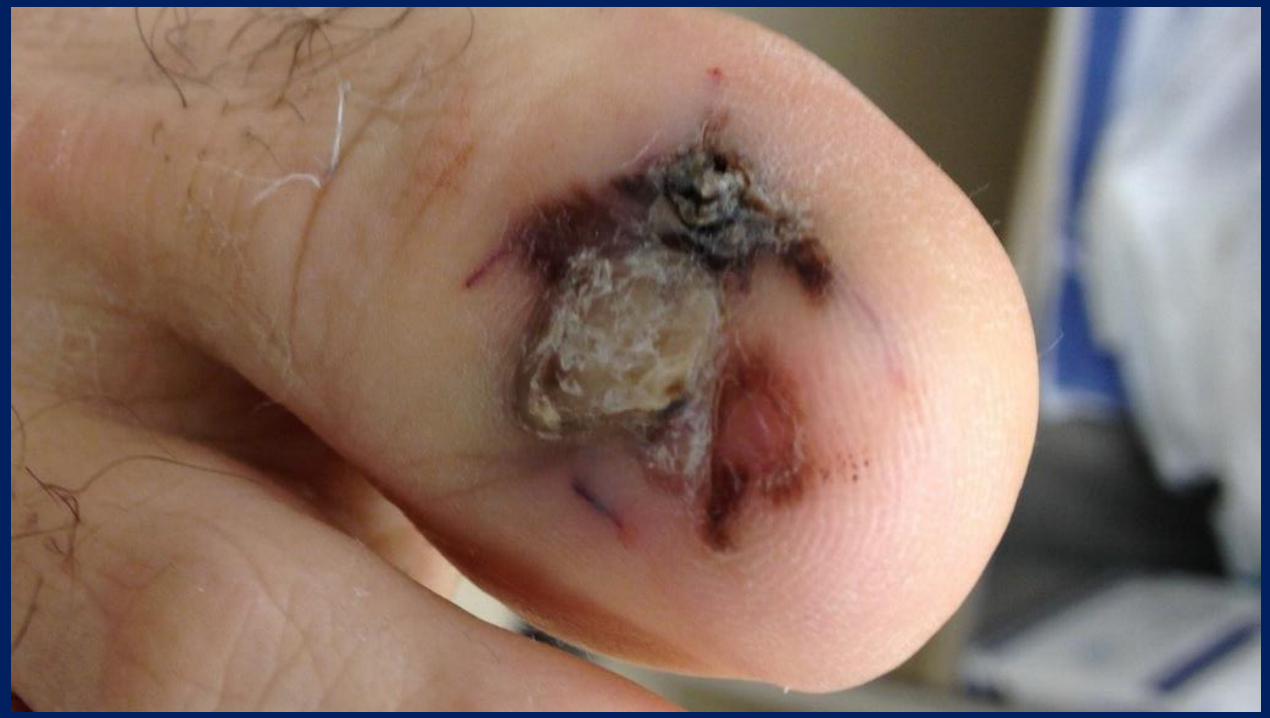
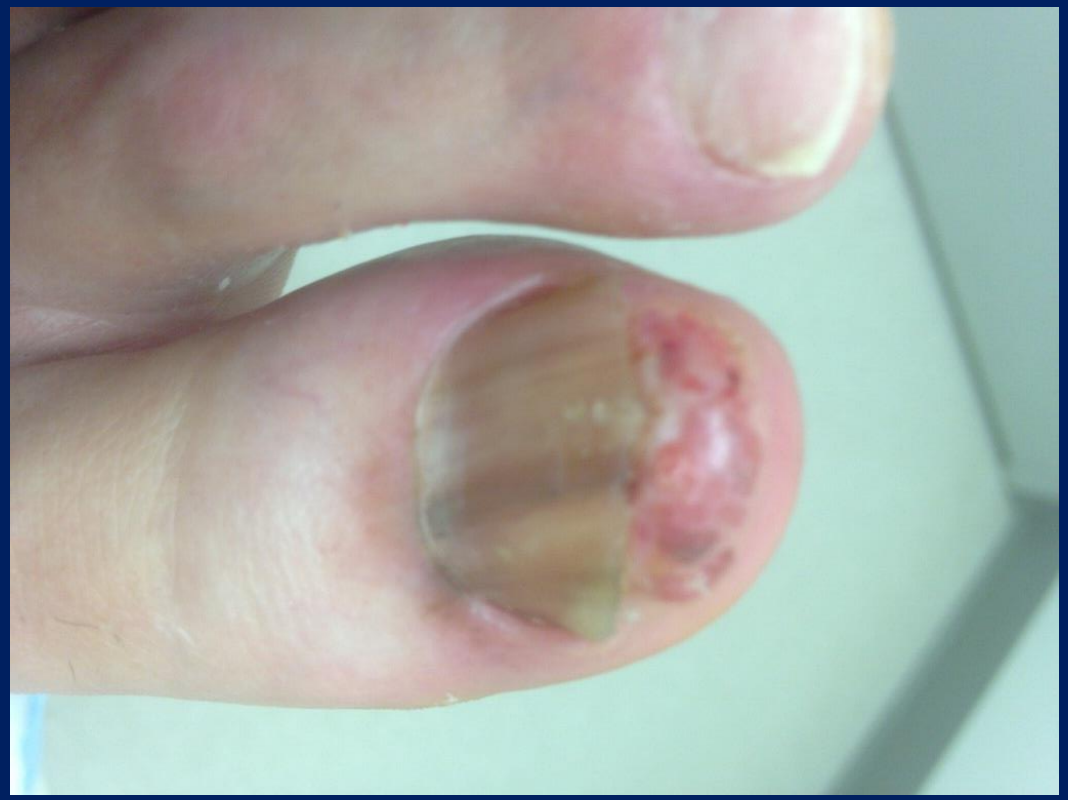
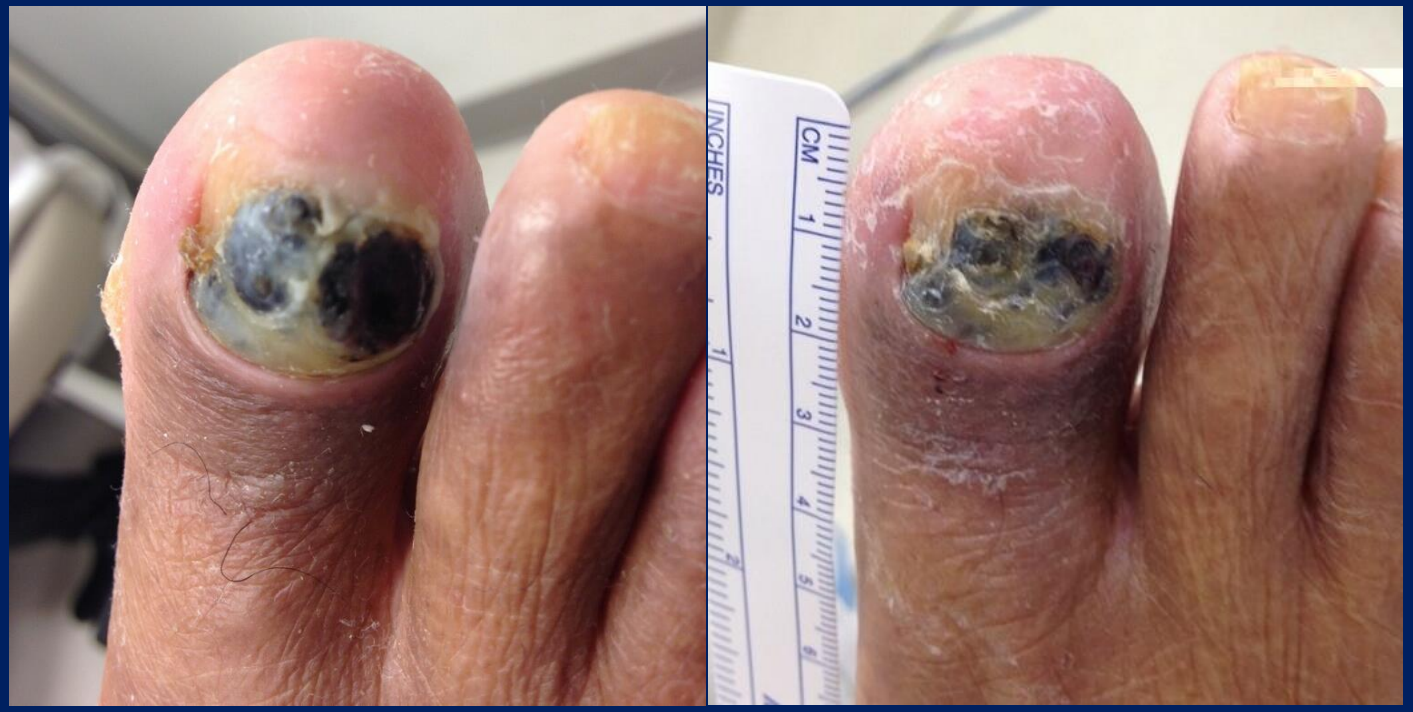


