CHAPTER 32

NEUROPATHY

32.1. Neuropathy Screening

Evaluation of neuropathy in Look AHEAD-C will be done using the Michigan Neuropathy Screening Instrument (MNSI) which includes the 15 self-administered Neuropathy Questionnaire, as well as a brief physical assessment including a physical exam of the foot, an assessment of ankle reflexes, an assessment of vibration sensation at the dorsum of the great toe and a monofilament test.

Some of the information in this chapter is adapted from the Diabetes Prevention Program Outcomes Study (DPPOS), the Epidemiology of Diabetes Interventions and Complications (EDIC) study and the Michigan Neuropathy Screening Test procedures.

32.2. Introduction/Rationale

Diabetic neuropathy is a type of nerve disorders that can occur if you have diabetes. Over time, individuals with diabetes can develop nerve damage throughout the body. Nerve damage can occur in all organ systems including the heart, digestive tract and the arms and legs. Some individuals will have no symptoms; others may have pain, numbness, or loss of sensation. The incidence of neuropathy is reported to be about 60 to 70 percent in individuals who have diabetes and the incidence increases with age and with how long the individual has had diabetes. In addition, it is more common in individuals who have problems controlling their blood glucose, are overweight, and have high blood pressure.

There are three types of neuropathy: autonomic neuropathy which is damage to the nerves that control heartbeat, blood pressure, urinary processes, digestion and sexual function; focal neuropathy which is damage to just one nerve for example the wrist, foot or eye muscle; and peripheral neuropathy which is damage to the peripheral nerves or nerves that sense hot and cold, touch and

pain as well as loss of reflexes and muscle weakness. Look AHEAD –C will concentrate on peripheral neuropathy.

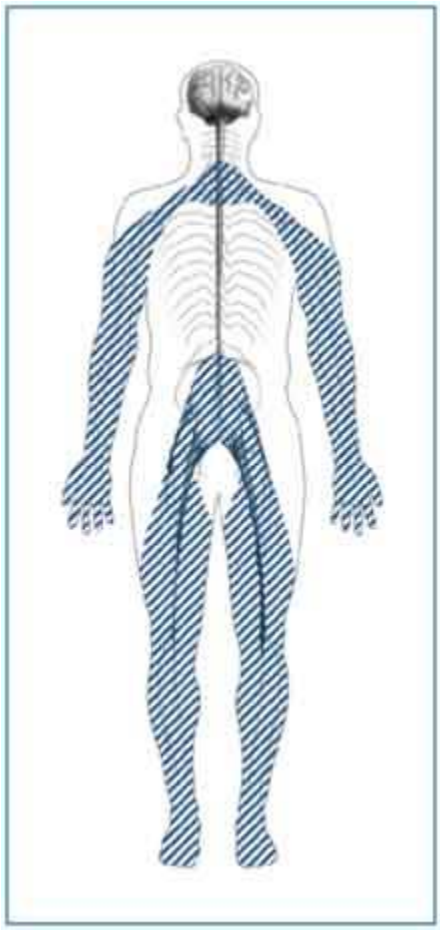
32.3. Background

The incidence of diabetic neuropathy is reported to be as high as 60% in both type 1 and type 2 diabetes. Individuals can develop nerve damage at any time, but the incidence increases with age and with duration of diabetes. Neuropathy is associated with a variety of factors including: neurovascular factors which can cause damage to the blood vessels that carry oxygen to the nerves, and metabolic factors, such as high blood glucose, low levels of insulin, and abnormal levels of fat in the blood. Neuropathy can be caused by mechanical injury of nerves, such as carpal tunnel syndrome and autoimmune diseases which cause inflammation that affects the nerves. Lifestyle factors such as alcohol use and smoking may also play a role.

Peripheral neuropathy is damage to the nerves that affect the sense touch, or the ability to tell the difference between hot and cold, and feeling pain. It also can affect the strength of the muscles and movement. Peripheral neuropathy is the most common form of diabetic neuropathy. Figure 1 shows the nerve path for peripheral neuropathy. While individuals can experience nerve damage throughout the body, most often the feet and legs are affected before the hands and arms (a stocking and gloves distribution). Symptoms of neuropathy may include numbness, tingling, burning, or prickling sensation, insensitivity to pain or temperatures, extreme sensitivity to touch, even the lightest touch or the weight of a blanket can cause pain. Some individuals experience loss of balance and coordination. Many individuals report that the symptoms are worse at night.

