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CORRELATION BETWEEN BIOELECTRICAL SPECTROSCOPY AND PEROMETRY IN ASSESSMENT OF UPPER EXTREMITY SWELLING

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ABSTRACT

Lymphedema is a common side effect of breast cancer treatment and is associated with increased upper extremity volume, functional impairment, and pain. While there is no cure for lymphedema, physical therapy treatment can often alleviate symptoms. To measure the efficacy of treatment, accurate assessment of the limbs is important. Current methods of assessment are complex (water displacement), marginally accurate (circumferential measurements), or expensive (opto-electrical systems). A new method for estimating tissue fluid is bioelectrical spectroscopy (BIS). This method measures impedance to small currents applied to the body and is easily performed. Acceptance of BIS devices for assessment of limb fluid will be dependent on the establishment of sufficient reliability and validity, and the objective of this study was to evaluate reliability and validity of this device compared to perometry. Both upper limbs of ten subjects previously treated for breast cancer were measured using BIS and perometry. We found that inter-rater reliability (r=0.987) and intra-rater reliability (r=0.993) were acceptably high for the BIS unit and concurrent validity was r=-0.904, when compared to perometry. These results confirm that BIS can produce valid and reliable data related to the assessment of upper limbs affected by lymphedema.

Keywords: bioelectrical spectroscopy, bioimpedance, breast cancer, lymphedema, volumetry

Lymphedema is a pathophysiological condition in which excess protein-rich fluid (lymph) accumulates in the extracellular spaces of the extremity or trunk. As a result, the extremity becomes swollen and excessively firm. This condition can be uncomfortable and lead to decreased ability to get dressed as well as various other limitations in activities of daily living (1,2). Both women and men view this condition as unattractive (poor cosmesis) and may tend to limit their social interactions because they feel self-conscious. Affected individuals also may limit or eliminate vocational and recreational activities due to discomfort with any movement of the upper extremity (3).

A common etiology associated with the development of lymphedema is breast cancer and its treatment. The American Cancer Society predicted (2007) that 178,480 women will develop invasive breast cancer, while 62,030 women will develop in situ breast cancer (4). Although positive outcomes for breast cancer have been demonstrated after various treatments including surgery (breast conserving surgery, mastectomy, or lymph node dissection), chemotherapy, radiation therapy, and hormonal therapy (5), the

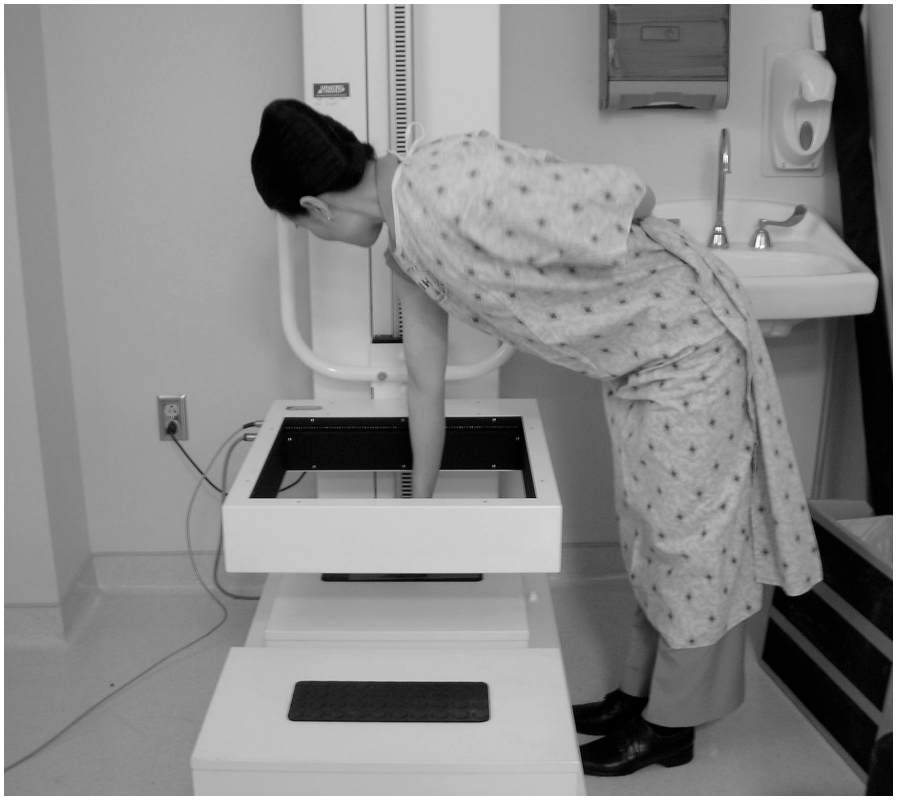

Fig. 1. Perometer®

subsequent occurrence of lymphedema is not uncommon with incidence estimated to be between 6-48% (6-9).

