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Validation of Hand-Held Bioelectrical Impedance Analysis for the Assessment of Body Fat in Young and Old Adults

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VALIDATION OF HAND-HELD BIOELECTRICAL IMPEDANCE ANALYSIS FOR THE ASSESSMENT OF BODY FAT IN YOUNG AND OLD ADULTS

by

Lynn Wheeler

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ABSTRACT

VALIDATION OF HAND-HELD BIOELECTRICAL IMPEDANCE ANALYSIS FOR THE ASSESSMENT OF BODY FAT IN YOUNG AND OLD ADULTS

by

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Under the Supervision of Ann M. Swartz, Ph.D.

Because of health concerns surrounding overweight and obesity, many individuals, health clubs, and physicians have begun using portable measures of body fat (BF) that are inexpensive and easy-to-use. Based on measures from these devices, health-related decisions are made and progress during fitness and/or dietary programs is tracked. However, accuracy of portable BF devices can be questionable, especially in free-living settings. ***Purpose***: The purpose of this study is to evaluate the validity and reliability of a commercially-available, hand-held bioelectrical impedance analysis (BIA) device as a measure of BF during a controlled laboratory condition and a free-living condition. ***Methods***: A total of 91 White individuals (41 men, 50 women), ages 19-39 (young group) and 55-75 years (old group), completed the study. During the laboratory visit, body fat measures from the hand-held BIA and to two additional methods, DEXA and tetrapolar BIA, were compared across age and sex when pre-testing guidelines were followed. Participants were then asked to take the hand-held BIA home to complete

four free-living BF% measures. A mixed between by within design comparing sex and age groups (between groups variables) across hand-held BIA, tetrapolar BIA and DEXA measurements (within groups variable) was performed to determine whether differences among body fat assessment devices exist. Post-hoc planned comparisons were performed to determine which devices are different in assessing BF among the hand-held BIA, the tetrapolar BIA and the DEXA. Repeated-measures ANOVA with post hoc comparisons were performed to determine differences in BF measures among hand-held BF measures over the free-living day. ***Results:*** BF results from the hand-held BIA were significant from DEXA and tetrapolar BIA for the female and young groups. Specifically in the female group, the hand-held BIA underestimated %BF by 2.7 percentage points compared to the DEXA. The tetrapolar BIA also underestimated %BF by 2.5 percentage points compared to the DEXA. In the young group, the hand-held BIA underestimated %BF by 3.5 percentage points compared to the DEXA. The tetrapolar BIA also underestimated %BF by 3.8 percentage points compared to the DEXA. In the male and old groups, there was no significant difference between BF measures from DEXA and hand-held BIA, but significant differences were present between the tetrapolar BIA and hand-held BIA. The hand-held BIA overestimated %BF by 2.6 and 1.9 percentage points in the male and old groups, respectively, as compared to the tetrapolar BIA. Despite the fact that there were statistically significant differences in BF measures from the hand-held BIA and the DEXA, these differences did not exceed the clinically acceptable level (±3.5%). ***Conclusion:*** The hand-held BIA device is designed for use by individuals to assess BF level. Although means were not clinically different

between the hand-held device and DEXA in all groups, difference scores between devices suggest that the hand-held BIA is not a valid device on an individual level and, therefore, not recommended for the assessment of %BF.

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LIST OF ABBREVIATIONS

%BF- body fat percent

ACSM- American College of Sports Medicine

ADP- air displacement plethysmography

BF- body fat

BIA- bioelectrical impedance analysis

BMC- bone mineral content

BMD- bone mineral density

BMI- body mass index

DEXA- dual-energy x-ray absoptiometer

ECW- extracellular water

FFM- fat free mass

FM- fat mass

HW- hydrostatic weighing

ICW- intracellular water

LBM- Lean body mass

TBW- Total body water

UWM- University of Wisconsin-Milwaukee

W:H- Waist-to-hip ratio

Chapter 1: Introduction

Background

The prevalence of overweight and obesity is high in the United States and other industrialized nations throughout the world. Based on self-report weight and height information, data from the 2007-2008 National Health and Nutrition Examination Survey (NHANES)— a nationally representative sample of U.S. adults— demonstrated that 34% of adults aged 20 years and older are overweight, 34% are obese, and 6% are extremely obese with the remaining 26% being classified as normal BMI (Flegal, Carroll, Ogden, & Curtin, 2010) . Given the numerous health risks associated with being overweight or obese including coronary artery disease, diabetes mellitus, hypertension, hyperlipidemia, and certain types of cancer (Burton & Foster, 1985; Goodpaster et al., 2005; Kaminsky, 2010; Must et al., 1999; Wagner & Heyward, 1999), physicians and other health practitioners are commonly recommending that their patients lose weight in order to reduce their body fat (BF) level.

There are several methods for assessing body composition, but not all are feasible or affordable for use by individuals, fitness centers, or physicians. Laboratory methods such as hydrostatic weighing (HW), air-displacement plethymography and dual-energy x-ray absorptiometry (DEXA) are commonly used and accurate tools for determining the body composition of various populations. However, these devices and procedures are expensive, time-consuming, and require trained technicians, and thus

are not readily-available for use at home or in local fitness centers and clinics (Weaver, Hill, Andreacci, & Dixon, 2009). In contrast, field devices to assess body composition are for the most part portable, relatively inexpensive, and often require less technician knowledge or skill. Two popular field methods include skinfold measurements and segmental bioelectric impedance analysis (BIA). However, these devices have been found to be less accurate in estimating body composition when compared to laboratory methods such as DEXA and HW (Duz, Kocak, & Korkusuz, 2009; Esco, Olson, Williford, Lizana, & Russell, 2011a).

Many individuals have taken to self-monitoring body composition using portable, inexpensive assessment tools given physician recommendations or their own desire to reduce BF. Individuals use information about their body composition to help them make health-related decisions (e.g., dietary or physical activity changes, medications, medical procedures) and to track progress of an exercise or diet program, or other health intervention (Heyward & Wagner, 2004). Clinicians use body composition information to identify patients at greater risk for developing chronic acquired diseases such as cardiovascular disease or diabetes mellitus, diagnose individuals with metabolic syndrome, or monitor disease state progression (Wagner & Heyward, 1999). Among athletes, there is an inverse relationship between increased percent body fat (%BF) and athletic performance in certain sports (Malina, 2007). Consequently, monitoring %BF during an athletic training program becomes important for athletes to optimize performance. Given that individuals, fitness centers, and physicians are using portable body composition assessment tools to guide health-related decisions and

recommendations, it is essential that tools used for assessing body composition outside of laboratory settings provide valid and reliable results (Weaver, et al., 2009).

One example of a commercially-available, inexpensive device (approximately 50 USD$, 2012) that is used by individuals, fitness centers, and physicians to measure body composition is the Omron HBF-306C (see Figure 1). This is a portable and safe hand-held BIA device that provides quick and easy estimates of %BF. The Omron HBF-306C works by introducing a single frequency electrical current through electrodes implanted in the handles of the device. The nature of this current is such that the subject being tested cannot detect it and the impedance to the current flow from one hand to the other is determined (Lintsi, Kaarma, & Kull, 2004b). The current will flow more rapidly through fat-free mass due to the larger water and electrolyte content of fat-free tissues. Greater impedance occurs when the current flows through adipose tissue which contains little water (Esco, Olson, Williford, Lizana, & Russell, 2011b).

Given the Omron HBF-306C's heavy reliance on water content within tissues, hydration status is critical to measures of impedance (Kaminsky, 2010). Factors that can influence an individual's hydration status include food and water consumption, use of diuretics, alcohol consumption and exercise. The consumption of food and water will directly increase the amount of fluid in the body. The use of diuretics will do exactly the opposite, increasing the excretion of water from the body through urination. Consumption of alcohol, a type of diuretic, will cause dehydration through increased urination. Exercise can affect BIA readings in two ways: 1) loss of fluid from the body due to sweating, 2) increased blood flow to the skeletal muscle and skin which increases

heat and will decrease the impedance to the current (Dehghan & Merchant, 2008; Weaver, et al., 2009). Careful control of all of these variables does not always occur when using a hand-held BIA in a free-living situation.

A small number of published studies have investigated the validity of hand-held BIA devices. Results of these validation studies have been contradictory and, therefore, inconclusive. Results have varied due to the populations studied and pre-testing conditions applied. In addition, most studies were performed under controlled conditions, limiting their external validity since these devices are commonly used in free-living situations.

Figure 1. Omron HBF-306C

Research Question

Is the Omron HBF-306C hand-held body fat analyzer accurate in estimating percent body composition in both a controlled and free-living environment?

Statement of Purpose

The purpose of this study was to evaluate the validity of a commercially-available hand-held bioelectrical impedance analysis device as a measure of body composition for adults in a controlled laboratory condition and during a free-living condition.

Specific Aims

Specific aim 1 was to compare body fat measures from the hand-held BIA to two additional methods used to estimate of body fat— DEXA and tetrapolar BIA— across age and sex when pre-testing guidelines were followed.

Specific aim 2 was to examine the reliability of body fat estimates from a hand-held BIA at four pre-determined times during one free–living day in the same population. These four body fat estimates taken during the free-living day helped determine variations in body fat measures when pre-testing guidelines were not followed.

Hypotheses

It was hypothesized that BF results from the hand-held BIA would not significantly differ from the tetrapolar BIA and DEXA BF measures taken during the controlled laboratory condition. However, significant variations in BF were expected during the free-living day demonstrating that, when pre-test instructions were not

followed, results would not be reliable and should not be used to make-health related decisions.

Assumptions

There were three main assumptions for this study. First, it was assumed that all participants were honest when answering screening questions to determine eligibility for study participation. Second, it was assumed that all participants followed the pre-testing guidelines prior to the first lab visit for the body composition assessments. Third, it was assumed that, during the free-living day, all participants followed the study instructions given to them at the first Laboratory visit, and were honest when recording their %BF from the hand-held BIA throughout the day.

Delimitations

A delimitation to the current study was that the results are only generalizable to a population that is free of any disease or medication that can alter hydration status, White individuals, and individuals within similar age ranges used in the current study (18-39 and 55-75 years of age).

Significance

To date, there has been little research on the validity of hand-held BIA devices for estimating %BF. The results of this study will have both scientific and practical significance.

Scientific Significance

Hand-held BIA devices are relatively new, commercially-available products. Very little research has been conducted on their validity and reliability, specifically, the Omron HBF-306C device. It is one of three hand-held BIA devices currently on the market for sale in 2012. Of the previous research on validity and reliability of hand-held BIA devices, even less has been completed across a large age span. Most of the previous studies have been completed using young adults, rarely including subjects over the age of 60. This is important because of the changes in FM and FFM as adults age and it remains unknown if the hand-held BIA devices are appropriate for use acrossthe age spectrum. Additionally, more research needs to be done on the accuracy and reliability across sex. The absolute and relative fat mass and fat distribution differs between men and women, and it is important to determine if those differences impact the validity and/or reliability of the device in these populations. It is, therefore, critical to validate this device across the two variables of age and sex. Lastly, although the concept of euhydration is extremely important in the assessment of body composition with BIA devices, only one of the previous validation studies on hand-held BIA devices has controlled for hydration using all of the ACSM pre-testing guidelines. This could be a major limitation to all of the validation studies previously conducted on hand-held BIA devices. It is also important to compare the results of BF measures from the hand-held BIA device to the criterion measures in both a controlled setting when individuals are

euhydrated, and in a free-living environment when the pre-testing guidelines are not necessarily followed.

Practical Significance

Because many individuals engage in the self-monitoring of body composition, and inexpensive, commercial devices are available to do so, it is important to make sure these devices are accurate in estimating %BF. And also important, if the devices are accurate in both a controlled setting when pre-testing guidelines are followed or in a free-living situation where pre-testing guidelines are often not followed. This becomes even more important when individuals are making health-related decisions in their own life, or someone else's, based on results from the hand-held BIA devices. There is a lack of literature available for the general public to understand how to properly use the hand-held BIA devices and how accurate they are when estimating %BF.

Chapter 2: Literature Review

Introduction

The prevalence of overweight and obesity is high in the United States and other industrialized nations throughout the world. Based on self-report information, data from 2007-2008 National Health and Nutrition Examination Survey (NHANES) demonstrated that 34% of adults aged 20 years and older are overweight, 34% are obese, and 6% are extremely obese (Flegal, et al., 2010) based on body mass index (BMI) classifications. Given the numerous health risks associated with being overweight or obese including coronary artery disease, diabetes mellitus, hypertension, hyperlipidemia, and certain types of cancer (Burton & Foster, 1985; Goodpaster, et al., 2005; L.A. Kaminsky, 2010; Must, et al., 1999; Wagner & Heyward, 1999), physicians are commonly recommending that their patients lose weight and reduce their body fat (BF) level.

Many individuals have taken to self-monitoring body composition given physician recommendations or their own desire to reduce BF, often using portable, inexpensive assessment tools. Individuals use body composition results from these devices to help them make health-related decisions (dietary or physical activity changes, medications, medical procedures) and also use this information to track progress of an exercise or recommended diet program, or other health interventions (Heyward & Wagner, 2004). Clinicians use body composition information to identify patients at

greater risk for developing cardiovascular disease or diabetes mellitus, to diagnose individuals with metabolic syndrome, or to monitor diseased state progression (Wagner & Heyward, 1999). In athletes of certain sports, previous research suggests that there is an inverse relationship between increased %BF and athletic performance (Malina, 2007). Consequently, monitoring %BF during an athletic training program becomes important to optimize performance. Given that individuals, fitness centers, and physicians are using portable body composition assessment tools to guide health-related decisions and recommendations, it is essential that tools used for assessing body composition outside of laboratory settings are accurate (Weaver, et al., 2009).

Body Composition

Understanding that it is important to monitor and control BF from a health perspective, it is equally important to know that BF is only one part of a larger picture: total body composition. Body composition includes all things that give mass, shape and function to living things, including elements, tissues and organs (Heymsfield, 2005). Knowledge of body composition comes mainly from chemical analysis of organs and cadavers (Heyward & Wagner, 2004). Body composition is not just limited to %BF or fat mass (FM), depending on the number of compartments being assessed, total body composition can include estimates of fat free mass (FFM), lean body mass (LBM), mineral-free lean tissue, bone mineral content (BMC) and total body water (TBW) in addition to %BF or FM. All are considered separate compartments of body composition.

Fat free mass and LBM have been used synonymously, but they are not the same. "Fat free mass is all residual chemicals and tissues including water, muscle, bone, connective tissue and internal organs" (Heyward & Wagner, 2004, p.5). Lean body mass is comprised of FFM plus essential lipids. Mineral-free lean tissue is FFM minus BMC. Fat mass is the most widely varied compartment accounting for anywhere between 6-60% of an individual's total body weight (S.B. Heymsfield, Lohman, Wang, & Going, 2005). Fat mass is comprised of essential lipids and stored adipose tissue and is present in many areas of the body. Subcutaneous fat lies just under the skin throughout the body. This is the type of FM that individuals can see and feel by pinching the skin and the underlying fat tissue. There is also fat that is not measurable without the use of imaging techniques called visceral fat. Visceral fat is located in the abdomen around the organs. Fat free can also be found in the yellow bone marrow in adults as well as within the muscule (intramuscular). TBW is the sum of extracellular water (ECW) and intracellular water (ICW) (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). The human body is made up approximately 62% water, depending on hydration level of the individual (Brozek, Grande, Anderson, & Keys, 1963) and the aqueous fraction of the fat-free mass of the theoretical standard reference man is 73.8%. Bone mineral content (BMC) is the amount of minerals per centimeter of bone (g/cm). Furthermore, bone mineral density (BMD) is the ratio of BMC to bone size (g/cm^2) and is commonly used as a marker for determining osteopenia and osteoporosis (Deng, Xu, Davies, Heaney, & Recker, 2002).

These compartments are then combined in different manners to create body composition models. Body composition models can be broken into two, three, four, five or even six compartments. These multicomponent models are defined by five specific levels of measuring body mass: atomic, molecular, cellular, tissue-organ and whole-body demonstrated in Figure 2 (Heyward, 1996). However, the most commonly used level in exercise physiology is the tissue-organ level. The tissue-organ level is made up of compartments of adipose tissue, skeletal muscle, visceral organs and bone. A widely-used two-compartment model includes measures of FM and FFM. A common three-compartment tissue-organ level model would be one that includes BMC, FM and Mineral-free lean tissue. A benefit to using this three compartment model is that there is no assumption in the hydration of FFM and therefore dismisses that variation between individuals (Withers et al., 1998). Another common three-compartment model is one that consists of TBW, FM and FFM. And a common four-compartment model would include BMC, FM, FFM and TBW. A four compartment model is considered most valid because it controls for variability between individuals in both BMD and TBW (Withers, et al., 1998), however, increasing the number of measure could also introduce more room for error.

The whole-body level utilizes anthropometric measures, not necessarily specific compartments. This would include measures of height, weight and circumferences.

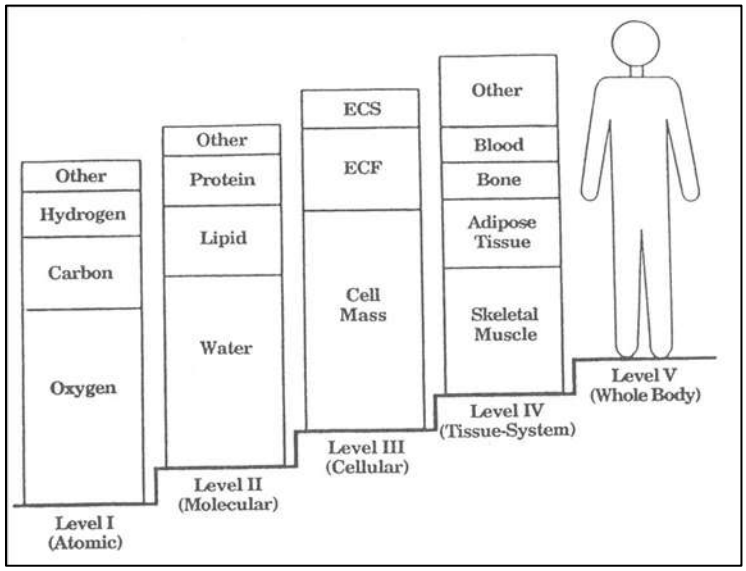


Figure 2. Five levels of measuring body mass. Adapted from Wang, Pierson & Heymsfield (1992)

Factors Impacting Body Composition

For all individuals, there are modifiable and non-modifiable factors in determining one's body composition. Body composition can vary greatly across age, sex, stature and race, all of which are non-modifiable. As adults age, there is usually an increase in FM, until about age 74, and then FM begins to decrease slightly (Kyle et al., 2001). Additionally, older adults experience a decline in FFM, mainly due to loss of bone mineral and skeletal muscle mass (Heyward & Wagner, 2004). This decrease in skeletal muscle, or sarcopenia, generally occurs after the age of 30-40 years and is heightened after the age of 60 years (Kyle, et al., 2001). The decline in skeletal muscle in older adults has been noted to be higher in men than women (Gallagher et al., 1997). The resulting age-related sarcopenia is associated with atrophy of muscle fibers, which may occur due to a decline in α-motor neurons, growth hormone production, sex steroid levels and physical activity (Thomas, 2007). Finally, research has shown that as adults age, there is an increase in waist circumference in both men and women, without an increase in weight (Stevens, Katz, & Huxley, 2010). This can be due to increased abdominal adiposity in combination with overall sarcopenia. This increase in waist circumference and abdominal adiposity can increase the risk of chronic disease such as cardiovascular disease and type 2 diabetes, associated with premature death (Janssen, Heymsfield, Allison, Kotler, & Ross, 2002; Snijder, van Dam, Visser, & Seidell, 2006) .

There are also differences in body composition between the sexes. Typically, men have more FFM and less FM as compared to women (Baumgartner, 2000; Janssen, Heymsfield, Wang, & Ross, 2000a). Janssen and colleagues (2000) found that men, on

average, have 36% more skeletal muscle than women. However, the rate of decrease in skeletal muscle after the age of 45 years is greater among men than among women. It has been found that women tend to have higher levels of subcutaneous fat when compared to men (Enzi et al., 1986). This higher level of body fat is necessary for reproductive processes. Also, body fat distribution may vary between sexs: men tend to carry more FM in the android region and women tend to carry more FM in the gynoid region (Stevens, et al., 2010). On average, women are also more likely to have lower bone density than men over a span of 18-80 years (Russo et al., 2003; Warming, Hassager, & Christiansen, 2002). In addition, women typically experience a dramatic decrease in BMC and BMD during the perimenopausal and early postmenopausal years due to the decline in endogenous estrogen, which aids in preserving bone density (Lindsay, 1996). On the other hand, men tend to have higher bone mineral density because of testosterone until about the age of 50 (Wishart, Need, Horowitz, Morris, & Nordin, 1995). However, as men age, their levels of testosterone decrease and BMD declines (Snyder et al., 1999). The rate of decrease in bone mineral density is greater in women immediately after menopause, but the rate in men and women is the same once adults reach about 65-70 years of age (National Institutes of Health Osteoporosis and Related Bone Diseases, 2011).

Other than sex and age differences in body composition, there are also differences in body composition between races. Wagner and Heyward (Wagner & Heyward, 2000) stated that African Americans, on average, have higher bone mineral density and higher muscle mass than Whites. Barondess and colleagues (Barondess,

Nelson, & Schlaen, 1997) conducted a study with black and white men to compare bone mineral density. They discovered that the black men had a higher BMD (1.25 g/cm²) than the white men (1.16 g/cm²). In 2001, Casas, Shiller, DeSouza and Seals (Casas, Schiller, DeSouza, & Seals, 2001) found Hispanic women to have higher percent body fat, total fat mass and BMI as compared to their White counterparts. Wulan, Westerterp and Plasqui (2009) found that Asians have higher body fat percentage compared to Whites. Furthermore, there were also differences in body fat percent between regions of Asia (Asian Indians, Malay, and Chinese).

In addition to the non-modifiable factors that can affect body composition, there are modifiable factors that can affect body composition: lifestyle and disease state (Crawford et al., 1994; Rippe & Hess, 1998). These factors can be acute or long-term. Acute factors could include hydration status and/or the use of diet or weight loss medication. Long-term factors include physical activity, diet and weight loss surgery. Increases in physical activity have the potential to increase FFM and decrease FM (Rippe & Hess, 1998; Stiegler & Cunliffe, 2006). In contrast, decreases in physical activity can lead to losses in FFM and increase in FM (Boonyarom & Inui, 2006). Diet has the ability to alter FFM and FM. High protein diets can potentially increase the amount of skeletal muscle mass or FFM (Rasmussen et al., 2000). Changes in diet can also increase or decrease the amount of FM. A substantial chronic decrease in calorie consumption can lead to a decrease in FM. Conversely, a chronic increase in calorie consumption can increase the total amount of FM. Weight loss surgery is also an acute and long-term method of changing body composition for morbidly obese individuals. Most often,

weight loss surgeries will restrict the amount of food intake by the individual both before and as a result of surgery, hence decreasing calories consumed daily (Kenler, Brolin, & Cody, 1990). Therefore, the individual will lose FM and maintain or potentially decrease FFM because there is less body mass for the individual to carry around (Chao et al., 2000; Weiss et al., 2007).