# “SUBUNGUAL HEMATOMA”

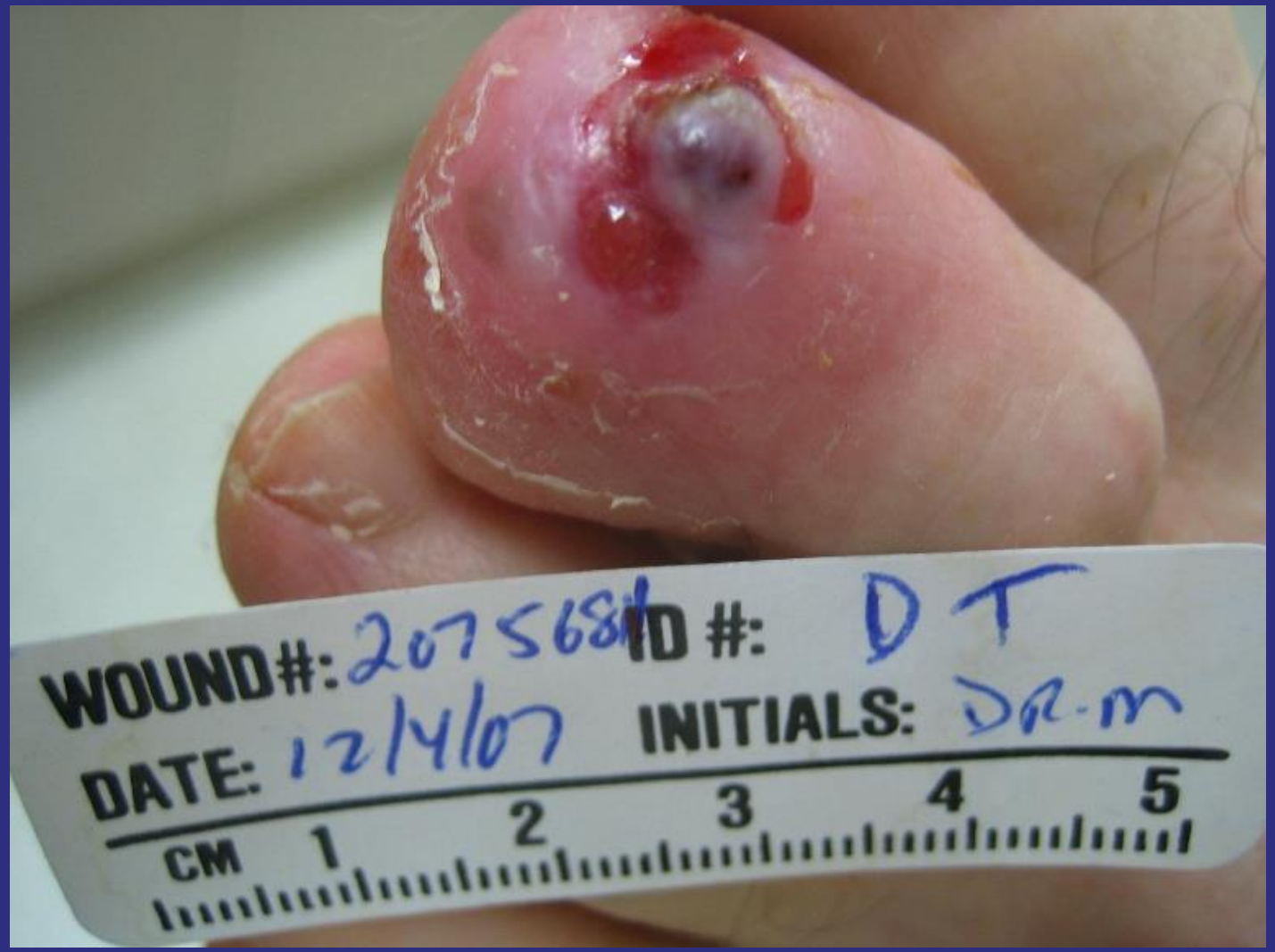


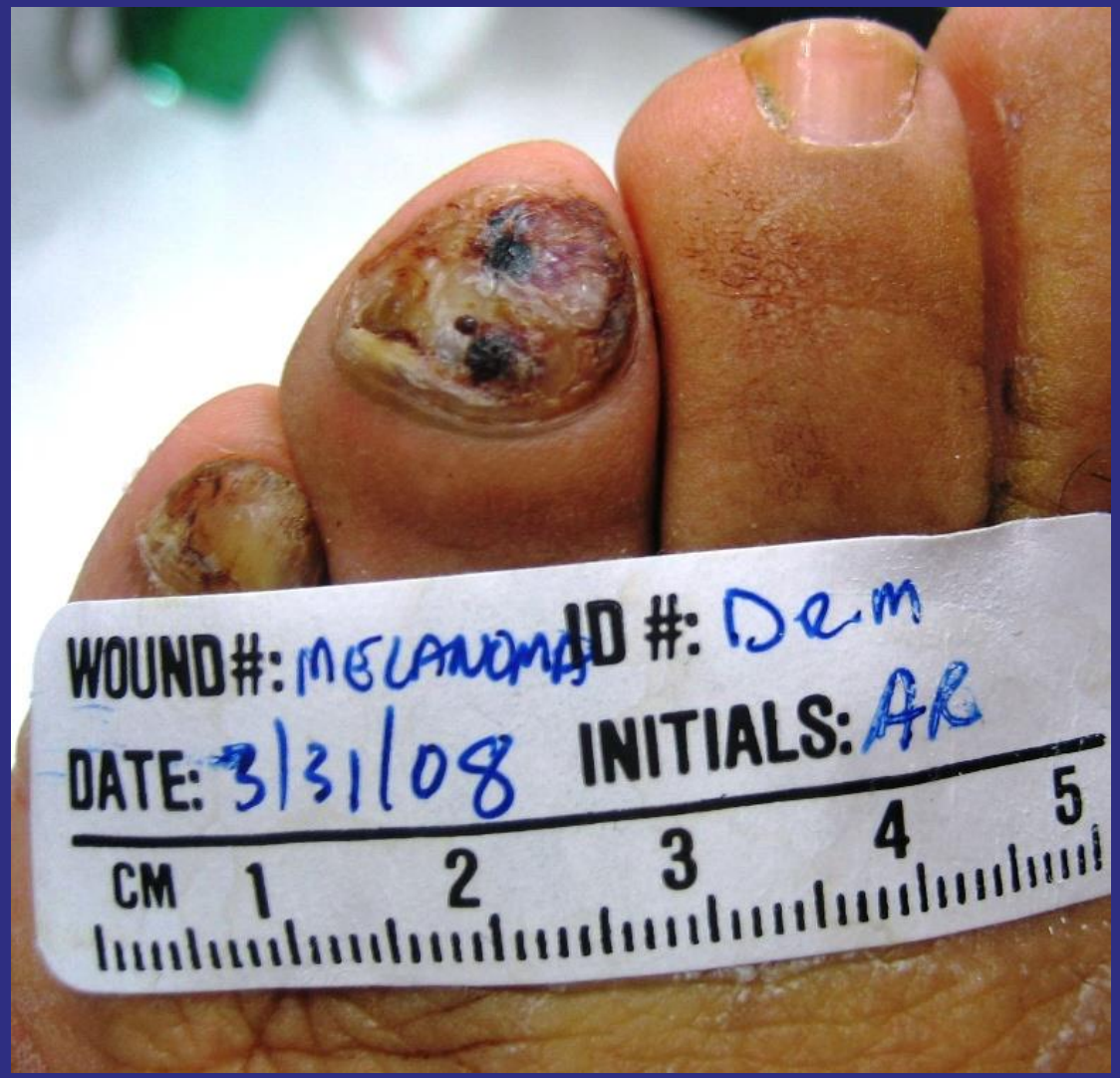
# “PARONYCHIA”