Reported incidence rates for lymphedema vary widely, and this variation may be due to differences in diagnostic criteria for lymphedema, differences in the cohorts studied, and the influence of different treatments. Diagnostic criteria have included among others a 200ml or 10% volume difference between limb volumes and a 2cm difference between limb circumference (10,11).

Clinical techniques for comparing limbs include water displacement (volumetry), circumferential measurements with a tape measure, volumetric measurements with use of an optoelectrical device such as the Perometer®, and most recently, a multi-frequency biospectroscopy unit (BIS, Impedimed®) (12,13).

Water volumetry, in which the exposed limb is lowered into a water tank, has been considered the standard reference method for determining limb volume (14). However, this technique is logistically difficult, and most clinics are not suitably outfitted.

The technique of circumferential measurement involves using a tape measure around the limb at specified anatomical locations. With the assumption that the limb segments are cylinders or truncated cones, these circumferences can be used in solid geometry formulae to calculate volumes (15). This technique is sensitive to tester error, which can include incorrect placement of the measuring tape, stretching of the measuring tape material, and erroneous calculations (16).

The Perometer® (400T, www.juzousa.com), is an opto-electrical device developed to minimize limb volume measurement error

Fig. 2. Impedimed® SFB7. Reprinted with permission from Impedimed®.

(17). It has a square frame, into which the extended extremity is placed. The frame emits infrared light inward on two sides with facing sensors on the opposite sides. During operation the square frame slides up and down, scanning the subject's extremity, and recording cross sectional information every three mm (*Fig. 1*). Limb volume is calculated based on the assumption that the cross section of the limb being measured is an ellipse or a circle. A coefficient of variance of 0.67% has been reported for this device (17). The Perometer has been reported to have better inter-rater and intra-rater reliability than volumetry measurements (18) and based on its accuracy and consistency of operation, is considered by many to be the modern "gold standard" for limb volume determination. Disadvantages of the Perometer® include its high purchase cost, bulky size of the equipment, lack of availability in most clinics, and unsuitability for use with patients who are bed-ridden. The manufacturer has recently developed a smaller, portable unit but it is still a bulky device compared to a bioelectrical spectroscopy unit.

The Impedimed® BIS unit (Imp™ SFB7, www.impedimed.com) is a single channel bioelectrical spectroscopy unit which uses sweep multi-frequency technology (256 discrete electrical frequencies between 4 kHz and 1 MHz) to estimate extremity fluid based on impedance. This portable device requires the placement of four electrodes to effect measurement of body impedance (*Fig. 2*), two for the active circuit and two for pickup. The subject lies supine during the procedure, and the electrical impulses emitted by the device are imperceptible.

Bioimpedance refers to a technique in

which the impedance to an electrical current passing through the body is measured. Electrical impedance is dependent on capacitive and inductive properties of the medium (in the body, bone, and fat provide greater impedance while muscle and other high water tissues provide lower impedance). The level of impedance is not only a function of the type of tissue but also the frequency of the current. At low frequencies, cell membranes are non-conductive and current passes only through the extracellular fluid while at high frequencies, current passes through cell membranes in addition to the extra- and intracellular fluids (19-22).

Changes in impedance are inversely proportional to the volume of extracellular fluid in the extremity. Ward et al (23) demonstrated that an increase in limb volume as determined by circumferential measurements correlated with a decrease in the resistance of an electrical current as it passed through the limbs of women with breast cancer-related lymphedema (inverse correlation at $r=-0.7$, $p<0.01$). The greater the amount of lymphedema in the limb, the lower is the impedance value (23). Other studies have demonstrated that impedance measures were sensitive to breast cancer-related lymphedema in women up to 10 months before clinical signs were apparent (24).

Use of earlier single frequency current systems has resulted in estimations that may not be fully sensitive to the differences of body composition, especially when there are changes in fluid composition of an extremity. The newer BIS unit emits multiple frequencies and produces a spectrum of impedance values related to the different components of the body segment (muscle, bone, fat, extracellular fluid, and intracellular fluid) via a proprietary algorithm. The advantage of using BIS for assessing limbs is its ability to detect changes specifically related to extracellular fluid. Traditional methods of measuring limb volume are unable to discriminate limb fluid changes and they are unable to account for changes in tissues including muscle, fat, or bone. Several previous studies have employed BIS for detection of lymphedema in women with breast cancer and to monitor the effectiveness of a lymphedema management program (23-25).

