MEASUREMENT OF BODY DENSITY USING THE BOD POD® VERSUS UNDERWATER WEIGHING: A VALIDATION STUDY IN ADULT BLACK WOMEN

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ABSTRACT

DANGAIA SIMS: Measurement of Body Density Using the Bod Pod® Versus Underwater Weighing: A Validation Study in Adult Black Women
(Under the direction of Bonita L. Marks, Ph.D.)

This study examined the validity of the Bod Pod®, using underwater weighing (UWW) as the criterion, for the determination of body density (D_b) and estimation of percent body fat (%BF). Thirty-six healthy Black women (25.2 ± 5.3) completed one UWW measurement period and one Bod Pod® measurement period to determine D_b. Percent body fat was estimated from D_b using the general Siri formula and the race/ethnicity-specific Ortiz formula. Results showed no significant differences between D_b (g/cm^3) as measured by the Bod Pod® and UWW in adult Black women ($p = 0.715$). A significant difference ($p < 0.001$) was found between the Siri and Ortiz %BF estimations, with Ortiz estimating %BF to be approximately 1.0% greater than Siri. These results suggest that while the Bod Pod® is valid in determining D_b in adult Black women, the use of race/ethnicity-specific equations are necessary when determining %BF in this population.

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DEFINITION OF TERMS AND LIST OF ABBREVIATIONS

General

Black: A term of ethnicity used to describe persons of whom all biological parents were of African descent, excluding Black Hispanics. This encompassed but was not limited to the following ethnicities: African American, Sub-Saharan African, and Afro-Caribbean.

Urine Specific Gravity (USG): A measure of hydration status as determined by a urinalysis screening (1). A reading between 1.00 and 1.025 was considered euhydrated.

Women: A term of gender used to describe females who were physiologically mature. This was restricted to females greater than or equal to 19 years of age. This was different from the term "females" which encompassed all age groups including those less than or equal to 18 years of age.

Body Composition: The make-up of the constituents of the body including fat, bone, and muscle (2).

Air Displacement Plethysmography (ADP): Body composition method used to assess body density (D_b) and estimate percent body fat (%BF) via the displacement of air in an enclosed chamber relative to one's total body volume (B_V) (3).

Isothermal Condition: A process permitting the transfer of heat to the surroundings, causing no change in the overall temperature. The largest sources of isothermal air are those contained in the lungs, near the skin or hair, and in clothing (4).

Body Density (D_b): Body mass (B_M) as expressed per unit body volume (B_V) measured in grams per centimeters squared (g/cc) (2,5).

$$D_b = B_M \div B_V$$

B_M equals body mass in air (i.e. dry weight in kilograms or pounds) and Bv equals body volume (the amount of space the body takes up on land and/or displaced in water).

Body Surface Area (BSA): The measured or calculated surface of the human body (2). Calculated as follows (6):

$$BSA\ (cm^2) = 71.84 \times Weight\ (kg)^{0.425} \times Height\ (cm)^{0.725}$$

Fat Mass (FM): All extractable lipids from adipose and other body tissues (2).

Fat Free Mass (FFM): All residual lipid-free chemicals and tissues, including water, muscle bone, connective tissue, and internal organs (2).

Density of Fat Free Mass (D_{ffm}): Insert here D_{ffm} term, abbreviation and explanation, indented

Lean Body Mass (LBM): FFM plus essential body fat (2).

Percent Body Fat (%BF): The percentage of total BM that is composed of fat and estimated from population-specific formulas (2).

- **Ortiz %BF Equation:** A method of calculating %BF from D_b for Black females. This equation assumes the two-compartment model of body composition that divides B_M into FM, of which the density is 0.901 grams per cubic centimeter (g/cc), and FFM, of which the density is 1.106 g/cc (7). This method was derived under the assumption that Blacks and Whites have differences in FFM, with Blacks having greater muscularity, bone density, bone mineral mass, body potassium, and body proteins than Whites (7–11). Percent body fat is calculated as follows:

$$\%BF = (485 \div D_b) - 439$$

- **Siri % BF Equation:** A method of calculating %BF from D_b based upon the two-compartment model of body composition. This equation assumes the two-compartment model of body composition that divides B_M into FM and FFM. The original equation was formulated from cadaver information obtained from young adult White male soldiers and was later expanded to White females. Siri's general equation assumes that the density of FM is 0.901 g/cc and the density of FFM is 1.10 g/cc (12,13). The widely accepted non-gender specific, non-population specific Siri Equation for %BF is then calculated as follows:

$$\%BF = (495/D_b) - 450$$

Underwater Weighing (UWW): Body composition method used to assess D_b and %BF via the displacement of water in a tank. In this procedure, whole D_b is calculated from B_V in accordance with Archimedes' principle, which states that an object submerged in water is buoyed up by the weight of the water displaced (14). It is also known as hydrostatic weighing or hydrodensitometry.

Pulmonary Function Tests (PFTs): An array of studies to measure lung function as shown in Figure 1 which follows the definitions (2).

Forced expiratory flow rate in one second (FEV_1): A dynamic measurement of lung function. The amount of air that can be forcefully exhaled in one second (2).

Forced vital capacity (FVC): Maximum volume expired after maximum inspiration. The women-specific equation is (2):

$$FVC = 0.1321 \times \text{Height (inches)} - 0.018 \times \text{Age (years)} - 4.360$$

Percent forced expiratory volume (FEV%): The ratio of FEV_1 to FVC.

$$FEV\% = FEV_1/FVC$$

Residual volume (RV): Volume in lungs after maximum expiration (2). The women-specific equation is (15):

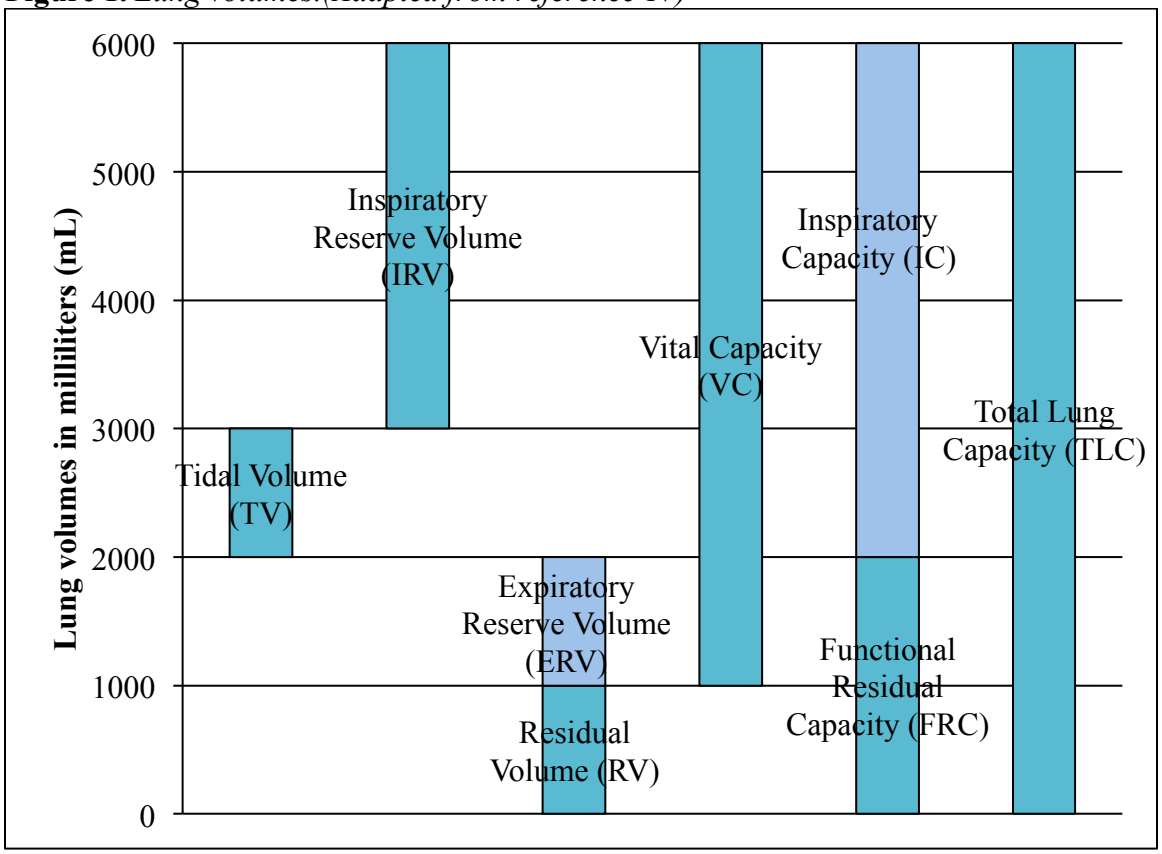
$$RV = 0.0813 \times \text{Height (inches)} + 0.009 \times \text{Age (years)} - 3.900$$

Thoracic gas volume (TGV): The absolute volume of gas in the thorax at any point in time and any level of alveolar pressure (16).

