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STUDY OF OSTEOPOROTIC FRACTURES (V2)

Bio-Resistance Measurement Protocol

1. Introduction:

Bio-resistance, or bio-electrical impedance, is a new indirect method for the assessment of body composition. The technique is non-invasive, rapid, safe, and painless. Estimation of body fat using bio-resistance technology is based on the assumption that lean tissue containing significant amounts of water and electrolyte is a relatively good electrical conductor, while fat tissue containing very limited amounts of water and electrolyte is a relatively poor electrical conductor. Resistance to the flow of current through a conductor (impedance, Z, or resistance, R, in ohms) is a function of the composition of the conductor and its volume. Bio-resistance analyzers introduce a low-level electrical signal (500 micro amps at 50 KHz) into a body segment through a sense electrode. Accurate estimation of body composition (total body water, lean body mass, fat mass), therefore, requires consistent electrode placement and careful measurement of body segment lengths. (Since we are measuring whole body resistance, the relevant segment length is standing height.) In addition, all subject pre-measurement guidelines must be followed in order for the measurement to be valid.

2. Subject Preparation:

Dietary and activity restrictions

- a) No vigorous exercise or other activity resulting in profuse sweating on the day of the clinic visit (12 hours prior to the test).
- b) No alcohol or caffeine (coffee, tea, colas) on the day of the clinic visit up to the time of the test (12 hours prior to the test).
- c) Tests should be performed from 2 to 5 hours after the most recent meal.
- d) In general, subject's should maintain a normal fluid balance by keeping fluid intake and voiding at normal levels.
- e) The following factors potentially affecting fluid balance are recorded:
 - current use of diuretics is recorded on the medication questionnaire
 - flu with diarrhea in the past 24 hours
 - one or more cups of caffeinated beverage in 12 hours before test
 - one or more drinks of alcohol in 12 hours prior to test

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"Now we're going to conduct some tests that measure your body composition, or the amount of water and muscle tissue in your body. We will do this with this machine, which measures the electrical properties of your body, similar to the way in which a routine EKG measures the electrical properties of your heart muscle. About 50-60% of your body is water. That is why your body conducts electricity. This machine operates on an electrical current about the same as a small flashlight battery. You will not feel anything during the test. By measuring the signal between your hands and feet, we will be able to estimate how much of your body is water and muscle. Scientists think this may be important in understanding osteoporosis and fractures." (*Script need not be verbatim.*)

3. Measurement procedures:

General: Resistance is measured between electrodes placed at specific bony landmarks of the arm and leg. At each anatomic site, a pair of electrodes, one distal and one proximal, is applied to the skin. The distal electrode introduces the current, and the proximal electrode senses the current. The black wire of the Valhalla bio-resistance analyzer is attached to the distal (source) electrodes. The red wire of the Valhalla bio-resistance analyzer is attached to the proximal (sense) electrodes. Resistance is measured at the two sense (proximal) electrodes. Careful electrode placement is essential. A positioning error of the sense electrode can result in a significant error in the resistance measurement. For this reason, the sense electrode (red lead) should be consistently placed on the designated landmark.

Calibration: The Valhalla 1990B has been programmed to calculate and display a measurement resolution of 0.1 ohm. Calibrate the 1990B before each day of data collection or each time the power is turned on.

- a) Press any key to turn the instrument on. Allow the 1990B to display the date and time. Press the "CALIBRATE" key. It will take about 2 minutes to complete the calibration routine. If the calibration readout is not 499 ohms, call the SOF Coordinating Center.
- b) Keep a log of each day's calibration readout.
- c) If the machine will not complete the calibration routine, call the manufacturer for service and notify the coordinating center so we can arrange for a temporary replacement.

Power source and battery charging:

The unit will run for approximately 3.5 hours of normal continuous operation between battery charges. The batteries fully recharge in 15 hours on 110 volt electrical output. There is no danger of electrical shock to the participant if the unit is run while plugged directly into a wall outlet.