OBJECTIVE

To correctly diagnose lymphedema in its early stages and to establish the effectiveness of physical therapy intervention, accurate measurement of limbs would be of value. Measurement techniques such as water volumetry are not practical, and manual circumferential measures may not be accurate. Opto-electrical systems such as the Perometer® may eliminate measurement error on the part of the examiner but perometry may be even less practical than water displacement due to the bulk of the device, its expense, and its unsuitability for bedside use. A bioimpedance device may overcome many of these problems, and some studies have reported on its validity compared to water volumetry and circumferential measurement (23,26). However, direct comparisons to an opto-electric device have not been made.

The primary objective of this study was to establish the inter- and intra-rater reliability of the BIS device. The second objective of the study was to establish concurrent validity of the BIS unit compared to perometry when determining ratios of affected to unaffected limbs.

METHODS

Participants

A sample of convenience of ten women volunteers previously treated for breast cancer whose ages ranged from 49-67 years (mean ± S.D., 59.6 ± 6.2) were recruited through a national breast cancer support organization. This particular sample was selected because they represented patients who are most likely to develop lymphedema.

TABLE 1
Individual and Group Demographics

Individual Demographics Characteristics				
Subject	Age (years)	Body Mass (kgs)	Height (cms)	BMI[a]
1	66	67.3	159	26.6
2	66	78.7	165	28.9
3	64	63.1	164	23.5
4	49	119.9	170	41.5
5	53	84.1	166	30.5
6	61	62.1	166	22.5
7	67	68.1	157	27.6
8	55	54.5	158	21.8
9	60	53.8	152	23.3
10	55	93.4	174	30.8
Group Demographic Characteristics				
Mean	60.5	67.7	164.5	27.1
Standard Deviation	6.3	20.4	6.6	5.9

[a]Body Mass Index calculated as BW (kg) / Ht (m^2)

Several already displayed classical signs of lymphedema (clinical judgment of the authors) at the time of data collection. Subjects included eight Caucasian, one Hispanic, and one African American woman. All the subjects were right hand dominant; four of the women had their pathology on the right. *Table 1* displays the subjects' individual and group demographic and anthropometric characteristics. This study was performed under a National Cancer Institute Institutional Review Board approved protocol. Due to the nature of the Institute's protocol, we were strictly limited to 10 subjects because the BIS devise was categorized as investigational at the time of this study. All subjects signed a document of informed consent.

Instrumentation and Procedures

Perometry measurements

After disrobing and donning a hospital gown, the subject stood next to the perometer and bent forward from the waist (hip approximately 90° flexion). The upper extremity to be examined was dependent (shoulder flexion approximately 90°) within the perometer frame and with the hand resting on a wooden block. The examiner slowly scanned the limb using the square frame (*Fig. 1*). Both limbs were measured. Data were stored in the perometer database (*Table 2*).

BIS measurement

The subject removed all jewelry (watches, bracelets, etc.), pantyhose/socks, and shoes. The subject was also required to void her bladder prior to the BIS assessment to eliminate the presence of extraneous fluids, which could have affected the full body impedance measures. The subject was then positioned in supine for 10 minutes, and electrode sites on the skin were cleaned using alcohol wipes. Adhesive electrodes were applied midway between the ulnar and radial styloid processes on the dorsal aspect of both wrists, one cm proximal to the third

TABLE 2
Individual and Group Perometry and BIS Measurements

GROUP PEROMETRY DESCRIPTIVE STATISTICS		
	VoA[a]	VoU[b]
Mean	1873.1*	1579
Standard Deviation	626.35	408.12
Minimum	1123	1064
Maximum	3037	2213

GROUP RAW BIS DESCRIPTIVE STATISTICS						
	R11A[c]	R21A[d]	R22A[e]	R11U[f]	R21U[g]	R22U[h]
Mean	333.73†	324.51††	325.29#	364.75†	358.98††	356.61#
Standard Deviation	93.87	95.49	98.15	59.57	63.51	61.98
Minimum	177.25	168.4	167.4	284.54	271.08	272.17
Maximum	500.24	490.92	502.32	494.84	481.19	480.37