Tidal Volume (TV): The normal volume of air displaced between normal inspiration and expiration (2).

Total lung capacity (TLC): Volume in lungs after maximum inspiration (2). TLC is equal to RV + FVC.

Figure 1. *Lung volumes.(Adapted from reference 17)*



Statistical Concepts of Variance

Coefficient of Determination (R^2): A statistic indicating the strength of fit between two variables (18).

Coefficient of Variance (CV): A statistic indicating the normalized measure of variance, or dispersion, of a distribution. The standard deviation divided by the mean (18).

Standard Deviation (SD): A statistic indicating the amount of variation, or dispersion, from the mean for an individual data point (18).

Standard Error (SE): A statistic indicating the amount of variation, or dispersion, from the mean for sample means (18).

Standard Error of the Estimate (SEE): A statistic indicating the accuracy of a prediction. The standard deviation of the difference between actual and predicted values (18).

Standard Error of the Mean (SEM): A statistic indicating how well the mean of a sample estimates the mean of a population (18).

CHAPTER ONE

Introduction

Percent body fat (%BF) is often used as an indicator of a person's general health and nutritional status. Furthermore, it provides an indication of risk for diseases including hypertension, diabetes, cardiovascular disease, hyperlipidemia and certain types of cancer (19). Rates of obesity, hypertension, and high cholesterol in Blacks have increased dramatically within the last decade (20). More notably, the incidence of major weight gain and the subsequent diseases associated with weight gain and obesity has increased considerably more in Black women as compared to other subgroups (21). In 2005-2006, 52.9% of Black women over the age of 20 were obese compared with 37.2% of Black men. Similarly, prevalence of extreme obesity was highest among Black women (13.7%) as compared to that of Black men (5.9%) and White women (6.7%) (22). Therefore, it is crucial for body composition assessment techniques in this population to be convenient, reliable, and accurate.

It has been suggested that the Bod Pod® provides a valid and reliable alternative for body density (D_b) measurement and %BF estimation (19,23). Non-significant differences have been reported between the Bod Pod® and criterion body composition methods including underwater weighing (UWW) and dual energy x-ray absorptiometry (DXA) (19,23–31). However, unlike UWW or DXA, the Bod Pod® does not require water submersion and

affords no exposure to x-rays. The machine operates via air displacement plethysmography (ADP), a technique that displaces air around the body to determine D_b in a similar sense that UWW displaces water (26).

Race/Ethnicity and the Bod Pod®. It is known that there are a number of differences in body composition between ethnicities, specifically Blacks as compared to Whites. Blacks have been shown to have a greater muscularity, bone density, bone mineral mass, total body potassium, and body protein content than Whites, resulting in a higher density of fat free mass (D_{ffm}) (7–11). Therefore, in order to obtain accurate D_b results for the Bod Pod® method, it is suggested that race/ethnicity must be taken into account. Using race/ethnicity-specfic equations, the Bod Pod® has been shown to provide accurate results in Blacks (9,32).

In contrast, using ADP, UWW, DXA and other multi-compartment models, research teams determined that there was no difference in D_{ffm} nor %BF, thereby repudiating the rationale for race/ethnicity-specific equations for measurement in Blacks (24,33–35). In fact, three of these studies concluded that there was no grounds to expect differences in body composition on the basis of race/ethnicity for ADP when specifically investigating Blacks, contending that race-specific equations were not needed in the first place (26,32,33).

Gender and the Bod Pod®. As with race/ethnicity, body composition differs between genders with respect to both fat mass (FM) and distribution and cellular composition of FFM distribution (36–38). The Bod Pod® has been shown to provide accurate results in women when compared to DXA and UWW (31,39,40), yet the samples used in these studies, like the race/ethnicity studies, included few, if any, Black women. Hornbuckle, Basset and Thompson (41) performed a study on a sample of 75 Black women under the assumption that the Bod Pod®, in association with the race/ethnicity-specific Ortiz formula, is a valid method

of body composition assessment. Additonally, Dioum et al. (8) conducted a study on a sample of 196 African women, where the Bod Pod® was used as the criterion variable to which skinfold analyses were compared. Assuming that the race/ethnicity-specific formulas (7) were valid to use in Black females, Hornbuckle, Bassett and Thompson (41) and Dioum et al. (8) measured body composition in the Bod Pod® without comparison to one of the "gold standard" criterions methods.

While the sample sizes of the aforementioned studies (n = 75, n = 196) appeared to be adequate for their specific investigation (8,41), it is not certain that these initial %BF estimations were valid given the lack of published validation studies utilizing an adequate sample of Black adult women. For example, after an exhaustive literature search, one study stood out regarding the sample size used for Black females (31). That study's sample size of 120 included 18 Black females (i.e., 15%). However, that study includes both adults and children and gives no information regarding how many of these 18 Black women were adults. Of the studies determining the accuracy of ADP and those strictly examining adults, Biaggi et al. (42) had a total sample size of 47, of which only 8.5% were Black women (i.e., n = 4). This same problem, lack of sufficient representation of Black women, occurred in the landmark ADP validation study conducted by Fields et al. (10). Based on these numbers alone, it is quite possible that no significant differences were found due to lack of power to detect a significant difference, thereby potentially creating a Type II error (18). Therefore, the Bod Pod® needs to be re-evaluated with a sufficient sample size using a criterion reference method in order to more confidentally state whether or not an ethnic variation exists for Black women.

In conclusion, the accuracy of the Bod Pod® for use in Black women must be better validated in order for the Bod Pod® to be a trusted measure of %BF in this population.

Statement of the Problem

With increasing attention allied to the relationship between obesity and race/ethnicity, valid body composition measurement techniques in Black women, a population with dramatically increasing rates of obesity (22), are critical. While numerous studies have been conducted on the validity of the Bod Pod®, data regarding these measurements in Black women is insufficient. Therefore, **the primary purpose of this study was to validate the Bod Pod®, using UWW as the gold standard criterion, in adult Black women for the determination of D_b and %BF**. A secondary purpose of this study was to evaluate the race/ethnicity-specific equations of the Bod Pod® to determine which equation was the most accurate for use in Black women when determining %BF.

Research Question and Hypotheses

Research Question: Will body density (D_b) measurements and consequent percent body fat (%BF) estimations differ when measured in the Bod Pod® versus underwater weighing (UWW) for adult Black women?

Hypothesis One. There will not be a significant difference between the Bod Pod® and UWW determination of D_b for adult Black women subjects.

Hypothesis Two. There will be a significant difference in %BF estimations between the race/ethnicity-specific equations of Siri versus Ortiz.

Delimitations

Due to the numerous hormonal and body composition changes known to occur with menopause, this study was delimited to healthy pre-menopausal Black females 19 to 39 years of age. Body fat estimations were based not only upon body mass but also lung volume exchange. Because the Bod Pod® uses lung volume measures to predict %BF, only those without significant respiratory issues were recruited for this study. Moderate to severe chronic obstructive pulmonary diseases (COPD) such as asthma, bronchitis, and emphysema as well as acute upper respiratory tract infections (URTI; e.g., cold, flu) may cause significant underestimations of percent body fat using the Bod Pod® (43). Women unable or unwilling to wear the required test clothing for UWW and the Bod Pod® (tight fitting bathing suit, lycra or spandex) were excluded from the study since it is known that loose-fitting garments will cause %BF estimation errors. Those with a self-reported risk of disordered eating were also excluded from the study due to the potential of exacerbating disordered eating behavioral patterns. Women with excessive body hair were required to shave prior to arrival. Hair has a thermal mass of its own and could potentially impact the volumetric results in the Bod Pod®. Because the Bod Pod® measurement requires subjects to sit motionless in a small-enclosed space for approximately two minutes, women with known severe claustrophobia were excluded. Lastly, those unwilling or unable to submerge their body in a tank of water were excluded since this is a requirement of UWW.

Limitations

Non-compliance to pre-test guidelines or the actual testing procedures may have produced errors in D_b and %BF calculations. To minimize the known potential errors, adherence to the medical exclusions and pre-test guidelines were verified via a brief health history questionnaire and a 24-hour health history questionnaire upon lab arrival. If a woman did not meet study inclusion criteria or failed to adhere to the pre-test guidelines, she was given the option to reschedule (if medically qualified) or be dismissed from the study. The specific limitations and preventive actions are detailed below.

