VIBRATION PERCEPTION THRESHOLD / PERIPHERAL NEUROPATHY

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1. Vibratory deficits background and rationale

Peripheral sensory deficits have previously been reported in osteoarthritis (OA) of the knee. Methods used to identify these deficits have included joint position sense, joint kinesthesia, and vibratory perception. Vibration perception threshold (VPT) and proprioceptive acuity are both measures of posterior column function and travel through similar anatomic pathways. Whether sensory deficits precede the development of OA and could be considered a risk factor for OA development or are a consequence of OA-related damage to a joint is still not clear.

Vibratory perception testing appears to be one of the most simple and reliable ways to evaluate peripheral sensory deficits in OA. It has been used extensively to evaluate diabetic neuropathy and has been associated with neuropathic arthropathy. Vibratory perception can be quantified through use of a biothesiometer. Vibratory perception is known to decrease with age. Vibratory perception may also differ depending on the body site being tested, with more proximal extremity locations (e.g., knee) demonstrating decreased vibratory perception compared to more distal locations (e.g., ankle). This may be due to increased soft tissue density at more proximal body sites. Vibratory perception has been shown to be decreased at the upper and lower extremities of subjects with both OA of the knee and OA of the hip.

2. General description of vibration threshold testing with the biothesiometer

Vibration perception threshold (VPT) is a method used to evaluate vibratory perception and can be performed using a biothesiometer. A biothesiometer is similar to a handheld tuning fork and allows for reliable and quantitative measurement of vibratory perception. The examiner places the handheld vibration applicator on pre-specified anatomical landmarks on the participant. The examiner should have full access to the participant's knees, wrists, and toes. Therefore, the participant should be wearing shorts, or a gown should be provided for the participant if necessary. The amplitude (strength) of the vibration increases as the voltage amplitude of the machine is gradually increased until the participant senses vibration from the instrument. The voltage at which vibration is noted defines the VPT and is recorded on the data collection form. A higher VPT value represents poorer vibratory perception. Two trials are performed at each site and the mean value later calculated as the VPT for that site.

A peripheral neuropathy screening exam will be done before VPT testing.

3. Equipment and supplies

- Examination table
- 10 gram monofilament for peripheral neuropathy screening
- Biothesiometer (Biomedical instruments, Newbury, OH)
- Alcohol pads
- Disposable shorts or examination gown (if participant forgets to bring shorts)
- Examination gloves

3.1 Monofilaments

Log date new filaments were first used and mark expiration date (6 months from when received) on filaments. Discard filaments when they are 6 months old and replace with new ones. Visually monitor for bent or broken filaments.

4. Safety issues and exclusions

4.1 Safety issues

There are no safety issues associated with this test.

4.2 Exclusions

Complete the VPT and Pain Sensitivity Exclusions form prior to testing.

- Above the knee amputation (do not test that leg). Test radial styloids regardless of leg amputation.
- Open or healing skin wounds or surgical scars on the big toe, tibial tuberosity, or radial styloid.
- Do not test radial styloid if the wrist on that arm had a fracture in the past 6 months.
- If participant regularly wears a wrist brace or splint, do not test the radial styloid on that wrist.

5. Preparation

Testing is done on bare skin at the big toe, tibial tuberosity, and radial styloid. Have the participant remove socks, stockings, etc., and wear shorts so that these sites are accessible.

The participant should first sit on the examination table and then lie down, face up. Lower the head of the examination table so that the participant is comfortable.

Make sure that the exam table is almost flat; a little incline for comfort is acceptable but the participant will be lying on their back for the test.

For testing of the radial styloid the participant's hand should be comfortably resting on the exam table, or, if there is no room on the exam table, on the side table. The side table's height should be adjusted such that the forearm is resting comfortably on it. Be sure that the side table is at a secure height and won't move down with pressure.

For peripheral neuropathy tests, the foot should be warm.

Prior to testing, participants should be given an opportunity to become familiar with the testing apparatus and with the expected vibratory sensation (see below).

The applicator tip of the biothesiometer should be thoroughly cleaned with an alcohol pad between participants. It is best to do this while the participant about to be tested is watching.