[a]VoA=volume of affected upper extremity; [b]VoU=volume of unaffected upper extremity; [c]R11A=Rater 1, trial 1, affected upper extremity; [d]R21A=Rater 2, trial 1, affected upper extremity; [e]R22A=Rater 2, trial 2, affected upper extremity; [f]R11U=Rater 1, trial 1, unaffected upper extremity; [g]R21U=Rater 2, trial 1, unaffected upper extremity; [h]R22U=Rater 2, trial 2, unaffected upper extremity. * † †† # Like symbols different $p<0.05$

metacarpal head on the dorsal aspect of the affected limb, and one cm proximal to the second metatarsal head on the dorsum of the right foot, for a total of four electrodes. Color coded metal clips were used to connect the electrodes to the BIS unit in a pattern determined by manufacturer's instructions.

BIS measurements were collected by two raters. Both raters collected data on the subjects' affected and unaffected upper extremities. Rater one (R1) completed one trial of BIS measurements while Rater 2 (R2) completed 2 trials of BIS measurement. The order of the testing by and between the raters was randomized. Electrodes were freshly positioned before each trial by the rater. Data were stored in the device database (summarized in *Table 2*).

Data Analysis

Data stored in the device memories were exported into Microsoft Excel® (version 2003) for analysis. Raw data in the data base represented limb volumes for perometry and impedance values for BIS (summarized in *Table 2*). Values for both instruments were converted into ratios of the affected to unaffected limbs for comparison (27) (*Table 3*). Because impedance decreases with increasing lymphedema, impedance ratios should be smaller when the affected limb is larger (has more fluid) while perometry ratios will increase. Student's t-tests were run comparing volumes of affected and unaffected extremities by perometry and comparison of impedance values. Pearson (linear) correlations between the BIS ratios of the affected to unaffected arms were calculated for the two trials of Rater 2 (R21A/R21U and R22A/R22U) and between the measurements of Rater 1 and the first trial of Rater 2 (R1A/R1U and R21A/R21U) to determine intra-rater and inter-rater reliability, respectively. Additionally, intra-rater and inter-rater reliabilities of the raw BIS scores were examined by using intraclass correlation (ICC; 1,1). Concurrent validity against perometry was determined by calculating Pearson's linear correlations between the

TABLE 3
Individual and Group Ratio of BIS and Perometry Values

Individual ratio of values				
		BIS		Perometry
Subject	R1A/R1U[a]	R21A/R21U[b]	R22A/R22U[c]	VoA/VoU[d]
1	0.945	0.962	0.941	1.058
2	0.981	0.978	0.991	1.063
3	0.971	0.956	0.985	1.231
4	0.623	0.621	0.615	1.578
5	1.012	0.989	1.003	1.015
6	1.021	0.972	0.979	1.144
7	0.575	0.568	0.566	1.411
8	1.011	1.02	1.046	1.06
9	1.011	1.031	1.01	1.052
10	0.907	0.845	0.879	1.145
Group statistics of ratio values				
		BIS		Perometry
Mean	0.906	0.894	0.902	1.1757
Standard Deviation	0.165	0.166	0.17	0.184

[a]Ratio of (Rater 1, trial 1, affected UE)/(Rater 1, trial 1, unaffected UE)
[b]Ratio of (Rater 2, trial 1, affected UE)/(Rater 2, trial 1, unaffected UE)
[c]Ratio of (Rater 2, trial 2, affected UE)/(Rater 2, trial 2, unaffected UE)
[d]Ratio of Perometry volume (affected UE)/(unaffected UE)

affected/unaffected ratios for perometry and BIS.

RESULTS

Perometry measurements identified significant volume differences between the affected and unaffected upper extremities (paired t-test $p<0.05$). BIS values based on the measurements by Rater 1 and trials 1 and 2 by Rater 2 also resulted in significant differences between the two upper extremities (all $p<0.05$, *Table 3*). Both inter-rater agreement between the two raters using the BIS device and intra-rater agreement for Rater 2 were very good ($r=0.987$, $p<0.005$; $r=0.993$, $p<0.005$, respectively, *Table 4*). ICC for raw data measurements of the affected and unaffected upper extremities between and within examiners were also in good agreement, ranging from 0.969 to 0.996 (*Table 4*). Perometry ratios (VoA/VoU) were inversely and significantly correlated with BIS ratios ranging from $r=-0.89$ to -0.90 ($p<0.005$) (*Table 4*).