1. Pre-Test Diet and Exercise. Some women may have had difficulty adhering to the requirements of abstinence from food and exercise four hours prior to testing. To verify they met the study's pre-test diet and exercise requirements, subjects completed a form self-reporting their compliance. All subjects complied with pre-test diet and exercise guidelines.

2. Hydration Status. Both dehydration and over-hydration can influence the %BF estimation. To counter this, all women were informed about appropriate fluid intake amounts prior to their testing session. Upon arrival to the lab, not only did they report their fluid intake for the past 24 hours, they also partook in a urinalysis screening to verify a euhydrated state. Those who appeared to be dehydrated or over-hydrated had their testing session rescheduled and were provided with more explicit hydration guidelines.

3. Predicted Lung Volumes. We anticipated that subjects may have had difficulty properly performing the breathing techniques required for determining residual volume (RV) for both the Bod Pod® and UWW testing. To eliminate breath control performance difficulty and subsequent lung volume and %BF prediction errors, RV and forced vital capacity (FVC) were estimated for all subjects by performing the common, short, two-minute

method for determination of %BF in the Bod Pod® which does not require the puffing technique for lung volume determination. The puffing technique is difficult for many subjects to perform reliably which then negatively impacts the lung volume and subsequent D_b and %BF predictions. Predicted lung volume estimates were based upon body surface area (BSA) (per age, gender, and height) (40). The use of predicted lung volume using predicted values could result in 2.0 - 3.5% error in the body fat prediction (44–46). Even so, this prediction error should not have impacted the ability to compare the validity between the test methodologies, as the D_b and %BF prediction error should be consistent between methods.

4. Underwater Weighing Technique. Because exhaling all one's air prior to submerging underwater is deemed "unnatural" and potentially frightening for the subject, subjects first practiced the exhalation component outside of the tank in order to learn how to perform this technique. Once in the tank, subjects engaged in several UWW trials in order to account for learning and fatigue effects of this exhalation technique. The best (and closest) three trials were averaged and used for the UWW %BF formulas (47).

5. Race/ethnicity-specific equations. A further limitation to this study was the ages of the samples used for development of the D_b equations. There is no published D_b formula for 19-23 year old women. The Ortiz formula for Black women age sample ranged from 24-79. Because the population in this study includes those between the ages of 19 and 23, these equations may have yielded unexpected results.

Significance

Black women are under-represented in body composition research. This proposed study will assist in determining whether or not the Bod Pod® is an appropriate means of body composition measurement in Black women, when race/ethnicity-specific equations are used. Considering that Black women are at major risk for the development of obesity and obesity-related diseases, determining whether the Bod Pod® is a valid body composition assessment method for this specific population may facilitate wider use of ADP technology in community health clubs and wellness centers.

CHAPTER TWO

Literature Review

Introduction

The Compartment Models

Traditionally, body composition methods involve the determination of body density (D_b) by underwater weighing (UWW), known as the two-compartment model (2C). The 2C model is based on the principle that the body can be divided into two compartments – fat mass (FM) and fat free mass (FFM). The Bod Pod® operates under a 2C model. However, it has been suggested that the 2C model lacks validity due to the fact that it makes assumptions regarding the density of FFM (44).

From the 2C model, the three-compartment (3C) model was developed, which breaks down the body into FM, FFM, and total body water (TBW) (13). To accurately track TBW, a common method is the isotopic dilution method requiring radioactive isotope ingestion. Bioelectrical Impedance Analysis (BIA) has been used as a substitute to estimate TBW in order to avoid exposure to radioactivity (48). The 3C model was expanded into a 4C model (dual energy x-ray absorptiometry, DXA) in order to also account for bone mineral, protein and other remaining elements (49). Although the 3C and 4C models are potentially more accurate, there are still health, cost, and compliance issues that can render these methods undesirable. Since the Bod Pod® is fast becoming the technology of choice in both clinical

and commercial wellness centers in lieu of UWW, it is important to determine the validity of the Bod Pod® as a method of body composition in the understudied Black female population.

Underwater weighing was the "gold standard" for body composition measurement, however, this method has proven to be time consuming, difficult to perform, and impractical in some populations (elderly, children, obese, disabled) (23). Thus, since the mid-1990s (3), air-displacement plethysmography (ADP) has become a popular method used to measure human body composition due to its ease of use. It is less intimidating for children, the elderly, disabled, and anyone adverse to water submersion (40).

Air displacement plethysmography offers no radiation exposure like dual energy x-ray absorptiometry (DXA) and requires no ingestion of radioactive compounds as with doubly labeled water. One such ADP unit, developed by Life Measurement Inc. (LMI, Concord, CA) is known as the Bod Pod®. This unit, now owned by COSMED (Rome, IT), is the most widely used ADP unit, consisting of several models to accommodate various body mass sizes, and contains numerous population-based body composition estimation formulas. However, the Bod Pod® does have limitations. First, the equipment is expensive, costing between $30,000 and $40,000 per unit (31). Second, certain Bod Pod® models have weight limitations due to a smaller internal chamber, thereby limiting its use in morbidly obese or athletically overweight populations (e.g., football linebackers). While measurement of body composition in the Bod Pod® is relatively quick, the small chamber may exacerbate feelings of claustrophobia in certain individuals, even with the viewing window. While the following may not be limitations of the Bod Pod® itself, there is a strict clothing requirement to achieve accurate results which may not be feasible for certain populations. Lastly,

information is limited on using the Bod Pod® in ethnic populations, especially Black women.

Thus, this research aimed to explore the use of body composition measurements comparing results obtained from both the Bod Pod® and UWW in Black women. It did so by comparing the Black %BF equation formulated by Ortiz (7) to the more common "default" Caucasian %BF equation developed by Siri (13).

Basic Principles of Underwater Weighing

Goldman and Buskirk (5) and Katch, Michael, and Horvath (50) were among the first to have determined UWW to be a valid and reliable measure for D_b, where the volume of the body is obtained from water displacement. This research paved the way for UWW to become the criterion method for body composition measurements. Underwater weighing is historically regarded as the "gold standard" of body composition techniques. Other more current "gold standard" reference methods include DXA and a multi-compartment model; however, UWW is still highly regarded as a body composition technique. The UWW procedure is based on Archimedes' principle which states that an object submerged in water is buoyed up by the weight of the water displaced (14). The difference between the weight of the body in air (W_a) and the weight of the body submerged in water (W_W) is the weight of the displaced water (5). Residual lung volume (RV) is also taken into account. In more relative terms, due to the fact that body fat is less dense than water, adipose tissue increases one's buoyancy. Conversely, FFM is denser than water thus decreasing buoyancy (14). Using a standard formula, body volume (B_V) is determined:

$$B_V = (W_a - W_W) \div D_W$$

Body density (D_b) is then calculated by including not only the components of the B_V formula, but also the additional components of W_a and lung and gastrointestinal (GI) gas volumes as illustrated in the standard D_b equation (5,14):

$$D_b = W_a \div [(W_a - W_W)/D_W - (RV + 100\ mL)]$$

The density of water (D_W) is determined via a Table and is partially represented in Table 1 below.

Table 1. *Partial Display of Water Density (D_W) Table (Adapted from Reference 47).*

Water Temperature (C°)	Water Density (g/cm^3)
20	0.998207
25	0.997047
30	0.995650
35	0.994034
40	0.992218

Residual volume (RV), the amount of air left in the lungs after a maximal expiration, can be measured directly using a variety of methods (nitrogen washout, helium dilution, or oxygen dilution methods) or estimated based on the combined personal characteristics of age, sex, height, and occasionally, physical activity level (14,51). Because males have larger RV values than females, gender-based estimation formulas have been developed as follows (15):

- Male RV (L) = (0.017 x age in years) + (0.06858 x height in inches) – 3.447
- Female RV (L) = (0.009 x age in years) + (0.08128 x height in inches) – 3.900

Some reports suggest that the general formulas listed above are not accurate for Blacks, especially females (52–54). Lapp et al. (53) suggested that there could be as much as 7-10% under-prediction error in Blacks and suggested that all estimated RV should be corrected

accordingly. However, Pellegrino et al. (54) state that, if available, a race/ethnic-specific reference equation should be used over a race/ethnic adjustment factor.

The last component in the D_b prediction formula corrects for the amount of non-expellable air in the gastrointestinal (GI) tract. Since the volume of air in the GI tract is difficult to measure, it is generally estimated as 0.1 liters and the correction factor of 100 mL is added on to the RV in the D_b equation (51). Percent BF is then calculated from D_b using population-specific equations (14).