Plug in the biothesiometer and push the red power button to turn on the machine.

Two examiners are required for the VPT exam. Examiner #1 will be the examiner communicating with the participant, locating the appropriate testing sites on the participant, and operating the applicator. Examiner #2 will control the voltage on the biothesiometer and record results on the data collection forms.

6. Detailed measurement procedures

6.1 Introduction of tests

<u>Script:</u> "During this examination I will be touching or applying pressure to various parts of your wrist, knees, and toes and asking about what you feel. There are no right or wrong answers. We're interested in your experience."

6.2 Peripheral neuropathy screening with 10 gram monofilament

The peripheral neuropathy screening test is completed before vibration perception threshold testing:

For this examination the participant is lying on the examination table with their knees bent and the soles of their feet flat on the exam table.

The monofilament should initially be prestressed (4 to 6 perpendicular applications to the dorsum of the examiner's first finger).

<u>Script:</u> "I'm going to touch the skin on the back of your wrist with this plastic bristle so you know what to expect." (Show how filament bends, then touch the filament to the back of the participant's hand.)

<u>Script:</u> "Now I'll touch you briefly with the bristle just above the big toe while you have your eyes closed." Please say 'Now' every time you feel the bristle touch your skin."

Apply the filament to the <u>dorsum of the great toe midway between the nail fold and the DIP joint</u> (See Appendix 1). Do <u>not</u> hold the toe directly during the test.

Test the right toe first. Briefly (<1 second) apply the filament 10 times perpendicularly with an even pressure. When the filament bends, the force of 10 grams has been applied. Wait several seconds between each touch, varying the time slightly.

A correct response requires a 'Now' while the filament is touching the toe or just as it is being removed. Count the number of trials completed on each toe and the number of times the participant did not respond to the stimulus on the toe. Record the data on the data collection form.

Repeat the test on the left toe.

After testing both toes, tell the participant they did fine. Do not discuss their results until the VPT testing is completed.

6.3 Vibration perception threshold test

Two examiners are needed to administer the VPT test: Examiner 1 will hold the biothesiometer applicator on the participant's skin and Examiner 2 will control and record voltage.

Examiner #1 needs to hold the applicator very lightly, just supporting it, so that most of the weight of the device is resting on the participant's skin (see photograph).



<u>Script:</u> "In the next tests I will be using a vibration applicator that looks like this to apply vibration to parts of your toes, knees and wrists. (Show participant applicator.) This test requires two people. This is (insert name here) and they will be helping me today.

"Let me show you how this will work on your hand. Please place your hand on the table. I'll now put the vibration applicator on the back of your hand to show you what the weight of the applicator feels like. Do you feel its weight resting on your hand? (Wait for response.) Okay, now we'll start turning up the vibration. This may be more subtle during the actual test but for now I will turn it up somewhat faster to give you an idea of what to feel for. Tell me when you feel a vibration. (Wait for response.) This is what we will be asking you to feel for during the test, although during the test the vibration will be increased more gradually."

Wait a few seconds between placing the applicator on the back of the participant's hand and the increase of the vibration to allow the participant to differentiate between the two different sensations.

6.3.1 Instructions for each test site

The two examiners work together in the same way for each test. If a test can not be done on any of the six sites for any reason other than VPT exclusions, fill in the bubble for the appropriate site(s) on the lower left hand side of the data collection form indicating that the test was not done.

Trial #1:

Examiner #1 should indicate to Examiner #2 each time with a nod or "ok" that they are ready to begin increasing the voltage on the machine.

After this confirmation, Examiner #2 should increase the machine voltage gradually. This is done by turning the dial on the biothesiometer clockwise. Since this is a manual dial, turn the dial continuously one volt (one black line on the dial) per second by counting "one one thousand, two one thousand, etc."

As soon as the participant vocalizes feeling the vibration, Examiner #2 should take their hand off the dial.

Read the number of volts set on the machine and record the number on the data collection form (Trial #1). This should be recorded to the nearest 0.5 volts. If the reading is in-between two numbers, round up.

If the participant does not report feeling vibration when the voltage has reached 50 volts, Examiner 2 should stop increasing voltage and record the voltage on the data collection form as 51.0 volts to indicate that no vibration was felt.