Complications from peripheral neuropathy include: muscle weakness and loss of reflexes, most often at the ankle, which can change the way an individual walks. Foot injuries are perhaps the most common form of complications. When the foot is numb, blisters or foot ulcers can appear and go unnoticed. If these

injuries go untreated they can result in serious infections which often spread to the bone and may result in amputation. Some research suggests that if foot injuries were caught and treated right away it could prevent approximately 50% of amputations. Figure 1. Peripheral Nerve Path



Look AHEAD- C provides a unique opportunity to examine the prevalence of neuropathy in an overweight population with diabetes as well to examine if there are differences between the original ILI and DSE groups.

32.4. Schedule of Administration

The Neuropathy Questionnaire is a self-administered questionnaire administered to all participants annually and is part of the My Health Part A packet. The physical exam, as well as the vibration, ankle reflex, and monofilament tests will

be administered at the annual clinic exam. This is a non-invasive procedure that can be easily performed by certified Look AHEAD staff in the clinical setting.

32.4.1. Administration of the Part 1 Michigan Neuropathy Screening Instrument (Question 6 Neuropathy from My Health Part A)

The Michigan Neuropathy Screening Instrument (MNSI) is a self-administered questionnaire administered to all participants. It begins with question 6 as part of the My Health Part A packet. The questionnaire is completed by the participant before the foot exam. Because the instrument is a self-administered questionnaire, staff should avoid prompting, or interpreting questions, unless the subject specifically asks for clarification or assistance. This form **MUST** be reviewed prior the physical exam.

To reduce errors, encourage participants to read each item carefully before answering.

Once the questionnaire has been completed, staff should review the form, paying particular attention to the following common errors:

1. **Question #7** ("…able to tell the hot water from the cold water?") and Question **#13** ("…sense your feet when you walk?") are frequently answered incorrectly. As most of the preceding items are answered "no", there is a tendency for the subject to scan the questions, and answer "no" to these items as well. A "no" response to items 7 and 13 would be indicative of advanced sensory loss, and would not be common in the absence of other signs of advanced neuropathy or other neurologic disorder. If the participant does check "no," ask the participant to review the item (or read the item to the subject) and confirm their response. You can preface the review with a phrase like "I just wanted to double check a couple of your answers. On this item, are you able to tell the hot water from the cold? Did you mean to say no?"

2. **Question #11** ("…symptoms worse at night?"). Many participants misunderstand the question, especially if they have responded in the negative to

preceding items, and will ask for clarification. If the participant asks, for example, “What symptoms,” then an appropriate response is “any of the symptoms previously asked on this survey.” If the participant says, “I don't have any symptoms,” then an appropriate response is “if you don’t have any symptoms, then you can answer no.”

32.4.2. Administration of Part 2 of the Michigan Neuropathy Screening Instrument (MNSI) Physical Exam, Reflex Exam, Vibration Exam and Monofilament Test

The monofilament test is used as an overall evaluation for neuropathy.
The MNSI and monofilament test is completed at the annual clinic visit to track the presence of neuropathic symptoms, identify foot problems and assess sensory function. This is consistent with existing clinical guidelines for the management of diabetic participants.

32.4.3. Required Equipment, Materials

• My Health Part A Questionnaire Question 6 Neuropathy a- o
• Michigan Neuropathy Screening Instrument Form Annual Visit
• 128 Hz tuning fork
• Stopwatch
• Tromner or Queen Square reflex hammer
• 10 gram monofilament
• Black pen to record measurements

32.4.4. Procedures

The procedures include following a foot inspection, ankle reflex assessment and the mono filament test and should be completed in the order that is given. Detailed information follows

32.4.5. Foot Inspection

The participant should be seated on the table with legs relaxed. The room should be comfortable and the foot is warm (≥ 30° C/86°F). The feet are inspected for excessively dry skin and cracks and any abnormalities including calluses, fissures, ulcerations, or deformities.

Please pay particular attention to the following:

1. Note only significant dry skin and callous formation.

2. Report findings such as fungal nails (see appendix 1 for pictures of foot abnormalities), thickened nails, etc. in the “Other” category. Anything can be noted and will be entered into the Look AHEAD database, the specify field will be reviewed by staff for grading at a later date.

3. Deformities include flat feet, hammer toes, overlapping toes, halux valgus, joint subluxation, prominent metatarsal heads, medial convexity (Charcot foot), and amputation.