DISCUSSION

Because there is no cure for lymphedema, management of its progression and minimization of its effect on cosmesis and function is important. Determination of the effectiveness of any lymphedema intervention requires the accurate measurement of changes in limb volume and fluid (27).

Edema of the upper extremity often

TABLE 4
Intra-Rater, Inter-Rater, and Concurrent Validities

INTRA- AND INTER-RATER RELIABILITY OF BIS		
ICC (1,1) raw impedance values	affected arm (A)	unaffected arm (U)
inter-rater reliability	0.984	0.969
intra-rater reliability	0.996	0.992
Pearson Correlation (ratio values)		A/U
Intra-rater reliability R21A/R21U and R22A/R22U		0.993
Inter-rater reliability R1A/R1U and R21A/R21U		0.987
all $p<0.005$		
CONCURRENT VALIDITY: BIS AND PEROMETRY		
Pearson Correlations of BIS and Perometry ratio values of affected to unaffected limbs		
R1A/R1U and VA/VU		-0.90196
R21A/R21U and VA/VU		-0.90425
R22A/R22U and VA/VU		-0.89839
all $p<0.005$		

follows treatment for breast cancer and may be an indication of incipient lymphedema. Our subjects had all been treated for breast cancer and were, therefore, representative of a population susceptible to the development of lymphedema. Our data for these 10 subjects indicate that BIS is able to produce reliable inter and intra-rater measurements of upper extremity edema, and there is also concurrent validity between this BIS and perometry.

Data from perometry are in cubic milliliters, which directly represent volume to practitioners and patients. Perometry displayed ratio differences between the subjects affected to non-affected limbs ranging from 1.5 to 41.1% (*Table 3*). The literature presents different values for identification of lymphedema with a common criterion being a difference of 10% (10,11), which clearly identifies some subjects exhibiting signs of lymphedema. Therefore, even though our sample size is small, we believe it is a representative of women for whom these measurements would be valuable.

Impedance data, in contrast to perometry, are expressed in ohms and are generally inversely correlated with volume due to its measurement of fluid. Because impedance decreases in the presence of increasing fluid volume, BIS measurements would decrease when fluid volume increases, and BIS data should be expected to negatively correlate with perometry data. This is one reason why ratios of limbs might be more useful than measures of an individual limb. When differences in limbs are present, ratios based on BIS measurement will be less than one while ratios based on Perometer measurement will be greater than one. Direct comparison of raw impedance data between two subjects is likely inappropriate (opposed to volume data) because the specific relationship between impedance data and edema has been shown to be dependent on gender, age, and body mass index (26,28). From a physics perspective, resistance (impedance) to current flow in a circuit depends on the specific tissues encountered. Although the subjects in this study were similar in age and hand

dominance, their body mass indices (BMI) varied widely (*Table 1*). Consequently, there was a large variance in the group data determined by the impedance unit. This is another reason why the use of limb ratios have been preferred in previous publications (28) and supported by the results of this study.

A limitation of the impedance device is its inability to restrict measurements to a single segment within the limb. Both perometry and circumferential measurements are techniques which are able to isolate segments (e.g., forearm, upper arm).

Although volume measurements by perometry clearly indicate that some subjects have defined lymphedema, it is interesting that none of the BIS ratios are above the accepted level to identify lymphedema (ratio values >1.066 or >1.139 depending on arm dominance) (24,25). This non-concurrence, despite a positive correlation in values between the devices, demonstrates that BIS measurements do reflect fluid values, and limbs may increase in volume due to multiple components (i.e., fat, fibrosis, extracellular matrix) and not increase in extracellular fluid compared to the other limb. The use of BIS is likely to be more important in following changes in fluid overtime from a pre-surgical baseline to establish the onset of lymphedema (when the condition is a predominately fluid-based problem) or in patients undergoing lymphedema treatment and not in a "snapshot" evaluation of patients as used in this study.

This study confirms the reliability of BIS and its concurrent validity when compared to perometry based on a sample of 10 women who were susceptible to the development of lymphedema. It supports an earlier study by Ward et al (29) who demonstrated a positive correlation (r=0.926) in patients with lymphedema between these measures by inverting the impedance ratios (unaffected compared to affected) before correlating with the perometry data. BIS appears to be sensitive to changes of extracellular and intracellular fluid and may be a useful instrument for clinical assessment of patients prone to lymphedema. Interpretation of impedance and how it relates to conditions within the body will require additional clinical investigation, and further studies will be necessary to substantiate the use of BIS for early detection of lymphedema and for use in other edematous conditions.

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