Return the voltage knob to zero, and notify Examiner #1 that you are ready to begin again.

Trial #2:

Trial #2 is done exactly the same way as Test #1. Results are recorded in the Trial #2 data field on the data collection form.

Examiner #2 will calculate the difference between Trial #1 and Trial #2 and record the information on the form. If the difference is > 4 volts for the MTP and radial styloid sites or > 6 volts for the tibial tuberosity sites, the examiners will complete Trial #3 and Trial #4 for that location. A result of 51.0 on any trial (to indicate that no vibration was felt) should be treated like any other number in calculating the difference between trials.

6.3.2 Order of tests

The order of the tests is as follows:

- 1. 1st MTP joint, Right
- 2. Tibial tuberosity, Right
- 3. Radial styloid, Right
- 4. 1st MTP joint, Left
- 5. Tibial tuberosity, Left
- 6. Radial styloid, Left

The anatomical landmarks for the 1st MTP joint will need to be marked with a half-inch "X" using a black magic marker. The tibial tuberosity and radial styloid will already be marked with an "X."

6.3.3 Positioning and general participant instructions

To help keep the applicator still and to make it easier on the examiner holding the applicator, the participant will bend their knee and place their foot flat on the exam table for the MTP site test; straighten their legs flat on the table for the tibial tuberosity test; and place their hand flat on the exam table or side table for the radial styloid exam. Ask the participant to close their eyes before starting each test.

6.3.4 Right MTP

<u>Script:</u> "Now please bend your right knee and place your foot flat on the table, and I'll begin the test. Close your eyes during testing. Remember I will increase the vibration slowly. When you feel the vibration it will be subtle and everyone feels it differently and at different times. There are not any correct or incorrect answers."

The first metatarsophalangeal joint of the big toe (1st MTP) is the bony prominence proximal to the big toe at the foot. Feel for this bony prominence on the top of the foot where the big toe joins the body of the foot (see Appendix 1) and place the applicator tip on it. Hold the applicator with both hands, one on the handle and one close to or on the top of the applicator. Do not apply pressure. Just let it rest on the joint.

<u>Script:</u> "Okay, now I'm going to place the applicator on a spot just above your big toe. This is only the weight of the applicator. Can you feel this?" (Wait for response.) Please close your eyes and say 'Now' as soon as you <u>start</u> to feel the vibration in the same spot where you feel the applicator. Now we will begin the test."

Follow instructions detailed in section 6.3.1

<u>Script:</u> "Okay. Now we'll repeat this test on the same spot. Again, please close your eyes and say 'Now' as soon as you <u>start</u> to feel the vibration on the spot where the applicator is. Now we'll start the test."

Follow instructions detailed in section 6.3.1.

If the difference between Trial #1 and Trial #2 is greater than 4 volts, the examiners will complete Trial #3 and Trial #4 at that location.

6.3.5 Right tibial tuberosity

The second test site is the tibial tuberosity. It is the bony prominence below the knee cap.

Script: "For the next part I need you to now lay your legs flat on the table." (Wait for them to straighten their legs.)

<u>Script:</u> "I'm going to place the applicator on a spot below your knee. This is the weight of the applicator. Please close your eyes and say 'Now' as soon as you <u>start</u> to feel the vibration in the same spot where you feel the applicator. Now we will begin the test."

Follow instructions detailed in section 6.3.1.

<u>Script:</u> "We will test this same spot again. This is the weight of the applicator only. Please close your eyes and say 'Now' when you start to feel the vibration. Now we'll start the test."

Follow instructions in section 6.3.1.

If the difference between Trial #1 and Trial #2 is greater than 6 volts, complete two more trials.

6.3.6 Right radial styloid

The next exam will be performed on the upper extremity (wrist) at the radial styloid. The posterior-medial aspect of the radial styloid is the bony prominence accessible when the participant's hand is flat on the table.

Script: "For the next part please lay your hand flat on the table." (Wait for them to position their hand.)

<u>Script:</u> "I will now feel at the wrist for the correct spot. Okay, this is the weight of the machine and we will begin the test. Let me know when you start to feel the vibration."