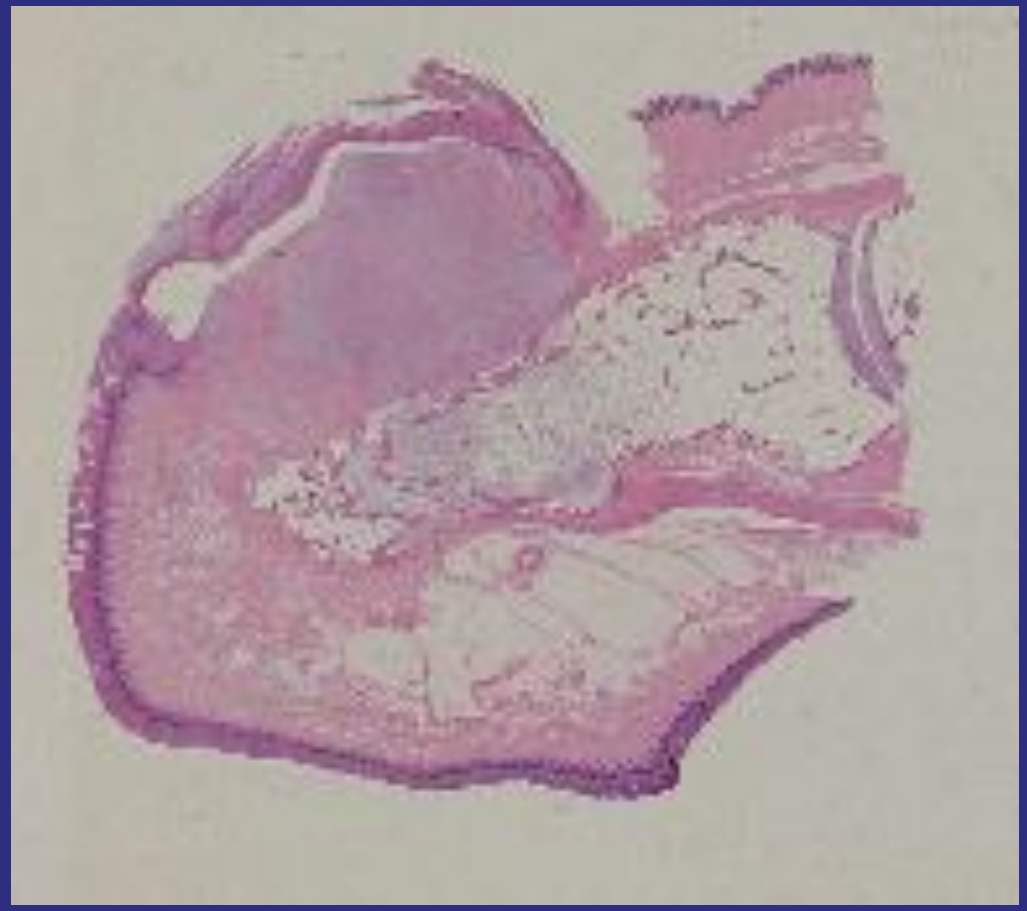

# “ONYCHOMYCOSIS”

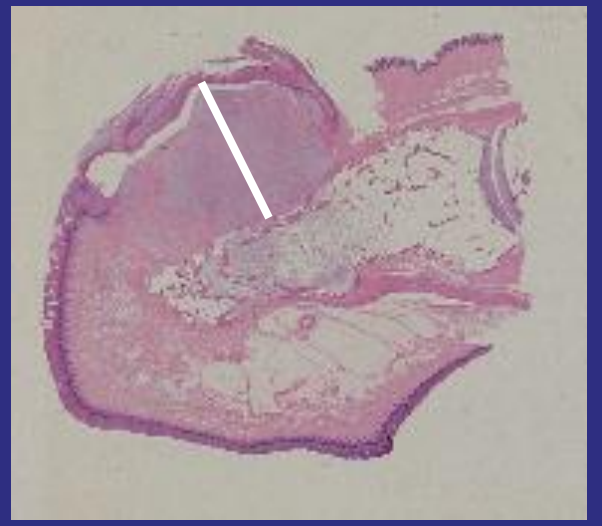
# Criteria over History




WOUND#: MELANOMA
ID #: Dem
DATE: 3/31/08
INITIALS: AR
CM 1 2 3 4 5

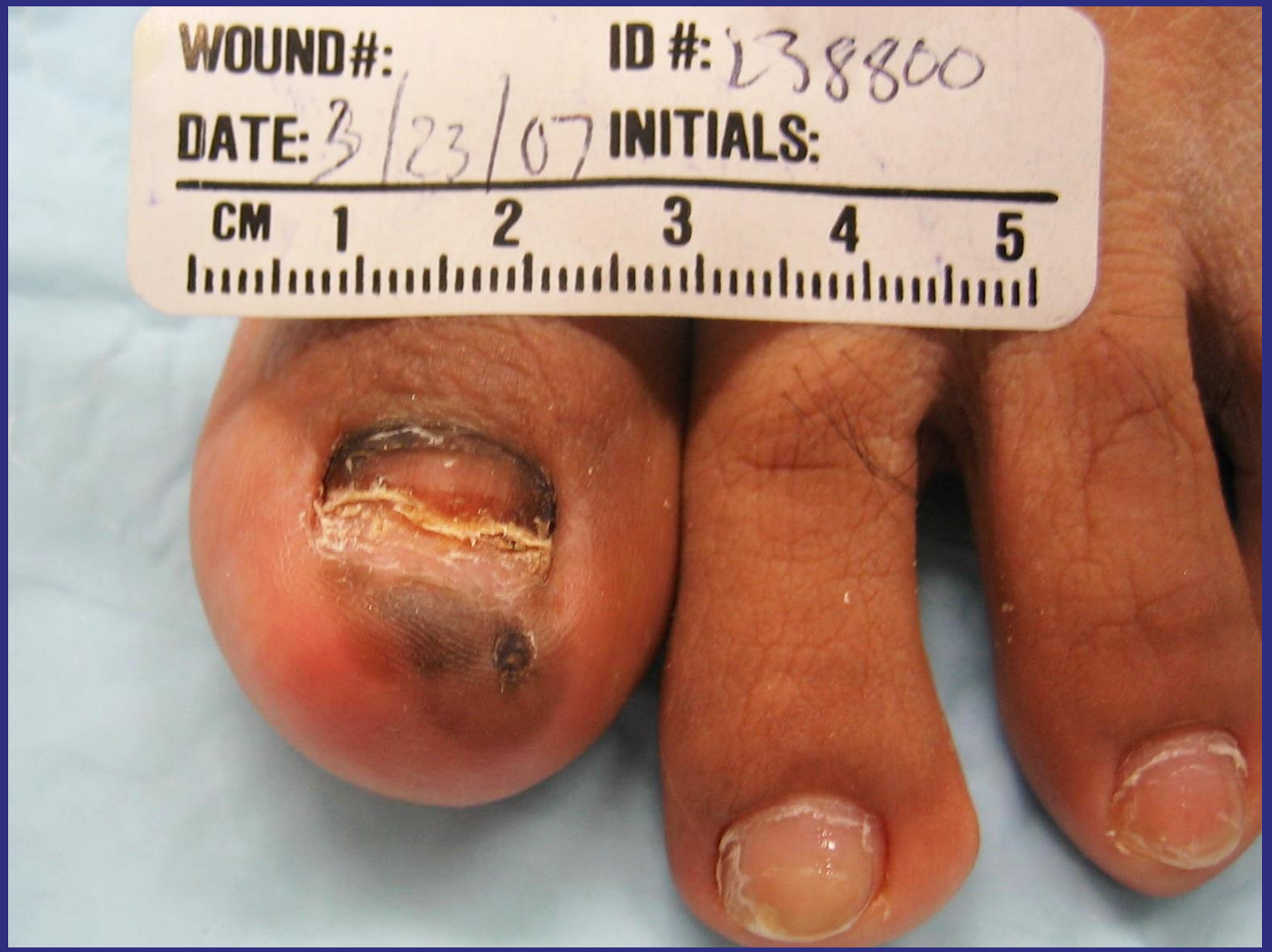
# Section through middle of tumor



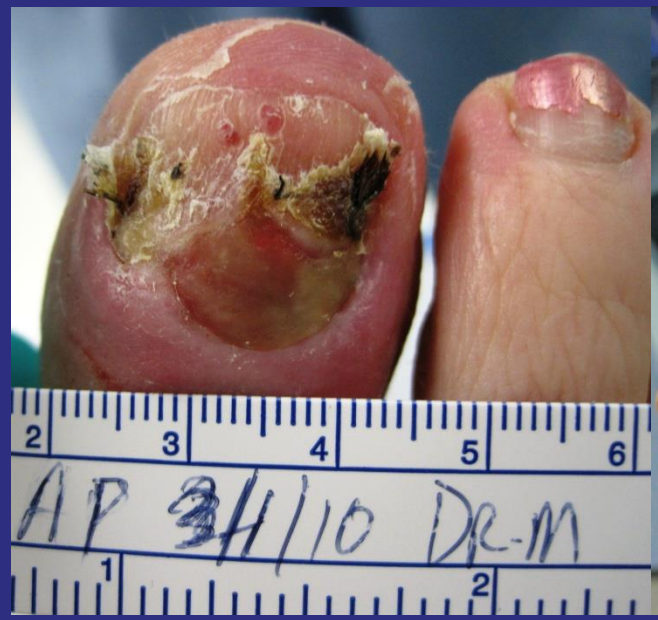


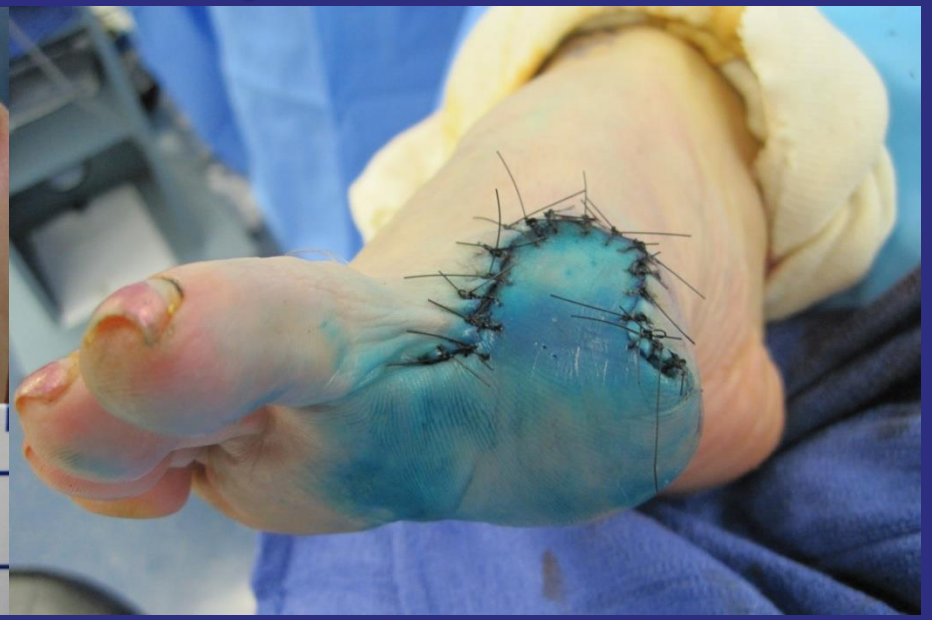
11mm

# Criteria versus History



# Pedicure complication?



This patient went for her regular pedicure in 8/09 and states she felt a sharp pain when some instrument was used. She did not bleed. She developed toenail lysis centrally two weeks later and saw a DPM for treatment who assumed infection based on history. Tx continued until she sought another opinion in late January 2010. Patient referred to me and biopsy was performed on 2/15/2010 revealing nodular amelanotic melanoma at least 2.7 mm in depth with many evident mitoses.

# Preventative clues/measures for avoiding diagnostic delay in skin cancer masquerading as ulceration:

- **Non weight bearing areas of ulceration should always be suspicious, even in insensate feet**
- **No signs of improvement/healing after appropriate treatment**
- **Worsening of lesion: discharge, diameter, bulk**
- **Ulceration anywhere in the presence of good circulation and neuro-sensory status**
- **No apparent inciting event for the lesion**
- **Multiple physician involvement without resolution**

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# Too Superficial Biopsy!

- Bx report from tissue removed via routine debridement on a painful keratotic lesion: "The tissue submitted may represent the superficial aspect of a verruca, with stratum corneum and parakeratosis, however **no epidermis is submitted. Deeper sections may reveal a more accurate diagnosis."**
- Patient went on to be treated for over thirty visits every three weeks for "ulceration due to parakeratosis" with not one description of the size, depth or color of lesion. There was no statement as to improving or not, or even possible causation. Finally patient was booked for metatarsal osteotomy and removal of skin lesion. Bx report now reveals invasive SCC
- **SOLUTION: Get a 3mm punch biopsy to the level of the subcutaneous fat in the most representative portion of the lesion**

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# History of skin cancer or malignancy in patient or family not elicited or ignored

- Two current cases hinge strongly on the patient's entry on intake forms that there was a history of cancer in the patient or a family member.
- Actually, the podiatrist becomes focused on the EMR, accumulating material for the completion of a note that would support billing for a level of service. It takes a matter of seconds to forget or not react and therefore not gain more information. This even becomes easier if the chief concern has nothing to do with the skinor nail issue.
- **SOLUTION: Have your EMR flag you when there is a yes response, so you would be sure to get the WWWWW**

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# Duration of Treatment

- You must fix in your mind a time frame after which no resolution of a lesion will trigger a change in your evaluation, therapy or diagnostic work up. A prudent change in therapy with firm clinical grounds can be defended. However, lesions that fail to resolve or improve after three months should be considered for biopsy or second opinion consultation.