4. Make note of any foot sores or ulceration on the form as being present or absent for both the right and left foot.

32.4.6. Ankle Reflexes

Absence of ankle reflexes has also been associated with increased risk of foot ulceration. This test is similar to the familiar test when a doctor hits just below an individual’s knee with a small mallet, causing the individual to kick. In this version, staff will tap on the Achilles tendon, which runs down the back of the ankle. If the nerves are in good condition, the foot will reflexively move down in a pointing motion. If the reflex is weak or nonexistent, the individual may have more advanced neuropathy.

1. Use a Tromner or Queen Square reflex hammer to assess ankle reflexes.

2. Elicit the reflex by sitting the participant on a firm surface so the leg is hanging freely and the foot is in a passive position; cup the foot in the palm of your hand and slightly dorsi-flex the foot to obtain optimal stretch of the muscles. The Achilles tendon should then be percussed directly with the reflex hammer.

3. Note that if the reflex is obtained, it is graded as present.

4. If the reflex is absent, the participant is asked to perform the Jendrassic maneuver (hooking the fingers of their hands together and pulling the hands apart while checking the reflex). Reflexes elicited with the Jendrassic maneuver are designated "present with reinforcement." The reflex is considered absent if there is no reflex elicited with the Jendrassic maneuver.

5. Get another staff member to verify if a reflex cannot be obtained.

32.4.7. Vibration Test

Loss of vibration is another indication that nerve function is deficient. It has been associated with risk of ulceration.

Vibratory Sensation:

The participant should lie down on the exam table with legs flat and big toe is unsupported facing towards the ceiling on table supported. The participant should be instructed to tell you when they feel the vibration and when they feel the vibration stop. Please pay particular attention to the following:

1. Vibratory sensation is tested bilaterally using a 128 Hz tuning fork.

2. A timing device is used to determine the length of time vibration is present on the examiner's finger.

3. The great toe is unsupported during the test.

4. The tuning fork is placed over the dorsum of the great toe on the bony prominence of the last joint.

5. A trial is conducted when the tuning fork is not vibrating and when the tuning fork is vibrating to ensure that the participant is responding to vibration and not pressure from the tuning fork. The tuning fork should be placed on the bony prominence of the last joint of the great toe.

6. The participant closes their eyes before the vibrating tuning fork is applied and indicates when they feel the vibration and when they can no longer sense the vibration from the tuning fork.

7. Examiner's fingers do not touch the prongs of the tuning fork during the test. This will attenuate the vibration that the participant detects and result in an inaccurate test.

8. When the participant tells you they can no longer feel the vibration, the examiner should start the stop watch. The examiner should be able to feel vibration from the tuning fork for 5 seconds longer on his/her distal forefinger than a normal subject can on his/her great toe. If the examiner feels vibration for >10 seconds longer than the participant, then vibration sensation is considered to be reduced. Vibration sensation is scored as:

- Present, if the examiner senses the vibration on his/her distal forefinger for <10 seconds longer than the participant
- Reduced, if sensed for ≥ 10 seconds
- Absent, if no vibration detected by the participant

32.4.8. 10-Gram Monofilament

This is another aspect of detecting abnormal sensory nerve function. Staff will test the top part of the foot as well as the bottom part of the foot.

Please pay particular attention to the following:

Test first on the hand of the participant so they know what they are feeling.

1. The participant's foot is supported by allowing the sole to rest on a warm flat surface.

2. Use a 10 gram monofilament.

3. The filament is pre-stressed by pressing it 4 to 6 times against the dorsum of the examiner's first finger.

4. The filament is applied to the distal of the great toe midway between the nail fold and the DIP joint. Ten applications are performed. The interval between applications should be staggered, and should be long enough to allow the patient to respond. Do not hold the toe directly. The filament is applied perpendicularly and briefly (<1 second) with an even pressure. The filament will bend when a force of 10 grams has been applied and forms a "C" shape. The participant, whose eyes are closed, is asked to respond "Yes" if he or she feels the filament.

5. Vary the interval between pricks to ensure that the participant actually feels the filament and is not just responding in a rote manner.

6. A normal test is defined as detecting 8 or more pricks out of 10 monofilament pricks; reduced sensation is defined as detecting 1 to 7 pricks; and absent sensation is defined as detecting no pricks.