Follow instructions in section 6.3.1.

<u>Script:</u> "We'll test this same spot again. This is the weight of the applicator only. Please close your eyes and say 'Now' when you start to feel the vibration. Now we'll begin the test."

If the difference between Trial #1 and Trial #2 is greater than 4 volts complete Trial #3 and Trial #4 at this site.

6.3.7 Left MTP, tibial tuberosity and radial styloid tests

The tests completed on the right side of the body will also be done on the participant's left side (see MTP instructions in section 6.3.4; see tibial tuberosity instructions in section 6.3.5; and radial styloid test instructions in section 6.3.6).

7. Results and alert values

7.1 Peripheral neuropathy results and alert values

Peripheral neuropathy testing results:

- Normal: 8+/10 correct responses
- Reduced sensation: 1 to 7/10 correct responses
- Absent sensation: 0/10 correct responses

Participants with absent sensation should be told to contact their primary care provider regarding reduced sensitivity to touch in the big toe area of the body. This information should be documented on the Participant Results Report.

7.2 Vibration perception threshold results

In response to participant questions about the VPT test, participants should be informed that it is a research examination and that there is very little information about how to interpret the results that we obtained.

The following response is suggested:

<u>Script:</u> "Right now there is very little information about how the Vibration Perception Threshold test relates to the health of people or their arthritis. We are doing this test to help understand if there is a relationship between feeling vibration and arthritis."

If participants are concerned because they did not feel vibration, the following response is suggested:

<u>Script:</u> "Everyone senses this test differently, and not everyone feels the vibration. We will be looking at how different responses to the test may relate to arthritis."

8. Quality assurance

8.1 Training requirements

Clinic staff require no special qualifications or experience to perform this testing. The single "master" examiner will train the clinic staff who will be administering the vibration perception exam. Staff will be initially certified following the below certification requirements and the 'master' examiner will conduct a second 'master' certification to insure inter-rater reliability. Staff will be retrained and recertified midway through each examination cycle. Training should include:

- Read and study manual
- Attend the MOST training session on VPT and peripheral neuropathy
- Practice the VPT and peripheral neuropathy protocol on other staff or volunteers
- Discuss problems and questions with local expert

8.2 Certification requirements

- Complete training requirements
- Conduct exam on two volunteers, one of whom should be re-tested
 - For re-test on one volunteer agreement should be
 - \rightarrow within one non-response to the peripheral neuropathy stimulations on first test
 - \rightarrow within 3 volts of the average of the first tests at the first MTP and radial styloid and 5 volts of the average of the first tests at the tibial tuberosity for VPT.
 - \rightarrow for VPT if Trials 3 and 4 were completed on first test, average of Trials 3 and 4 rather than Trials 1 and 2 should be used to determine if agreement is within range above

8.3 Quality assurance checklist

General preparation for tests

- Participant wearing shorts
 - Participant's shoes and socks removed

Exclusions

All exclusions correctly assessed and documented

Peripheral Neuropathy

	Participant's feet appropriately warm for testing
	Filament appropriately prestressed
	Correctly describes testing procedure
Right 🗌 Left 🗌	Participant's eyes closed during testing
Right 🗆 Left 🗆	Correctly applies filament during testing
Right 🗆 Left 🗆	Correctly records whether entire set was completed
Right 🗆 Left 🗖	Correctly records number of times participant did not feel the filament (stimulus)

Preparation for VPT tests (Examiner 1)

- Exam table flat (head can be lightly raised)
- Correctly describes testing procedure
- Holds hand-held applicator (biothesiometer) correctly
- Correctly demonstrates use of hand-held applicator

1st MTP (Examiner 1)

Right 🗆 Left 🗆	Correct script used to introduce test
Right 🗆 Left 🗆	Participant lying on back, with bent knee and right foot flat on table
Right 🗆 Left 🗖	Correctly locates MTP joint
Right 🗆 Left 🗆	Reminds participant to close eyes

Tibial tuberosity (Examiner 1)

Right 🗆 Left 🗆	Correct script used to introduce test
Right 🗆 Left 🗖	Participant lying on back, with legs straight on table
Right 🗌 Left 🔲	Correctly locates tibial tuberosity
Right 🗆 Left 🗖	Reminds participant to close eyes