Basic Principles of the Bod Pod®

In ADP, the volume of air displaced inside the enclosed chamber indirectly measures the volume of an object. The subject sits inside the large, egg-shaped, fiberglass chamber and a volume of air is displaced equal to the B_V of the subject.

Boyle's law states that at a constant temperature, pressure (P) and volume (V) are inversely related:

$$P_1/V_1 = P_2/V_2$$

The Bod Pod® is functionally divided into two chambers: the anterior test chamber where the subject is seated (≈ 450 L) and the posterior reference chamber (≈300 L) (4). Between the chambers, a diaphragm oscillates to create small volume changes that are equal in magnitude but opposite in sign between the two chambers. This produces small pressure fluctuations (3). The air in the chambers is allowed to compress and expand during which it freely gains and loses heat (i.e. adiabatically). In this sense, the Bod Pod® utilizes Poisson's law:

$$P_1/P_2 = (V_2/V_1)\gamma$$

Where γ is the ratio of specific heat of the gas at a constant pressure to that of a constant volume and is equal to 1.4 for air (23) and 1.3 in gases such as carbon dioxide (CO_2) and water (H_2O) (3). To maintain equivalency of gas composition in the two chambers, and thus constancy of γ, an air circulation system mixes the air between the chambers. A two-point calibration process preceding each test accounts for variations in conditions such as chamber size (3).

To accurately measure B_V, it is necessary to account for the effects of isothermal conditions. Body surface area (BSA) is estimated by the Dubois formula (6):

$$\text{BSA } (cm^2) = 71.84 \times \text{Weight } (kg)^{0.425} \times \text{Height } (cm)^{0.725}$$

BSA is then multiplied by the constant *k* to yield surface area artifact (SAA) (6):

$$\text{SAA } (l) = k(l/cm^2) \times \text{BSA}(cm^2)$$

SAA is used to correct for the negative volume caused by isothermal effects related to skin surface area (3). Other pulmonary measurements are extractable from the Bod Pod® for use in the body composition equations.

General Reliability and Validity of the Bod Pod®

Nunez et al. (31) showed a high positive correlation ($r = 0.93$; $p < 0.0001$) in D_b between the Bod Pod® and UWW in a sample of 110 subjects (gender: 66 females, 54 males; age range: 6 to 86 years). In another Bod Pod® comparison study, Ballard et al. (39) examined a sample of 47 female division II athletes and determined no significant differences in predicting %BF between ADP and DXA ($\%BF_{ADP} = 22.5 \pm 5.5\%$, $\%BF_{DXA} = 22.0 \pm 4.7\%$; $p = 1.0$).

However, data regarding between-day and within-day reliability on the Bod Pod® yielded mixed results. When measuring %BF, the Bod Pod® produced a wide range of results for within-day reliability. The coefficient of variation (CV) for these studies ranged from 1.7% to 4.5% (19,25,29,42,55). It was noted by Miyatake et al. (55) that the 4.5% CV was the result of an outlier in the data. Though not as extreme as the within-day reliability data, the Bod Pod® produced a wide range of results when examining between-day reliability. The CV for these studies ranged from 2.0 to 2.3% (30,31,55). The coefficient of variation expresses the standard deviation (SD) as a percentage of the sample mean – the lower the CV the higher the precision (18). This indicates a small difference in the tests and thus a high degree of replicability.

Validitity of the Bod Pod® as compared to UWW, DXA, and multicompartment models also produced inconclusive results. When validating the Bod Pod® against the 2C UWW model, mean group differences ranged from -4.0% to 1.9% BF (4). Five studies showed there was no significant difference between the two measurement techniques (19,28,29,34,42), five showed that %BF was lower with the Bod Pod® and two showed that %BF was higher with the Bod Pod® (23,24). When validating the Bod Pod® as compared to the 4C DXA model, four studies showed no significant difference (28,31,53,55), four showed a positive significant difference (26,29,30,34), and one showed a negative significant difference (24). Multiple researchers compared the Bod Pod® to multicompartment models to determine its validity (26,28,34). Results showed that the 2C Bod Pod® considerably underestimated %BF (1.8-2.8%) compared to 4C model estimates of %BF.

In summary, reliability and validity results for the Bod Pod® remain inconclusive. While most of the studies suggest that the Bod Pod® yields both reliable and valid results, some

suggest otherwise. Therefore, more population-specific research involving reliability and/or validity is warranted for the Bod Pod.

Race/Ethnicity

For the purposes of this study, Black is described as a person of whom all biological parents were of African descent, excluding Black Hispanics. This encompassed but was not limited to the following ethnicities: African-American, Sub-Saharan African, and Afro-Caribbean. This definition differs from that of strictly African or of mixed raced Blacks.

Race/ethnicity-specific Equations. Blacks have greater muscularity, bone mineral mass, and bone density compared with Whites (7–10). This has led to speculation that these differences would correspond to higher density of FFM (D_{ffm}), however the effect on D_{ffm} in Blacks may be compensated for since the mineral fraction is relatively low (less than 7% of FFM) (17). In any case, the specific race/ethnicity equations that have been developed for predicting %BF for D_b (7,58) have yielded conflicting results. Millard-Stafford et al. (34) and Visser et al. (35) both determined via measurement of D_{ffm} in Blacks using a multi-compartment model that there is no difference in D_{ffm}, repudiating the rationale for race/ethnicity-specific equations. Subjects in both the Siri and Brozek equations were Caucasian cadavers that were then generalized to the population (11). Despite these conflicting race/ethincity %BF reports, the Bod Pod® provides the option to select the appropriate equation to estimate %BF based on age and race/ethnicity of the individual. Table 2 shows the most common %BF equations used for Blacks and the general population.

Table 2. *Equations for Determining Percent Body Fat from Body Density.*

Author (citation)	Population	%BF equation
Siri (13)	General	$(495 \div D_b) - 450$
Brozek et al. (12)	General	$(457 \div D_b) - 414.2$
Schutte et al. (58)	Black males	$(437.4 \div D_b) - 392.8$
Ortiz et al. (7)	Black females	$(485 \div D_b) - 439$

Reliability and Validity of the Bod Pod® in Blacks

There is limited data regarding the reliability and validity of the Bod Pod® in the assessment of body composition in Blacks, most of which investigate Black men. Furthermore, studies involving Black women usually consist of very small subject samples.

Bod Pod® Studies in Adult Black Men. An ADP ethnic-equation validity study (6) investigated the use of the Schutte equation (49) in adult Black men (n = 30; aged 19-45 years). That study consistently found the Bod Pod® to slightly, but significantly ($p < 0.01$), underestimate D_b (0.00450 ± 0.00718 g/cc^{-1}) and overestimate mean %BF when compared to UWW (+1.73%). Collins et al. (10) suggested that a confounding factor likely accounted for the differences in the Wagner study (24), however, they did not specify the potential confounding factor(s). It is speculated that lack of a White control group may have been one of the limitations. Collins et al. (10) did note that the effects are impossible to discern as individuals from multiple ethnic groups were treated as one. Collins et al. (26) also found no difference on the basis of race by ADP in Black versus White male collegiate football players.

In contrast, Collins et al. (10) studied 39 adult Black males and 25 adult White males. They found that race did not influence the acurracy of ADP to estimate %BF. These results are in accordance with several earlier studies that all found no effect of race on %BF

estimated obtained with ADP, UWW, and DXA, and various multi-compartment models (24,31,33–35). Furthermore, Wagner and Heyward (9) indicated that the Schutte equation (58), which provides an additional 3.0% BF in lean Black male athletes, overestimates %BF.

Bod Pod® Studies in Adult Black Women. Gallagher and Heymsfield (37) have shown that White women have less upper muscle mass as compared to White men. Similarly, Nindl et al. (38) showed there are significant differences ($p \leq 0.05$) between men and women for lean soft tissue mass of the arm (men: 7.1 kg vs. women: 6.4 kg) and fat mass of the leg (men: 5.3 kg vs. women: 6.8 kg) regardless of race. Therefore, several women-specific formulas have been developed. Ortiz et al. (15) developed the Black women-specific body composition formula in a sample (n = 28) of Black women aged 24-79 years. Unfortunately, the formula must be used with caution in younger populations, as a major limitation is women under 24 years of age were not included in this subject sample.

In general, the Bod Pod® has been shown to provide accurate results in women when compared to DXA and UWW (31,39,40), however most of the studies involved relatively few adult Black women. For example, 43 White college-aged women participated in an ADP versus DXA body composition study (26). Results indicated no significant differences ($p < 0.01$) between ADP (24.3 ± 1.1) and DXA (23.8 ± 0.8) when measuring %BF. This suggests that the Bod Pod® is valid for assessing body fat in White college women but lends no information regarding the applicability to Black women collegians.