- **SOLUTION: PERFORM A BIOPSY! IF NOT PERFORMING A BIOPSY TRY TO FORMULATE A STATEMENT AS TO WHY YOU ARE NOT DOING SO. Example: "The lesion is completely macular, homogenously pigmented, less than 6mm in diameter, with no surface changes such as bleeding or ulceration. HAVE YOUR EMR FLAG YOU AFTER THREE MONTHS WITH A QUERY SUGGESTING BIOPSY**

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# Poor knowledge of pathological processes

- A recent case involves a DPM who did a punch biopsy into a vascular malformation creating a bleeding episode and a wound that subsequently has not healed after 2-3 years. On intake the patient reported having an MRI three years prior which revealed the malformation, BUT DPM AT DEPOSITION STATED HE PROBABLY SHOULD HAVE REVIEWED THE PRIOR MRI RESULTS.

- **SOLUTION: NEVER PROCEED WITH SURGICAL INTERVENTION, INCLUDING BIOPSY, PRIOR TO REVIEWING and RESPECTIING PREVIOUS DIAGNOSTIC RESULTS.**

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# Multiple Physician Involvement

- Whenever there have been 2, 3, or more providers preceding consultation with you, you should have a heightened index of suspicion!

- **SOLUTION: DON'T REPEAT WHAT HAS ALREADY FAILED. OFTEN, THAT MEANS IT IS NOW TIME FOR A BIOPSY**

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# Cloned Chart Notes - EMR

- It is easy to tell when chart notes are written solely to the billing rules and not addressing the real issue(s). For example, documenting the follow up of a skin lesion, ulceration, or rash without ever establishing cause or diagnosis or mentioning size and other characteristics. For example "Patient for follow up of lesion  left heel…." One case in Virginia revealed 9 months of visits to locate a note that finally documented the exact location and size of the lesion. Unfortunately that note was the first visit to a MD surgeon who took a biopsy that revealed melanoma. See "Multiple Physician Involvement." See "Duration Of Treatment."
- **SOLUTION: Impossible?**

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# Assumption of care by another provider

- One DPM based his defense of neglecting a pigmented and ulcerated lesion of 11 months duration under the hallux on the fact that the patient had also been seen by a dermatologist. At deposition he stated that he "just cut nails."

- **SOLUTION: Make sure that all consultations result in communication between providers to prove that the consult actually happened and to record treatment and/or diagnostic recommendations aswell as a hand off of care.**

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# Histologic Analysis

- Fix specimen in formalin
- Send to Dermatopathologist.
- If using HMO required multi-service lab, ask for reading by dermatopathologist!
- If diagnosis unexpected either way – speak to pathologist about a second look or new cut from paraffin block.

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# Risk Management

- Keep a log of all biopsies done that lists:
  - Name of patient
  - Date
  - Type of biopsy
  - Lab sent to
  - Method of sending
  - Date picked up
  - Date report received and put in chart
  - When and how results communicated to patient