Radial styloid (Examiner 1) Right | Left | Correct script used to introduce test Right | Left | Participant's hand flat on table Right | Left | Correctly locates radial styloid Right | Left | Reminds participant to close eyes

1 st MTP (Examiner	2)
Right 🗆 Left 🗆	Correctly increases voltage
Right 🗆 Left 🗆	Correctly records voltage when participant first feels vibration (both trials)
Right 🗆 Left 🗆	Correctly assesses whether to complete two additional trials and informs Examiner 1 if necessary
Right 🗆 Left 🗆	If Trials 3 and 4 are necessary, correctly records voltage
Tibial tuberosity (E	Examiner 2)
Right 🗆 Left 🗆	Correctly increases voltage
Right 🗆 Left 🗆	Correctly records voltage when the participant first feels vibration (both trials)
Right 🗆 Left 🗆	Correctly assesses whether to complete two additional trials and informs Examiner 1 if necessary
Right 🗆 Left 🗆	If Trials 3 and 4 are necessary, correctly records voltage
Radial styloid (Exa	miner 2)
Right 🗌 Left 🗌	Correctly increases voltage
Right 🗆 Left 🗆	Correctly records voltage when the participant first feels vibration (both trials)
Right 🗆 Left 🗆	Correctly assesses whether to complete two additional trials and informs Examiner 1 if necessary
Right 🗌 Left 🔲	If Trials 3 and 4 are necessary, correctly records voltage

9. Data collection form

;	59041	O 60-month			Staff ID#		
VPT	' & Pain Se	0 84-month			MO	ST	
. H	Have you ever had either of your knees replaced? ○ Yes ○ No ○ Don't know/Refused ↓						
a. \	Which knee was ○ F ↓	replaced? Right	⊖ Left		⊖ Both knees ⊥		
	Do NOT test R	patella.	Do NOT test L p	atella.	Do NOT test R or	L patella.	
		articipant's legs a	ant the following question amputated above the kne No				
		as amputated at Right	oove the knee? ○ Left ↓		⊖ Both legs		
	10 11	exclusions		unt I	f no other exclusions		
Evam	test le	eft leg.	If no other exclusions to right leg.		test wrist.		
	test le	eft leg. <i>t the participant's</i> healing skin wou	right leg. s <i>legs.</i> inds or surgical scars on		test wrist.		
	test le iner Note: Look a re there open or	eft leg. <i>t the participant's</i> healing skin wou	right leg. s <i>legs.</i> inds or surgical scars on		test wrist.		
	iner Note: Look a re there open or ♀ Y	eft leg. <i>t the participant's</i> healing skin wou ⁄es O I	right leg. s <i>legs.</i> inds or surgical scars on	the patella or	test wrist.		
	test le <i>iner Note: Look a</i> re there open or ♀ Ŷ a. Where?	eft leg. <i>t the participant's</i> healing skin wou /es O I	right leg. s <i>legs.</i> inds or surgical scars on	the patella or	test wrist.	y.	
	test le <i>iner Note: Look a</i> re there open or ♀ Y a. Where? ○ Right pate	eft leg. <i>t the participant's</i> healing skin wou 'es O I ella	right leg. s <i>legs.</i> inds or surgical scars on	the patella or Do not t	test wrist. tibial tuberosity? not test right patella.	y.	
	iner Note: Look a re there open or ♀Y a. Where? ○ Right pate ○ Right tibia	eft leg. <i>t the participant's</i> healing skin wou 'es O I ella al tuberosity —	right leg. s <i>legs.</i> inds or surgical scars on	the patella or Do not t	test wrist. tibial tuberosity? not test right patella. est right tibial tuberosit		



tested? Yes entire set comple Yes low many trials rere completed?	 ○ No, unable to test eted? ○ No trials 	⊖ Refused		
e entire set comple > Yes low many trials	eted? ○ No ↓	○ Refused		
⊃ Yes łow many trials	○ No ↓	7		
	trials			
any times did the	participant NOT respon	d to the stimulus?		
⊖ Yes ↓ e entire set comp		⊖ Refused		
	trials			
nany times did the	e participant NOT respon	nd to the stimulus?		
	e entire set comp O Yes łow many trials /ere completed?	e entire set completed? Yes No, unable to test e entire set completed? Yes No How many trials vere completed? trials hany times did the participant NOT respon	e entire set completed? Yes No, unable to test Refused e entire set completed? Yes No How many trials vere completed? trials hany times did the participant NOT respond to the stimulus?	tested? Yes ONO, unable to test ORefused e entire set completed? OYes ONO How many trials vere completed? trials hany times did the participant NOT respond to the stimulus?