Nunez et al.'s (13) historical Bod Pod® validation study included 18 Black females (i.e. a mix of children and adults) out of a study sample of 120 (i.e., 18%). Nunez and colleagues found the Bod Pod® to have potential to provide accurate body composition results in

children. However, that study included both adults and children and gave no information regarding how many of these 18 Black females were adult women. The overall objective of the study was to determine the accuracy of the Bod Pod® for use in children when compared to UWW, but 66.7% of subjects were over 18 years of age and therefore could be considered adult-aged. Of the studies determining the accuracy of ADP and those strictly examining adults, Biaggi et al. (42) had a total sample size of 47, of which only 8.5% were Black women (i.e., n = 4). They (28) found no significant difference between %BF as measured by ADP (25 ± 8.9%) and UWW (25.1 ± 7.7%). Lack of sufficient representation of Black women also occurred in the landmark ADP validation study conducted by Fields et al. (10) which showed no significant differences ($p = 0.35$) in D_b when comparing ADP (1.0349 g/cm^3) to UWW (1.0352 g/cm^3). The number of Black women in Fields et al.'s study (10) was only three. It is quite possible that no significant differences were found in any of the studies discussed above due to lack of power to detect a significant difference, thereby potentially creating a Type II error (18). Therefore, the Bod Pod® needs to be re-evaluated with a sufficient sample size using a criterion reference method such as UWW in order to more confidentally state whether or not an ethnic variation in %BF estimation exists for Black women when comparing UWW to ADP using the Bod Pod® .

Two relatively large studies did assess body composition with the Bod Pod® in Black women. Hornbuckle, Basset and Thompson (41) performed a study that aimed to evaluate the relationship between physical activity (determined by a pedometer) and body composition in middle-aged African-American women. Their sample included 75 Black women between the ages of 40 and 62 and the race/ethnicity-specific Ortiz forumla was implemented using the Bod Pod®. Additonally, Dioum et al. (8) conducted a study on a sample of 196 Black

African women ages 19-56, in which the Bod Pod® was used as the criterion variable to which skinfold analyses were compared. Their purpose was two-fold: 1) to test the validity of an equation for predicting body density from skinfolds in Africans and 2) to determine the effect of calculating %BF from D_b the Ortiz formula rather than the Siri equation. The limitation common to both studies (8,41) was that neither measured body composition in the Bod Pod® in comparison to one of the "gold standard" criterions methods (i.e., either UWW or DXA). Therefore, the validity of the Bod Pod® remains quesionable for Black adult women.

Conclusion

The accuracy of the Bod Pod® using the race/ethnicity-specific equation of Ortiz et al. (7) in Black women must be better validated in order for it to be a trusted apparatus to measure %BF in this population. Furthermore, the conflicting D_b and %BF validation results from past studies utilizing the Bod Pod® suggest that race/ethnicity must be explored further. If shown to be valid for Black women, the Bod Pod® will provide a convenient measurement tool to determine %BF. Information gathered via the Bod Pod® will enable practitioners to provide a more complete health risk evaluation and set better goals for the prevention/reduction of the cardio-metabolic disease profile epidemic in the Black population.

CHAPTER THREE

Methodology

This was a cross-sectional prospective study that aimed to address the limited data on the validity of the Bod Pod® for use in Black women. Therefore, the primary purpose of this study was to validate the Bod Pod®, using UWW as the gold standard criterion, in adult Black women for the determination of D_b and %BF. A secondary purpose of this study was to evaluate two race/ethnicity-specific equations of the Bod Pod® to determine which equation would be most accurate for use in Black women when determining %BF.

Subjects

Recruitment. Based upon published data from several references (19,24,27,30), it was determined that 36 healthy Black female subjects needed to complete this study in order to achieve a power of 0.70 at an alpha level of 0.05 (18). Subjects were recruited from the central North Carolina area via posters, informational emails, and word of mouth, specifically targeting community businesses, organizations and university classes with Black customers/students. To facilitate successful completion of the study, all subjects were pre-screened with a telephone interview (**Appendix A**).

Age and Ethnicity Determination. To be eligible to participate, subjects had to be Black women between 19-39 years of age. This limited age range was selected due to known biological growth changes that occur during adolescence (prior to age 19) and the pre-

menopausal transition, which can occur as early as 40 years of age (59). As detailed in the Definition of Terms section, subjects must have self-reported that all of their biological parents are of African heritage. This was to ensure a more pure biological sample as those of mixed race/ethnicity may have different bone and D_b values. Black Hispanics were excluded from this population, as there are also Hispanic % BF formulas. It is acknowledged that self-reporting is not optimal, however it is beyond the scope of this investigation to perform genetic testing to quantify the true percentage of their African heritage.

Pulmonary Health and Breathing Technique. All subjects were free from moderate to severe chronic obstructive pulmonary disease (COPD: e.g. asthma, bronchitis, emphysema) and will not have an acute upper respiratory tract infection (URTI; e.g., cold, flu). The presence of an upper respiratory tract infection or moderate to severe COPD has been shown to lead to an underestimation in %BF as compared to healthy subjects (43,60). Subjects must have also be willing and able to perform the appropriate breathing techniques as required by the Bod Pod® and UWW.

Disordered Eating Risk. Those at risk for disordered eating (as determined by self-report) would have been excluded from this study, however, no subjects reported disordered eating or disordered eating tendencies. Body composition results were given to the subjects, therefore, to prevent unintentional exacerbation of disordered eating behaviors, subjects determined to be at risk for disordered eating (via their self-reported behaviors) were excluded from the study. Educational information to prevent disordered eating was provided to all subjects at their first lab appointment.

Phobias. Those with known severe claustrophobia were excluded from the study as testing requires subjects to sit motionless in an enclosed chamber for two to five minutes. No

subjects reported severe claustrophobia. Those with mild claustrophobia were included if their practice period demonstrated the ability to remain in the Bod Pod® for the required testing time. Finally, those with known hydrophobia were excluded from the study as testing requires subjects to sit in a tank of water submerged for up to 10 seconds for each UWW trial.

Test Clothing. All subjects were willing and able to wear the mandatory test clothing per the Bod Pod® testing instructions (i.e., tight fitting bathing lycra or spandex one or two piece bathing suit) (61). They brought with them their own bathing suit, as one was not provided.

Body Hair. Hair creates an isothermal condition, as opposed to an adiabatic condition, which results in a negative volume when measured by air displacement plethysmography (ADP) resulting in an underprediction of %BF (62). Therefore, all subjects were required to wear a lycra bathing cap (provided) and those with excessive body hair were required to shave/depilate at home prior to lab arrival. Failure to meet any one of the above conditions was grounds to exclude the volunteer from the study.

Instrumentation

The PulmoLife hand-held pulmonary function screening device (MicroDirect, Lewistown, ME) was used to measure FEV_1 and FEV% to determine risk for COPD. An electronic scale was used to measure body mass (B_M) (Tanita Corp., Tokyo, Japan). A stadiometer (Perspective Enterprise, Portage, Michigan) was used to determine height to the nearest centimeter (cm). Lung volumes, D_b and %BF was determined in the ADP unit known as the Bod Pod® (Cosmed, Rome, Italy), which consisted of two chambers: a front

chamber in which the subject sat during measurement and a rear reference chamber. A molded fiberglass seat separated the two chambers. An oscillating diaphragm within the Bod Pod® created small volume changes, which produced small pressure fluctuations. Temperature of the water was determined using a submergible thermometer (Springfield Instruments, Inc., Woodridge, New Jersey). Body density was determined using a five-foot depth UWW tank outfitted with an electronic load-cell system (Avery Weigh-Tronix, Fairmont, Minnesota). Urine specific gravity (USG) was determined with a handheld refractometer (Reichert, Depew, New York).

Procedures

Pre-Telephone Screening. Fifty-one subjects were first interviewed over the telephone by the principle investigator to determine study eligibility. The telephone script and screening questions are contained in **Appendix A**. Thirty-six subjects were tentatively accepted into the study; they were booked for their first (and only) appointment and a copy of the consent form was e-mailed to them for pre-review (**Appendix B)**. Subjects were given instructions over the phone and via e-mail regarding the following information: 1) directions to UNC and parking, 2) no eating or exercising two hours prior to testing, 3) the lycra-type of bathing suit required for testing, 4) to bring a bathing suit cover-up for walking between labs, and 5) hair removal if necessary. Failure to follow any of the above requirements resulted in being rescheduled or excluded from the study. All subjects properly adhered to the above pre-testing guidelines. A fuller description of the bathing suit required is described within the Body Composition Procedures section. A reminder email was sent to the subject a day before the scheduled appointment.