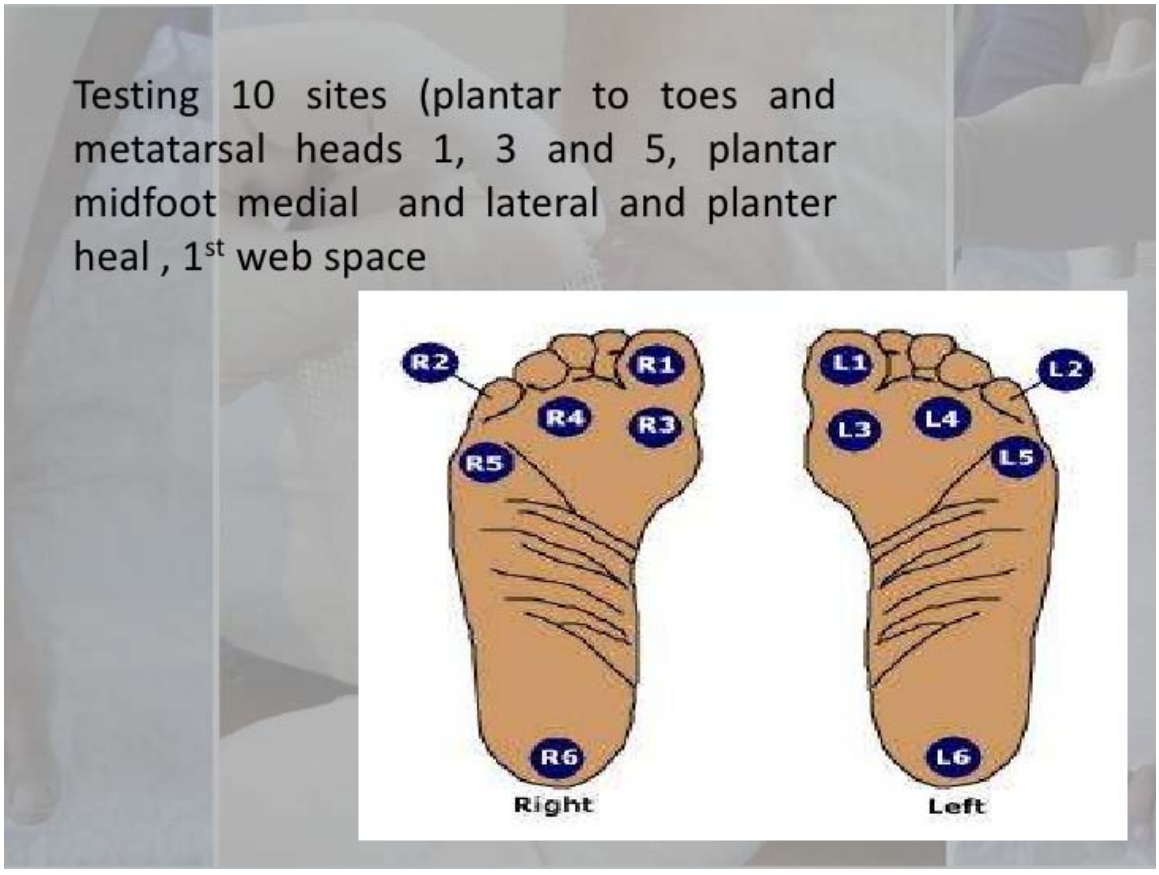
7. The examiner will document the number of pricks detected out of 10 on each toe.

8. Next the participant's legs are down resting on the table with toes facing the ceiling and staff will test the bottom of the foot.

The foot is supported by allowing the sole to rest on a warm flat surface. The filament is applied to the 10 sites on the plantar fascia of each foot using the diagram below and varying the interval between pricks to ensure the participant actually feels the filament and is not just responding in a rote manner. Staff must

do R1 through R6 at least one time as part of the 10 options and these may be in any order.

Record the number felt out of 10 on the form.



9.5. Quality Control

All staff performing the Neuropathy Screening assessments on Look AHEAD participants must be certified for this procedure at the central training Session, or

by the Program Coordinator or another certified individual. Certification must be renewed annually.

Initial certification includes the following components: staff should correctly perform the MNSI on 2 individuals during the central training practice session. When they return to their clinics, they should practice on staff or volunteers and then under the Program Coordinators supervision, they should correctly perform the exam on 5 participants who have varying durations of diabetes and or neuropathy so that the staff will be familiar with a broad range of possible responses that may be measured. Staff will be expected to meet the following objectives:

Staff will read the MOP chapter and review the two forms related to Neuropathy.

Staff will have an understanding of neuropathy and its complications, and how neuropathy is assessed.

Staff can verbalize the items to check on the MNSI to verify an accurate history of peripheral neuropathy.