Methods to Estimate Body Composition

This section will include a detailed review of the most common methods used to assess body composition, specifically focusing on 1) the outcome measure of the body composition assessment method, 2) how the method works, 3) assumptions, 4) special considerations (participant preparation, risks, etc.) 5) validity and reliability, 6) advantages and disadvantages. For discussion purposes, field-based methods will be addressed first, then laboratory methods.

Field-Based Methods

A field-based method for assessing body composition is one that can be used in many different locations and not restricted to use in a laboratory or clinical setting. While numerous body composition assessment methods are available, the following field-based methods will be discussed in this section: BMI, skinfold measures and bioelectrical impedance analysis (BIA). There are many common advantages to all of the

field-based methods for assessing body composition. First, most field devices are portable making them easy to use at home or in fitness centers and clinics. Second, the majority of these methods are cost-efficient. The low cost makes these devices more available more accessible to individuals and groups. Field devices generally require relatively little technician skill or knowledge to operate. Although many field devices have been created and are usually validated with laboratory methods, previous research has demonstrated that most field devices are less accurate and reliable than laboratory methods (Duz, et al., 2009).

Body mass index (BMI) is an anthropometric method that is used to estimate obesity. BMI is calculated as a ratio of height and mass (kg/m^2). Based on the results of this calculation, individuals are then classified as underweight, normal BMI, overweight or obese. Underweight BMI is defined as a BMI of 18.4 kg/m^2 or lower, normal BMI is defined as a BMI of 18.5-24.9 kg/m^2, overweight is defined as a BMI of 25.0-29.9 kg/m^2 and obese is defined as a BMI of 30.0kg/m^2 or more (L.A. Kaminsky, 2010; National Institutes of Health, 1998). The main assumption of BMI is that there are no differences between age and sex when designating adults into obesity categories (Gallagher et al., 1996b). There are many advantages to using BMI to classify level of obesity. It is cost effective requiring minimal equipment, there is no necessary participant compliance prior to taking measures, there is no risk to the participant, and it is a fast and easy measurement and calculation, requiring minimal technician experience. However, there are some major drawbacks to using BMI. It does not take into account regional fat distribution, muscle mass or bone mineral density and therefore may misclassify

individuals into the categories of underweight, normal weight, overweight or obese (Burton & Foster, 1985; Nevill, Stewart, Olds, & Holder, 2006; Romero-Corral et al., 2008). For example, an individual could have a normal BMI, but still be classified as overweight or lean based on estimations of %BF. This misclassification occurs due to the known differences in mass between adipose tissue, muscle tissue, as well as the individual's bone mineral density. Muscle tissue is more dense than adipose tissue, 1.34 g/cm³ and 0.9 g/cm respectively (Brozek, et al., 1963). Therefore, an individual with more muscle mass will have a greater body mass, all other things equal. Likewise, an individual that has higher bone mineral content will have greater body mass, all things being equal. Consequently, an individual such as a body builder or an athlete with more muscle mass or higher bone mineral density than the average adult, may be misclassified as overweight because of the additional mass of the muscle tissue and bone (Nevill, et al., 2006). They may be misclassified as overweight or even obese by BMI, however based on a body composition measure, they may be considered lean or normal. On the other hand, individuals with low muscle mass and high levels of fat can also be misclassified (Kennedy, Shea, & Sun, 2009). For example, as adults age, they gain more adipose tissue and lose muscle mass, perhaps being classified as having a normal BMI however, may actually be overweight or obese based on a body composition measure (Kyle, et al., 2001). Many studies have assessed the validity of BMI as an indicator of obesity. Gallagher and colleagues (Gallagher et al., 1996a) found that when they compared young and old adults with the same BMI, that the older adults actually had a higher %BF indicating misclassification of obesity level. Similarly, they

found that BMI cannot be used when comparing obesity level between men and women because women, on average, have a higher %BF than men. Additionally, Kennedy and colleagues (Kennedy, et al., 2009) found that there was a large discrepancy between obesity level classified by BMI and that estimated from DEXA. They suggested that using BMI as a classification of obesity level should be viewed with caution because it may misclassify some individuals and therefore ignore the possibility of health interventions that may be necessary. In conclusion, BMI is widely used as a broad indicator of obesity in large epidemiological studies, but is discouraged for use in small scale studies and for clinical diagnosis of obesity (Kennedy, et al., 2009).

Skinfold measures are a two-compartment model for body composition assessment providing estimates of FM and FFM. This method is based on the assumption that "subcutaneous fat in a particular skinfold is proportional to the total amount of overall body fat" (Kaminsky, 2010, p.62). Lohman estimated that one-third of the human body is made up of subcutaneous fat (T.G. Lohman, 1981). Secondly, it assumes that a skinfold is a good measure of subcutaneous fat (T.G. Lohman, 1981). Additionally, it assumes that water and mineral content is the same in all individuals (Lintsi, et al., 2004b). The technician pinches a fold of skin while only taking the subcutaneous fat and skin, not muscle tissue. A caliper then measures the thickness of the fold that includes skin and subcutaneous fat. Based on the amount of sites used to measure skinfolds (as well as an individual's race and sex), prediction formulas are then used to estimate body density and %BF (L.A. Kaminsky, 2010). The accuracy and reliability for the skinfold technique in estimating BF depends on the skill of the

technician, the selection of sites to administer the skinfold measure, the size of the individual being measured and also the prediction formula used. Linsti and colleagues (Lintsi, et al., 2004b) found that, when compared to DEXA, there were significant differences in skinfold estimates of BF with the Durnin & Womersley skinfold equation but no significant different when using the Deurenberg *et al.* skinfold equation. Duz and colleagues (Duz, et al., 2009) found that, when using the Jackson and Pollock (1978) and Jackson *et al.* (1980) prediction equations, skinfold measures (12.4±5.5% for males, 20.8±1.0% for females) significantly underestimated BF estimations when compared to DEXA (18.5±6.2% for males, 28.4±1.3% for females). In order to have proper skinfold thickness measures, calibration of skin calipers is important. Gore and colleagues (Gore, Woolford, & Carlyon, 1995) determined that springs in the calipers need to be tested regularly to avoid fatiguing of the springs and, thus, allowing for less compression of the caliper jaw. Although skinfold method is portable, inexpensive and quick, it still requires a trained technician to obtain measurements.

On the other hand, segmental BIA devices are easy to use and require no training to operate. These devices are portable and can be used in many locations for a low cost. Segmental BIA will be discussed further in the BIA Technology section.

Laboratory-Based Methods

Laboratory-based methods for assessing body composition are often large, non-portable methods. There are common advantages to laboratory-based methods for

assessing body composition. First, a majority these methods have demonstrated great accuracy and have been validated against cadaveric analysis (because exact measurements can't be done in vivo) for use in laboratory and clinical settings by previous research (Erceg et al., 2010). Second, most, but not all, procedures using laboratory techniques are relatively quick. There are common disadvantages associated with laboratory-based techniques. The majority of these methods require costly equipment, ranging from as little as USD$5,000 up to millions of dollars, resulting in many of these methods being inaccessible for most clinicians, researchers and the public. In addition to being costly, most of the equipment is generally large and not portable. Lastly, almost all methods require a trained and knowledgeable technician to operate the equipment and analyze results. Dual-energy x-ray absorptiometry (DEXA), hydrostatic weighing (HW), air displacement plethysmography (ADP), and tetrapolar bioelectrical impedance analysis (BIA) are all commonly used laboratory methods for body composition analysis that will be discussed in the following paragraphs.

Originally created for assessing bone mineral composition for older adult females, DEXA has recently been considered a gold standard in assessing body composition. DEXA assesses three compartments of the body: bone mineral content (BMC), mineral-free lean mass and FM. Mineral-free lean mass, FM and BMC are estimated based on the tissue attenuation of two different energies (Pietrobelli, Formica, Wang, & Heymsfield, 1996). The x-ray beams pass from the posterior to anterior of the body to a detector that is above the participant (Duz, et al., 2009). Based on the attenuation, and known densities of FM and FFM, the three compartments can

be distinguished. DEXA has, in recent years, been considered a gold standard method for assessing body composition because previous research has shown it to be both valid and reliable (Heyward, 1996). Pritchard, Nowson, Strauss, Carlson, Kaymakci and Wark (1993) found that DEXA had greater precision when estimating fat mass when compared to HW, with a coefficient of variability of 1.8% for percent body fat and 2.1% for fat mass. Lohman, Tallroth, Kettunen and Marttinen (Lohman, Tallroth, Kettunen, Marttinen, 2009) conducted reliability a study using the Lunar Prodigy densitometer. They found total body DEXA measures to be repeatable for LM (r=0.99), FM (r=1.00) and BMD (r=1.00). DEXA is a quick, safe, can be used on almost all populations, and requires little pre-testing guidelines to be followed by the individual (Heymsfield, et al., 2005; Heyward, 1996). There are disadvantages to using DEXA to assess body composition. Because DEXA is an x-ray device, participants will be exposed to small amounts of radiation. The device being used for this study emits approximately 0.00004 mRem of radiation which is similar to a cross-country flight and is fractions less than the amount of radiation from a typical x-ray, such as a chest x-ray. Therefore, it is considered safe for almost all populations (T. G. Lohman, 2005). Because of the size of the Lunar Prodigy table, there are usage restrictions based on a participant's size. The total table size is 262cm long and 89cm wide, however, the area for scan is much smaller. Individuals that are taller than 193cm and wider than 60cm, will not receive accurate assessments as their entire body will not fit within the scan area. The weight limit for the device is 159.0 kg, limiting usage to those weighing at or less than that amount.

DEXA is an expensive and non-portable device, and therefore may not be available for use by all individuals.

Hydrostatic weighing (HW) has been considered a gold standard by some experts in the field and has been used as a criterion method in validating new body composition assessment methods (S.B. Heymsfield, et al., 2005; Heyward, 1996). HW estimates body composition in two compartments—FFM and FM— by first measuring body volume, then body density is determined mathematically by dividing body mass by body volume (S.B. Heymsfield, et al., 2005). HW estimates body volume by using Archimedes principle "that a body immersed in a fluid is acted on by a buoyancy force, which is evidenced by a 'loss' of weight and equal to the weight of the displaced fluid" (S.B. Heymsfield, et al., 2005), p. 19). Individuals are submerged under water while under water mass or water displacement is measured. Measures of body volume are corrected for residual air in the lungs and in the gastrointestinal tract. There are four main assumptions for HW: the components of the fat and FFM are known and additive; that the density of all tissues is constant for all individuals: lean body mass (FFM and bone) and FM; the proportions of water, mineral and protein comprising the FFM are constant within and between individuals; and the individual being measured differs from the reference body only in the amount of BF or adipose tissue (Heyward & Wagner, 2004) p. 8). There are advantages to using HW to assess body composition. The method has been demonstrated as accurate. Additionally, a water tank is not necessarily needed. The procedure can be done in any pool, of proper depth for complete submersion, which can be accessed. However, there are disadvantages to

using this technique due to the fact that there are more practical techniques available for assessing body composition. One disadvantage is that the technique relies on the three assumptions stated earlier. These assumptions will not always be met due to differences in composition of the different tissues that were discussed in the section *Factors Affecting Body Composition* earlier in the chapter. Second, there is a great amount of participant compliance required for accurate measurement. Participants should follow specific pre-testing guidelines (Heyward & Wagner, 2004) prior to the test. Additionally, the technique itself requires a lot of participant compliance, and may be impossible for some participants to do. For example, some individuals may not be able to correctly position their body, exhale completely when under water, or remain still while under water (Wagner, Heyward, & Gibson, 2000). Moreover, the procedure is done multiple times until three trials are within 100g of each other (Wagner & Heyward, 1999) are achieved. Therefore, the procedure can be very time consuming (Wagner, et al., 2000). Lastly, a great deal of technician knowledge and skill is required to complete the procedure. It is more difficult to find validity and reliability information on HW because it is often used as a criterion measure for other methods for assessing body composition.

Air Displacement Plethysmography (ADP) employs a two-compartment model to assess body composition, very similar to HW, that first measures body volume and calculates body density with air displacement instead of water displacement (Heyward & Wagner, 2004). Volume is measured using Poisson's law, a variation of Boyle's law that accounts for adiabatic conditions, in an enclosed chamber. The only commercially

available ADP device is the BodPod (Fields, Goran, & McCrory, 2002). While inside of the BodPod, small pressure changes determine the air displacement of the body, and therefore, body volume is measured. Because body volume is being measured, measurements are taken for lung volume to estimate the most accurate total body volume. Body fat percent is then calculated from body density via the same conversion formulas as HW. There are many assumptions when assessing body composition with the ADP method. First, because the BodPod device is measuring body volume, all of the four main assumptions from HW will apply here. Another assumption is that all of the isothermic effects that affect body volume are being controlled: clothing, body hair, and thoracic gas volume (Heyward & Wagner, 2004). There are many advantages when using ADP as a method for assessing body composition. First, the process is quick, safe, non-invasive, painless and comfortable (Wagner & Heyward, 1999). The system is computerized and does not require a lot of technical skill to operate. Also, the BodPod device can be used on many different populations including children, older adults and obese individuals (Fields, et al., 2002). Because of these advantages, ADP using the BodPod may be preferable to utilizing HW (Wagner & Heyward, 1999). However, there are disadvantages to using ADP to assess body composition. First, there are assumptions of tissue density that are made when measuring body volume. Second, method used to measure the thoracic gas volume can be difficult for some individuals to do, therefore, the volume will need to be estimated causing room for error. Most research on the validity and reliability of the BodPod has been done in the past 10 years and has used both DEXA and HW as criterion methods. Results have been inconsistent

across different populations (Fields, et al., 2002). Ball and Altina (Ball & Altena, 2004) point out that comparing the BodPod to HW as a criterion method may not be appropriate because they are both assessing the body in two compartments, and therefore HW is not technically more accurate than the BodPod. Ball and Altena (2004) found a large discrepancy when comparing the BodPod to DEXA as the criterion, with a range of individual %BF differences from -6.6 to 9.0%. They also noted that the difference in %BF increased as the individual's BF increased. Concluding that the estimations of %BF should be used with caution when classifying individuals as obese. However Ballard and colleagues (Ballard, Fafara, & Vukovich, 2004) found with the BodPod that mean results of %BF when compared to DEXA as the criterion did not differ significantly (P=1.0). They concluded that the Bod Pod is a valid and reliable method for assessing %BF.

Tetrapolar BIA can be considered both a laboratory and field technique for assessing body composition. Tetrapolar BIA will be discussed further in the following section.

BIA Technology

Bioelectrical impedance analysis (BIA) is a safe, fast, noninvasive and relatively inexpensive method for assessing body composition (Gibson, Heyward, & Mermier, 2000; Houtkooper, Lohman, Going, & Howell, 1996). BIA estimates TBW by way of electrical current through segments of the body and ultimately predicts BF and FFM. In the following section, BIA will be extensively reviewed. Discussion of the history,

assumptions, and properties of BIA, as well as how BIA assesses body composition and the types of BIA devices available for use both healthy individuals and clinical patients (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004).

History of BIA

Beginning in the 1930s, early studies using BIA and body composition focused on the "relationship of impedance (of the electrical current) to TBW and to physiological variables" (S.B. Heymsfield, et al., 2005), p. 81). Most research was done using a frequency of 50kHz to asses total body water as it related to things such as thyroid function and blood flow. At this low frequency (50kHz), the current only flows through extracellular water and does not permeate the cell membrane to assess intracellular water. However, at frequencies greater than 100kHz, the intracellular water can be assessed (Foster & Lukaski, 1996; Wagner & Heyward, 1999a). Multifrequency BIA was introduced in the 1970s, when assumptions of BIA were more established, to describe the proportion of extracelluar water (ECW) to TBW (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Multifrequency BIA was also used to assess body fluid distribution in diseased populations such as those with congestive heart failure, and renal disease (S.B. Heymsfield, et al., 2005). Until the mid-1980s, BIA technology was primarily used in research and in the medical field. In the mid 1980s, BIA devices became available for commercial use and marketed as a way to measure body composition, and thus provide estimates of absolute and/or relative fat mass (S.B. Heymsfield, et al., 2005). By the 1990s, many different BIA devices were on the market

for assessing body composition in laboratories, at home, fitness centers, for athletic teams, to name a few (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Because of the widespread use of BIA technology, the National Institutes of Health (NIH) conducted a one-day summit in 1994 where BIA researchers and industry experts discussed safety and standardization of BIA use as well as the validity of the BIA devices to estimate body composition (National Institutes of Health, 1996). The experts concluded that BIA is a safe method for assessing body composition in healthy adults. However, there are many limitations to using BIA as a method for assessing body composition such as body position, individuals with certain diseases, individuals with body asymmetry and individuals that are severely obese.

What is Impedance and how is it Measured?

Many authors and researchers have explained how impedance is measured (Dehghan & Merchant, 2008; Heyward & Wagner, 2004; Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Terminology between authors is not always consistent; however, the theory behind it is the same. Impedance to the flow of an electrical current is measured as an electrical current passes through the body between two electrodes. The voltage drop in electrical current between electrodes is due to the impedance of the current flow. Body composition is estimated based on the principle that electrical current flows with less impedance in areas that have high water and electrolytes, such as skeletal muscle, compared to less hydrated tissues such as adipose

tissue (Esco, et al., 2011a). Fat-free mass of the theoretical standard reference man contains approximately 73% water and electrolytes which makes a good conductor of electrical current. Whereas adipose tissue, which contains very little water, is a poor conductor, or it impedes or resists the flow of electrical current (Wagner & Heyward, 1999). Thus, the higher the TBW and FFM, the lower the resistance to the electrical flow, resulting in a lower impedance value (Wagner & Heyward, 1999).

Based on that principle, total body water (TBW) and hydration status are critical to obtaining valid body composition results from a BIA device. Certain activities and behaviors performed in close proximity to BIA testing must be controlled such as alcohol consumption, consuming products with diuretic properties, food and water consumption, and exercise (Dehghan & Merchant, 2008).

Factors Affecting Impedance Measures

Given the heavy reliance on water content within tissues, hydration status is critical to valid and reliable measures of impedance (Dehghan & Merchant, 2008). Factors that can influence hydration status include food and/or water consumption or lack thereof, use of diuretics, alcohol consumption and exercise. The consumption of food and water will directly increase the amount of fluid in the body. Use of diuretics will do exactly the opposite, increasing the excretion of water from the body through urination. Consumption of alcohol, a type of diuretic, will also result in dehydration through an increase in urination. Exercise can affect BIA readings in two ways: 1) loss of fluid from

the body due to sweating, 2) increased blood flow to the skeletal muscle and skin which increases heat and will decrease the impedance of the current (Dehghan & Merchant, 2008; Weaver, et al., 2009). Careful control of all of these variables in a free-living environment does not commonly occur when using a hand-held BIA. But because these variables should be controlled in order to obtain an accurate estimate of BF, guidelines on pre-test instructions have been created.

A few published studies have investigated the BIA devices have been and are currently used in many fitness facilities, laboratories, clinic and at home. However, the pre-testing guidelines prevent BIA from being a practical way to get valid estimations of body composition. The American College of Sports Medicine (L.A. Kaminsky, 2010) recommends the following pre-test guidelines to follow prior to taking BIA measurements:

- No alcohol consumption for previous 48 hours before the test
- No products with diuretic properties (e.g., caffeine and chocolate) for 24 hours before the test
- No exercise for the 12 hours immediately before the test
- No eating or drinking for the 4 hours immediately before the test
- Void bladder within 30 minutes prior to the test

Because hydration level and pre-testing guidelines are so important in accurate impedance measures, many at-home users of segmental devices may not obtain reliable or valid results if pre-testing guidelines are not followed.

BIA assesses body composition based the impedance of an electrical current that passes through a person's body using Ohm's law. A person's TBW will determine the impedance of the currents flow. As explained by Heyward (2004), there are two bioelectrical principles that apply when using BIA. First, "biological tissues act as conductors or insulators, and the flow of current through the body will follow the path of least resistance"(Heyward & Wagner, 2004, p. 89).

Second, impedance is a function of resistance (R) and reactance (Xc) (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Impedance (Z) is the frequency-dependant opposition of a conductor to the flow of an alternating current. Resistance (R) is defined as the pure opposition to the current flow through the body. Reactance (Xc) is defined as the opposition to current flow cause by capacitance (voltage storage) produced by the cell membrane (Heyward & Wagner, 2004)p. 89). Therefore, BIA does not necessarily measure FM directly, rather it determines electrical impedance, which can be used to estimate TBW. Based on assumptions concerning the aqueous fraction of the FFM, estimates FFM and BF via prediction equations have been generated (National Institutes of Health, 1998).

The biological principles of BIA measurements also follow certain assumptions. Estimations of body composition measured by whole-body BIA are based on the equation of V= p X (S/R) (Houtkooper, et al., 1996), where V is the conductance volume and signifies the volume of TBW or FFM, p is the specific resistivity of the body, S represents the length of the conductor or stature, and R is the resistance to the current

(Houtkooper, et al., 1996). The assumptions for this equation are that "the conductor has a homogeneous composition, a fixed cross-sectional area and a uniform distribution of current density" (Houtkooper, et al., 1996), p. 436). In summary, this assumes that the body is shaped like a perfect cylinder, meaning that ICW and ECW ratios are constant providing uniform conductance (Ellis et al., 1999; Gibson, et al., 2000). This is not the case and this assumption is routinely violated. Because limbs have a smaller cross-sectional area than the trunk, "whole body impedance is predominantly determined by resistance in the limbs" (Gibson, et al., 2000), p.221). It is also assumed that body tissue is at a constant hydration level, that a 50kHz frequency will penetrate all cells equally, and impedance is equal to resistance (Ellis, et al., 1999). This assumption is also not met because of different factors. First, an individual's hydration level can vary throughout the day. This could be due to activities that cause dehydration such as vigorous exercise or consumption of medications or stimulants that have diuretic properties (Dehghan & Merchant, 2008; Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Manuel Gomez, et al., 2004). There are also differences in hydration level of FFM and fat tissue, with FFM being approximately 73% water and fat tissue being relatively anhydrogenous (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Because these assumptions are not met, regression analysis has been applied in previous research to mathematically predict estimates of TBW, FFM and FM from BIA impedance measures, anthropometric measures and demographic variables.