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Summary of measurement procedures:

- a) Have the subject remove shoes and socks and lie down slightly spreadeagle on the examining table.
- b) Place electrodes at the proper anatomical sites on the right hand and wrist and the right and left ankle and foot. (See figures.)
- d) Attach the alligator clips on the red and black lead wires to the correct electrodes on the right wrist and hand and right ankle and foot. (See figures.)
- e) Record the first series of measurements for the right side of the body after the subject has been supine for two minutes.
- f) Move the alligator clips and leads from the right to the left ankle and foot. Record the measurements for the right arm to left leg axis. If the difference in resistance between the first and second measurements is > 20 , check all connections and repeat the measurements. Record the measurements from the trial with the least difference between right and left foot resistance
- g) Compute the body composition measures, as appropriate.

Subject Positioning: Remove the subject's shoes and socks or stockings to access the electrode attachment area. The subject should be in a supine (face-up) position on a dry, non-conductive surface. Instruct the subject to remain motionless and relaxed with her arms and legs slightly apart. The arms should be slightly bent at the elbow with palms down. Neither arms nor legs may touch any other part of the body.

If necessary, the participant may be propped up on pillows if she cannot lie supine. Record the position on the exam form.

The participant should be supine for no more than 3 minutes prior to completing the measurement.

Skin Preparation: Prepare each contact area by rubbing gently with an alcohol wipe to remove such substances as hand lotion, etc. Let the alcohol evaporate before attaching the electrodes.

Electrode Preparation: The electrode supplied by the manufacturer is a solid state, natural gum conductive pad laminated to a thin metallic backing. Electrodes are precut into two equal halves. Use one half electrode for each of the six landmarks (thus 3 electrodes per subject).

Electrode Placement (See Figure):

Wrist (right): Center the electrode on a line on the dorsal (back) surface of the wrist on a line bisecting the styloid processes of the radius and ulna. Attach the red lead.

Hand (right): Apply the electrode over the distal end of the middle metacarpal, at least 5 centimeters distal to center of the wrist electrode. Attach the black lead.

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Ankle (right and left): Center the electrode on a line on the ventral (front) surface of the ankle bisecting the lateral and medial malleoli. Attach the red lead.

Foot (right and left): Apply the electrode over the distal end of the middle metatarsal (on a flat surface, not ridged by tendons) at least 5 centimeters distal to the center of the ankle electrode. Move the black lead from the deltoid and connect it at this location.

NOTE: The placement of the proximal electrode is critical. The distal electrode position is less critical, but be sure to maintain at least the minimal distance from the proximal electrode.

Special circumstances: If circumstances prevent the above placement of electrodes (e.g. amputation, cast, etc.), record alternative placement of electrodes. Alternative placement: left hand/left leg, left hand/right leg.