Testing Locations. All appointments took place in the labs on the ground floor of Fetzer Hall at UNC-Chapel Hill's Main Campus. The consent form, COPD screening, and questionnaires were completed in the Applied Physiology Lab (APL) and/or private conference room. Bod Pod® testing was conducted in a private body composition assessment room in the Sports Medicine Research Lab (SMRL; contains a private restroom for changing into a bathing suit and voiding for the urinalysis). UWW was conducted in a private area in the APL. The subjects were able to change out of their wet bathing suit following the UWW in a women's locker room located adjacent to the APL. Both labs are located in close walking proximity of each other.

Parking. Subjects not affiliated with the University were able to park for free in designated visitor parking spaces behind Fetzer Hall per space availability. Visitor permission parking must be requested in advance so a pass can be obtained upon arrival, but free visitor parking is not guaranteed. All others used their regular modes of transportation/parking when on the UNC campus. The testing appointment required approximately one hour.

Test Appointment Day.

1. Consent Form. Upon arrival to the ESTL, the subject reviewed and signed the Consent Form with the principal investigator (**Appendix B**), after which she completed the following questionnaires and screening tests:

2. Health History Screening (Appendix C). This questionnaire verified that there were no health contraindications for participation. This was a non-exercise study, but conditions such as an acute upper respiratory tract infection (URTI) or moderate to severe COPD were grounds to exclude the subject. Although it was anticipated that the subject's information

would be known via the telephone interview, it was possible a potential subject could have COPD and not know it or the subject may have contracted a cold/flu after the telephone interview. Another risk we attempted to avoid was facilitating those with known or suspected disordered eating. Thus, the health history screening form contained a few standard-screening questions pertaining to disordered eating. If the subject's responses were suggestive of disordered eating patterns (answering "yes" to any one of the screening questions), she was excluded from this study and given information for recognizing and treating disordered eating behaviors (31). Fortunately, this did not pertain to our recruitment sample. Previously approved educational pamphlets and contact information was provided (IRB Study #: 08-0093, PI: Bonita L. Marks, Ph.D., Study Title: Influence of light clothing on percent body fat estimations using the Bod Pod®). Subjects were also asked to verify their weeklong hydration status and the potential for either claustrophobia and/or hydrophobia. No subjects reported claustrophobia or hydrophobia and all complied with the hydration guidelines.

3. Twenty-four-Hour History Form (Appendix D). The subject completed a short questionnaire regarding her 24-hour health status and when she last ate, consumed fluids, and exercised. For accurate Bod Pod® results, the subject was instructed not to have an acute illness nor to have eaten or exercised within two hours of the test – she must have been rested and hydrated. If it was determined that the subject did not meet these criteria then the appointment was rescheduled. No subjects were rescheduled due to non-compliance of a subject in regards to her 24-hour history.

4. Pulmonary Function (COPD) Screening. The subject performed the COPD screening test after completing the questionnaires. Those having scores suggestive of

"moderate to severe" COPD (FEV_1 < 80% of predicted) were excluded from the study (43,60). All subjects received information about COPD and a UNC contact number for further evaluation. Previously approved educational pamphlets and contact information were provided (IRB Study #: 08-0093, PI: Bonita L. Marks, Ph.D., Study Title: Influence of light clothing on percent body fat estimations using the Bod Pod®). The spirometry equipment measured forced expiratory flow rate in one second (FEV_1) and percent forced expiratory volume (FEV%). Analyzed data provided a percentage of normal indication (FEV_1) which was then compared to predicted values to determine the presence and severity of the disease (64). Disposable one-way valve cardboard mouthpieces (exhalation only) were used. The unit was cleaned with an antiseptic wipe between subjects. For this test, the subject was asked to sit and provide a maximal exhalation into the unit. This unit is accurate to ± 3.0%, which complies with industry standards (65). The subject performed this test three times, resting one to two minutes between trials. The 'best' score was used as the test score. If accepted into the study, the subject proceeded with the urinalysis and body composition testing. Fortunately, no subjects had to be excluded due to the presence of moderate to severe COPD.

5. Urinalysis and Body Composition Testing. Following completion of the screenings, the subject was escorted to the SMRL for the urinalysis screening and first body composition test using the Bod Pod®. She was then escorted back to the APL to complete the UWW test. Descriptions of each methodology are described below.

Urinalysis Screening (66). Hydration status via measurement of urine specific gravity (USG) was confirmed using a urine refractometer. In the restroom and prior to changing into her bathing suit, the subject voided into a small plastic cup. A USG reading between 1.00

and 1.025 was considered euhydrated; a USG reading of greater than 1.025 was considered potential dehydration and the subject was rescheduled. One subject was rescheduled due to her hydration status.

6. **Air Displacement Plethysmography (ADP; Bod Pod).**

If the urinalysis screening was acceptable, then the subject changed into her bathing suit, removed her jewelry (put in a safe location among her personal belongings), exited the bathroom, and entered the Bod Pod® testing room. The subject participated in one test in the Bod Pod® using the appropriate formulas, Ortiz (37) and Siri (38). Once body composition results are recorded for the first formula, the equation initially input into the Bod Pod® software was changed to the second formula. This eliminated the need for multiple testing procedures within the Bod Pod®. To reduce bias, use of these two formulas was presented in a counterbalanced order per subject. This results in the Ortiz (7) formula used first for 18 subjects and the Siri (13) formula used first for the other 18 subjects as illustrated in Table 3 below, where "O" refers to the Ortiz formula and "S" refers to the Siri formula.

Table 3. *Sample of Counterbalanced Schema.*

Subject	Formula 1	Formula 2
1	O	S
2	S	O
3	O	S
4	S	O
5	O	S
6 etc. to 36	S	O

Calibration Procedure. Prior to each testing session, a two-point calibration of the Bod Pod® was performed without the subject in the equipment: a baseline calibration with the chamber empty and a phantom calibration with the manufacturer's 50-liter calibration

cylinder. It was ensured that the calibration cylinder was handled with care to avoid causing any dents to the cylinder as this may have altered the volume and thus calibration.

Measurement Period. The subject was clothed in her bathing suit, provided a clean study-supplied lycra bathing cap required for the testing and enter the Bod Pod®. The subject was instructed to sit in the chamber while staying as still as possible and breathing normally. The subject was first given a three-minute practice/familiarization session so she could become accustomed to the unit and to determine if she was able to sit in the unit without a claustrophobic reaction. After the familiarization period, the door was opened and the subject was asked to complete two measurements with the Bod Pod®, with the formulas presented in a counterbalanced order between subjects as previously described.

If results from the first and second test measurement periods were inconsistent, it was repeated up to three times. The entire testing phase required approximately 20 minutes. At the conclusion of the Bod Pod® testing session, the subject was escorted to the UWW tank area in the APL. The Bod Pod® chamber was cleaned with an antiseptic disposable cloth and re-calibrated prior to testing a new subject.

7. **Underwater Weighing**. For UWW testing, the subject was asked if she needed to empty her bladder and then, after voiding as needed, was escorted to the APL. Prior to the subject's entrance into the UWW tank, the temperature of the water was taken. The subject was asked to remove all jewelry since it has a density of its own. For comfort, the temperature of the water in the UWW tank was between 34 and 38 degrees Celsius (equivalent to Fahrenheit, similar to bathwater). Water density (D_W) was determined from the water temperature via the water density chart (Table 1) previously presented (47). Care was taken to manually expel any trapped air from the swimsuit and hair via a self pat-down

method; this included wetting the head. The tare weight of the electronic load cell system was zeroed out. Basic instructions were given to the subject regarding how to sit in the chair suspended within the UWW tank so that the head remained above the water level prior to the submersion procedure. With minimal water movement, the subject grasped one side of the PVC piping chair and slowly lowered herself into the chair, grasping the other side when seated.

The subject was then instructed to fully submerge her head underwater by bending forward slowly, so that all parts of the body are completely submerged. At the same time, she exhaled maximally. The feet did not touch the bottom or sides of the tank. If the subject "floated" off of the seat, she was required to wear a weight belt and the weighing procedure was repeated. The subject remained motionless while seated completely submerged underwater until the scale reading had minimal fluctuation and no more exhalation bubbles were seen. It took up to ten seconds underwater for the computer to determine the underwater weight of the subject. At the completion of the trial, the tester knocked on the tank to cue the subject to slowly come up from underneath the water. Six to ten trials of UWW were administered. The average of the closest and highest three trials were used for D_b and %BF determinations. If the sinking belt was used, the weight was then subtracted out.