Over the years, many prediction equations developed by multiple researchers. These prediction equations were originally based on cross-sectional studies using

hydrostatic weighing as a criterion measure (Duz, et al., 2009). Prediction equations most often take into account not only impedance values, but also anthropometric values such as height and weight and the individual's sex and ethnicity to reduce inter-individual differences in impedance values (Ellis, et al., 1999). It is difficult to develop a BIA prediction equation for a diverse population because, as stated earlier in the *Body Composition* section, previous research has shown that race and age may affect body composition and fat distribution (Heyward, 1996). Most prediction equations have been developed and cross-validated for a specific population making results only generalizable to like groups (Ellis, et al., 1999; Heyward, 1996). Another factor that may affect prediction equations is amount of body fat. Some equations overestimate %BF in lean populations and underestimate those that are obese (Duz, et al., 2009; Park, Lee, Park, Kim, & Kang, 2009; G. Sun et al., 2005; Swartz, Jeremy Evans, King, & Thompson, 2002). Lastly, prediction equations are only as accurate as the criterion method used to produce the equation (Houtkooper, et al., 1996). If an equation is based off of a criterion measure that itself introduces error when assessing body composition, then that prediction equation will have similar errors of estimate. Because of all of these factors, an individual's estimated %BF could differ by as much as 10% when a specific BIA equation is applied (National Institutes of Health, 1998).

Impedance can be measured by both single-frequency (SF-BIA) and multi-frequency BIA (MF-BIA) devices. Most SF-BIA use a frequency of 50kHz that usually passes from two different points in the body via surface electrodes to estimate TBW and

body composition. Conversely, MF-BIA estimates body composition using multiple frequencies across a large range to assess FFM, TBW, ICW and ECW.

Single-frequency BIA is technically not measuring TBW, rather it takes a weighted sum of ECW and ICW resistance measures (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). With a combination of impedance values based on the assumption that FFM is 73% water and other data, such as height, weight age and sex, body composition can be estimated. Common SF-BIA devices that are used in the field or at home are hand-to-hand and foot-to-foot models, also referred to as segmental impedance analyzers. These devices became available in the 1990s and are portable, inexpensive, easy to use and require little to no technician/user experience. Hand-held BIA devices have to two handles that contain electrodes where the electrical current will be sent out via one electrode and received by the other electrode. Users of this device are instructed to stand upright, firmly grip each to handle with arms outstretched at a 90-degree angle to the floor and the current flows from the right to left hand. The technology assumes that the amount of body water in the arms is proportional to the whole body (Deurenberg & Deurenberg-Yap, 2002). There has been very little research done on the validity and reliability of the hand-held BIA devices. Results have been contradictory, and therefore, inconclusive. A similar segmental BIA device is the foot-to-foot BIA. In the foot-to-foot device, there are electrodes built in to a digital floor scale. There are usually four electrodes, one for each heel and one for each ball of the foot. Users stand upright, with bare feet positioned properly on the electrodes. The electrical current is sent out via the electrodes at the ball of the foot

and received by the electrodes in the heel of the foot (Heyward & Wagner, 2004; Lee, 2009a). Body fat percentage is then estimated using manufacturer's propriety equations, which will be discussed in detail later. Body fat percent is the only result displayed for most hand-held and foot-to-foot devices. Similar to hand-held devices, results of validity studies on foot-to-foot devices has been contradictory.

Unlike SF-BIA, multi-frequency BIA (MF-BIA) devices are able to distinguish between ICW and ECW using a combination of low and high frequencies, as low as 1kHz up to over 1000kHz (Heymsfield, et al., 2005). This is important as multifrequency impedance measures are able to precisely estimate TBW, ICW and ECW, which was limited with single frequency impedance analysis. MF-BIA has the ability to monitor changes in hydration level and fluid shifts in the body. These devices are helpful in monitoring patients with abnormal fluid distribution, such as final stage renal failure (Heymsfield, et al., 2005; Heyward & Wagner, 2004). However, in regards to body composition estimates, previous research has shown that single and multifrequency impedance measures show similar results. One example of a MF-BIA device is the tetrapolar BIA. This device is considered a whole body impedance analysis, which uses multiple frequencies. Technically, no measures of BIA can be whole body because the head and neck are ignored (Heymsfield, Wang, Visser, Gallagher, & Pierson, 1996). While the patient is in a supine position, electrodes are placed on the dorsal surfaces of the hand, wrist, foot and ankle on the right side of the body. The position of the electrodes is very important as it can affect the impedance values. A displacement of a mere 1cm can result in a 2% different in impedance (National Institutes of Health, 1998).

The proximal electrodes are placed at the metacarpal-phalangeal and metatarsal-palangeal joints and the distal electrodes are placed at the "piliform prominence of the wrist and between the medial and lateral malleoli of the ankle" (National Institutes of Health, 1998, pg. 526S). The electrical current is sent out via the distal electrodes (hand and foot) and received by the proximal electrodes (wrist and ankle) (Heyward & Wagner, 2004). Based on measures of TBW, estimations can be made of body %BF, FFM, ECW, and ICW. Previous research has found whole body BIA measures to be accurate and reliable for estimating %BF, FFM and TBW. In 1996 Houtkooper, Lohman, Going and Howell reported that when different researchers used the same procedures, population, criterion method and same prediction equations, the SEE for FFM was 1.7-3.0 and 0.23-1.5kg for TBW. They concluded that whole-body BIA would be accurate for assessing body composition for large epidemiological and field studies. More recently, Bosy-Westphal et al. (2008) found a tetrapolar BIA to have good relative and absolute agreement when assessing %FM, percent skeletal muscle mass and total body bone-free lean mass when compared to both DEXA and magnetic resonance imaging (MRI). They concluded that terapolar BIA would be a valid tool for assessing body composition in individuals. Furthermore, Fornetti, Pivarnik, Foley and Fiechtner (1999) found tetrapolar BIA to be a reliable and valid tool for assessing body composition. When compared to DEXA, tetrapolar BIA had approximately a 1.8% prediction error in estimating %BF.

Validity of the Hand-held BIA

Very few research publications are available on the validity of the hand-held BIA device in estimating %BF. Moreover, even less has been published on the validity of the Omron HBF-306C which is a recently released hand-held device by Omron Healthcare that will be used in this study. There have been conflicting results on the validity because the populations in the published studies have differed in age, race and sex, all which affect the proprietary prediction equation used in each of the hand-held devices. For discussion purposes, previous validation studies will be addressed in order by type of hand-held device examined. That will be followed by critical gaps in the literature based on the nine validation studies that have been published and discussed in this section.

In 2000, Gibson, Heyward and Mermier (Gibson, et al., 2000) published a validation study of one of the earlier model of the Omron hand-held body fat analyzers, the Omron HBF-300 (see Figure 3). With a subject population of 25 men (age 19-55 years, mean BF 18.7±8.1%) and 23 women (age 18-48 years, mean BF 21.8±7.2%), both White and non-White, they compared the %BF from the BIA device with HW as the criterion method. Prior to all assessments, subjects were instructed to fast from food and drink for four hours, emptying bladder and bowels within 30 minutes of testing, and avoiding strenuous exercise for at least 12 hours prior to testing. Results indicated that approximately 70% of men and 66.6% of women tested received an accurate estimate

of %BF from the hand-held BIA. Accuracy was defined by an estimate within ± 3.5 %BF when compared to the HW as the criterion method.

Duz, Kocak and Korkusuz (2009) investigated the validity of the Omron BF-300 Body Fat Monitor in estimating %BF when compared to DEXA as the reference method. It is not clearly stated if the subjects followed pre-testing guidelines to control for hydration status. Among 18-26 year old males (*n*=104) and females (*n*=104) college students, they found that BIA significantly underestimated %BF in females and males (19.2±1.0% for females and 13.7±4.9% for males), however, more so in females when compared to DEXA (28.4±1.3% for females and 18.5±6.2% for males). In addition, they determined that the bias in BIA increased as body fat increased in participants. They concluded that different prediction equations should be developed or current prediction equations be revised to accurately represent a diverse population.

The most recent published study investigating the accuracy of a hand-held BIA device was conducted by Esco and colleagues and published in 2011. A total of 40 female collegiate athletes, between the ages of 18 and 27 years, participated in the study. All participated in either soccer (*n*=19), tennis (*n*=10) or basketball (*n*=11). Prior to the lab visit, participants were instructed to fast two hours prior to testing and to avoid alcohol consumption for 24 hours prior to testing. The Omron HBF-300 was used and compared to DEXA as the criterion method for estimating %BF and FFM. It was determined that %BF was significantly underestimated and FFM was significantly higher from the hand-held BIA as compared to the DEXA. These results are parallel to most

previous validation studies of the hand-held BIA that the devices lack accuracy when estimating %BF when compared to a criterion method.

Varady, Santosa and Jones, in 2007, conducted a validation study on the Omron BF-302 (see Figure 4) hand-held BIA device. Percent body fat differences were compared between the hand-held BIA and Magnetic Resonance Imaging (MRI) as the criterion method. The participant pool consisted of overweight, Caucasian females (*n*=31) aged 35-60 years who were free of any diagnosis of any disease leading to fluid imbalance and not taking any medication affecting water and salt balance. Participants were given several pre-testing guidelines to control for hydration status prior to BIA measurements: fasting for three hours, avoid strenuous exercise for 12 hours, and void bladder within 30 minutes of assessments. Results indicated that the hand-held BIA significantly underestimated mean %BF and FM when compared to MRI. In addition, hand-held BIA overestimated %FFM and FFM when compared to MRI. The authors concluded that the validity of the device is in question.

Erceg and colleagues (2010) published a report on the accuracy of the Stayhealthy BC1 hand-held BIA device (see Figure 5) when compared to DEXA as a criterion method. This device is different from all of the Omron models in that it gives not only measures of BF but also LM and hydration index. Additionally, the data can be uploaded from the device to a personal computer. Adults (117 men and 128 women) ages 18-80 participated in the study. Participants were divided into the following age ranges: 18-35, 36-50, 51-60, 61-70 and 71-80. The study was one of the first to analyze

accuracy of a hand-held BIA across a large age span. Participants had BMI ranging from normal to obese and the sample was ethnically diverse. There was no mention of participants following pre-testing guidelines prior to BIA measures. Results were contrary to many previous reports on validity of hand-held BIA devices. There were no significant differences across age groups for each sex when comparing %BF from the hand-held BIA and DEXA measurements, indicating that the Stayhealthy hand-held BIA device is a valid tool for estimating percent %BF in a diverse population of healthy adults.

Deurenberg and Deurenberg-Yap (2002) conducted a validation of the Omron BF-306 (see Figure 6) hand-held body fat analyzer using a four-compartment model as the reference method in Chinese, Malay and Indian subjects. Participants' age ranged from 18 to70 and they were also purposefully selected to include a large range of BMI values over the age span. Before assessments, subjects were instructed to abstain from food and drink for at least 6 hours and were instructed to void bladder just prior. Significant differences between %BF from BIA and the reference method were found in Malay and Indian men, who were higher in mean age and also had the highest mean %BF based from the reference method among sex and ethnicities. They also found that Indian subjects, who had a larger arm span relative to their height (women 1.0±0.0 and men 1.0±0.0) compared to the other ethnic groups, had higher impedance values. The authors concluded that factors of ethnicity and body type play a role in observed bias when using prediction equations that were validated on mostly white, European subjects.

Lintsi, Kaarma and Kull (2004) included multiple models of hand-held BIA devices: two Omron BF-300 (series 8), one Omron BF-300 (series 9), and one Omron BF-306 in a study aimed at examining differences in %BF among the three hand-held devices and DEXA as the criterion method in 17-18 year old males in the military. The subjects were given no pre-testing guidelines to follow, meaning that researchers were not controlling for hydration status. All four hand-held BIA devices underestimated %BF when compared to DEXA, and three of them were statistically significant. The two Omron BF 300 (series 8) devices provided means for %BF of the group and difference estimates that were not significantly different. The Omron BF-300 (series 9) had the largest difference in %BF compared to DEXA and the Omron BF-306 had the closest estimations of %BF compared to DEXA. Although three of the devices were provided %BF means that were statistically different from DEXA, the estimations of %BF were not necessarily clinically significant.

Weaver, Hill, Andreacci and Dixon reported results in 2009 on the validity of the Omron HBF-306C in estimating %BF as compared to air displacement plethysmography (ADP) as the reference method (Weaver, et al., 2009). Not only was the study a cross-sectional study comparing %BF in a single laboratory visit with subjects complying to pre-testing guidelines, an exercise component was added. Forty-one, healthy young adult men and women, ages 18-32y, volunteered for the study. Subjects came in for the first laboratory visit for validation purposes, where they were given pre-testing guidelines to control hydration status, such as fasting, avoiding exercise, avoiding alcohol consumption and no diuretic mediation within certain timeframes of testing.

Percent body fat was analyzed with the Omron HBF-306C device as well as the BodPod body composition system. During the second visit, %BF was assessed before and after a 30 minute exercise bout to determine the impact of changes in body temperature and hydration on BIA measures. The validation measures resulted in an underestimation of %BF by the hand-held BIA when compared to ADP, but the difference was only statistically significant in women. Results also indicated that the hand-held BIA device overestimated %BF in subjects with lower %BF and underestimated those with higher %BF. This is consistent with previous literature that suggests BIA underestimates %BF as %BF increases in populations (Deurenberg & Deurenberg, 2002; Duz et al., 2009, Varady, et al.,2007). Even more, 50% of women and 40% of men had %BF estimations by hand-held BIA that fell outside of acceptable range (±3.5%). When hand-held BIA measurements were taken pre- and post-exercise, there was a significant drop in %BF as a group, but differences were not significant when analyzed separately by sex. Author's concluded that estimations of %BF by hand-held BIA are not as accurate as desired on a group and individual basis. Most of the differences that were found statistically significant are not, however, clinically significant. The only clinically significant difference in %BF from the hand-held BIA compared to ADP was found when validating the device in women.

Figure 3. Omron BF 300

Figure 4. Omron BF 302

Figure 5. Stayhealthy BC1

Figure 6. Omron HBF-306C

Gaps in the Literature

Because hand-held BIA devices are relatively new, commercially-available products, there is very little research is available on their validity and reliability. One major gap in the literature is evaluating the accuracy and reliability of, specifically, the Omron HBF-306C device. It is one of three hand-held BIA devices currently on the market. However, there has been some research done examining accuracy of previous versions of the HBF-306C and other similar devices. Another major gap in the literature is the accuracy and reliability of hand-held devices across a large age span. Most of the previous research has been completed using young adults, rarely including subjects over the age of 60. This is important because of the changes in FM and FFM as adults age. Additionally, more research needs to be done on the accuracy and reliability across sex. The amount of BF and BF distribution is most often different between men and women, and it is important to determine if those differences alter the validity of the device. It is, therefore, critical to validate this device across the two variables of age and sex. Lastly, although the concept of euhydration is extremely important in the assessment of body composition with BIA devices, only one of the previous validation studies on hand-held BIA devices has controlled for hydration using all of the ACSM pre-testing guidelines. This could be a major limitation to all of the validation studies previously conducted on hand-held BIA devices. It is also important to compare the results of BF measures from the hand-held BIA device to the criterion measures in both a controlled setting when individuals are euhydrated and in a free-living environment when the pre-testing guidelines are not necessarily followed. This comparison is important as it will

determine whether the pre-testing guidelines, in fact, do need to be controlled for when estimating BF with hand-held BIA devices.

Summary

Because of the increase in overweight and obesity, and the associated health risks, many individuals are self-monitoring body composition. There are many methods available to monitor body composition, more specifically body fat; however, not all are readily-available or cost-effective for many individuals to use. Bioelectrical impedance analysis is one method that has been used to assess body composition since the 1930's, but as early as the 1990's this technology has been commercially-marketed as an easy-to-use, inexpensive, portable hand-held device. These hand-held devices are used to monitor %BF at home, fitness centers and clinics. Based on BF results from these devices, individuals make health-related decisions about diet and exercise programs. Therefore, it is critical that these devices are valid in estimating body fat. Because hand-held devices are relatively new, there is little research done on the validity or reliability. Previous research has been contradictory, and therefore inconclusive. More research needs to be focused on the validity of hand-held devices in controlled and free-living settings to see if hydration status does, in fact, play a critical role in accurate BF measures. Moreover, research on validity of hand-held devices needs to be expanded across both sexes and across young and old adults.

Chapter 3: Methods

Many individuals self-monitor their body composition based on physician's fitness and health recommendations or their own desire to favorably alter their body composition , often using portable, inexpensive body composition assessment tools. Individuals use the body composition information obtained from these devices to help them make health-related decisions and to track progress of an exercise or recommended diet program, or other health interventions. Therefore, it is important that these devices are valid in assessing body composition.

The purpose of this study was to evaluate the validity and reliability of a commercially-available hand-held bioelectrical impedance analysis (BIA) device as a measure of body composition for adults in a controlled laboratory condition and during a free-living condition. This section will include descriptive information of the participants, a description of instruments used, details of the study protocol and the statistical analysis.

Study Design

This study used a cross-sectional design with two data collection periods to investigate the validity and reliability of a hand-held bioelectrical impedance analyzer. Time point one, which addressed specific aim 1, was a controlled laboratory condition when body composition measures from the hand-held BIA was compared to two criterion measures of body composition, DEXA and tetrapolar BIA, across age and sex when pre-testing guidelines had been followed.

Independent Variable: Body composition assessment device

Dependent Variables: %BF

The second time point, which addressed specific aim 2, was during the free-living condition, occurring within 72 hours of the laboratory visit. Participants used a hand-held BIA at four pre-set times to estimate BF, when pre-testing guidelines may or may not have been followed.

Independent Variable: Time of measure

Dependent Variables: %BF

Other Variables of Interest

Variables for this study included body mass index, waist circumference, hip circumference, and arm span.

Participants

Participants were recruited via flyers posted on the University of Wisconsin-Milwaukee (UWM) campus, at local fitness centers, local businesses and senior living facilities in the Milwaukee metro area (Appendix A); presentations in large classes including both health and non-health majors; word of mouth; website information; and database including individuals that have consented to receiving phone calls for recruitment of studies held in the UWM Physical Activity & Health Research Lab.

The participants in this study included adults between the ages of 18 and 39 years and between the ages of 55 and 75 years. A screening form was administered over the phone or in person to determine eligibility for participation in the study (Appendix B). Inclusion criteria included participants who are White and English-speaking. Because of the many differences in body composition between different races, this study focused on White individuals first, with aspirations of continuing with other races in the future. Also, participants had to be English-speaking as all study-related documents were written in English, and the laboratory staff were only fluent in English. Purposeful sampling was used to recruit an equal number of males and females in each age category, as well as selecting a range of BMI among participants in each age category.

Exclusion criteria included individuals with a condition or taking medication that alters hydration status of the body including diuretic medication or calcium channel blocker; current diagnosis of a metabolic or kidney disease, pulmonary disease, or cirrhosis. Participants were also excluded if they had any cardiovascular condition or a pacemaker. Because BIA uses a small electrical current to measure body composition, the BIA devices should not be used on individuals that have a pacemaker in the rare instance that it may alter the electrical rhythm of that pacemaker. Any female that was pregnant or trying to become pregnant was excluded because of the radiation from the DEXA scan. Any female age 55 years and older that was still in the stages of menopause because previous research has demonstrated that BIA may not be a valid device for this population (Dehghan & Merchant, 2008). Lastly, any individual with a limb amputation

because previous research has shown that the assessment of body composition with BIA may not be accurate in those that have body asymmetry (National Institutes of Health, 1996).

Participants were also asked to self-report their height and weight in order for purposeful sampling of participants that span a wide range of body mass indexes. Because previous research has shown hand-held BIA to overestimate %BF in leaner individuals and underestimate %BF in overweight individuals, it was important to include participants of all sizes in the study (Deurenberg & Deurenberg-Yap, 2002a).

Protection of Human Participants

All study procedures were approved by the University of Wisconsin-Milwaukee Institutional Review Board and the Radiation Safety Program in the Department of University Safety and Assurances at the University of Wisconsin-Milwaukee, assuring protection of study participants. All participants were required to sign an informed consent document prior to participating (Appendix C).

Instrumentation

Body composition measures were estimated used three different devices. Both the hand-held and tetrapolar bioelectrical impedance analyzers estimate total body water and FFM, and calculate body fat using predictive regression formulas. Dual-energy x-ray absprtiometry provides information on body fat, as well as bone mineral content (BMC) and mineral-free lean tissue.

Hand-Held Bioelectrical Impedance Analysis

Commercially-available hand-held BIA devices are used to estimate %BF. While the individual is standing, gripping the handles of the device with arms straight out from the body, a 50kHz electrical current travels from one hand to the other, while the device measures the drop in voltage, or impedance to the current's flow. In the case of the Omron HBF-306C, the Impedance, along with height, mass, age and sex, are entered into a proprietary regression equation to estimate %BF. The current study used the battery-operated Omron Fat Loss Monitor (HBF-306C, Omron Healthcare, Bannockburn, Ill). More details on the procedure of using this device are presented in Study Protocol section.

There are numerous advantages to a using a hand-held BIA including the following:

- It is easy to use and little technical skill required.
- This method is non-invasive. The device uses a 50kHz electrical current that is not felt by the participant. The frequency is very low and therefore is safe for most individuals to use.
- The device is lightweight, weighing approximately 8 oz. The device is small and portable with dimensions of 8in (length), 5in (height) and 2in (width). Because the device is lightweight and portable, it can be used in many different settings such as at home, in fitness center or clinics.

- The device is cost effective and can be owned and utilized by individuals, clinics, and health/fitness facilities.

Although the device is easy to operate, there are strict pre-testing guidelines that the user must follow to elicit accurate results. These guidelines may make this device less practical than marketed. Additionally, users of the device may not even be aware of these pre-testing guidelines, resulting in invalid estimations of %BF.

There is very little research conducted on the validity and/or reliability of the Omron HBF-306C, and those results have been contradictory. Because of the contradictory results, the current study will be testing the validity of this device across age and sex. This may be due to the different subject populations used in the studies and the pre-testing guidelines that were used to control for hydration status (Deurenberg & Deurenberg-Yap, 2002b; Lintsi, Kaarma, & Kull, 2004a; Weaver, et al., 2009).

Tetrapolar Bioelectrical Impedance Analysis

Absolute and relative total body fat mass was assessed using a tetrapolar bioelectrical impedance analysis (BIA) device. A battery-operated, multifrequency bioelectrical impedance analyzer, The QuadScan 4000 (Bodystat®, Douglas, Isle of Man), will be used in the current study. Using this device, impedance can be measured at frequencies of 5, 50, 100 and 200kHz, however, for the purpose of assessing body composition, only 50kHz will be used. Self-adhesive, disposable electrodes are placed on the right hand and foot. Two sets of source and sensor electrical leads are required,

one set for the foot electrodes and one set for the hand electrodes. Distal electrodes (attached to the red lead) send out the electrical current and proximal electrodes (attached to the black lead) receive the electrical current. More details on the procedure will be presented in the "Procedure" section.