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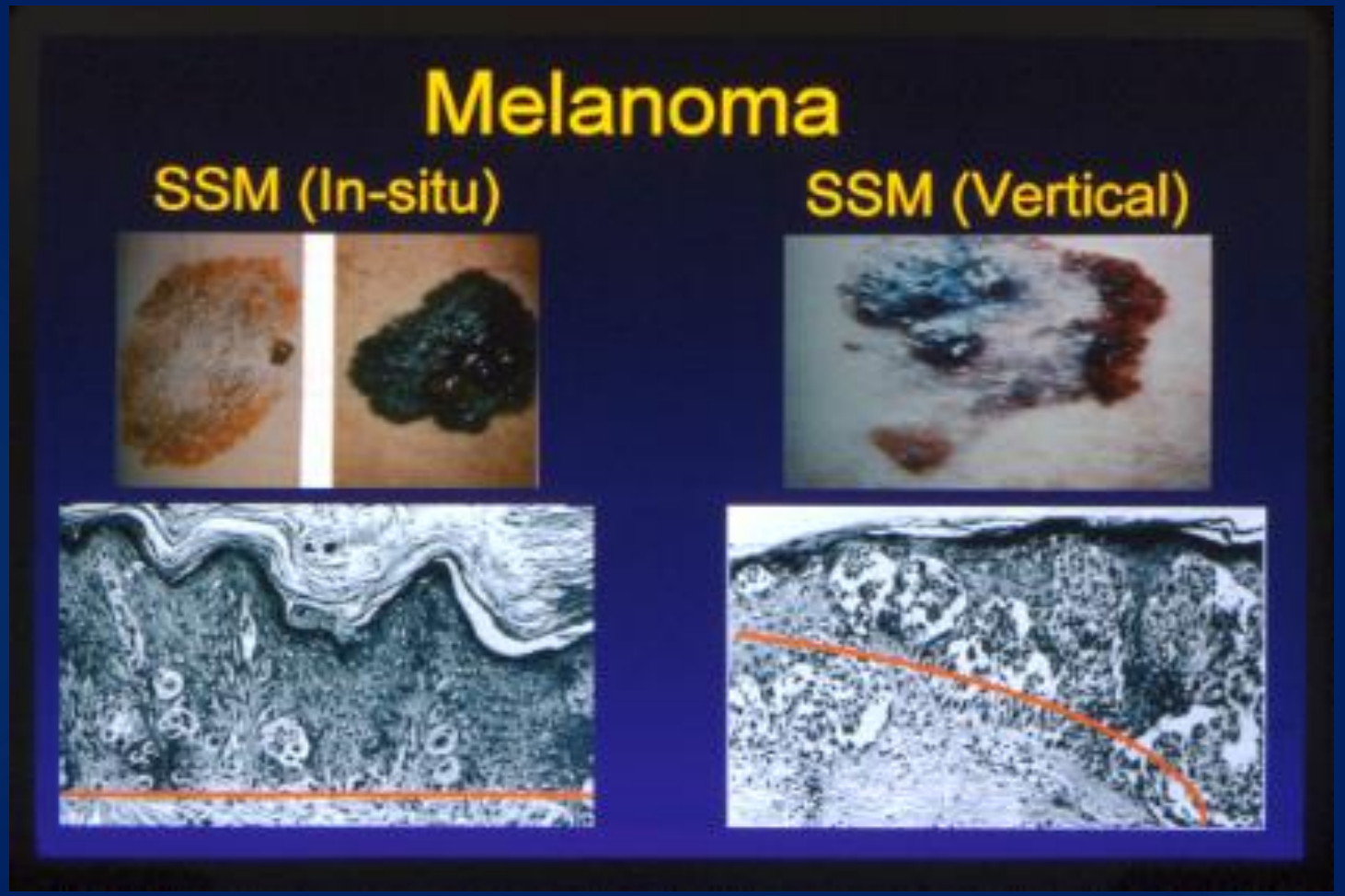
# In-situ versus Invasive

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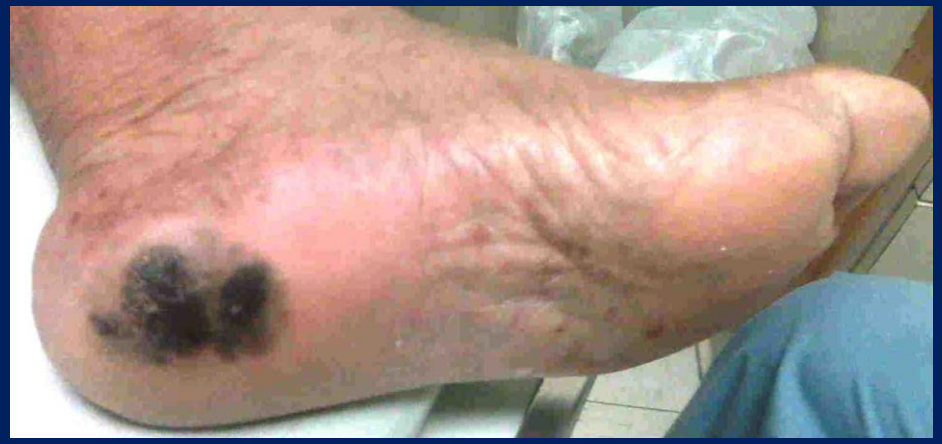
# It’s Melanoma!! What do I do now?




**Bryan C. Markinson, DPM**

**The Leni and Peter W. May Department of Orthopedics**
**Department of Dermatololgic Surgery**
**Melanoma and Skin Cancer Program-Tisch Cancer Institute**
**Icahn School of Medicine at Mount Sinai**
**Consultant – Bako Integrative Podiatric Solutions**


Mount Sinai

# Making the diagnosis

- Suspicious lesion :
  - meets ABCD criteria for high index of suspicion
  - Patient reports change in character of the lesion
  - You notice a change from visit to visit
  - New pigmented streak in Caucasian patient
  - New lesion in patient with prior melanoma or family history
  - Patient history of risk factors
  - PHOTOGRAPH LESION
  - PHOTOGRAPH LESION
  - PHOTOGRAPH LESION!

# Perform Biopsy

- Excision – if lesion small enough – elliptical excision to level of fat in shape of a boat, not a pie wedge.
- Punch – 3-4mm to level of fat
- Shave – must include dermis – take deeper portion if pigment still visible

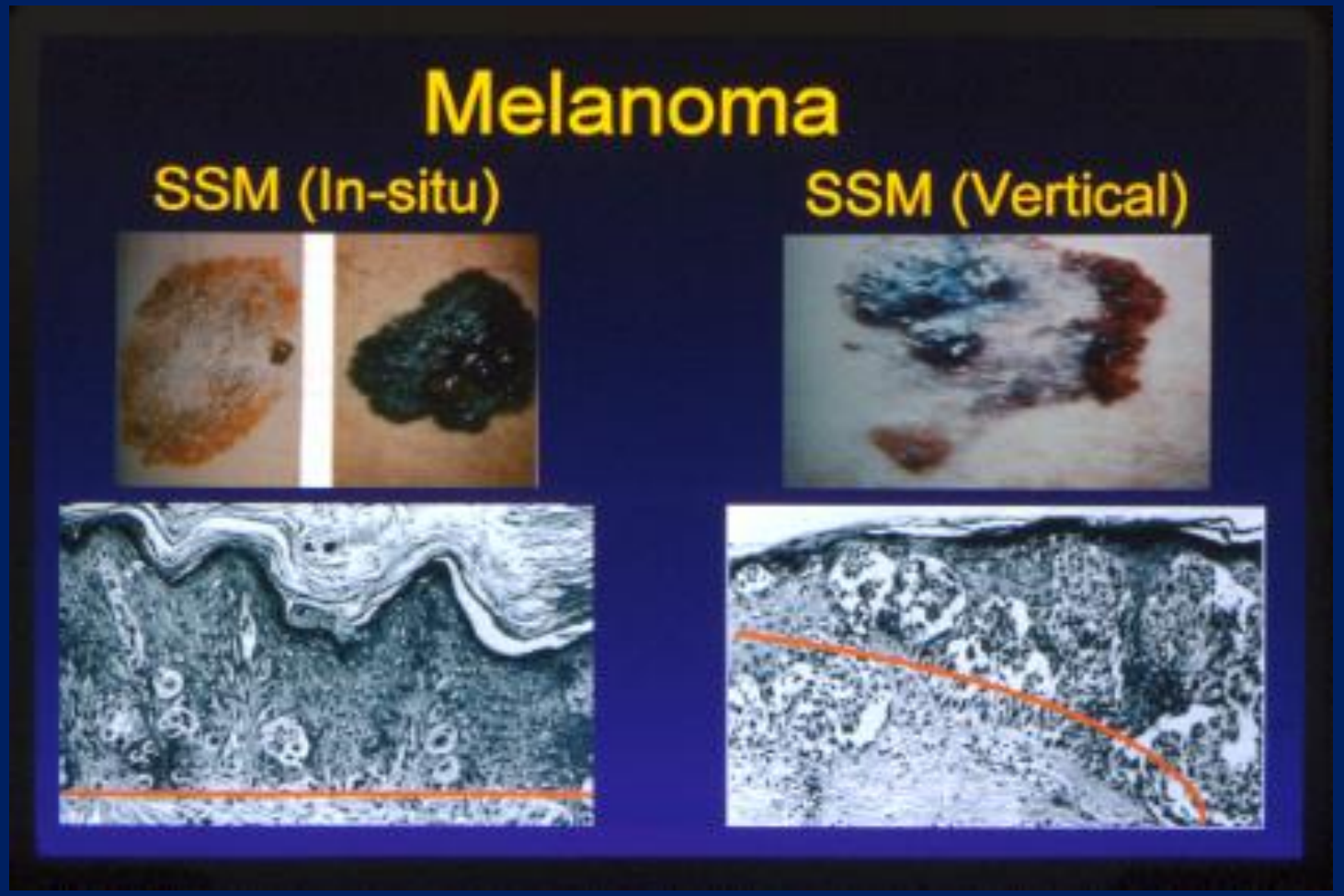
# Histologic Analysis

- Fix specimen in formalin
- Send to Dermatopathologist.
- If using HMO required multi-service lab, ask for reading by dermatopathologist!
- If diagnosis unexpected either way – speak to pathologist about a second look or new cut from paraffin block.