***Residual Volume Estimation* (67).** Residual volume (RV) was estimated using the Wilmore formula for females:

$$RV\ (L) = (0.009 \times \text{age in years}) + (0.08128 \times \text{height in inches}) - 3.9$$

Body Density Determination. Body density (D_b) was calculated per the Goldman and Buskirk equation (5):

$$D_b = W_a \div [(W_a - W_W)/D_W - (RV - 0.1)]$$

where W_a and W_W are measured in kilograms (kg) and RV and the constant of 0.1 were measured in liters (L). Standard published %BF equations were selected for Black females using the following formulas:

- Ortiz formula (7): $\%BF = (485/D_b) - 439$
- Siri formula (13): $\%BF = (495/D_b) - 450$

Research Design and Statistical Analyses

This cross-sectional quasi-experimental study utilized a partially randomized counterbalanced design with subjects serving as their own control. Paired t-tests were used to compare estimates of D_b and %BF for ADP and UWW. If significant differences were found, post-hoc Bonferroni adjustments were performed to prevent type I family-wise error. Ninety-five percent confidence limits of the mean differences between body composition methods were determined. The agreement between methods was explored using a simple linear regression and Bland-Altman plots. A simple linear regression with age entered as an independent factor was also used to determine if the nearly 20-year age span of the subjects impacted the results. Descriptive statistics (means, standard deviations) were used to characterize both the demographic and the body composition scores. Statistical significance was set a priori at $p < 0.05$ for all analyses. The data was analyzed using the SPSS (v. 20.0) Statistical Software Package (IBM Solutions, Durham, North Carolina). The following analyses were used to test the specific research questions and corresponding hypotheses:

Research Question: Will body density (D_b) predictions and consequent percent body fat (%BF) estimations differ when measured in the Bod Pod® versus underwater weighing (UWW) for adult Black women?

Hypothesis One. There will not be a significant difference between the Bod Pod® and UWW determination of D_b for adult Black women subjects.

Hypothesis Two. There will be a significant difference in %BF estimations between the race/ethnicity-specific equations of Siri versus Ortiz.

CHAPTER FOUR

Results

Subjects

The primary purpose of this study was to validate the Bod Pod®, using underwater weighing (UWW) as the gold standard criterion, in adult Black women for the determination of body density (D_b) and estimation of percent body fat (%BF). A secondary purpose of this study was to evaluate the Siri and Ortiz race/ethnicity-specific equations to determine which equation would be most accurate for use in Black women when determining %BF from D_b. Fifty-one subjects were screened for the study, however, nine subjects did not fit the racial criteria, four subjects were not in the required age range, and two subjects noted severe claustrophobia. Therefore, thirty-six adult Black women with both Black biological parents volunteered to participate, signed the UNC-IRB approved consent form, and completed the body composition protocol. The protocol included D_b measurement in the Bod Pod® and UWW tank plus %BF estimations via the Siri and Ortiz %BF equations. Thirty-five subjects successfully completed the required testing during their first (and only) visit; however, due to suspected dehydration, one subject was rescheduled and successfully completed the study at her rescheduled second visit. Histogram reviews suggested all data was normally distributed, therefore parametric statistical testing procedures were used to determine if there were any statistically significant differences. Table 4 provides a summary of the subjects' physical characteristics.

Table 4. *Physical Characteristics of the Sample (n=36).*

Variable	Means (± SD)	Minimum	Maximum
Age (y)	25.2 ± 5.3	19	38
Weight (kg)	73.0 ± 2.8	45.5	114.9
Height (cm)	164.0 ± 1.4	147.3	180.9
BMI (kg/m^2)	27.2 ± 6.31	15.6	44.8
D_bUWW (g/cm^3)	1.034 ± 0.002	1.010	1.063
W_W (kg)	1.22 ± 0.62	0.10	2.70
D_W (g/cm^3)	0.9940 ± .0015	0.9909	0.9972
D_bBodPod (g/cm^3)	1.033 ± 0.003	0.987	1.068
RV (L)	1.58 ± 0.27	1.04	2.07
Highest FEV_1 (L)	2.80 ± 0.36	2.06	3.34
Highest FEV%	97.2 ± 9.3	83	116
USG	1.015 ± 0.006	1.003	1.025

Notes: BMI = body mass index; D_bUWW = body density by underwater weighing; D_bBodPod = body density by Bod Pod®; RV = estimated residual volume, 0.0813 x Height (inches) + 0.009 x Age (years) - 3.900; W_W = water weight by underwater weighing; D_W = water density by underwater weighing; USG = urine specific gravity.

Body Density Measurement and Percent Fat Estimation

To answer the research question, "*Will body density (D_b) measurements and consequent percent body fat (%BF) estimations differ when measured in the Bod Pod® versus underwater weighing (UWW) for adult Black women*?" several paired samples t-tests were performed. As shown in Table 5 the results of the paired t-tests suggested that there was not a significant difference in determination of D_b using either the Bod Pod® or UWW method despite the D_b measurement obtained from UWW being approximately 1% greater than the Bod Pod® D_b measurement. However, their degree of association for the D_b values was high ($r = 0.783$, $p < 0.001$). Nevertheless, statistically significant mean differences were found between the %BF estimation methods. The Bonferroni adjustment required a p value of ≤ 0.017 for three paired comparisons ($0.05 \div 3$) and the detected p values were < 0.001 for

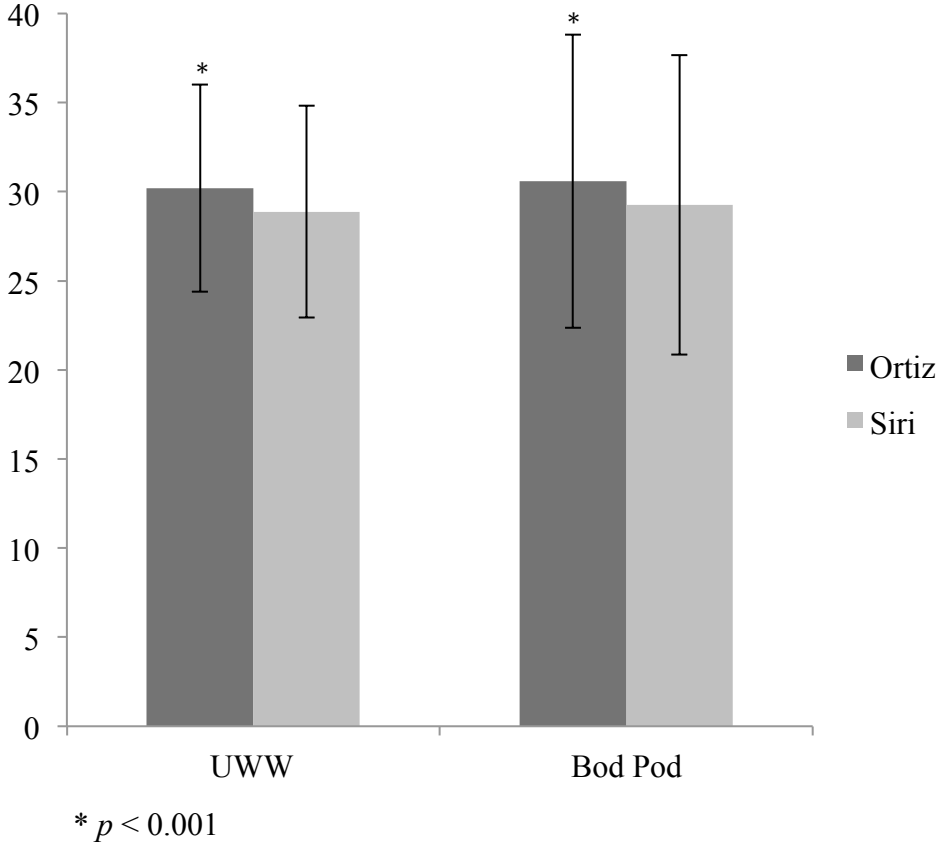
the estimated %BF comparisons. The Ortiz formula consistently estimated higher %BF regardless of the D_b method used. The %BF estimation results are depicted in Figure 2.