Previous research has found the QuadScan 4000 device to have contradictory results when estimating %BF. Fornetti, Pivarnik, Foley and Fiechtner (Fornetti, Pivarnik, Foley, & Fiechtner, 1999) found tetrapolar BIA to be a reliable and valid tool for assessing %BF. When compared to DEXA, tetrapolar BIA had approximately a 1.8% prediction error in estimating %BF. Sun and colleagues (G. Sun, et al., 2005) found that the QuadScan 4000 significantly underestimated overall %BF in both men and women (p<0.001) when compared to DEXA. Although the results were statistically significant, they may not be considered clinically significant. When the authors examined the group more closely, they found that the QuadScan 4000 overestimated %BF in lean individuals (%BF <20% for males and <25% females) and underestimated %BF in overweight or obese individuals (%BF >30% for males and >33% for females). Sun and colleagues concluded that the QuadScan 4000 is a valid tool for estimating %BF in individuals within a normal body fat range. Overall, tetrapolar BIA devices, including the QuadScan 4000, have been found to be valid devices for estimating %BF in most populations. Therefore, the QuadScan 4000 was used as another comparison method in this study.

Advantages to using the tetrapolar BIA method for assessing body composition are that the procedure is quick and non-invasive. The device also requires little training to operate and is relatively inexpensive as compared to other laboratory-based

methods. Although the use of the device requires little training to operate, the placement of the electrodes on the hand and foot is very important. A displacement of a mere 1cm can result in a 2% different in impedance (National Institutes of Health, 1998). Similar to the hand-held BIA device, there are also strict pre-testing guidelines that the participant must follow in order to be normally hydrated. If these guidelines are not met, the impedance measures of the tetrapolar BIA will not be accurate.

The QuadScan 4000 self-calibrates prior to each measurement. Additionally, there is an option for the technician to manually calibrate the device, which was done weekly. To manually calibrate prior to each measurement, both sets of leads are connected to a manufacturer-provided calibrator. There were no abnormal results when manually calibrating the device.

Dual-energy X-ray Absoptiometry

Dual-energy x-ray absorptiometry is a tool originally designed to estimate bone mineral density, but has more recently emerged as a tool for estimating FM as well as mineral-free lean mass (T. G. Lohman, 2005). Individuals lay supine and are positioned in the center of the DEXA table. Mineral-free lean mass, FM and BMD are estimated based on the tissue attenuation of two different x-ray energies (Pietrobelli, et al., 1996). The x-ray beams pass from the posterior to anterior of the body to a detector that is above the participant (Duz, et al., 2009). Based on the attenuation, and known densities of FM and FFM, the three compartments can be distinguished. The device used for this study was the Lunar Prodigy Advance software version (GE, Madison, WI).

There are many advantages to using DEXA to assess body composition. First, because this is a three compartment model of body composition, taking into account BMC, there are fewer assumptions that must be met and results are more consistently valid. Another advantage is that little participant compliance needed. Participants are not required to following any pre-testing guidelines such as fasting or avoiding strenuous exercise that are required for BIA assessments. Lastly, the DEXA is non-invasive and participants will not feel anything during the scan.

There are disadvantages of using DEXA to assess body composition. DEXA assesses body composition using an x-ray method, and therefore participants will be exposed to radiation. The device being used for this study emits approximately 0.00004 mRem of radiation which is similar to a cross-country flight and is fractions less than the amount of radiation from a typical x-ray, such as a chest x-ray. Therefore, it is considered safe for almost all populations (T. G. Lohman, 2005). Because of the size of the Lunar Prodigy table, there may be restrictions based on participant's size. The weight limit for the device is 159.1 kg. The total table size is 262cm long and 89cm wide, however, the area for scan is much smaller. Individuals that are taller than 193cm and wider than 60cm, will not receive accurate assessments as their entire body will not fit within the scan area. DEXA is an expensive and non-portable device that, depending on state laws, may require a certified or registered technician. Because of these reasons, DEXA may not be available for use by all individuals.

DEXA has, in recent years, been considered a gold standard method for assessing body composition because previous research has shown it to be both valid and reliable. Because of this, it will be used as a criterion measure in this study. Pritchard, Nowson, Strauss, Carlson, Kaymakci and Wark (1992) found that DEXA had greater precision when measuring fat mass when compared to HW, with a coefficient of variation of 1.8% for percent body fat and 2.1% for fat mass. Lohman, Tallroth, Kettunen and Marttinen (M. Lohman, Tallroth, K., Kettunen, J. A., Marttinen, M. T., 2009) conducted reliability a study using the Lunar Prodigy densitometer. They found total body DEXA measures to be repeatable for lean mass (LM) (r=0.99), FM (r=1.00) and BMD (r=1.00).

The Lunar Prodigy was calibrated daily prior to all measures using the manufacturer provided calibration block and using the manufacturer's instructions. The device was also calibrated weekly using the calibration phantom and using the manufacturer's instructions. There were no abnormal results when calibrating the DEXA.

Procedure

Laboratory and Experimental Information

All testing took place in the Physical Activity and Health Research Lab at UWM (Enderis 434). The cross-sectional research design included data collection during one laboratory visit that lasted approximately one hour and 15 minutes, and a second visit that lasted approximately 15 minutes. Laboratory visits were separated by a 24-hour

free-living day, within 72 hours of the first laboratory visit. The free-living day was a repeated-measures reliability research design.

Information Provided to Participants

When individuals inquired about participation in the study, a screening form (Appendix B) was administered over the phone or in person to determine eligibility. Participants were informed that they were eligible if they met all inclusion criteria and were found to have no exclusion criteria. Individuals were informed of the details and time requirement of the study protocol, after which, it was of the individual's discretion if he/she would like to enroll in the study. If individuals wanted to enroll as participants, they determined, along with the researcher, the scheduled dates and times to come in for the laboratory visits. Because all participants completed the same protocol, there was no randomization into treatment groups. The participants were given directions to the Physical Activity & Health Research Laboratory as well as instructions on parking.

Seventy-two hours prior to attending the first laboratory visit, participants were asked via phone and/or email to strictly adhere to pre-visit instructions: No alcohol consumption 48 hours before visit 1; no products with diuretic properties (caffeine, chocolate) for 24 hours before visit 1; no exercise 12 hours immediately before visit 1; no eating or drinking 4 hours immediately before visit 1; and void bladder within 30 minutes prior to the BF assessment.

Participants were asked to abide by these pre-testing guidelines to ensure that each individual was euhydrated. This was important for the BIA measurements that was

completed during the first laboratory visit. If these guidelines could not be met, the participant could reschedule the laboratory visit date, otherwise, they were withdrawn from the study. One participant was withdrawn from the study due to not abiding by the pre-testing guidelines.

Study Protocol

Laboratory Visit 1

Participants reported to the Physical Activity and Health Research lab at his/her individually scheduled time. During the first laboratory visit, participants were given a full description of the study and informed consent was obtained (Appendix C). Due to the x-ray exposure during the DEXA procedure, all female participants of child-bearing age were required to take a pregnancy test. If the pregnancy result was positive, participants were not be able to complete portions of the study, and were considered ineligible. No participants had a positive pregnancy result. All participants then completed a general health history and demographic questionnaire (Appendix D) to determine any current health risks or conditions that would limit normal daily living activities and confirm eligibility. Following the health history questionnaire, measures of resting heart rate and blood pressure were taken to evaluate cardiovascular risk factors. If participants were hypertensive, they were instructed to speak with their physician and were withdrawn from the study. Blood pressure was measured following protocol as outlined in The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Chobanian et

al., 2003) with a mercury sphygmomanometer (972 Series; American Diagnostic Corp, Hauppauge, NY). Resting heart rate and blood pressure were measured two times with the right arm and averaged for reporting. Anthropometric measures of body mass, standing height, and waist and hip circumference measures were obtained using guidelines outlined by the American College of Sports Medicine (ACSM) (Ehrman, 2010; Leonard A. Kaminsky, 2010). Body mass (kg) was measured to the nearest 0.01kg using a balance-beam scale (339; Detecto, Web City, MO) while participants wore light clothing, were instructed to remove items from pockets and jewelry, if possible, and wear no shoes. While shoes were still removed, standing height (cm) was measured to the nearest 0.1cm using a wall-mounted stadiometer (3PHTROD; Detecto, WebCity, MO). Participants were instructed to stand upright with heels together, looking straight ahead. Next, they were instructed to take a deep breath and hold it while the horizontal bar of the stadiometer is lowered to the head, compressing the hair. Body mass index (BMI) was then calculated using the measured height and body mass measures (kg/m^2). Next, waist and hip circumference (cm) was measured to the nearest 0.5cm using a Gulick tension-fitted tape measure (M-22C; Creative Health Products, Ann Arbor, MI). Waist circumference was measured with the participant standing upright with arms at the side and feet together. The tape measure was placed horizontally at the narrowest part of the torso, above the umbilicus and below the xiphoid process (Leonard A. Kaminsky, 2010). Hip circumference was measured with the participant standing and feet together. The tape measure was placed horizontally and measurement was taken at the largest circumference of the buttocks (Leonard A. Kaminsky, 2010). Two

measurements were taken at each site. If measures were not within 0.5cm, additional measures were taken until two measures were within 0.5cm to be averaged for analysis. Lastly, arm span was measured to the nearest 0.1cm using procedures specified in the Arlie Conference Proceedings (Lohman, Roche, & Martorell, 1991). Arm span was measured with a wall-mounted tape measure while participants' back was up against the wall, feet are together, arms abducted laterally forming a 90 degree angle with the body, and palms facing forward. The measure was made from the end of the middle (or longest) finger on the right hand, directly across the back of the body to the end of the middle (or longest) finger on the left hand, excluding fingernail. Arm span measures were used to determine if arm length affects impedance values assessed with the two BIA devices.

Participants then had their BF measured by three separate devices always in the same order: dual-energy x-ray absorptiometry (DEXA; Lunar Prodigy, GE, Madison, WI), tetrapolar BIA (Bodystat® Quad Scan 4000; Douglas, Isle of Man), and an Omron HBF-306C (Omron Healthcare, Bannockburn, IL) hand-held device. The tetrapolar BIA and DEXA were calibrated prior to each assessment. There was no calibration process for the Omron HBF-306C device.

Prior to the DEXA assessment, participants were asked to remove any metal objects on their body such as jewelry, buttons and zippers. If participants did not have alternate, metal-free clothing, a t-shirt and shorts were provided. Additionally, participants were asked to remove socks and shoes. The participant's, height, body mass, age, sex and race were entered into the DEXA computer software program. The

participant remained supine on the DEXA table, with his/her body positioned within the scan area that is denoted by a white rectangle on the table. Additionally, the body was positioned so that the white center line on the DEXA table was directly in line with the center of the participant's body. The participant was instructed to lie as still as possible without talking, but breathe normally during the scan. The scan took between six and 12 minutes, depending on the height and scan mode selected for measurement of the participant.

Immediately following the DEXA measurement, participants remained supine and completed the second measure: tetrapolar BIA. The technician positioned the participant's body so that all of the four limbs were separated and not touching any of the other limbs. Once positioned, the participants' dorsal surfaces of the hand, wrist, foot and ankle on the right side of the body was cleaned with alcohol pads. Electrodes were placed on the four cleaned areas. The proximal electrodes were placed at the metacarpal-phalangeal and metatarsal-phalangeal joints and the distal electrodes were placed at the piliform prominence of the wrist and between the medial and lateral malleoli of the ankle (Stamatakis, Davis, Stathi, & Hamer, 2011). Participants' height, body mass, sex, age, waist and hip circumferences were entered into the QuadScan 4000 device and body composition was assessed using the tetrapolar BIA. Once electrodes were placed and information was entered into the device, the technician started the tetrapolar BIA measure which lasted approximately one minute.

After completion of the supine BF measures, participants were asked to stand for 3 minutes. Participants remained in the same clothing with shoes still removed. Height, body mass, age and sex were entered into the hand-held device. All measures with the hand-held BIA device were done on the "normal" setting as opposed to the "athlete" setting. After three minutes of standing, two consecutive BF measurements were completed with the hand-held Omron HBF-306C. Participants were asked to grip the handles of the device firmly with thumbs pointing up and extend arms out straight in front of his/her body, parallel to the floor. After the first measure was completed, the participant remained standing with arms relaxed at his/her side for 60 seconds. Then, a second measure was taken with the hand-held device. The two measures were averaged and recorded for analysis.

Once BF measures were completed, participants received detailed verbal and written instructions (Appendix E) on how to use the hand-held BIA for the free-living day. Participants were advised of specific times of the day to take and record BF measures with the hand-held BIA device. Participants were asked to complete an event log (Appendix F) during the free-living day which included times when the following actions occurred: waking time, eating meals or snacks, ingesting beverages or medications, time of any food or beverage comsumption, time of structured exercise (if they exercise during that day), time of any leisure activites throughout the day, time of going to bed, and hand-held BIA body fat measures at the four pre-selected times.

Free-living condition

Participants brought home the Omron HBF-306C hand-held BIA device. The 24-hour free-living day occurred within 72 hours of the first laboratory visit for all participants. Participants were instructed to assess BF via the Omron HBF-306C device at specific times of the free-living day: 1) immediately upon waking and voiding bladder, 2) immediately after eating lunch, 3) right before going to bed, and 4) immediately after exercising (if exercise was done during the day). These times were specifically selected because some are the most popular times of the day to take body weight measures (Klos, et al., unpublished data), and are thus times that an individual will likely self-monitor their BF level. However, some of the measures were specifically taken after activities that have been shown to affect hydration status, and therefore, were expected to affect BIA output.

Participants also recorded specific events during the free-living day in the event log. Events that were documented include the following: waking time, eating meals or snacks, ingesting beverages or medications, time of any food or beverage comsumption, time of structured exercise (if they exercise during that day), time of any leisure activites throughout the day, time of going to bed, and hand-held BIA body fat measures at the four pre-selected times.

Laboratory Visit 2

Participants returned the hand-held BIA device, daily log and accelerometer to the laboratory within four weeks of the free-living day where they were provided with results from their DEXA and tetrapolar BIA measurements.

Statistical Analysis

All statistical analysis was conducted using SPSS 18 for Windows (SPSS, Inc. Chicago, Il). An alpha level of greater than 0.05 was used for the statistical significance level. Demographic variables including height, body mass, BMI, waist and hip circumferences, waist-to-hip ratio, and arm span were assessed and are displayed as means, standard deviations, minimum values and maximum values.

To address the primary aim of the study, a mixed between by within design comparing sexes and age groups (between groups variables) across hand-held BIA, tetrapolar BIA and DEXA measurements (within groups variable) was performed to determine whether differences among devices exist. Post-hoc comparisons were performed to determine which devices are different in assessing BF among the hand-held BIA, the tetrapolar BIA and the DEXA. Additionally, Bland Altman Plots were created to visually depict the agreement between %BF estimates form the hand-held BIA as compared to the DEXA for individual participants. Medical researchers often need to compare two methods of measurement to determine whether these two methods can be used interchangeably. The 95% limits of agreement are for visual judgment of how well two methods of measurement agree. The smaller the range between these two limits the better the agreement is. That definition depends on the clinical acceptance standard for the method, which in this case is ±3.5%. Waist circumference, arm span and BMI were examined as potential covariates in the validity

of the hand-held BIA measures. These variables were added if determined to fit covariate assumptions

To address the second aim of the study, repeated measures analysis of variance was performed to determine if there are differences in the hand-held BF measures over the duration of the free-living day and also with the controlled laboratory hand-held BF measures. Post-hoc comparisons were performed to determine what specific measurement times and situations cause significant differences in BF measures.

Chapter 4: Results

Introduction

Because of the increase in overweight and obesity, and the associated health risks, many individuals are self-monitoring body fat with affordable and easy-to-use devices. There are many different methods available to self-monitor body fat (BF). One such device, the hand-held BIA device, is an affordable and easy-to-use method that is increasing in popularity. The purpose of this study is to evaluate the validity of a commercially-available hand-held bioelectrical impedance analysis (BIA) device as a measure of body fat for adults in a controlled laboratory condition and evaluate the reliability of this device during a free-living condition. In order to address this purpose, this study focused on two specific aims.

Specific Aim 1: To compare body fat measures from the hand-held BIA to two additional methods used to estimate body fat, DEXA and tetrapolar BIA, across age and sex, when pre-testing guidelines were followed.

Specific Aim 2: To examine the reliability of body composition estimates from a hand-held BIA at four pre-determined times during one free–living day. These four body fat estimates during the free-living day helped determine variations in body fat measures when pre-testing guidelines are not followed.

This chapter presents the results of this study. The chapter will begin with the presentation of demographic characteristics of participants as a whole, by age group

and by sex. Next results from the statistical analyses performed to address each of the specific aims will be presented. Finally, the data will be summarized.

Participants

A total of 116 individuals were screened to participate in the study, of which 96 were eligible and 20 did not qualify. Of the 20 individuals that did not qualify, five were disqualified due to age, four due to race other than White, five due to current diagnosis of a metabolic disease, five due to currently taking a medication or substance that would affect hydration status, and one female (age 55) did not meet the post-menopausal inclusion criteria. Of the 96 eligible, a total of 91 completed the study. One participant was not able to complete the study due to not abiding by the pre-testing guidelines prior to the first laboratory visit. The other four participants were not able to complete the study due to time constraints. The final analysis included 91 men and women.

Table 1 displays descriptive information for all 91 participants. Slightly more females (55%) than males (45%) completed the study. Participants ranged in age from 19-39 and 55-75 years.

Table 1. *Descriptive Characteristics of All Participants and by Sex.*

	All (*N*=91)				**Females (*n*=50)**				**Males (*n*=41)**			
	Mean	*SD*	*Min*	*Max*	*Mean*	*SD*	*Min*	*Max*	*Mean*	*SD*	*Min*	*Max*
Age (years)	42.4	17.3	19.0	75.0	41.0	17.1	20.0	73.0	44.1	17.6	19.0	75.0
Height (cm)**	171.8	8.7	153.8	190.0	166.3	6.2	153.8	182.0	178.5	6.3	161.5	190.0
Mass (kg)**	74.2	14.5	49.4	125.7	67.1	10.4	49.4	101.2	82.8	14.2	60.1	125.7
BMI (kg/m²)*	25.1	3.9	19.0	36.4	24.3	3.9	19.0	34.7	25.9	3.7	20.9	36.4
Waist Circ (cm)**	82.2	11.2	67.3	113.0	76.9	8.9	67.3	106.4	88.7	10.3	71.4	113.0
Hip Circ (cm)	101.4	8.3	87.6	124.2	101.2	8.4	87.9	122.9	101.7	8.1	87.6	124.2
Waist-to-hip ratio**	0.81	0.08	0.76	1.00	0.76	0.05	0.68	0.91	0.87	0.06	0.75	1.00
Arm span (cm)**	172.8	10.8	151.1	200.7	166.7	7.7	151.1	186.7	180.5	9.0	154.6	200.7

Note. * $p < 0.05$, significant differences between females and males, ** $p<0.001$, significant differences between females and males. BMI=body mass index, Circ=circumference.

Analyses were conducted to determine significant differences in descriptive characteristics between the female and male groups. There were no significant differences in age ($t(89)=-0.84$, $p=0.40$) and hip circumference ($t(89)=-0.32$, $p=0.75$). There were significant differences in height ($t(89)=-9.23$, $p<0.001$), body mass ($t(89)=-6.10$, $p<0.001$), BMI ($t(89)=-2.02$, $p=0.046$), waist-to-hip ratio ($t(89)=-9.53$, $p<0.001$), arm span ($t(88)=-7.84$, $p<0.001$), and waist circumference ($t(89)=-0.32$, $p<0.001$). On average, males were 12.2 cm taller than females, 15.7 kg heavier than females, had a BMI 1.6 kg/m² higher than females, had a waist circumference 11.8 cm larger than females, had a waist-to-hip ratio (W:H) 0.11 more than females and an arm span of 13.8 cm longer than females.

Next, independent t-tests were conducted to determine differences between young and old groups for females and males. Within the female group, there was no significant difference in height ($t(48)=1.89$, $p=0.064$), body mass ($t(48)=0.58$, $p=0.576$), BMI ($t(48)=0.12$, $p=0.123$), hip circumference ($t(48)=0.12$, $p=0.118$), and arm span ($t(48)=1.59$, $p=0.119$) between young and old female groups. The difference between W:H between the young and old female groups approached significance ($t(48)=-2.00$, $p=0.052$). The old female group had a waist circumference approximately 8% larger than young females ($p=0.02$), however, the mean waist circumference for both young and old female groups fell in the low risk category for cardiovascular disease (ACSM, 2006). A large range of BMI was present within both the young and old female groups. Body mass indexes ranged from Normal to Class 1 Obesity, with the mean BMI of the young females falling within the Normal classification, and the mean BMI of the old

female group falling in the Overweight classification (National Institutes of Health, 1998). Table 2 displays descriptive characteristics of all female participants and divided by young and old groups.

Table 2. *Descriptive Characteristics of Female Participants Displayed by Age Group.*

	Young (*n*=30)				**Old (*n*=20)**			
	Mean	*SD*	*Min*	*Max*	*Mean*	*SD*	*Min*	*Max*
Age (years)	27.7	5.1	20.0	39.0	60.8	5.5	55.0	73.0
Height (cm)	167.6	6.0	158.0	182.0	164.3	6.1	153.8	175.5
Mass (kg)	66.5	10.8	49.4	101.2	68.2	9.8	54.2	87.3
BMI (kg/m²)	23.6	3.5	19.7	34.2	25.4	4.4	19.0	34.7
Waist Circ (cm)*	74.6	6.9	67.3	97.5	80.5	10.5	67.6	106.4
Hip Circ (cm)	99.6	8.2	87.9	122.9	103.5	8.5	88.9	117.1
Waist-to-hip ratio	0.75	0.04	0.68	0.84	0.78	0.06	0.71	0.91
Arm span (cm)	168.1	7.9	154.3	186.7	164.6	6.9	151.1	179.1

Note. * $p < 0.05$, significant differences between young and old groups. BMI=body mass index, Circ=circumference.

Differences between descriptive characteristics were also examined in the male group for both the young and old male groups. There was no significant difference in height (t(39)=-0.67, *p*=0.506), mass (t(39)=-0.56, *p*=0.576), BMI (t(39)=-0.47, *p*=0.635), hip circumference (t(39)=-0.56, *p*=0.582) and arm span (t(39)=-0.27, *p*=0.788) between young and old male groups. However, there was approximately a 10% higher W:H in old male group compared with the young male group (*p*=0.003). The mean W:H for the young and old male groups fell in the normal range (18-59 years, W:H< 0.95; >60 years, W:H <1.03; ACSM, 2006) . Additionally, the old male group had a waist circumference approximately 11% larger than young males (*p*<0.001). The mean waist circumference for the young and old male groups fell in the low risk category for cardiovascular disease (ACSM, 2006). Additionally, a large range in BMI was present within the young and old male groups. Body mass index levels ranged from Normal to Class 2 Obesity, with the mean BMI of the young and old male groups falling within the Overweight range (National Institutes of Health, 1998). Table 3 displays descriptive characteristics of the young and old male groups.

Table 3. *Descriptive Characteristics of Male Participants Displayed by Age Group*.

