STUDY OF OSTEOPOROTIC FRACTURES (V4)

Bio-Resistance Measurement Protocol
Body Composition Cohort

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. Hence, test should be done approximately 2 hours after the Ca45 snack.

d) In general, subject's should maintain a normal fluid balance by keeping fluid intake and voiding at normal levels.

e) Record the following factors that can affect fluid balance:

- 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

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 programed 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.

"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 or 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.*)

Summary of measurement procedures:

a) Prepare the participant while she is sitting on the edge of the table.

b) Have the subject remove shoes and socks and lie down slightly spreadeagle on the examining table.

c) 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) Observe the feet for marked edema at the ankle and marked foot deformities (e.g. halux valgus deformity), and record on the scoring form.

f) Record the first series of measurements for the right side of the body after the subject has been supine for two minutes.

g) 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.

h) If the difference in resistance between the right and left foot measurements is >20, remove the electrodes, apply a new set of electrodes, and repeat the measurements. Record the measurements from both trials. Circle the measurements of the trial with the least difference in resistance between right and left foot. The circled measurements will be entered in the data system.

i) Compute the body composition for the participant.

Subject Positioning: Remove the subject's shoes and socks or stockings to access the electrode attachment area.

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.

For testing 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.

Electrode Preparation: The electrode supplied by the manufacturer is a solid state, natural gum conductive pad laminated to a thin metalic backing. Electrodes are precut into two equal halves. Use one half electrode for each of the six landmarks (thus 3 electrodes per subject). The electrode wires should not touch one another.

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.

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, reapply electrodes and 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.

h) Record:

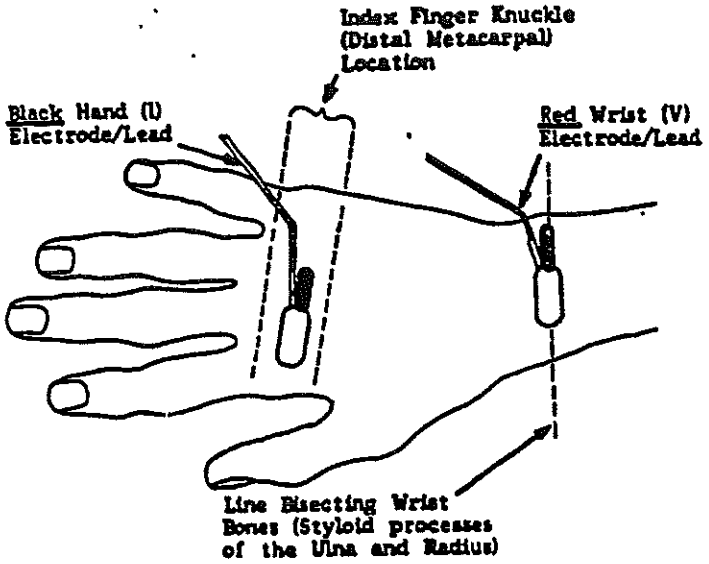
i) diarrhea or vomiting in the past 24 hours

ii) caffeinated and alcoholic beverages in past 12 hours

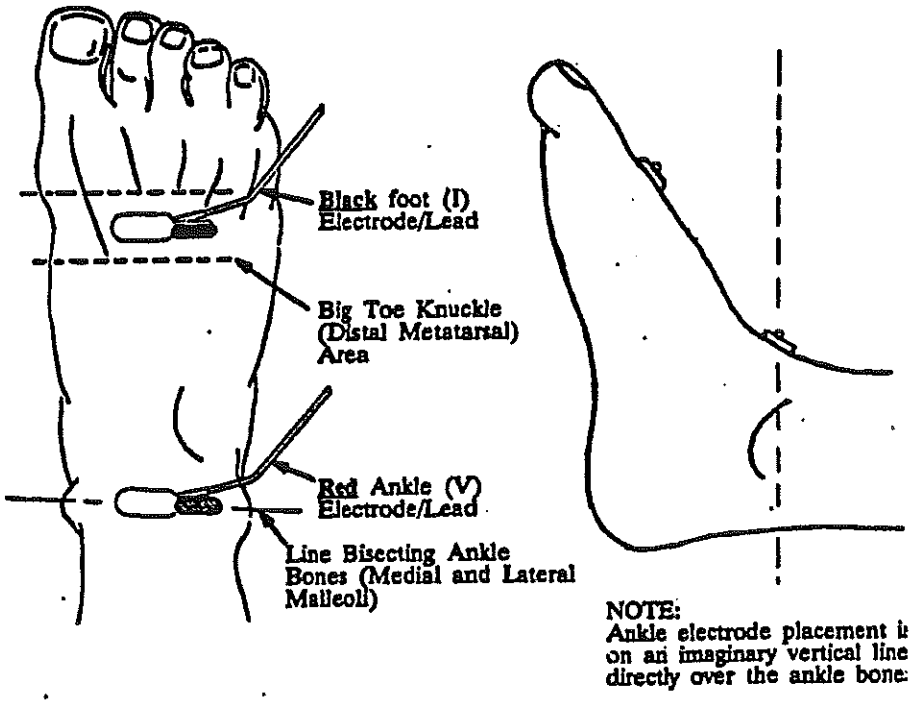
iii) subject positioning

iv) ankle edema and foot deformity by observation

v) alternative placement of electrodes



Right Hand/Wrist Electrode Placement



Right Foot/Ankle Electrode Placement

3/10/93
ver 4.0

BIOELECTRICAL IMPEDANCE

PPT. ID _____

Screening questions:

HAVE YOU HAD:	yes*	no	don't know
Diarrhea or vomiting in the past 24 hours?	☐	☐	☐
One or more cups of a caffeinated beverage in the past 12 hours?	☐	☐	☐
One or more drinks of alcohol in the past 12 hours?	☐	☐	☐

***If yes, do not continue. This participant no longer a BCC participant**

POSITION

☐ **SUPINE** ☐ PROPPED UP (sitting or half sitting)

MEASUREMENTS

Electrode Positions

	1. Right Hand/ Right Foot	2. Right Hand/ Left Foot
Resistance	___ ___ ___	___ ___ ___
Reactance	___ ___ ___	___ ___ ___
Impedance	___ ___ ___	___ ___ ___
Phase Angle	___ ___.___	___ ___.___

* If resistance measures differ by more than 20, repeat both sets of measurements.

REPEAT MEASUREMENTS

Electrode Positions

	1. Right Hand/ Right Foot	2. Right Hand/ Left Foot
Resistance	___ ___ ___	___ ___ ___
Reactance	___ ___ ___	___ ___ ___
Impedance	___ ___ ___	___ ___ ___
Phase Angle	___ ___.___	___ ___.___

Amputation, cast, or other reason for alternative hand electrode placement?

☐ Yes → Alternative electrode positions: 1. Left hand/ Left foot; 2. Left hand/ Right foot

☐ No