# Risk Management

- Keep a log of all biopsies done that lists:
  - Name of patient
  - Date
  - Type of biopsy
  - Lab sent to
  - Method of sending
  - Date picked up
  - Date report received and put in chart
  - When and how results communicated to patient

# In-situ versus Invasive



# Diagnosis: Melanoma

## In-situ

If lesion totally excised in biopsy procedure – no further local care required

Refer patient for total body skin exam

## In-situ

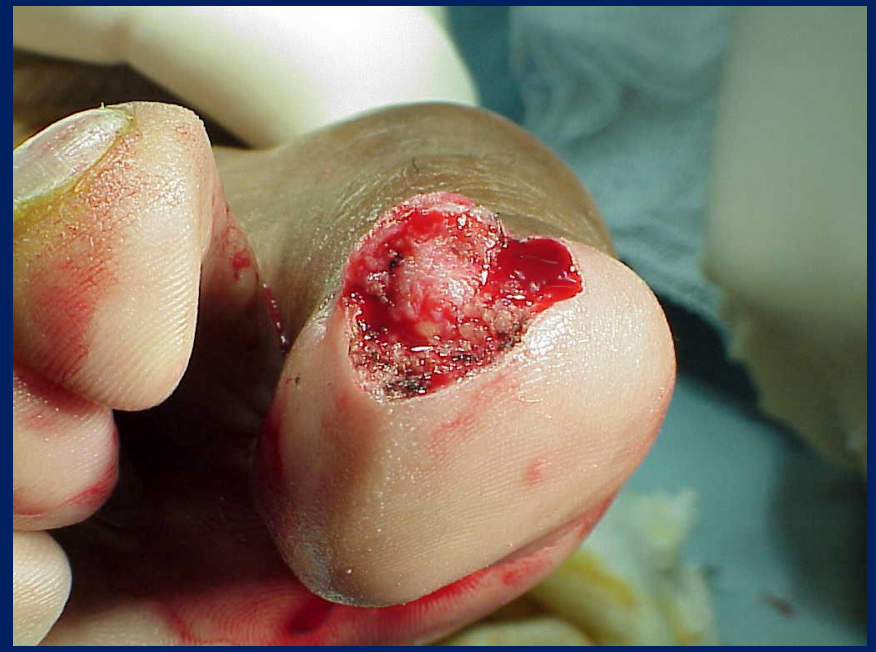
If pathology extends to margins

Lesion must be completely excised to make sure all is in-situ and completely excised

# What is a total body skin exam?

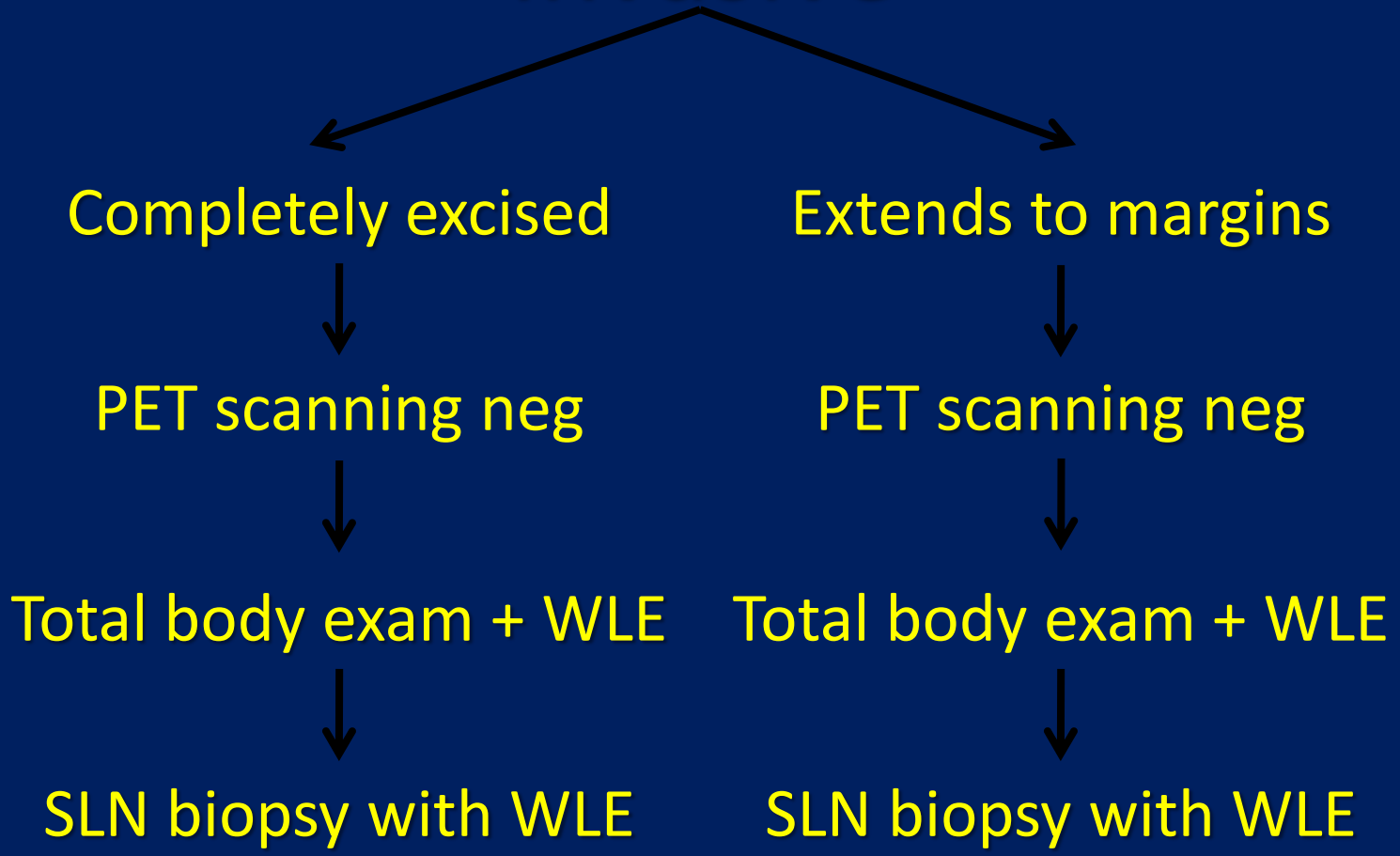
- A total body skin examination is a “no modesty protected” completely disrobed examination, including examination of the scalp, genital, breast and anal region regardless of location of primary melanoma
- When patient returns after such an exam, you must frankly ask, “were you disrobed, and were the scalp, genital, and anal regions, and breasts examined?
- Any hesitation on the part of the patient usually means the exam was lacking
- It is disturbing how many dermatologists fall short on this!
- Also inform patients to let their ophthalmologist and gynecologist know about a skin diagnosis of melanoma