	Young (*n*=22)				**Old (*n*=19)**			
	Mean	*SD*	*Min*	*Max*	*Mean*	*SD*	*Min*	*Max*
Age (years)	28.8	5.2	19.0	39.0	61.9	6.2	55.0	75.0
Height (cm)	177.9	7.1	161.5	190.0	179.2	5.4	169.0	187.5
Weight (kg)	81.7	17.1	60.1	125.7	84.2	10.3	70.4	104.8
BMI (kg/m²)	25.7	4.3	20.9	36.4	26.2	2.8	21.9	31.0
Waist Circ (cm)*	84.5	11.7	71.4	113.0	93.5	5.3	83.1	103.9
Hip Circ (cm)	101.1	9.8	87.6	124.2	102.5	5.8	95.3	115.1
Waist-to-hip ratio**	0.83	0.05	0.75	0.95	0.91	0.04	0.86	1.00
Arm span (cm)	180.2	8.2	163.2	200.7	181.0	10.2	154.6	198.1

Note. * $p < 0.05$, ** $p<0.001$ significant differences between young and old groups. BMI=body mass index, Circ=circumference.

Summary

A total of 91 participants successfully completed the study, 50 females and 41 males, between the ages of 19-75. Of the females, 30 were in the young group and 20 in the old group. Of the males, 22 were in the young group and 19 were in the old group. Overall, mean waist circumference and waist-to-hip ratio fell in the normal range or low risk for cardiovascular disease in both females and males (ACSM, 2006). There was a large range of BMI among female and male participants, ranging from Normal to Class 2 Obesity. The mean BMI for the young female group fell in the Normal classification and the mean BMI for the old female group and the young and old male groups fell in the Overweight classification (National Institutes of Health, 1998). Males were generally taller, heavier, had a larger waist circumference and longer arm span than females.

Specific Aim 1: Validity of the Hand-Held Bioelectrical Impedance Analysis Device

The goal of specific aim 1 was to compare body fat measures from the hand-held BIA to a criterion measure of body fat (DEXA) and also to a like method of assessing body composition (tetrapolar BIA) across age and sex in a controlled setting when pre-testing guidelines have been followed. It was hypothesized that BF results from the hand-held BIA would not significantly differ from DEXA or tetrapolar BIA measures during the controlled laboratory condition. To address specific aim 1, a mixed between-by-within design comparing BF between sex and age groups (between

groups variables) and across hand-held BIA, tetrapolar BIA and DEXA measurements (within groups variable) was employed. The main effect from these analyses will be presented first. Two-way interaction will then be presented with simple main effects and post hoc comparisons where appropriate. Finally three-way interactions will be presented.

Results indicate that there was no significant main effect of device (F(1.3,103.8) = 2.30, p=0.13) meaning that, in the total group, there was no difference in %BF measures between the hand-held BIA, DEXA and tetrapolar BIA. Despite a non-significant main effect of device, the interaction between device and sex was significant (F(1.3,103.8) = 4.44, p=0.03) indicating that %BF was measured differently across devices for females and for males. Results are presented in Table 4 and Figure 7. In the female group, results showed there was a significant difference in BF estimates from the hand-held BIA as compared to DEXA (p<0.001) and from the tetrapolar BIA as compared to DEXA (p<0.001). Specifically, the hand-held BIA underestimated %BF by 2.7 percentage points compared to the DEXA. The tetrapolar BIA also underestimated %BF by 2.5 percentage points compared to the DEXA. There was no significant difference between the BF estimates from the hand-held BIA and the tetrapolar BIA in the female group (p=0.512).

In the male group, the pattern of over and underestimation of the %BF by hand-held BIA and tetrapolar BIA differed from the pattern in the female group. There was a significant difference in %BF estimates between the hand-held BIA and the tetrapolar

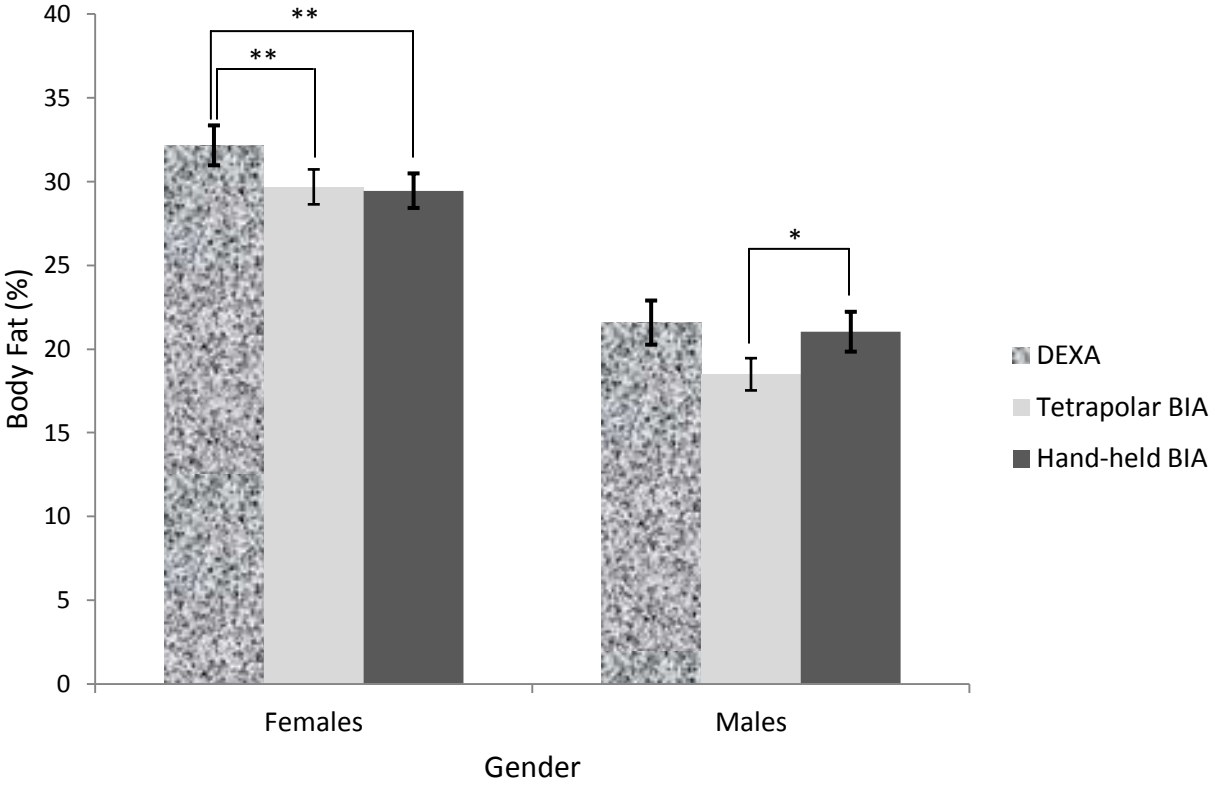
BIA (p<.001), with the hand-held BIA overestimating %BF by 2.6 percentage points as compared to the tetrapolar BIA.There was no significant difference between the tetrapolar BIA and DEXA (p=0.07) and between hand-held BIA and DEXA (p=0.53).

Table 4. *Mean Body Fat Measures Assessed by the Three Devices for Females (n=50) and Males (n=40).*

	BF DEXA (%)		**BF HHBIA (%)**		**BF TBIA (%)**	
	Mean	*SEE*	*Mean*	*SEE*	*Mean*	*SEE*
Females	32.2	1.2	29.5*	1.0	29.7*	1.0
Males	21.7	1.3	21.2**	1.2	18.6	1.0

Note. *p<0.001, significant difference from DEXA; **p<0.001, significant difference from TBIA. BF=body fat, DEXA=dual-energy x-ray absoptiometry, HHBIA=hand-held bioelectrical impedance analysis, TBIA=tetrapolar bioelectrical impedance analysis

Figure 7. *Mean Body Fat Measures Assessed by the Three Devices for Female and Male Groups (N=90).*



*Note. *p<0.05, **p*<0.001. DEXA=dual-energy x-ray absoptiometry, BIA= bioelectrical impedance analysis

Additionally, the two-way interaction between device and age ($F(1.3,103.8) = 12.92$, $p<0.001$) was also significant, demonstrating that the %BF measures from the hand-held BIA and tetrapolar BIA were not consistent between young and old groups. In the young group, there was a significant difference in BF estimates from the tetrapolar BIA compared to DEXA ($p<0.001$) and from the hand-held BIA compared to DEXA ($p<0.001$). Specifically, the hand-held BIA underestimated %BF by 3.5 percentage points compared to the DEXA. The tetrapolar BIA also underestimated %BF by 3.8 percentage points compared to the DEXA. There was no significant difference between the BF estimates from the tetrapolar BIA and the hand-held BIA ($p=0.13$). Results are presented in Table 5 and Figure 8.

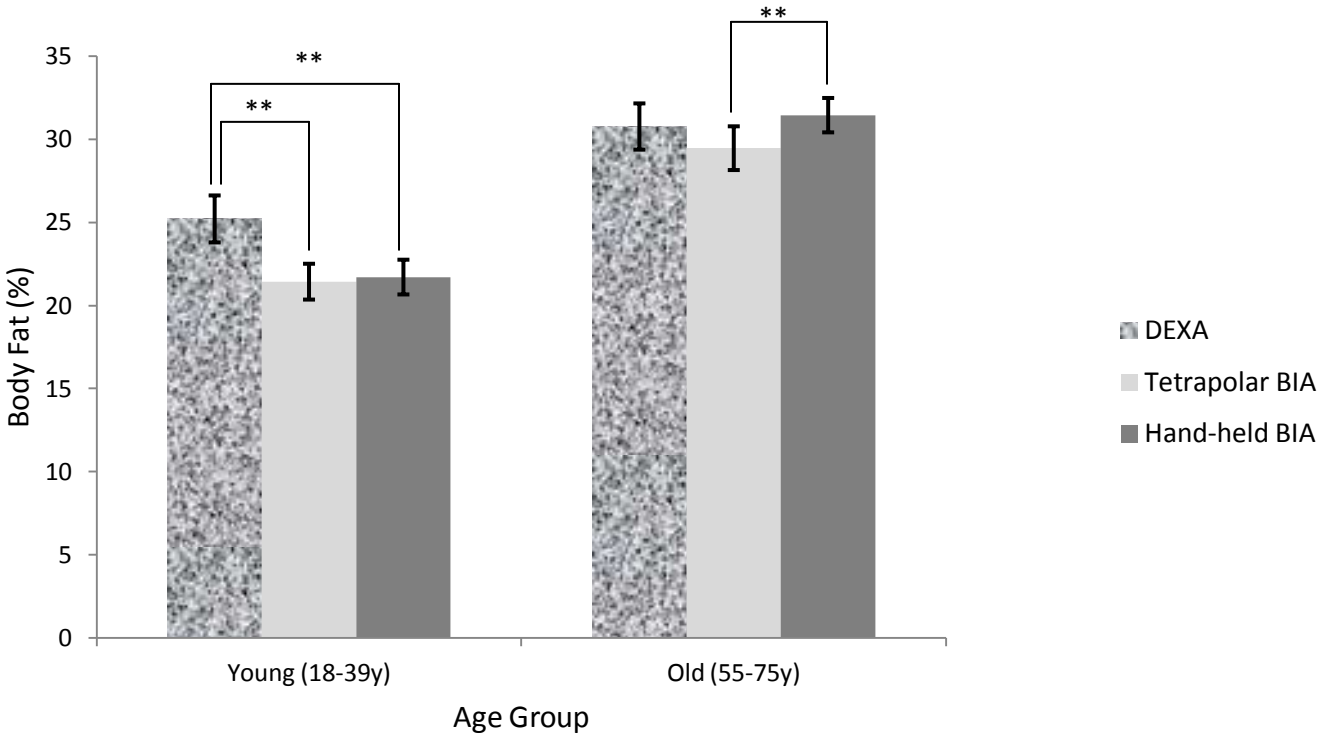
In the old group, the pattern of over and underestimation of BF by the hand-held BIA and tetrapolar BIA differed from the pattern in the young group. There was a significant difference in BF estimates from the tetrapolar BIA and the hand-held BIA ($p<0.001$), with the hand-held BIA significantly overestimating %BF by 1.9 percentage points. There was no significant difference in BF measures in the old group between the DEXA and the hand-held BIA ($p=.13$) and the DEXA and tetrapolar BIA ($p=0.38$). Table 5 displays the means, standard deviations and standard error for the BF measures between the three devices for young and old participants. Figure 8 plots differences in mean BF estimates for each device by age.

Table 5. *Mean Body Fat Measures Assessed by the Three Devices for Young (n=58) and Old (n=32).*

	BF DEXA (%)		**BF HHBIA (%)**		**BF TBIA (%)**	
	Mean	*SEE*	*Mean*	*SEE*	*Mean*	*SEE*
Young	25.2	1.4	21.7*	1.0	21.4*	1.1
Old	30.5	1.4	31.1**	1.0	29.3	1.3

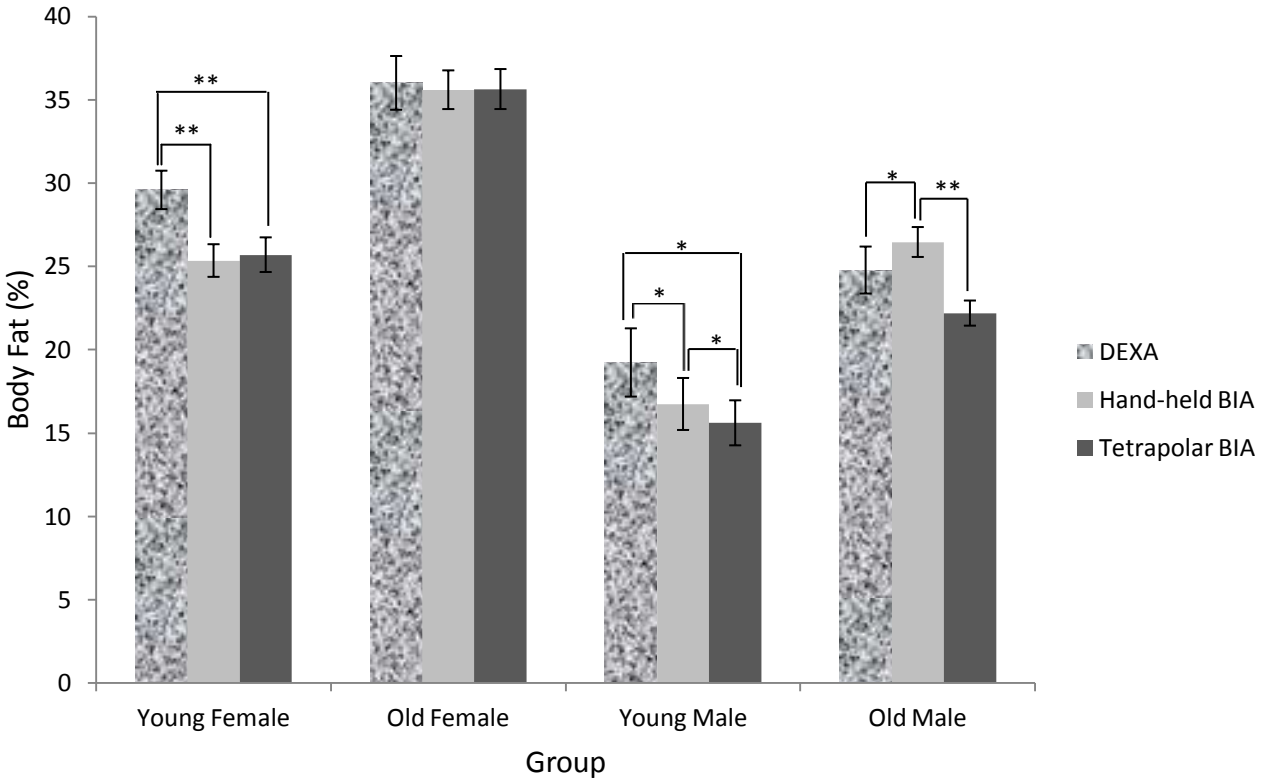
Note. * $p < 0.05$, significant difference from DEXA; ** $p<0.001$, significant difference from TBIA. BF=body fat, DEXA=dual-energy x-ray absoptiometry, HHBIA=hand-held bioelectrical impedance analysis, TBIA=tetrapolar bioelectrical impedance analysis.

Figure 8. *Mean Body Fat Measures Assessed by the Three Devices for Young and Old Groups*.



Note. ***p*<0.001. DEXA=dual-energy x-ray absoptiometry; BIA=bioelectrical impedance analysis

Figure 9. *Body Fat Percent Assessed by Three Devices for All Participants by Age Group and Sex (N=91).*



*Note. *p<0.05, **p*<0.001. DEXA=dual-energy x-ray absoptiometry; BIA=bioelectrical impedance analysis

There was no significant three-way interaction between device, age and sex (F(1.3,103.8) = 1.21, p=.29).

The variables of BMI, waist circumference and arm span were examined as potential covariates in the model and tested for violations of assumptions. No violations were detected and the variables were entered into the model. Results indicate that there is no significant interaction between device and BMI (F(1.3,103.8) = 0.06, p=0.87), device and waist circumference (F(1.3,103.8) = 0.99, p=0.34), and device and arm span (F(1.3,103.8) = 0.59, p=0.48).

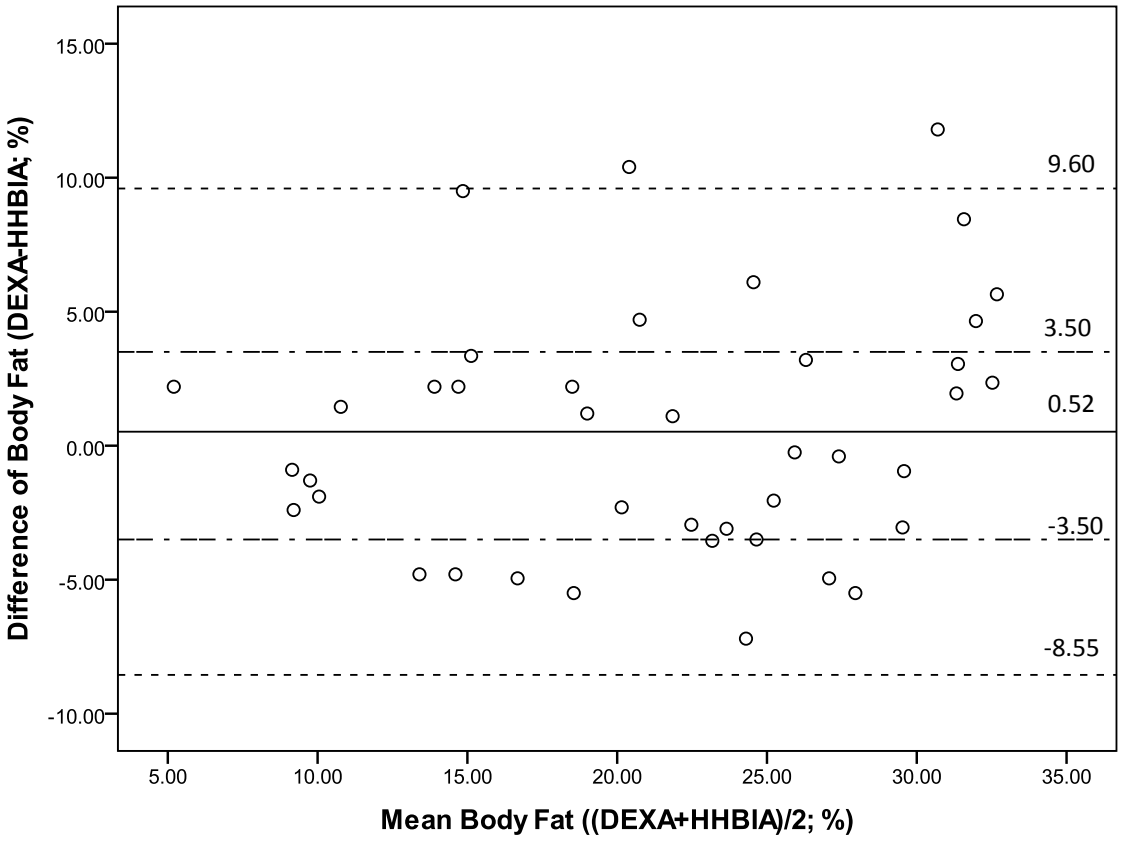
Summary of Specific Aim 1

Overall, results show that the hand-held BIA device is not statistically significantly different from DEXA for the male group and the old group, suggesting that the hand-held device is a valid tool for assessing body composition at a group level in these populations. However, careful examination of Bland Altman Plots, which graphically depict the agreement between the DEXA and hand-held BIA for estimates of BF, displays a large range of agreement across individual participants (See Figures 10 and 11). Therefore, the hypothesis for specific aim 1 cannot be accepted for individuals in those two groups.

Results also show that the hand-held device is statistically significantly different from the DEXA in the female and young groups, suggesting that the hand-held device is

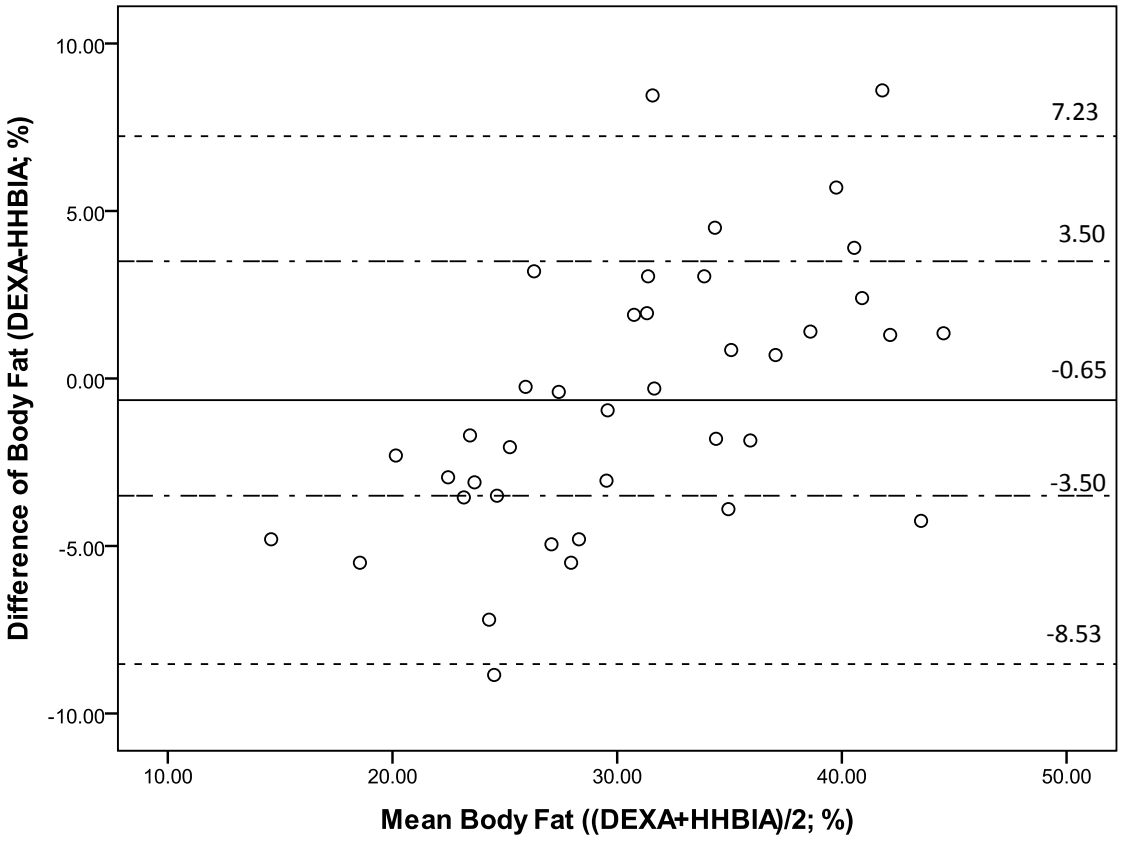
not valid in these two groups for assessing body composition. Therefore, the hypothesis for specific aim 1 was not accepted for the female and young groups. Additionally, Bland Altman Plots show in the female and young groups the large range of agreement between DEXA and hand-held BIA (see Figure 12 and Figure 13). Figure 9 displays means and standard error for the BF estimates from the three devices across age and sex.