Staff can perform an acceptable physical assessment of feet.

Staff can perform an acceptable vibratory test of feet.

Staff can perform an acceptable Achilles tendon reflex.

Staff can perform an acceptable monofilament exam of feet.

Annual recertification: under the Program Coordinators observation, clinic staff should correctly perform the MNSI on 2 volunteers in order to be recertified.

Required Materials:

- Review of the Neuropathy Questionnaire
- Form F02 Annual Visit Inventory, Part II, Section F
- 128 Hz tuning fork
- Stopwatch
- Tromner or Queen Square reflex hammer

• 10 gram monofilament

• Black pen to record measurements

• MNSI certification form

• Two volunteers for annual re-certification (5 volunteers for initial certification)

*For further information, go to

http://www.med.umich.edu/mdrtc/profs/survey.html.

†Adapted from the Epidemiology of Diabetic Interventions and Complications (EDIC) Manual of Operations.

‡Five successful assessments are required for initial certification. Two successful assessments are required for recertification.

9.6. Replacement of filament:

It has come to our attention that the package insert with the Owen Mumford device indicates that a monofilament should be replaced after 100 uses. Several coordinators have asked if that means 100 “pricks” or 100 “participants.” The Outcomes Committee has reviewed the available information and DOES NOT feel there is sufficient evidence to support discarding monofilaments after 100 “pricks” (or ~ 5 patients). Our view is that the variability potentially introduced by monofilament “fatigue” is minor compared to other sources (room temperature, force of application, pace of repeated applications, patient attention, etc.) and should not materially affect our outcome. Replacing the monofilament after use on 100 patients seems prudent, although evidence that this will improve test precision is also limited. At a minimum, please replace the monofilament annually, or if it becomes bent or buckled.

. From Amazon.com ($29.99): http://www.amazon.com/Mumford-Neuropen-Peripheral-Neuropathy-Screening/dp/B0014IZR5U/ref=pd_sim_hpc_1

B. from J&B Medical Supply ($24.95): http://www.jandbmedical.com/jandb/owen-mumford-neuropen.html

3) Owen Mumford Monofilament Refills 10g for Neuropen 5/box:

a. From Amazon.com ($28.85): http://www.amazon.com/Owen-Mumford-Monofilament-Refills-Neuropen/dp/B0014ISN9C

b. From J&B Medical Supply ($24.95): http://www.jandbmedical.com/jandb/diabetes-supplies-catalog/neuropathy-testing/owen-mumford-neuropen-10g-monofilament.html

Appendix 1 Certification Checklist **Certification Checklist**

Name: _____ ID_____

Observed by: _____

1. Staff has read the MOP chapter and reviewed the two forms related to Neuropathy? Yes___ No___
2. Staff has an understanding of neuropathy and its complications, and how neuropathy is assessed? Yes___ No___
3. Staff can verbalize the items to check on the MNSI to verify an accurate history of peripheral neuropathy? Yes___ No___
4. Staff can perform an acceptable physical assessment of feet? Yes___ No___
5. Staff can perform an acceptable Achilles tendon reflex? Yes___ No___
6. Staff can perform an acceptable vibratory test of feet? Yes___ No___
7. Staff can perform an acceptable monofilament exam of feet? Yes___ No___
8. Staff can correctly score the form? Yes___ No___