# Complete excision after biopsy of in-situ melanoma of hallux

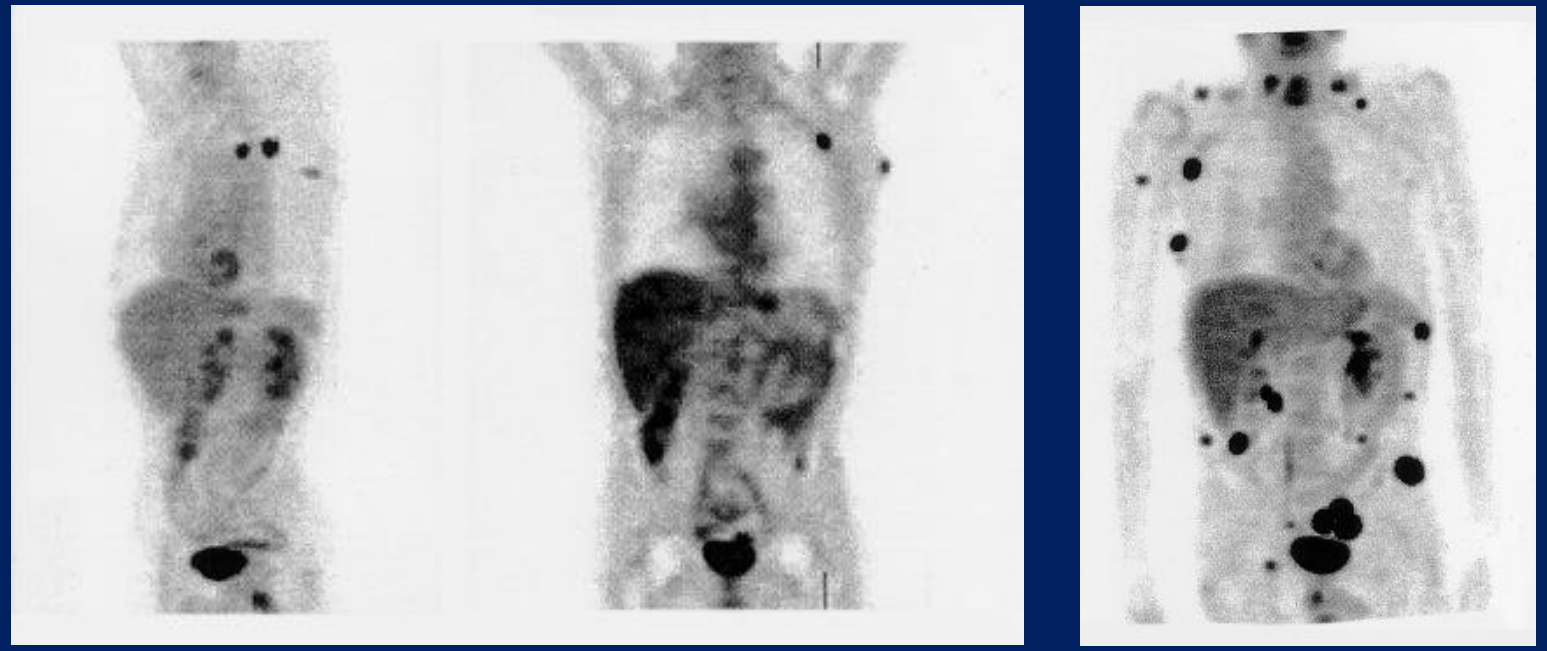


# Diagnosis: Melanoma

## Invasive



# Positron Emission Tomography
# PET Scanning





Basically a radioactive tracer attached to a sugar molecule which is taken up in tissues used to diagnose, stage and monitor course of disease

# PET Scanning and SLN Biopsy

- If PET Scan positive: may indicate need for further surgery if met(s) are resectable
- If widespread mets are found, further local surgery (WLE) with amputation and/or skin grafting may be moot and therefore not done
- Definitely indicates need for interferon and possibly other chemotherapy.
- Significance of negative sentinel node is hopeful but uncertain: tumor may pass through a node without staying there
- Positive sentinel node usually indicates need for interferon therapy but may be hopeful that lesion has been contained, but again uncertain

# Blood Examination

There are currently no known blood markers for  melanoma

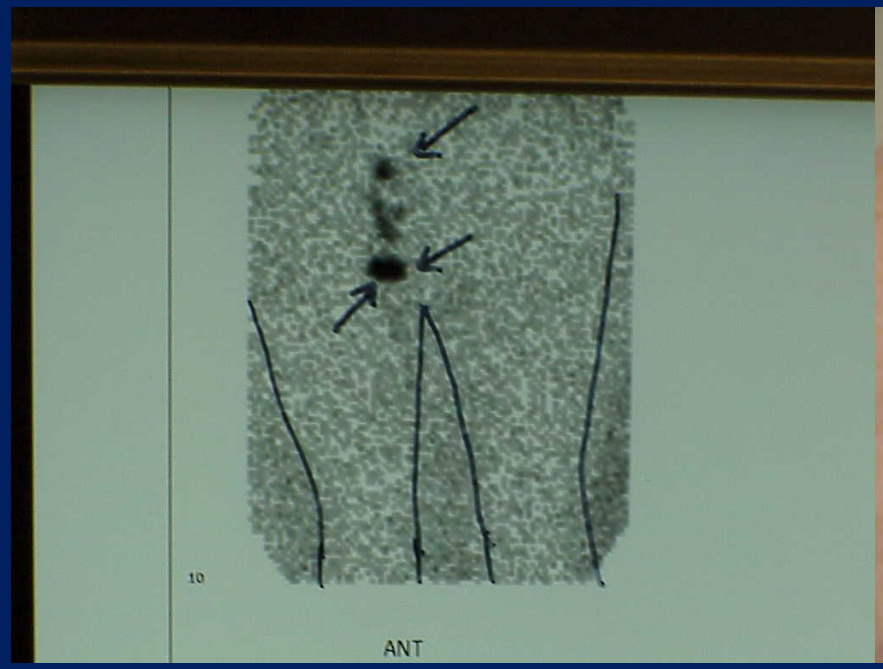
# Extent of WLE

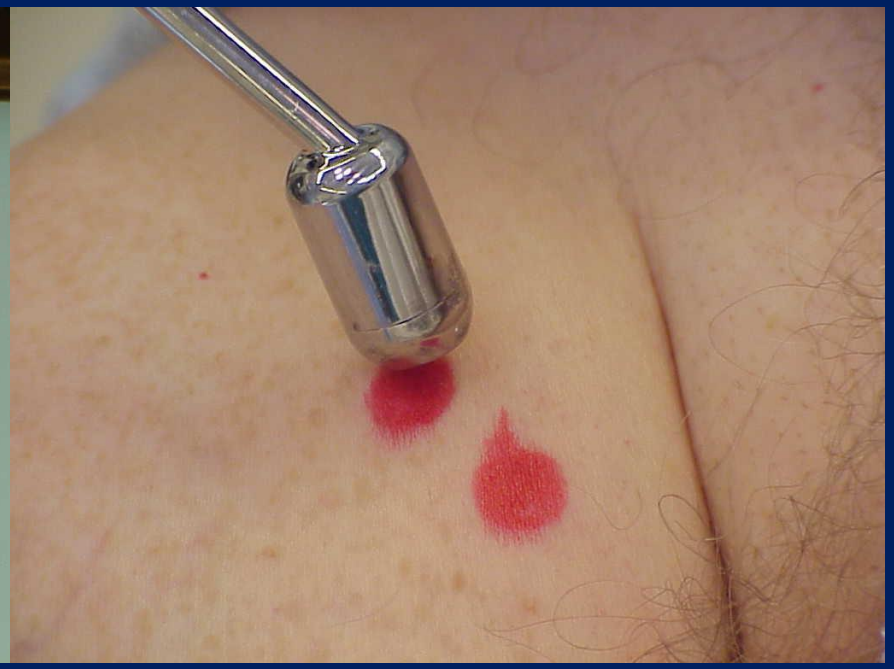
- The extent of WLE is dependent on depth in millimeters and has been controversial
- Optimal WLE may only limit local recurrence but not affect long term survival
- In general, 1 cm of resection margin required for each 1 mm of depth. Depending on anatomical location, this may not be possible.

# Sentinel Lymph Node Biopsy Procedure

- Based on the principle that all spots on the skin have a unique drainage path to a regional node. Foot melanoma usually drains to the inguinal node basin.
- Eliminates the need for initial elective node dissection which has morbidity of infection and permanent swelling