Figure 10. *Bland Altman Plot depicting agreement between estimates of body fat by DEXA and hand-held BIA in males (n=40).*



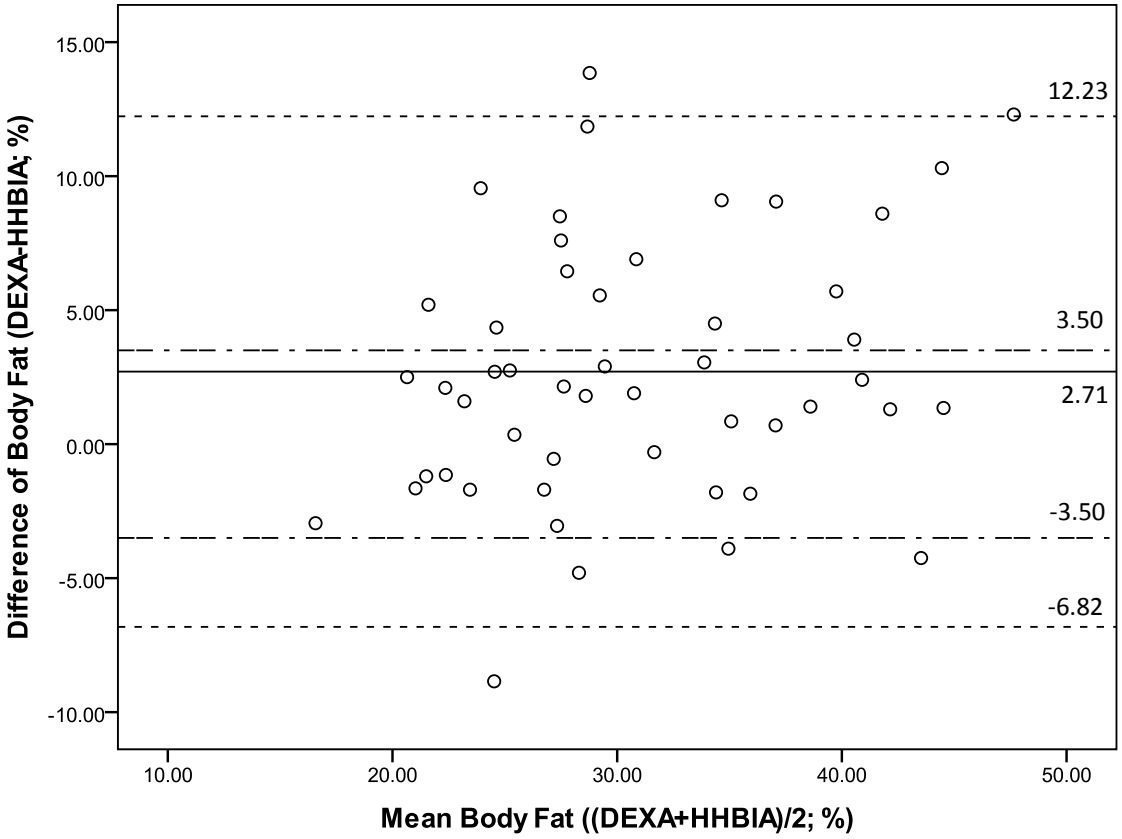
Note. DEXA=dual-energy x-ray absorptiometry; HHBIA=hand-held bioelectrical impedance analysis. Solid line represents mean body fat percent from DEXA and HHBIA. Dotted lines represent 1.96 standard deviations from the mean. Dashed lines represent clinically acceptable range of ±3.5%.

Figure 11. *Bland Altman Plot depicting agreement between estimates of body fat by DEXA and hand-held BIA in the old group (n=38).*



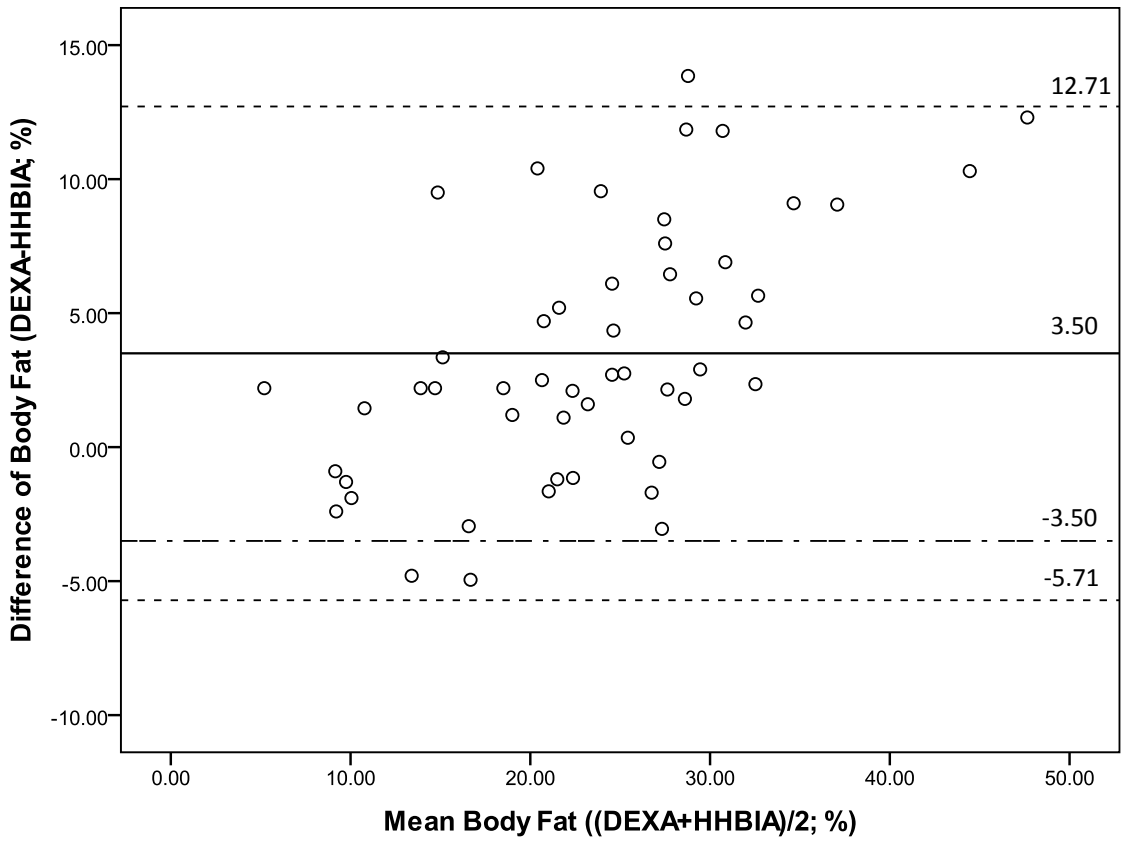
Note. DEXA=dual-energy x-ray absorptiometry; HHBIA=hand-held bioelectrical impedance analysis. Solid line represents mean body fat percent from DEXA and HHBIA. Dotted lines represent 1.96 standard deviations from the mean. Dashed lines represent clinically acceptable range of ±3.5%.

Figure 12. *Bland Altman Plot depicting agreement between estimates of body fat by DEXA and hand-held BIA in females (n=50).*



Note. DEXA=dual-energy x-ray absorptiometry; HHBIA=hand-held bioelectrical impedance analysis. Solid line represents mean body fat percent from DEXA and HHBIA. Dotted lines represent 1.96 standard deviations from the mean. Dashed lines represent clinically acceptable range of ±3.5%.

Figure 13. Bland Altman Plot depicting agreement between estimates of body fat by DEXA and hand-held BIA in the young group (n=52).



Note. DEXA, dual-energy x-ray absorptiometry; HHBIA=hand-held bioelectrical impedance analysis. Solid line represents mean body fat percent from DEXA and HHBIA. Dotted lines represent 1.96 standard deviations from the mean. Dashed lines represent clinically acceptable range of ±3.5%.

Specific Aim 2: Reliability of the Hand-Held BIA Device

Specific Aim 2 sought to examine the reliability of BF estimates from a hand-held BIA at four pre-determined times during one free–living day in the same population: immediately upon waking after voiding bladder, immediately after eating lunch, prior to bed and immediately after exercise. It was hypothesized that significant variations in BF were expected during the free-living day demonstrating that, when pre-test instructions are not followed, BF results from the hand-held BIA may not be reliable. Repeated measures analysis of variance (RM ANOVA) were performed on the hand-held BF measures to determine if there were differences in the hand-held BF measures over the duration of the free-living day and also with the controlled laboratory (LAB) hand-held BF measures. Post-hoc comparisons were performed, where appropriate, to determine where specific differences in estimates of BF were present between the measurement times. All participants completed three of the four free-living measures: after waking, after eating lunch and prior to bed. However, only 53 subjects participated in exercise on the assessment day and were, therefore, able to complete the fourth free-living measure that was taken immediately after exercise. Results of the RM ANOVA including after waking, after eating lunch, prior to bed and LAB, indicate that there was a significant difference between the BF estimates performed over the course of the day and the LAB ($F(2.82,236.97) = 13.51$, $p<0.001$). Post-hoc comparisons showed that there were significant differences between BF measures assessed in the LAB and waking ($p<0.001$) and LAB and prior to bed ($p=0.008$), with both free-living measure times underestimating the LAB measure. There was no significant difference in BF measures

assessed in the LAB and after eating lunch (p=0.27). Results suggest that the hand-held BIA device is not statistically reliable over the course of a day when pre-testing guidelines are not followed. Results are presented in Table 6 and Figure 13. However, among the three free-living measure times there was only a difference of 0.2-0.8 percentage points as compared to the LAB setting, indicating that the hand-held device is reliable over the course of one day.

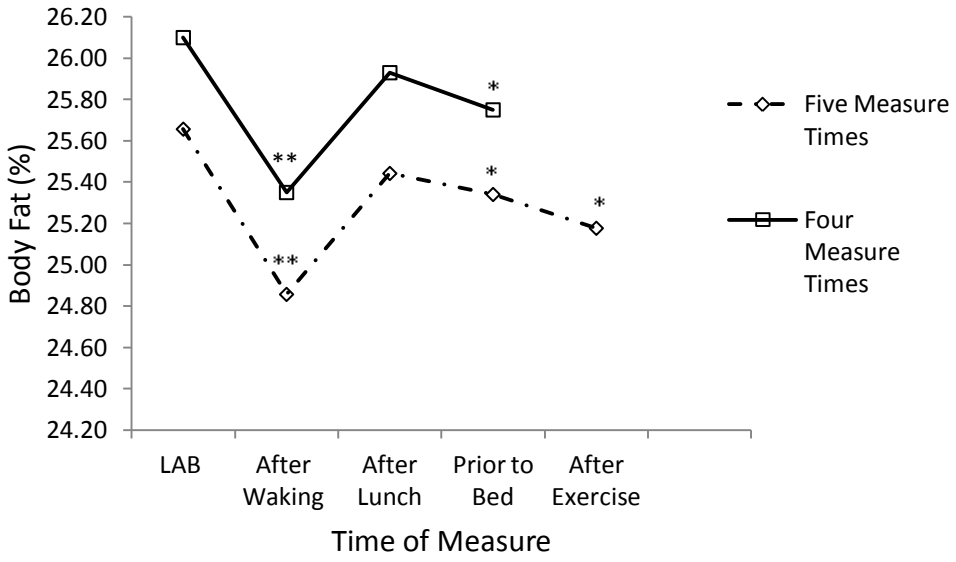
Because not all participants exercised, RM ANOVA was also performed using a subset of participants that completed all five measure times, the four free-living measures and the laboratory hand-held measure. Results indicated that there was a significant difference across the five measurement times (F(2.95,141.78) = 6.92, p<0.001). Post-hoc comparisons showed a statistically significant difference between the LAB and after exercise (p=0.004), specifically, with the measure after exercise underestimating that of the LAB measure. However, among the four free-living measure times there was only a difference of 0.3-0.8 percentage points as compared to the LAB setting, indicating that the hand-held device is clinically reliable over the course of one day. Table 6 displays mean BF measures over the free-living day for participants with four measures and participants with five measures. Figure 14 displays changes in BF estimates over the course of the free-living day and also compared to the laboratory setting.

Table 6. *Body Fat Measures Assessed by a Hand-held Bioelectrical Impedance Analyzer Over the Course of a Free-living Day.*

	4 Measure Times (*n*=88)		5 Measure Times (*n*=52)	
	Mean	SEE	Mean	SEE
LAB	26.1	0.9	25.7	1.1
T1	25.4**	0.9	24.9**	1.2
T2	25.9	0.9	25.5	1.1
T3	25.2*	1.2	25.3*	1.2
T4	—	—	25.2*	1.1

Note. * $p < 0.05$ significant difference from LAB measure, ** $p<.001$ significant difference from LAB measure. LAB=laboratory setting. Four measure times: LAB, T1=after waking, T2=after eating lunch, T3=prior to bed. Five measure times: LAB;, after waking, after eating lunch, prior to bed, and T4=after exercise.

Figure 14. Hand-held bioelectrical impedance analysis measures during the free-living day and laboratory setting.



Note. * $p < 0.05$ significant difference from LAB measure, ** $p<.001$ significant difference from LAB measure. LAB= laboratory setting. Solid line indicates analysis with four measure times: LAB, after waking, after eating lunch, prior to bed. Dotted line indicates analysis with five measure times: LAB, after waking, after eating lunch, prior to bed and after exercise.

Summary of Specific Aim 2

Data from this study on 88 females and males between, the ages of 19-39 and 55-75, demonstrate that the hand-held BIA device is not a statistically reliable device, on a group level, for estimating %BF over the course of a free-living day when hydration levels may be changing. Significant differences were found between the LAB measure and after waking, before bed and after exercise. No significant different was found between the LAB measure and after eating lunch, suggesting that after eating lunch may be the best time to take BF measures with the hand-held device. Although the differences were statistically significant, they are not considered clinically significant in the group, with a difference range of only 0.3-0.8 percentage points. Therefore, the hypothesis for Specific Aim 2 was not accepted.

Summary

Data from this study on 91 female and male participants, ages 19-75 years, showed that the hand-held BIA device was a valid tool for assessing body composition in the male and old groups on a population level, however, not on an individual level which is the intended use of the product. The hand-held BIA device was not a statistically valid tool for assessing body composition in the female and young groups on both a population level and an individual level.

The hand-held BIA device was found to be not statistically reliable when estimating %BF over the course of one free-living day. However, differences between BF measures over the free-living day were not clinically significant.

Chapter 5: Discussion

Introduction

Many individuals have taken to self-monitoring body composition often using portable, inexpensive assessment tools given physician recommendations or their own desire to reduce body fat (BF). Individuals use information about their body composition to help them make health-related decisions (e.g., dietary or physical activity changes, medications, medical procedures) and to track progress of an exercise or diet program, or other health intervention (Heyward & Wagner, 2004). The purpose of this study was to evaluate the validity and reliability of a commercially-available hand-held bioelectrical impedance analysis (BIA) device to estimate body composition for adults in a controlled laboratory condition and during a free-living condition.

Results from this study have demonstrated that the hand-held BIA device was not a clinically valid tool for assessing body composition in the female, male, young and old groups. Although the hand-held BIA device is valid for estimating %BF on a group level, the hand-held BIA device is marketed for and used by individuals. Bland Altman plots displayed large ranges of agreement for all groups, indicating that the device is not valid on an individual level. When examined on an individual level, only 52.8% of

females, 47.2% of males, 54.7% young and 45.3% old participants fell within the clinically acceptable range of ±3.5% from the criterion method.

The hand-held BIA device was found to be not statistically reliable when estimating %BF over the course of one free-living day. However, differences between BF measures over the free-living day were not clinically significant.

This chapter begins by discussing the influence of sex and age on the validity of body composition measures from the hand-held BIA device. The results are discussed in terms of their statistical significance as well as their clinical acceptability. To address clinical acceptability, the minimal acceptable standard for estimating %BF is ±3.5% BF from the criterion measure (Heyward & Wagner, 2004) will be employed. Next, the reliability of the hand-held BIA will be discussed. The significance of these results, both from a scientific and a practical perspective will be addressed. Limitations and assumptions of the current study will be outlined, and the impact of these limitations and assumptions on the results of this project will be reviewed. Finally, recommendations for future research will be explained.

The Influence of Sex on Validity of Body Composition Measures

It is well known that there are differences in body composition and body fat distribution between females and males. When examining validity of the hand-held BIA, the results of the study showed that there were statistically significant differences between %BF estimations from the hand-held BIA and the criterion measure (DEXA) and

a like method (tetrapolar BIA) in the controlled laboratory setting across sex. Results from this study show the HH BIA to be a statistically valid tool for assessment of body fat in males, but not females.

Previous literature has investigated differences in hand-held BIA estimates of %BF when compared to a criterion measure in females and males. However, previous research has used subject populations with different characteristics and some have used different models of hand-held BIA device. Therefore, the published literature contains conflicting conclusions about the validity of hand-held devices for estimating %BF.

One common theme among previous research is that the hand-held BIA device tends to be not only less accurate in females than males, but it tends to underestimate %BF more in females than males when compared to a criterion measure. In the current study, the hand-held BIA significantly underestimated %BF by 2.7 percentage points compared to DEXA for the female group. Although this was a statistically significant difference, this error falls within the clinically acceptable range (± 3.5%). There was no statistically significant difference between the hand-held BIA and DEXA for the male group, with the hand-held BIA only underestimating DEXA by 0.5 percentage points. These findings were similar to other previously published hand-held BIA validation studies. In a study focusing on a population of females and males similar in age to the young group of the current study, Weaver and colleagues (2009) examined the validity of the Omron HBF-306C and found results consistent with the current study. They employed a similar study design and included similar pre-testing hydration controls.

The researchers found that the only significant difference in %BF output from the hand-held BIA and the criterion measure was in women. There were no statistically or clinically significant differences between %BF output from the hand-held BIA and the criterion measure in men. Other researchers have found similar results. Gibson and colleagues (2000) and Duz and colleagues (2009) found that the %BF results from a hand-held BIA device significantly differed from a criterion measure. Both research groups found that the hand-held device, more often and to a larger degree, underestimated the body fat in women as compared to men. Additionally, Esco and colleagues (2011) found that a hand-held BIA device underestimated %BF when compared to DEXA in a group of college female athletes by a mean of 5.1 percentage points. Varady and colleagues (2007) showed that, in a group of 31 overweight women, %BF from a hand-held BIA device was significantly underestimated by a mean of 5.6 percentage points when comparing to MRI as a criterion measure for assessing body composition.

The common theme in this body of research is that the hand-held BIA tends to underestimate %BF in women to a greater extent than in men when compared to a criterion method. It could be argued that because women tend to carry a larger portion of BF in the gynoid area and men tend to carry a larger portion in the android area, body geometry could affect the results of the hand-held BIA. Hand-held BIA devices have to two handles that contain electrodes where the electrical current will be sent out via one electrode and received by the other electrode. The electrical current flows through the upper body and may not accurately assess lower body fat (Lukaski, 2003).

The results also demonstrated that there were no significant differences in %BF estimates between the DEXA and hand-held BIA device and DEXA and tetrapolar BIA in the male group. However, there were significant differences between the two BIA devices when estimating %BF in the male group. Males tend to have less subcutaneous fat than women and carry more FM in the android region. Having more centralized areas of BF could potentially influence the effectiveness of the whole body, tetrapolar BIA measure, as compared to a segmental hand-held BIA device. The trunk of the body provides little impedance to the current flow as opposed to the limbs, therefore, centralized body fat may not be accurately assessed (S.B. Heymsfield, et al., 2005; Stevens, et al., 2010). Additionally, BIA estimates TBW by way of electrical current through segments of the body and ultimately predicts BF and FFM. Given the heavy reliance on water content within tissues, there could be a difference in the relative FFM in the total body and upper body in males as compared to females (Dehghan & Merchant, 2008). Previous research has demonstrated that men have higher overall amounts of skeletal muscle than women, and sex differences are greater, specifically in the upper body (Janssen, Heymsfield, Wang, & Ross, 2000b). Tetrapolar BIA is a whole body method that places electrodes on the right hand and right foot whereas the hand-held BIA is a segmental device that only estimates TBW in the upper body (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). If there are differences in FFM distribution in the total or upper body in males, the impedance values will differ within person between devices.

Lastly, another factor that could affect validity of estimations of BF and FFM from BIA devices in males is the prediction equation used to estimate percent BF or FFM. For the hand-held and tetrapolar device, anthropometric and demographic variables are entered into the device prior to taking the measure. Because the prediction equations used in the QuadScan 4000 tetrapolar BIA and the Omron HBF-306C are proprietary, the equations are not known by the researcher. Therefore, it is unknown how heavily weighted the factors impedance values and anthropometric measures are in the estimation of BF.