Appendix 2 Abnormalities of Feet

Foot Edema

Visual Inspection

medicinenet.com, footpainexplained.com, bendomd.com

- Foot edema

- Pitting Foot Edema

Visual Inspection

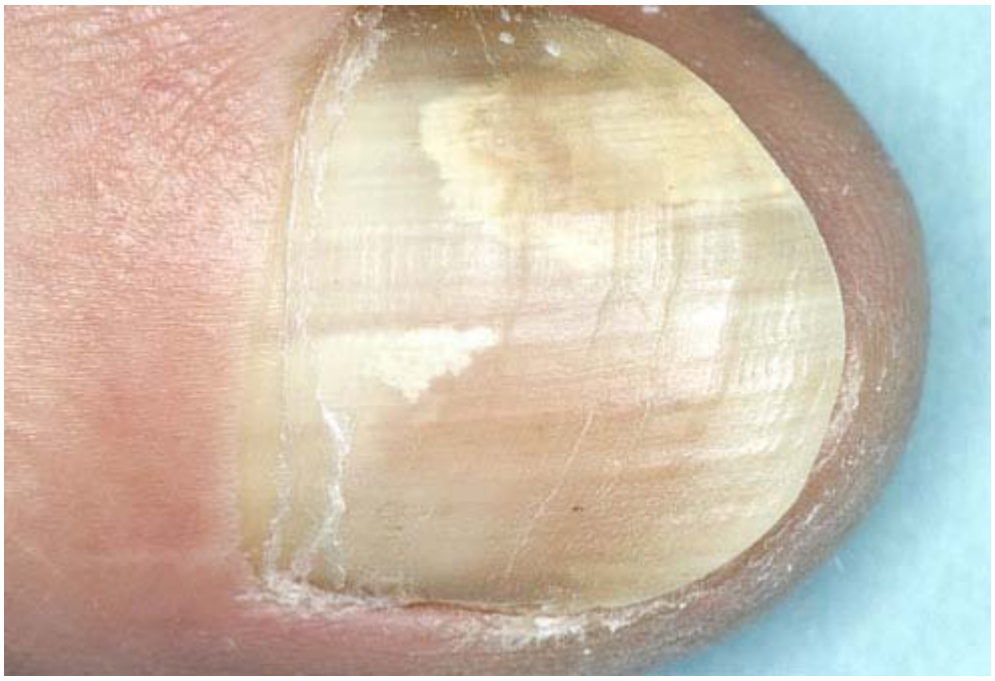
- Look for excessively dry skin and cracks

http://whysickness.blogspot.com/2009/12/cracked-foot-dry-cracked-heels-winter.html

Corns and Calluses

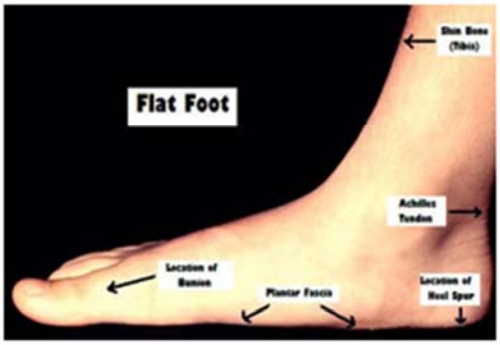
Nail Problems

Nail fungus

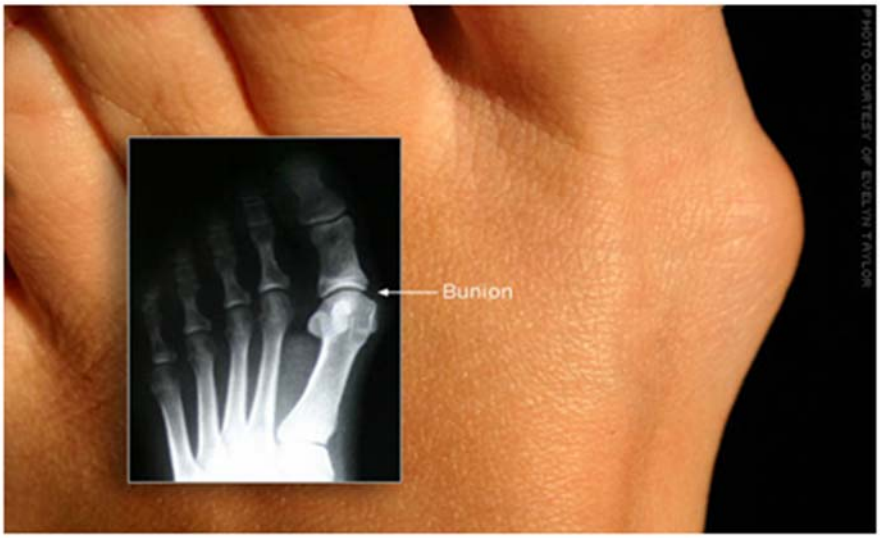


Ingrown Toe Nail

Visual Inspections Look for Deformities such as Flat Foot



Visual Inspection Deformities such as Bunion



Visual Inspection Deformities such as Hammer Toes

Visual Inspection Deformities such as Overlapping toes

http://www.drfootdick.com/whatwetreat/overlap.html

Visual Inspection Deformities such as Halux Valgus

www.surgicalnotes.co.uk

Visual Inspection Deformities such as Joint Subluxation

American College of Rheumatology

Visual Inspection Deformities such as Prominent Metatarsal Heads

American College of Rheumatology

Visual Inspection Deformities such as Charcot Foot

Visual Inspection Infections Cellulites

Visual Inspection Infections
Foot Ulcers and Amputations