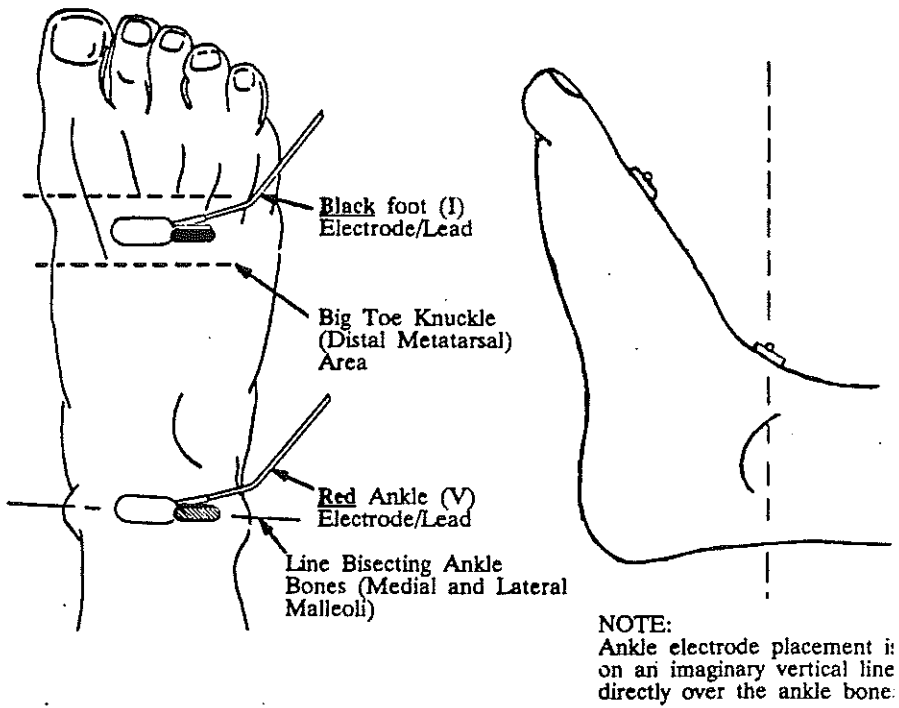
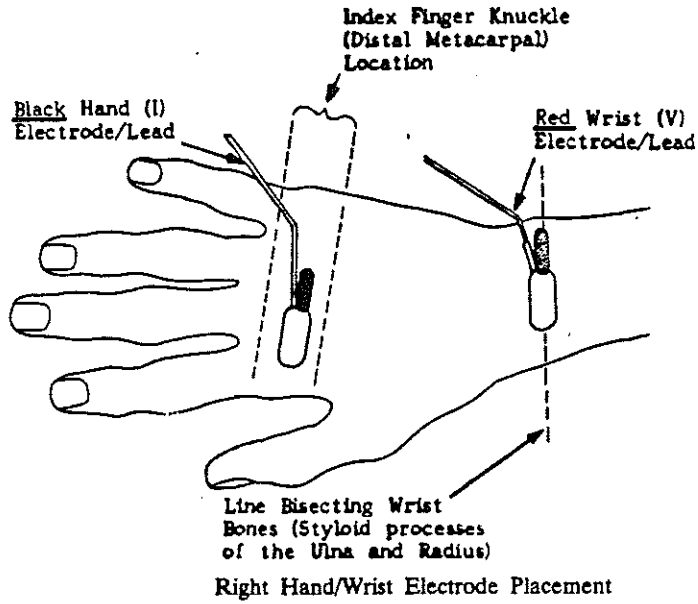
Bio-resistance measurement procedures:

- a) Connect the red (sense) leads to the right wrist and right ankle electrodes (the proximal electrodes). Connect the black (source) leads to the right hand and right foot electrodes (the distal electrodes). **BE SURE THE LEAD CLIP DOES NOT PIERCE THE GEL ON THE ELECTRODE.**
 - b) Press the "RUN" key. Enter the subject's weight in pounds, height in inches, and gender, as prompted by the unit. Press the "ENTER" key after each entry.
 - c) The unit will display "CONNECT CLIENT YES OR NO". Press the "YES" key. The unit will then display measurements for resistance, reactance, impedance, and phase angle. Allow the ohms displayed to stabilize prior to recording these four measurements.
 - d) If the display reads "BAD CONNECTION", a) disconnect and reconnect lead clips without piercing electrode gel, or b) apply new electrodes.
 - e) Disconnect the leads from the electrodes on the right foot and reconnect to the appropriate electrodes on the left foot. The unit will momentarily display "BAD CONNECTION" and then display "CONNECT CLIENT YES OR NO". Press the "YES" key and record resistance and compare with the 1st measurement. If the difference is greater than 20 ohms, repeat the measurements.
- The normal range for resistance is 400 to 700 ohms. For readings outside this range, check electrode placement and all connections.
- f) Compute body composition for the subject by pressing the "LEAN" and "FAT" keys.
 - g) Remove the electrodes from the subject.

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h) Record:

- i) diarrhea or vomiting in the past 24 hours
- ii) caffeinated and alcoholic beverages in past 12 hours
- iii) subject positioning
- iv) alternative placement of electrodes



Right Foot/Ankle Electrode Placement