6324	Visit O 60-month O 84-month	MOST ID # Acrostic MOST
 Examiner #1 indicates to Examiner "ok" that they are ready to begin in "ok" that they are ready to begin in gradually by turning dial clockwise volt per second by counting "one of one thousand, etc." As soon as the participant vocalized vibration, Examiner #2 should take dial. Read number of volts set on the monto the data collection form (Trial recorded to the nearest 0.5 volts. I between two numbers, round up. Continue to Trial #2, etc. RIGHT 1st MTP, participant suptable 1. Trial 1 2. Trial 2 3. Difference between Trial 1 & Trial 1 4. Is the difference between Tria greater than 4 volts? Yes Complete Trials 3 and 4 below. 5. Trial 3 6. Trial 4 	creasing voltage. creases voltage continuously one one thousand, two es feeling the their hand off the achine and record #1). This should be f the reading is in- ine, foot flat on volts volts volts	Examiner #1 (applicator) Examiner #2 (voltage knob) Staff ID# ID# ID# RIGHT TIBIAL TUBEROSITY, participant supine, leg straightened out 7. Trial 1 · 9. Difference between · Trial 2 · 9. Difference between · Trial 1 & Trial 2 · 10. Is the difference between Trial 1 and Trial 2 9 Yes O No Complete Trials 3 and 4 below. Go to Item #13. 11. Trial 3 · volts 12. Trial 4 · volts 13. Trial 1 · volts 14. Trial 2 · volts 15. Difference between Trial 1 and Trial 2 16. Is the difference between · volts 15. Difference between · volts 16. Is the difference between Trial 1 and Trial 2 · Volts · volts 16. Is the difference between Trial 1 and Trial 2 · O Yes O No Complete Trials 3 and 4 below. Go to Item #19. · volts
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1030	O 60-month O 84-month		MOST
Examiner #1 indicates to Examiner "ok" that they are ready to begin inc			
After confirmation, Examiner #2 inc gradually by turning dial clockwise of volt per second by counting "one or one thousand, etc."	continuously one	LEFT TIBIAL TUBEROSITY, participant supine, leg stra	
As soon as the participant vocalizes vibration, Examiner #2 should take dial.		25 . Trial 1	volts
Read number of volts set on the ma onto the data collection form (Trial # recorded to the nearest 0.5 volts. If	≰1). This should be	20. That 2 27. Difference between Trial 1 & Trial 2	·volts
between two numbers, round up. Continue to Trial #2, etc.	-	28. Is the difference betwee greater than 6 volts? Q Yes	en Trial 1 and Trial 2 Ọ No
LEFT 1st MTP, participant supi table	ne, foot flat on	Complete Trials 3 and 4 bel	ow. Go to Item #31
19. Trial 1		29 . Trial 3	· volts
20. Trial 2 21. Difference between	• volts	30 . Trial 4	volts
Trial 1 & Trial 2 22. Is the difference between Tria greater than 4 volts?	J•volts al 1 and Trial 2	31 . Trial 1	and flat on table
O Yes	O No	32 . Trial 2	volts
Complete Trials 3 and 4 below. 23. Trial 3	Go to Item #25.	33. Difference between Trial 1 & Trial 2	volts
24. Trial 4	volts	34. Is the difference betwee greater than 4 volts? O Yes	
		Complete Trials 3 and 4 be	Iow. Go to next test.
		35 . Trial 3 36 . Trial 4	volts
			volts
	◆Page	59♦ MOST F Clinic Visit V	Follow-up

Appendix 1 Anatomical Landmarking MTP Joint