Despite the numerous published studies where results are consistent with results of the current study, there is also some conflicting evidence to the current study. Deurenberg and Deurenberg-Yap (2002) conducted a validation study of the Omron BF-306 hand-held body fat analyzer using a four-compartment chemical model as the reference method in female and male Chinese, Malay and Indian subjects. Significant differences between %BF from the hand-held BIA and the reference method were found in Malay and Indian men, which is not consistent to findings in the current study that found no significant differences between DEXA and hand-held BIA estimates of %BF. The researchers also did not find a significant difference between the hand-held BIA and the reference method in females, which is also not consistent to the findings of the current study that found significant difference between the criterion measure (DEXA) and the hand-held BIA measure for females. A possible reason for different findings could be due to the fact that the participants were not given similar pre-testing instructions to control for hydration status as the current study. The published results

do not state any control for hydration. Bioelectrical Impedance Analysis devices assess TBW from which an estimate BF or FFM is calculated (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Total body water is assessed by impedance to the flow of an electrical current that is measured as an electrical current passes through the body between two electrodes on the hand-held device. The voltage drop in electrical current between electrodes is due to the impedance of the current flow. Body composition is estimated based on the principle that electrical current flows with less impedance in areas that have high water and electrolytes, such as skeletal muscle, compared to less hydrated tissues such as adipose tissue (Esco, et al., 2011a). Therefore, if the participants were not normally hydrated, the estimations of BF and FFM can be skewed, with those who are overhydrated having lower impedance values and those who are dehydrated having higher impedance values. Second, because there are known differences in body composition among different racial groups, those differences may introduce observed bias when using prediction equations from a hand-held BIA device that were validated on mostly White, European subjects. The population used in the study consisted of all Asian participants, who have higher body fat percentage on average compared to Whites (Wulan et al., 2009). Wang et al. (2000) also reported lower hydration of FFM in Asian individuals, which would result in higher impedance values as compared to White individuals. Furthermore, there are also differences in body fat percent between regions of Asia, such as Chinese, Indian and Malay individuals, which could increase observed bias (Wulan, Westerterp, & Plasqui, 2012).

Erceg and colleagues (2010) also found conflicting results to the current study. In a racially diverse sample of 128 females and 117 males, ages 18-80 years, they found no significant differences in %BF estimates from the Stayhealthy BC1 hand-held device as compared to the DEXA in the female or male groups. Whereas, the current study found that there were statistically significant differences between the BF measures from the hand-held as compared to the DEXA. They concluded that the hand-held BIA device is a valid tool for estimating BF among both groups. One potential reason for the contradictory results to the current study is that the Stayhealthy BC1 hand-held device may have different proprietary prediction equations for estimating %BF in males and females as compared to Omron models of hand-held BIA devices.

In summary, sex played a significant role in the validity of the hand-held BIA device. Body fat measures from the hand-held BIA were not significantly different compared to BF measures from DEXA in the male group. Although there was a statistically significant difference in BF measures from the hand-held BIA as compared to DEXA for the female group, the underestimation of 2.7 percentage points is not clinically significant. Therefore, the hand-held BIA could be considered a valid device for estimating BF in female and male groups on a population level. However, Bland Altman plots display a large range of agreement for both females and males, indicating that the device is not valid on an individual level. The smaller the range between these two limits the better the agreement is. That definition depends on the clinical acceptance standard for the method, which in this case is ±3.5%.

The Influence of Age on Validity of Body Composition Measures

It is well established that BF increases with age and FFM declines with age (Kyle et al., 2001); therefore, it is important to have valid devices to estimate body composition across the life span. This study found that age significantly influenced the validity of the hand-held BIA compared to DEXA in the young group but not in the old group.

There are conflicting results from previous research on the validity of a hand-held BIA device as it relates to age. However, few studies have included older adults in the population samples. Furthermore, of those that included older adults, none made direct comparisons between young and old groups. Based on the lack of information on validity of hand-held BIA between young and old groups, drawing conclusions may be difficult.

There are many factors that could potentially affect the validity of the hand-held BIA device in estimating %BF in the young group as compared to the old group. In the young group, there was a statistically significant underestimation of BF as compared to DEXA. Even more, the difference was 3.5 percentage points, which is at the limit for clinical significance. Younger adults tend to have more subcutaneous fat and less arm fat than older adults (Kuscmarski, 1989; Deurenberg & Deurenberg-Yap, 2002). Therefore, less arm fat in young adults will record in lower impedance values, which will result in lower BF estimates in young adults by the hand-held BIA device.

In the old group, there was no statistically significant difference between DEXA and the hand-held BIA; however, there was a significant difference between the two BIA devices. There are a few potential reasons why different types of BIA devices could estimate BF differently in the old group. Older adults tend to have less subcutaneous fat and carry more FM in the android region as compared to young adults (Kuczmarski, 1989). Having more centralized areas of BF could potentially influence the effectiveness of the whole body, tetrapolar BIA measure, as compared to a segmental hand-held BIA device (Stevens, et al., 2010). As previously mentioned, the trunk of the body provides much less impedance to the current flow than the limbs, therefore, centralized body fat may not be accurately assessed (S.B. Heymsfield, et al., 2005; Stevens, et al., 2010).

Additionally, as adults age, there is an increase in intramuscular fat and arm fat (Deurenberg & Deurenberg-Yap, 2002b). This will affect the ratio of fat and TBW in the arms, which can affect the impedance values. Body composition is estimated based on the principle that electrical current flows with less impedance in areas that have high water and electrolytes, such as skeletal muscle, compared to less hydrated tissues such as adipose tissue (Esco, et al., 2011a). Therefore, if the hand-held BIA is measuring impedance only in the arms and upper body, impedance values may be different from a whole body tetrapolar BIA measure that assess lower body, trunk and arms.

Lastly, the differences in criterion measure from the original validation of the device compared to the current study could potentially have an effect between the young and old groups. The Omron HBF-306C was originally validated against both HW

and DEXA, whereas, the current study only used DEXA as the criterion method. When assessing body composition with HW, an assumption is made that there is no difference in densities of FFM across all individuals (Wagner & Heyward, 1999). However, there are known differences in BF and FFM in young and old adults, therefore, the method is only as good as the conversion formula employed (Kyle, et al., 2001).

In summary, age played a significant role in the validity of the hand-held BIA device to accurately estimate %BF in the current study. There was a statistically significant difference between DEXA and hand-held BIA in the young group. This significant difference was also nearing a clinically significant difference, with an underestimation of %BF by the hand-held BIA by 3.5 percentage points. There was no significant difference between the %BF estimates between DEXA and hand-held BIA for the old group. Therefore, the hand-held BIA would be considered a valid device, on a population level, for these two groups. However, Bland Altman Plots visually suggest large ranges of agreement between DEXA and the hand-held BIA, suggesting that the device is not valid on an individual level for young or old groups.

Influence of Body Fat Level on the Validity of the Hand-held BIA Device

One finding from this study that is consistent with previously published validation studies is that the hand-held BIA tends to underestimate %BF as mean BF increases and overestimate %BF as mean BF decreases. In the current study, this trend was found in both the young and old groups. Weaver and colleagues (2009)

demonstrated similar over- and underestimations among a group of individuals aged 18-32 years, similar to the young group of the current study. Esco and colleagues found that in young females, the hand-held BIA significantly underestimated %BF as compared to the DEXA as mean BF increased. Lukaski and colleagues (Lukaski & Siders, 2003) found that both hand-held and foot-to-foot segmental BIA devices significantly underestimated %BF as total body fat increased in a group of individuals ages 18-60 years. Finally, Duz and colleagues found, in both men and women, that the hand-held BIA significantly underestimated %BF as mean BF increased in a group of young, healthy adults. This difference in under- and overestimating BF for extremely lean and obese individuals is due to regressing each individual to the mean BF within the prediction equation. Equations are not meant to predict extremes, rather, are created to predict something that is more central to the mean. Therefore, those that are overfat tend to have an underestimation of BF by the hand-held BIA and those that are underfat tend to have an overestimation of BF by the hand-held BIA.

In contrast, Erceg and colleagues (2010) did not find this trend in their subject sample as a whole, with age ranges from 18-80y. However, they used a different make and model of a hand-held BIA device than the current study which may use different technology and different prediction equations when estimating %BF.

Reliability of the Hand-Held BIA Device in Assessing Body Composition

The ability of a body composition assessment device to provide consistent estimates of body composition over the course of a day or between days is very important when using the device to determine change, or lack of change, in body composition. There are very few studies that have examined the reliability of hand-held BIA devices to estimate body fat levels after an event where hydration is expected to change in a single day (Weaver, 2009) and over the course of multiple days (Lukaski et al., 2003). Results of these two studies are not consistent, with one showing the device is reliable, and one demonstrating the device is not reliable. This study aimed to build on the limited published literature and address the question of reliability within day using a novel concept in assessing changes in BF output based on different times of a free-living day when hydration level may vary in individuals in the entire subject sample. It was hypothesized in the current study that significant variations in BF were expected during the free-living day demonstrating that, when pre-test instructions were not followed, results may not be reliable and should not be used to make-health related decisions.

In the current study, the only factor that had a statistically significant interaction with the %BF output by the hand-held device was the time of measure. It was found that there were statistically significant differences between BF measures from the LAB and three of the free-living measure times: after waking and voiding bladder, prior to bed and immediately after exercise. No significant difference was observed between

the LAB measure and after eating lunch during the free-living day. Although the current study found statistically significant differences in BF estimates during the free-living day as compared to the LAB, those differences were minimal and fall within a clinically acceptable range.

The hand-held device is a popular method to assess BF in health clubs, where clients often chose to self-assess their BF prior to or after exercise. It is important to note that after a bout of exercise, TBW would be expected to change, therefore, potentially altering %BF estimates from a hand-held BIA device. In the current study, there was a statistically, but not clinically, significant difference between the controlled LAB measure and after exercise measured during the free-living day. This current finding was also consistent with the finding reported by Weaver and colleagues (2009) when examining the changes on %BF measures from a hand-held BIA device during a controlled laboratory setting when pre-testing guidelines compared to after a 30 bout of exercise. They found that body fat decreased significantly by 0.3 percentage points post-exercise indicating there was no clinically significant difference. These findings suggest that hydration status or TBW may not be heavily weighted in the propriety prediction equation used to estimate %BF with a hand-held BIA device. Based on the findings of the current study, it is concluded that hydration status does not play a large role in the prediction equation of the Omron HBF-306C device, therefore, these factors do not significantly affect the %BF output from the device.

Because the prediction equation used in the Omron HBF-306C to estimate BF is proprietary, how different variables are weighted in the equation is unknown. Prior to assessing BF using the Omron HBF-306, individuals must enter their height, mass, age and sex. In previously published prediction equations for healthy adults, the most common variables include sex, age, stature (height), weight (mass) and resistance (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004; Sun et al., 2003). There are also previously validated equations for specific groups and ethnicities that may not be valid for the general population (Kyle, Bosaeus, De Lorenzo, Deurenberg, Elia, Gomez, et al., 2004). Each validated and published BIA prediction equation places more emphasis on certain variables and less on others. The results of the current study suggest that hydration status or impedance values may not be heavily weighted in the proprietary prediction equation in the hand-held BIA device. Other factors that could potentially cause changes in hand-held BIA %BF over the free-living day include skin temperature, skin integrity, correct placement of hands on the electrodes and proper arm abduction and straightness when taking the measure. However, the current study did not control for these variables. Participants were given instructions about placement of hands and arms while using the hand-held BIA device, but it was not monitored.

In addition to these findings, Lukaski and Siders (2003) found large day-to-day variations in %BF measures over a five day period with the Omron HBF-301 hand-held BIA device. They randomly selected 10 of the 110 participants to monitor BF over the 5 day period to determine how much variation would occur. There is no mention of time of day the measures were taken or if there was any control for hydration status. They

found that with body mass only changing by approximately 1% over the five days, that the estimated BF had a variation of 2-10% over the five days. They concluded that the ability to monitor BF over time and changes in body fat is still in question. The current study found no clinically significant differences over the course of the day; however, these results indicate that, possibly, over a longer period of time, the hand-held device may not be reliable in estimating BF. Further investigation is needed to determine reliability of the hand-held device over days, weeks or months.

The current study found that there are statistically significant differences in %BF measures with the hand-held BIA over the course of a free-living day when compared to the LAB measure. Only one measurement time during the free-living day was not statistically significant; after eating lunch. However, the statistically significant differences are small, 0.2-0.8%, and fall within a clinically acceptable range. The main finding is that the hand-held device is clinically reliable in estimating %BF over the course of a free-living day. However, this study did not investigate the reliability over days or weeks and these results cannot be used to indicate changes in body composition over time.

Significance

Scientific Significance

When examining the validity and reliability of a hand-held BIA, numerous gaps in the literature exist. The results of this study add to the literature by addressing some of those gaps.

The first gap in the literature is the knowledge of the validity of the hand-held BIA in estimating BF across sex. Previous research has investigated these relationships; however, conflicting results have been documented (Deurenberg & Deurenberg-Yap, 2002; Erceg et al., 2010; Weaver et al., 2009). The amount of BF and BF distribution is most often different between men and women, and it is important to determine if those differences alter the validity of the device.

The findings also add to previous literature because there is a gap in information and knowledge on the accuracy of hand-held devices across a large age span. Most of the previous research has been completed using young adults, rarely including subjects over the age of 60 (Deurenberg & Deurenberg-Yap, 2002; Erceg et al., 2010). This is important because of the changes in FM and FFM as adults age. These changes in FM and FFM pose a challenge when selecting a body composition method to accurately assess differences between young and old groups.

Additionally, only one of the previous studies on hand-held BIA devices has controlled for hydration using all of the ACSM pre-testing guidelines (Weaver et al., 2009). It has been documented that hydration and TBW play a large role in the ability of BIA devices in estimating BF (Kyle et el., 2004). Based on the results of the current study, it may not be necessary to abide by the pre-testing guidelines when using the hand-held BIA as a measure of body composition in a group.

There is also a lack in information about the reliability of hand-held devices in estimating %BF, especially within one day. Only two published studies have examined

the reliability of the hand-held BIA in estimating %BF during times of hydration changes, and have found conflicting results (Weaver et al., 2009; Lukaski & Siders, 2003). The current study adds a novel component of a free-living situation to assess the reliability over time and across changes in hydration status.

Practical Significance

Because the Omron HBF-306C BIA is commercially available it could be purchased by any individual interested in self-monitoring or changing their body fat level. Individuals may use the results from this device to make health-related decisions such as modifying a diet or exercise program or altering medications that may affect body weight or body fat. If individuals are not receiving accurate BF results, they may elect to alter their lifestyle or diet in a way that may be detrimental to their health. Although the current study's results indicate that the device is a valid and reliable tool for assessing BF, there is still some concern about the validity on an individual level. There is a high level of disagreement between the hand-held BIA and the criterion method of DEXA, indicating that the two methods do not provide similar measures and should not be used interchangeably.

Assumptions

There were three main assumptions for this study. First, it was assumed that all participants were honest when answering screening questions to determine eligibility for study participation. Second, it was assumed that all participants followed the pre-testing guidelines prior to the first lab visit for the body composition assessments. Third, it was assumed that, during the free-living day, all participants followed the study instructions given to them at the first Laboratory visit, were gripping electrode properly and were honest when recording their %BF from the hand-held BIA throughout the day.

Limitations

No study is without limitations. This study contained a few limitations that should be considered when interpreting and applying the results. First, the results are only generalizable to a similar population studied within this project, a population that was free of any disease or medication that can alter hydration status and between the ages of18-39 years or 55-75 years of age. Additionally, because of the known differences in body composition between races, the results of the current study can only be generalizable to White individuals. Lastly, there was no control for menstrual cycle in the female group; however, previous research has demonstrated that there are not significant changes in TBW during a female's menstrual cycle (McKee and Cameron, 1998).

Future Research

This study provided results that added to the current body of knowledge focusing on BIA technology, specifically hand-held BIA technology. From these results, however, a number of additional questions were generated. Results demonstrated that the hand-held device was statistically valid in adults ages 55-75 but not for adults ages 18-39. Changes in body composition with age play a role in the validity of the hand-held device and should be explored. Due to differences in body composition between race, future research should investigate the validity and reliability of the hand-held device among races other than White. Many researchers have developed BIA prediction equations for specific ethnic groups; therefore, it is known that ethnic differences BIA devices to estimate BF. The Omron HBF-306C does not have an input for ethnicity; therefore, ethnicity is not accounted for when predicting body fat level. If future research demonstrates that the device is only valid within White individuals, then it is important the prediction equations be created for use by other ethnicities.

Because the results suggested that the hand-held BIA device is only reliable over the course of one day, future research should focus on reliability of the device across an extended period of time. Additionally, it may be worth investigating if the BIA device is also reliable with fluctuations in body mass over time. Results also indicated that the hand-held BIA device was only valid after eating lunch, which is not a recommended time for BIA measures (ACSM, 2006). Future research could focus on the reliability over time to investigate if that is the optimal time to take the BF measures.

There are also some technical limitations to the current device. The device is only able to estimate body fat between 4-50%. Future research could focus on new devices or prediction equations that can accurately assess BF in those that are extremely lean or excessively obese. Due to health complications that can arise from both of those extremes, it is important that those individuals are able to accurately estimate body fat to make necessary health-related decisions.

Final Conclusion

The main finding of the current study is that, according to clinical standards, the Omron HBF-306C is a valid device for estimating %BF across age and sex on a population level. Although there were statistically significant differences between %BF measures from the hand-held BIA device and DEXA for the females and young groups, that difference falls within the minimal clinically acceptable standard for estimating %BF of ±3.5% BF from the criterion measure (Heyward & Wagner, 2004). However, the validity results must be viewed with caution when estimating %BF on and individual level, which is the marketed use of the product. Examination of Bland Altman Plots depicts large ranges of agreement between the BF estimates from the hand-held BIA and the DEXA in all groups: female, male, young and old. Therefore, the hand-held BIA device is not a valid tool for assessing BF on an individual level. It is important to note that sex and age were the only two variables that impacted the validity of the hand-held BIA device as

compared to the DEXA and tetrapolar BIA. There was no interaction with device and arm span, waist circumference and BMI.

Additionally, the Omron HBF-306C is a reliable device for estimating %BF on a population level over the course of one day. Although there were some statistically significant differences in %BF estimates from the free-living day compared to the LAB measure, the differences were not clinically significant. Future research is warranted for reliability over multiple days, weeks or months.

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APPENDIX A: RECRUITMENT FLYER

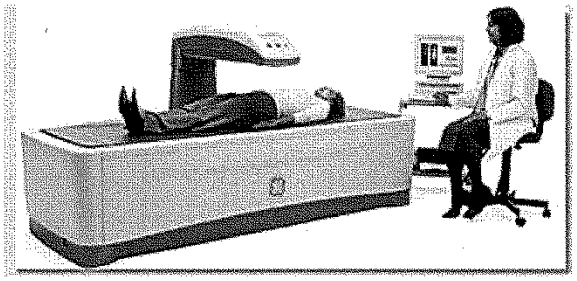
Research Opportunity

FREE Body Composition Assessment!

Would you like to have your body fat measured by a **gold standard** method?

The Physical Activity & Health Research Lab at UWM is looking for men and women (18-39 and 55-75 yrs old), White and healthy to take part in a research study on the validity of hand-held body fat analyzers.

For more information, please call or e-mail
Lynn Wheeler
(414)-229-4392
hoffma67@uwm.edu



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APPENDIX B: SCREENING FORM

Physical Activity & Health
Research Lab
Department of Human Movement Sciences
Enderis Hall, Rm. 434 (414)229-4392

CALL LOG:	DATE/ TIME	COMMENT

Hello, my name is _____ and I am a_____ working with the Physical Activity & Health Research Laboratory at the University of Wisconsin-Milwaukee. You have indicated that you are interested in participating in physical activity research with our Lab. If you have a moment, please let me tell you about a study that we are currently working on. It is a study designed to examine the validity of a hand-held body fat analyzer. Before I tell you about the study, do you mind if I ask you a few questions about yourself to determine if you qualify for the study.

1. What is your current age?_____ Date of birth: _____

   *The individual qualifies if aged 18-40 and 50-75 years.

2. What is your gender: M F
3. What is your ethnicity: _____ *Individuals qualifies if white.
4. Are you currently pregnant, think you could be pregnant or nursing? ☐ Yes ☐ **No**
5. Have you been diagnosed with congestive heart failure, cardiomyopathy disease, heart valve disease or have a pacemaker? ☐ Yes ☐ **No**
6. Have you been diagnosed with any pulmonary disease such as Chronic Obstructive Pulmonary Disease? ☐ Yes ☐ **No**
7. Do you have a metabolic disease such as diabetes or thyroid disease? ☐ Yes ☐ **No**
8. Have you ever been diagnosed with Cirrhosis or kidney disease? ☐ Yes ☐ **No**
9. Are you currently taking a diuretic medication, calcium channel blockers or other substance that would affect hydration status of the body? ☐ Yes ☐ **No**
10. Have you had a barium or nuclear medical test within the past week? ☐ Yes ☐ **No**

11. Please self-report your height and weight:

Height: _____ Weight:_____

*****They are eligible to participate if:**

- INDIVIDUAL ANSWERS "NO" TO QUESTIONS ABOVE
- IS BETWEEN 18-40 and 50-75 YEARS

IF THEY QUALIFY…

You are one of 120 men and women who are being asked to participate in this study at the Physical Activity & Health Research Laboratory of the University of Wisconsin-Milwaukee. This research study will consist of two laboratory visits separated by one unsupervised free-living day

Visit 1:

On the day of your first visit, you will report to the Physical Activity & Health Research Laboratory. A pregnancy test will be conducted for all female participants prior to any assessments. If you are pregnant or nursing or trying to become pregnant, you will not be able to complete portions of the study, and therefore, are ineligible. We will ask you to provide us with some information on your current and previous health. Additionally, we will ask you to complete five pen and paper questionnaires. Next, measures of resting heart rate and blood pressure as well as anthropometric measures of body weight, standing height, arm span, and waist and hip circumference measures will be taken. You will then have their body fat measured by three separate devices: tetrapolar bioelectrical impedance analysis (BIA), dual-energy x-ray absorptiometry (DEXA), and a hand-held BIA. Following BIA guidelines, you will rest supine for five minutes, after which body fat levels will be assessed using the tetrapolar BIA, followed by a DEXA scan. After completion of the supine body fat measures, you will be asked to stand where two consecutive body fat measurements will be completed with the hand-held BIA. Once body fat measures are completed, you will receive detailed verbal and written instructions on how to use the hand-held BIA for the free living day, including specific times of the day to take and record BF measures. In addition, you will be given instructions on the proper wear of a physical activity assessment device that you will wear for the free-living day as well as instructions to record body fat readings from the hand-held BIA that will be completed during the free-living day.

Free-living Day:

You will bring home the Omron HBF-306C hand-held BIA device. Within 72 hours of the laboratory visit, you will be asked to assess BF via the Omron HBF-306C device at specific times of the day: 1) immediately upon waking and voiding bladder, 2) immediately after eating lunch, 3) right before going to bed, and 4) immediately after exercising (if exercise was done during the day) all within one 24 hour time period. In addition, you will wear the physical activity assessment device during the same 24 hour time period and complete a daily event log for all activities performed during that time as well as any food, beverage or medications ingested.

Visit 2:

Within 48 hours of the free-living day, you will return the hand-held BIA device to the laboratory where they will be provided with results from their DEXA and tetrapolar BIA measurements. You will be asked to complete five questionnaires after receiving your DEXA and tetrapolar BIA measurements.

Just a few more questions…

1. Is there any reason why you cannot complete this study?
   □ Yes □ **No**
2. Do you have any medical conditions or vacations scheduled which would interfere with completion the study.

   □ Yes □ **No**

Are you still interested? IF YES, SCHEDULE THEM FOR THE STUDY

IF THEY DO NOT QUALIFY…

Unfortunately, due to _____ you do not qualify to participate in this project at this time. If you would like to be contacted in the future for other studies taking place in the Physical Activity and Health Research Lab, I would can keep your name on file. Would you like to hear about such studies in the future?