# Sentinel Lymph Node Biopsy



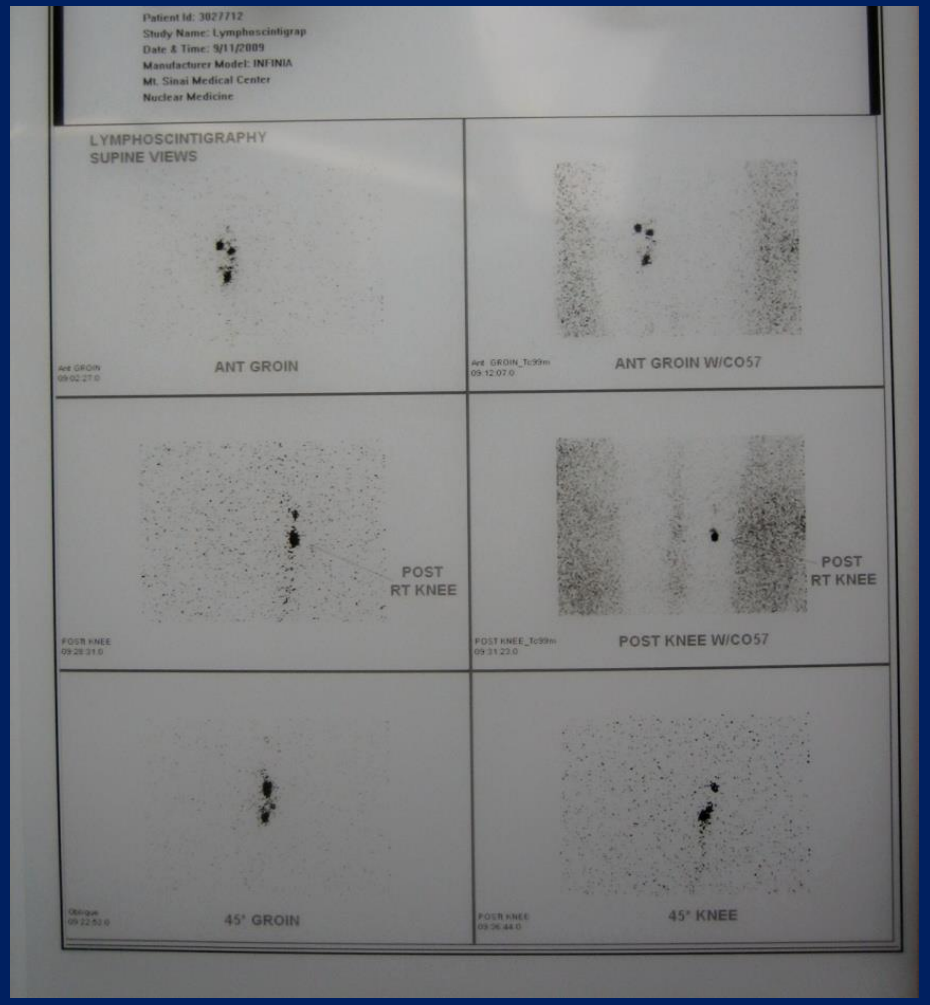



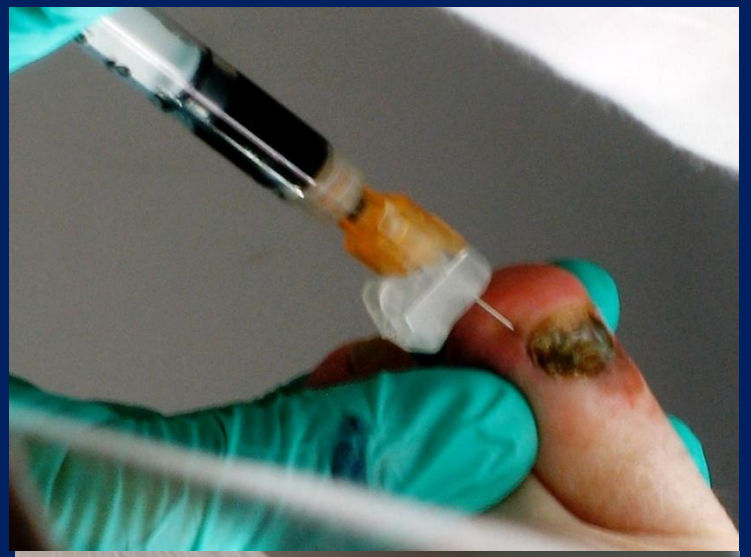
Lymphoscintigraphy: 1 Hour prior to surgery – injection of radioactive sulfur colloid at site of lesion. Patient comes to OR with skin markings approximating location of node(s) taking up the tracer.

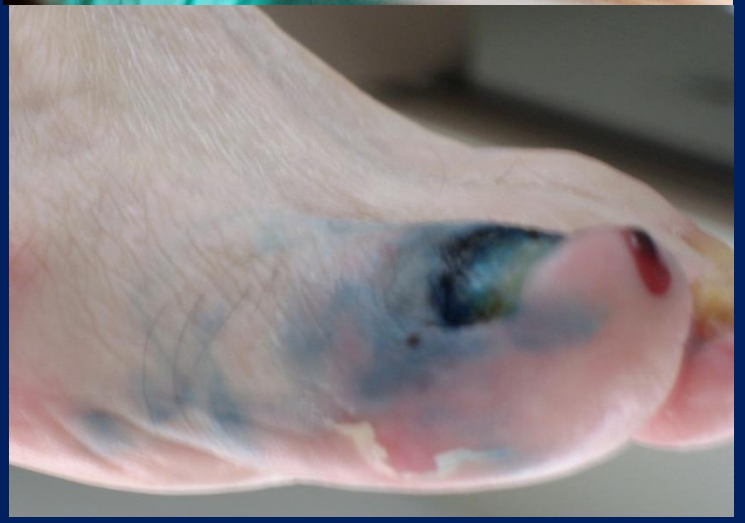
# Sentinel Lymph Node Biopsy


Geiger Counter

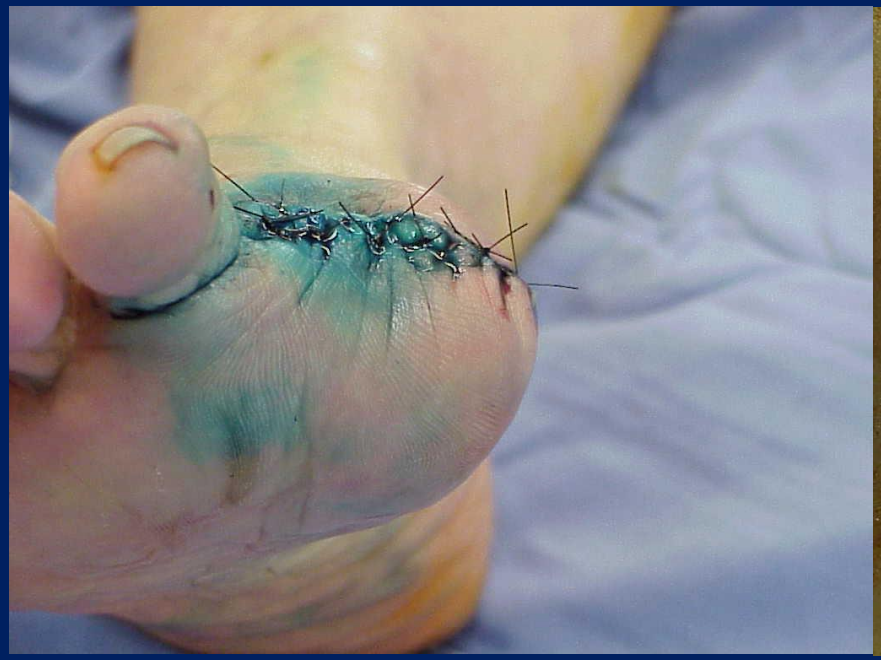
# Sentinel Lymph Node Biopsy
# Blue Dye Injection

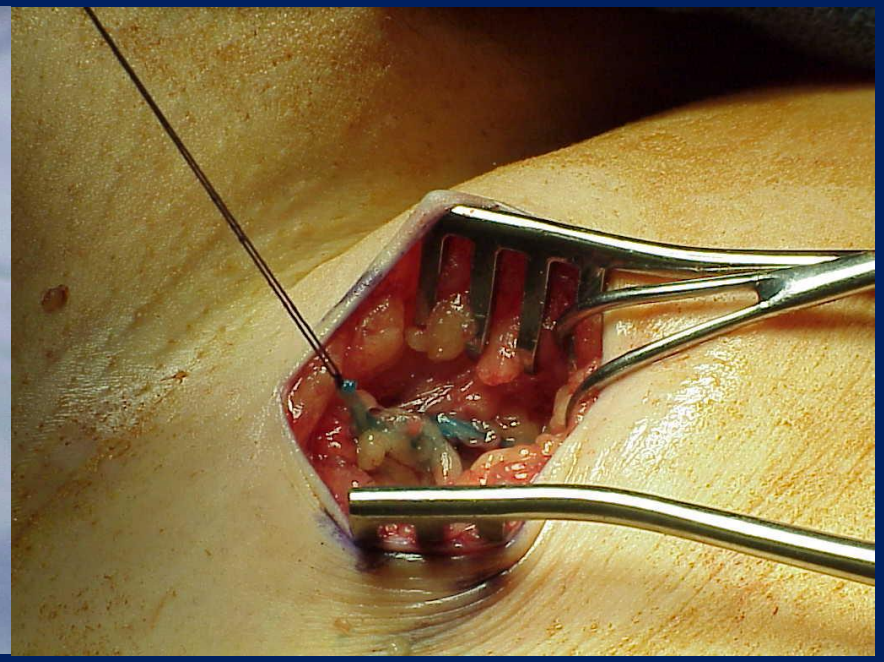




# Blue Dye Injection





# Summary

- Excisional biopsy if possible, punch biopsy, and shave for subtle lesions suspicious of melanoma in that order are the best options for pigmented lesion diagnosis
- Specimens should be reviewed by a dermatopathologist
- The management of melanoma, when in-situ, can be an office based situation, but dermatology consultation must be made for total body examination.
- Treatment of invasive melanoma should be hospital centered, as in addition to local podiatric surgery, surgical oncology, medical oncology, nuclear medicine, and other services may be required

# Anatomy of a Delayed Diagnosis of Cancer Lawsuit

## 2016 DermFoot West

American Society of Foot and Ankle Dermatology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