□ Yes □ **No**

Initials and date of person who filled out this form_____

APPENDIX C: INFORMED CONSENT

UNIVERSITY OF WISCONSIN – MILWAUKEE
CONSENT TO PARTICIPATE IN RESEARCH

1. GENERAL INFORMATION

Study title: Validation of hand-held bioelectrical impedance analysis for the assessment of body fat in young and old adults.

Person in Charge of Study:

Ann M. Swartz, Ph.D.
Associate Professor
Department of Human Movement Sciences
University of Wisconsin – Milwaukee

2. STUDY DESCRIPTION

Study description:

The primary purpose of this study is to examine the accuracy of a hand-held body fat analyzer. You will be one of 120 White individuals (18-39yrs or 55-75yrs) participating in a research study at the Physical Activity and Health Research Laboratory of the University of Wisconsin-Milwaukee. The study will be conducted over two visits, separated by one free-living day (24 hours). The free-living day must be completed within 72 hours of the first laboratory visit. The first laboratory visit will last approximately one hour and 15 minutes. During the first visit, a pregnancy test will be conducted prior to any assessments. If you are pregnant or nursing or trying to become pregnant, you will not be able to complete portions of the study, and therefore, are ineligible. You will be asked to complete a questionnaire on your current and previous health history, as well as demographic information. You will be asked to complete an additional six, short questionnaires and have your height, weight, waist and hip circumference, arm span, bone mineral density, and body fat assessed. During the free-living day you will be asked to measure and record your body fat using a hand-held body fat analyzer four times in one day, and wear a physical activity assessment device. After completion of the free-living day you will be asked to return to the laboratory for your final visit. At the final visit, you will return the hand-held body fat device and be given

the results of the bone mineral density and body fat assessments. Following this, you will be asked to complete six, short surveys. Participation in the research study is completely voluntary, and you do not have to participate if you do not want to.

3. STUDY PROCEDURES

What will I be asked to do if I participate in the study?

This research study will consist of two visits to the Physical Activity and Health Research Laboratory of the University of Wisconsin-Milwaukee separated by one unsupervised free-living day. The free living day must be completed within 72 hours of the first laboratory visit.

Lab Visit #1 (approximately 1 hour and 15 minutes in duration)

Pre-Visit Instructions

Prior to attending the fist lab visit, you will be given the following pre-visit guidelines via telephone and/or email, depending on your communication preference:

- Do not consume alcohol 48 hours before laboratory visit 1
- Do not consume products with diuretic properties (caffeine, chocolate) for 24 hours before laboratory visit 1
- Do not exercise 12 hours immediately before laboratory visit 1
- Do not eat or drink anything except water 4 hours immediately before laboratory visit 1
- We will ask you to void your bladder 30 minutes prior to the body fat assessments

On the day of your testing session, you will report to the Physical Activity and Health Research Laboratory. At the time of this visit you will be given an introduction to the study.

Pregnancy Test

In order to ensure that you are not pregnant for the body composition assessments, we will ask you to perform a pregnancy test if you are a woman of child-bearing age. You

will be escorted to a nearby restroom for completion of this test. You will be provided with a stick for the pregnancy test. You will be asked to remove the cap of the stick and hold the stick in your urine stream. You will then recap the stick, and give it to the researcher. The researcher will place it in a plastic bag and escort you back to the lab. The pregnancy test will then be placed on a horizontal surface for 5 minutes, afterwhich the results will be available. If the stick shows one line, this will indicate that you are NOT pregnant. If the stick shows 2 lines, this indicates that you ARE pregnant (positive test). If this test confims a pregnancy, we will discontinue your participation in the study, and will provide you with some educational information from Norris Health Center about pregnancy and refer you to your family physician. According to the manufacuter, this test is 99.9% accurate.

Demographic Measures

You will be asked to complete a questionnaire on your current and previous health status and demographic information. These measures will be completed in order to gather necessary information to ensure that you meet the inclusion/exclusion criteria for this study.

Questionnaires

You will be asked to complete six questionnaires. The information from these questionnaires will help to create a better overall description of the research participants in the study. The first three questionnaires will be used to assess your motivation to change your exercise habits, your calorie and fat intake, and your weight. These questionnaires range in length from one to four questions. The next questionnaire will be used to assess your satisfaction with various parts of your body. This is a 9-item questionnaire using a Likert scale. You will be asked how strongly your agree or disagree with various statements about your body. Another questionnaire will assess anxiety about your physical appearance. You will be asked to answer each question based on how you are feeling at the current moment. The final questionnaire consists of questions asking you to provide your estimate or opinion about your body, your body weight, the amount of fat within your body, how your levels rank compared with other women your age. This questionnaire will also include questions regarding whether you have had your body fat measured before and with what method(s) or tool(s). It will take approximetly 10-15 minutes to complete these surveys, and it is important to take your time with the surveys and answer each question honestly and completely.

Baseline Measurements

You will have your height, weight, arm span and the distance around your waist and hips measured. We will measure resting blood pressure and heart rate. To measure blood pressure, we will place a cuff around the upper right arm. This cuff will be inflated with air, and then slowly let down again. By listening to the sound of the pulse in the arm we are able to determine a blood pressure reading.

Body Fat Measure 1

We will measure your body fat with a tetrapolar bioelectrical impedance analysis (BIA) device (Bodystat® Quad Scan 4000; Douglas, Isle of Man). You will be instruted to lay still on the padded table and your body will be positioned properly for the measurement. After five minutes of rest, the back of your right hand and the top of your right foot will be cleaned with an alcohol pad. Once your skin has dried, two stickers will be placed on the back of the right hand and two on the top of the right foot. The technician will attach the cords from the body fat measuring device to the electrode stickers and will administer the test. This test will take approximately one minute. A very low frequency current is sent from electrode to electrode in the hand and foot and body fat will be estimated. This test is included solely for research purposes. This is a non-invasive, safe, and painless procedure.

Body Fat Measure 2

The second measure of body fat, will consist of assesment with a dual energy x-ray absorptiometer or DEXA scan. We will be using this device to measure your body fat level, but it will also measure the strength of your bones (bone mineral density). At the end of the study we will provide you with the results from this measure, which will include your body fat level and the strength of your bones. This is a common and painless procedure that involves lying still on a padded table for approximately 10 minutes while the machine takes an x-ray picture of your whole body. During the test you will be able to breathe normally. Because the test involves taking an x-ray picture of your body, you will be exposed to radiation. However, the amount of radiation used for this test is very low. It is about the same amount one would get on a long plane flight (from New York to Los Angeles) and much less than one is exposed to during a typical chest x-ray. This test is included solely for research purposes and is not considered part of your standard clinical care. Please do not wear clothing with any metal (buttons, snaps, or zippers) on the day of the test. If you do wear metal, we will ask you to remove it for the test. If you have recently had x-ray tests using barium or any nuclear medicine tests, you should have your DEXA scan performed at least a week after those tests.

Body Fat Measure 3

Body fat will be estimated using a third device, a hand-held bioelectrical impedance analysis, or BIA, device. This portable and lightweight device measures body fat using by sending a very low frequency current from the electrode on one handle to the electrode on the other handle. You will be asked to stand upright and to grip the handles of the device firmly and extend arms out straight in front of your body, parallel to the floor. After the first measure is completed, you can relax for 60 seconds, and then a second measure will be taken with the hand-held device. Each measure will not take more than 20 seconds. This test is included solely for research purposes. This is a non-invasive, safe, and painless procedure.

Accelerometery & Accelerometer Instructions

You will receive instructions on the correct use of the acclerometry-based motion sensor that we would like you to wear for all waking hours of the 24 hour free-living day, except when you are showering and swimming- because this device is not waterproof . This device is about the size of a matchbox and will be worn on an elastic belt that will be provided to you around your waist. Although you will not be able to glean any information from this device while you wear it, it will be measuring the intensity of activity in which you are engaging. In order to obtain the data, the device must be downloaded onto a computer using the necessary software.

Hand-held BIA & Event Log Instructions

You will receive instructions on the use of the hand-held BIA device to use at home as well as instrutions on recording the body fat measures. Items that will be documented in the event log include the following: waking time, time of any food, beverage or medicine comsumption, time of any structured exercise such as running or cycling (if you exercise during that day), time of any leisure activites throughout the day such as casually walking the dog or activities with friends, activities of daily living such as shoveling the snow or mopping the floor, and hand-held BIA body fat measures at the four pre-selected times.

Free-living Day

The free-living day should be a typical day for you. Please do not alter your dietary or physical activity patterns from your normal or typical daily rountine.

Hand-held BIA Measures & Event Log Completion

You will bring home the hand-held BIA device. Within 72 hours of the laboratory visit, you will be asked to measure body fat with the hand-held BIA device at specific times of the day: 1) immediately upon waking and voiding bladder, 2) immediately after eating lunch, 3) right before going to bed, and 4) immediately after exercising (if exercise was done during the day). Additionally, you will be asked to complete an event log during the free-living condition. Items that will be documented include the following: Waking time, time of any food or beverage comsumption, time of exercise (if they exercise during that day), time of any leisure activites throughout the day, and hand-held BIA body fat measures at the four pre-selected times.

Lab Visit #2 (approximately 25 minutes in duration)

Within 48 hours of the free-living day, you will return the hand-held BIA device to the laboratory where you will be provided with results from the measures on lab visit #1: DEXA and tetrapolar BIA measurements. You will also be asked to complete a few questionnaires.

Questionnaires

You will be asked to complete six questionnaires after receiving your DEXA and tetrapolar BIA measurements. If you wish to not receive the results from the DEXA and tetrapolar BIA measures, you will not complete the five questionnaires. These questionnaires will include four that you completed on your first visit: the three questionnaires assessing your motivation to change your exercise habits, your calorie and fat intake, and your weight as well as the questionnaires assessing your satisfaction and anxiety with various areas of your body. Finally, you will be asked to complete a questionnaire addressing your reaction to your body fat results. It will take approximetly 10-15 minutes to complete these surveys, and it is important to take your time with the surveys and answer each question honestly and completely.

4. RISKS & MINIMIZING RISKS

What risks will I face by participating in this study?

You will face very minimal risks by participating in this research study. The main risks you face by participating in this research study include risks associated with the body fat test (DEXA scan). While taking part in this study as a participant, as a part of the research, you will be exposed to a small amount of radiation during the body fat test. The overall effect of radiation on the human body is measured in terms of Roentgen equivalents in man, or "rem", which is a unit of uniform whole body exposure. Radiation you will be exposed to in this study will amount to 0.00004 rems. The effects on your body of this radiation exposure will be added to your overall lifetime radiation risk. Your lifetime radiation risk includes the background radiation you are exposed to naturally like everyone else living on this planet, which is on the average 0.3 rem per year. In terms of radiation a person may get exposed to during medical care, the amount you will receive in this study will be small compared to the amount of radiation received during a routine chest x-ray, which is 0.01 rem. The risk of harm from radiation exposure of this amount is too small to estimate.

There is also a risk of psychological stress when having your weight, height, waist and hip circumference, and body fat measured. You will have the option of not receiving any of this information to reduce this risk of psychological stress. If you would like this information, we will fully explain and interpret all of your results.

There is a chance that the adhesive used on the tetrapolar BIA electrodes may cause some mild skin irritation, in the form of redness, similar to the redness seen after taking off a band-aid. Additionally, you will be asked to shave body hair from the wrist and ankle area, where electrodes will be placed, if there is an excessive amount of body hair. There is a possiblity that the razor could cause mild skin irritation or a potential cut to the skin.

As with any research study, there may be additional risks of participating that are unforeseeable or hard to predict.

5. BENEFITS

Will I receive any benefit from my participation in this study?

Yes, we will provide you with information on your bone mineral density and body fat if you would like this information. The researcher will not provide any medical diagnosis as the result of the study.

Are subjects paid or given anything for being in the study?

Extra credit will be offered to students at the discretion of professors. No monetary compensation will be given for participating in the study.

6. STUDY COSTS

Will I be charged anything for participating in this study?

You will not be responsible for any of the cost associated with participating in this research study. However, you will be responsible for transportation and/or parking fees when attending the laboratory visits.

7. CONFIDENTIALITY

What happens to the information collected?

The information collected in this study is kept strictly confidential. Only the people directly involved in this study will have access to the information. However, the Institutional Review Board at UW-Milwaukee or appropriate federal agencies like the Office for Human Research Protections may review your records. Your name will never be associated with any of the information collected. Your name will be associated with an identification number which will not allow your information to be traced back to you. We may decide to present what we find to others, or publish our results in scientific journals or at scientific conferences. If this happens, your name will never be associated with any of the data collected, and your identity will always remain strictly confidential. All research data is stored electronically on a password protected computer as well as in hard copy in a locked cabinet.

8. ALTERNATIVES

Are there alternatives to participating in the study?

There are no known alternatives available to you other than not taking part in this study.

9. VOLUNTARY PARTICIPATION & WITHDRAWAL

What happens if I decide not to be in this study?

Your participation in this study is entirely voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study. You are free to not answer any questions or withdraw at any time. Your decision will not change any present or future relationships with the University of Wisconsin Milwaukee. The investigator may stop your participation in this study if she feels it is necessary to do so or if the results of the pregnancy test confirm a pregnancy.

10. QUESTIONS

Who do I contact for questions about this study?

For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Ann M. Swartz, Ph.D.
Associate Professor
Department of Human Movement Sciences
University of Wisconsin – Milwaukee
P.O. Box 413, Milwaukee, WI 53201
Telephone Number: (414) 229-4242

Who do I contact for questions about my rights or complaints towards my treatment as a research subject?

The Institutional Review Board may ask your name, but all complaints are kept in confidence.

Institutional Review Board
Human Research Protection Program
Department of University Safety and Assurances
University of Wisconsin – Milwaukee
P.O. Box 413
Milwaukee, WI 53201
(414) 229-3173

11. SIGNATURES

Research Subject's Consent to Participate in Research:

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read or had read to you this entire consent form, including the risks and benefits, and have had all of your questions answered, and that you are 18-40 or 50-75 years of age.

_____

Printed Name of Subject/ Legally Authorized Representative

_____ _____

Signature of Subject/Legally Authorized Representative Date

Principal Investigator (or Designee)

I have given this research subject information on the study that is accurate and sufficient for the subject to fully understand the nature, risks and benefits of the study.

_____ _____

Printed Name of Person Obtaining Consent Role on Study

_____ _____

Signature of Person Obtaining Consent Date

APPENDIX D: HEALTH HISTORY QUESTIONNAIRE

Physical Activity & Health Research Lab

Department of Human Movement Sciences

Enderis Hall, Rm. 434 • (414)229-4392

PROJECT ID	HEALTH HISTORY AND DEMOGRAPHIC QUESTIONNAIRE	CURRENT DATE

Name: _____

Address: _____
City: _____ **ZipCode:** _____

Phone: _____ **Date of Birth:** _____ **Current Age:** _____

E-mail address: _____

Gender (circle one): M F If Female, have you reached menopause? (circle one) Yes No
If YES, at what age? _____
Are You Pregnant or Breast Feeding Or Trying To Get Pregnant? Y N

Do you currently have any diagnosis of congestive heart failure, cardiomyopathy disease, heart valve disease or have a pacemaker? (circle one): Yes No

Do you currently have a diagnosis of Cirrhosis, kidney disease or metabolic disease such as diabetes or thyroid disease? (circle one): Yes No

Have you been diagnosed with any pulmonary disease such as Chronic Obstructive Pulmonary Disease? (circle one): Yes No

Occupation: _____ **Full Time? (circle one):** Yes No

Marital Status (circle one): Single Married Divorced Widowed

Education (circle highest level completed): Elementary High School College Graduate School

Race (circle ethnicity): White American Indian Asian Hispanic

Black / African American Native Hawaiian / Pacific Islander

Are you taking any prescription or over-the counter medication? (circle one) YES NO
If YES, please indicate the names, reasons, and how long you have been taking the medication below.
Name of Medication Reason for Taking For How Long?

_____

_____

_____

Emergency Contact Information:
Name: _____
Relationship: _____ Phone: Work: _____
Home: _____
Personal Physician Name: _____ **Location:** _____

YOUR PAST HEALTH HISTORY

Circle any of the following medical conditions you have either been diagnosed with or have experienced.

High blood pressure
Any heart problems
Arthritis
Diabetes
Recurring leg pain (not related to arthritis)
Liver or Kidney Disease
Any breathing or lung problems
Ankle swelling (not related to twisting)
Low back or joint problems
Diabetes
Stroke
Blood Clots
Cancer

FAMILY HEALTH HISTORY

Circle any of the following medical conditions experienced by any immediate family and indicate who has/had the condition and when (brothers/sisters, children, parents).

Heart attacks
High blood pressure
High cholesterol
Congenital heart defect
Heart operations
Other family illnesses _____
Stroke
Early death
Diabetes

YOUR PRESENT HEALTH (SIGNS & SYMPTOMS)

Circle any of the following signs and symptoms you are currently experiencing (within the last year).

Chest pain / discomfort
Shortness of breath
Heart palpitations
Skipped heart beats
Heart Attack
Diabetes
Cough on exertion
Coughing of blood
Dizzy spells
Frequent headaches
Orthopedic / joint problems
Back Pain

Have you been hospitalized in the last year?(circle one) Yes No

Have you ever had your cholesterol measured? (circle one) YES NO If YES, (list value) _____

Do you currently smoke? (circle one) YES NO If YES, what? (circle) Cigarettes Cigars Pipe

How much per day: (circle one) < 0.5 pack 0.5 to 1 pack 1.5 to 2 packs >2 packs

Have you ever quit smoking? (circle one) YES NO If YES, how old were you when you quit?_____

How many years did you smoke? _____

Do you drink alcoholic beverages? (circle one) YES NO If YES, how many beverages in 1 week? _____

_____

APPENDIX E: FREE-LIVING DAY INSTRUCTIONS

Instructions for free-living day:

You will be asked to use the hand-held body fat monitor at home throughout the course of one free-living day and also to document certain activities on the Free-living Day Log.

Items that will be documented in the event log include the following: waking time, time of any food, beverage or medicine comsumption, time of any structured exercise such as running or cycling (**only if you exercise during that day**), time of any leisure activites throughout the day such as casually walking the dog or activities with friends, activities of daily living such as shoveling the snow or mopping the floor, and hand-held BIA body fat measures at the four pre-selected times. Directions for use of the hand-held BIA device are below. Please see the Free-living Day Log attached.

Additionally, you will be asked to wear an accelerometer throughout the course of the free-living day in order to measure the intensity of activity in which you are engaging. Instructions for the accelerometer are found on the back side of this sheet.

Instruction for use of hand-held BIA device:

1. Press the yellow (On/Off) button.
2. Press the white (Up) button until you see the number 1 flashing.
3. Press the green (Start) button.
4. You will be asked to stand upright and to grip the handles of the device firmly, thumbs pointed up and extend arms out straight in front of your body, parallel to the floor. See photos:

5. After the first measure is completed, Press the yellow (On/Off) button.

6. You can relax for 60 seconds, and then a second measure will be taken with the hand-held device using the previous five steps. Each measure will not take more than 20 seconds.

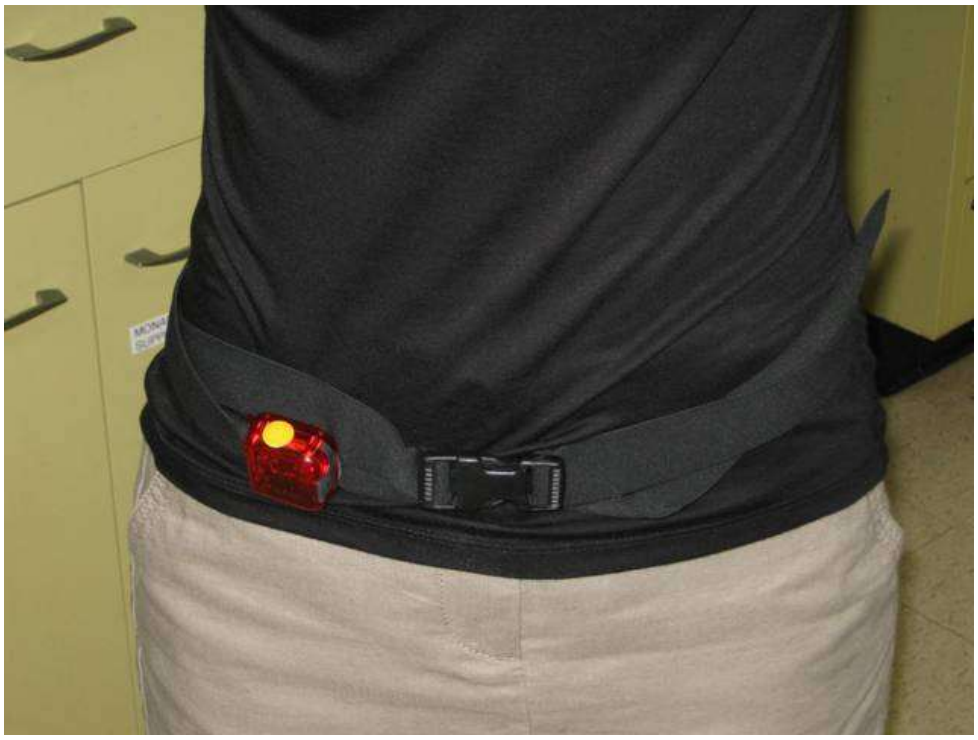
Instructions for wearing the accelerometer

1. The accelerometer is the red unit. Please wear during all waking hours of the free-living day

2. Wear the accelerometer on your right hip, in line with your right knee cap. **Please make sure that the accelerometer is as vertical as possible (not slanting away from or toward your body).

3. Wear the accelerometer for all hours you are awake. Only remove the accelerometer for showering/bathing or swimming and while sleeping. It is essential that the accelerometer stays in a specific orientation with the **orange dot facing up**.

4. You are not required to record any information, press any buttons, etc. for the accelerometer. Simply wear it as instructed for the free-living day and return on your next visit.



APPENDIX F: EVENT LOG

Study #:_____

Day:_____

Date:_____

Free-living Day Log

Please use the Omron HBF-306C device to measure body fat at these four specific times. Take two measures, separated by 60 seconds of rest.

	Time (00:00am/pm)	Measure 1 (00.0%)	Measure 2 (00.0%)	Describe the 30 minutes prior to the BIA measurements. Please include consumption of any food, beverage or medication, as well as any structured exercise or leisure activity.
1. Immediately upon waking and voiding bladder				*include consumption of alcohol, caffiene or other stimulants of the previous evening.
2. Immediately after eating lunch				
3. Right before going to bed				
4. Immediately after exercising (if exercise was done during the day)				

Structured exercise: planned exercise for health benefits such as jogging, cycling, resistance training, etc. Leisure activity: light activities not done for health benefits such as shopping, gardening, or casual walk with a friend.