Table 5. *Paired Sample T-Tests for Body Density and Percent Body Fat Estimations.*

	Mean (± SD)	SEM	Lower 95% CI	Upper 95% CI	t*	p-value
D_b	0.0007 (± 0.0113)	0.0019	-0.0031	-1.2850	-66.277	0.715
%BF	--	--	--	--	--	--
UWW – Siri vs. Ortiz	-1.33 (± -0.12)	0.020	-1.366	1.375	46.552	< 0.001
BodPod – Siri vs. Ortiz	1.32 (± 0.17)	0.028	1.260	0.005	0.368	< 0.001

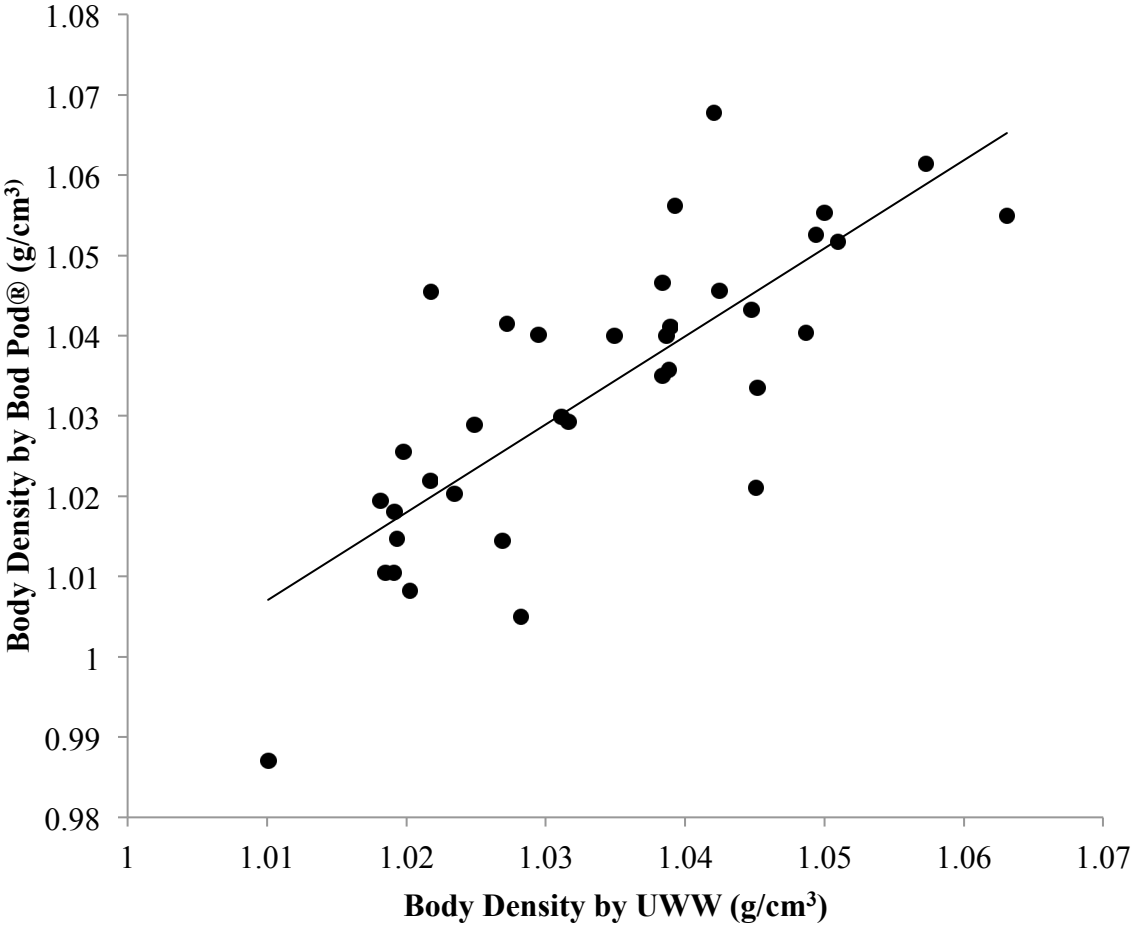
Notes: Siri = using Siri %BF estimation formula; Ortiz = using Ortiz %BF estimation formula; UWW = underwater weighing method; BodPod = Bod Pod® method; D_b = body density calculation, * degrees of freedom = 35.

Figure 2. *Percent Body Fat Means (± SD) using Siri and Ortiz Conversion Formulas for the Bod Pod® and UWW.*



To determine the degree of association between the UWW and Bod Pod® methods for determining D_b, a simple linear regression analysis was used. With the Bod Pod® D_b variable assigned as the dependent variable and the criterion UWW D_b assigned as the independent variable, the following scatter plot was created (see Figure 3).

Figure 3. *Scatterplot of Body Density Values with Bod Pod® Designated as the Dependent Variable and UWW as the Independent Variable.*



As shown in the regression summary tables below (Tables 6-8) where the dependent variable is Bod Pod® D_b and the independent variable is UWW D_b, the regression analyses produced a highly significant adjusted R^2 value. The adjusted R^2 value approximates the

"goodness of fit" of the model (18) and suggests that approximately 60% of the variance of the Bod Pod® D_b was explained by UWW D_b.

Table 6. *Model Summary.*

R	R Square	Adjusted R Square	SEE
0.783	0.613	0.602	0.01136

Table 7. *ANOVA Summary.*

	Sum of Squares	Mean Square	F	p-value
Regression[a]	0.007	0.007	53.932	< 0.001
Residual[b]	0.004	0.000	--	--
Total[c]	0.011	--	--	--

Notes: [a] df = 1; [b] df = 34, [c] df = 35

Table 8. *Coefficients.*

	B[a]	SE[a]	Beta[b]	t	p-value
(Constant)	-0.101	0.154	--	-0.653	0.518
UWW D_b	1.097	0.149	0.783	7.344	< 0.001

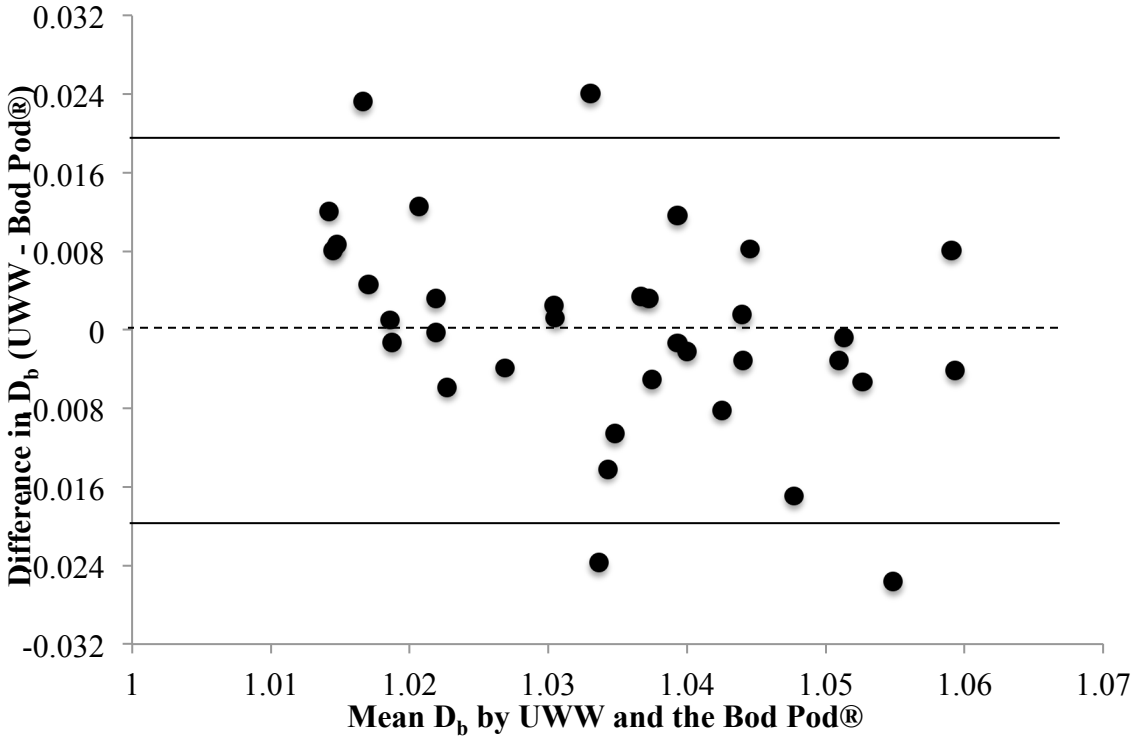
Notes: [a] Unstandardized Coefficients, [b] Standardized Coefficients.

Bland Altman Plot of Agreement between Body Density Determination Methods

The body composition assessment literature often uses Bland-Altman plots for demonstrating the degree of agreement between body composition variables. Therefore, the agreement between D_b for UWW and the Bod Pod® is shown via a Bland-Altman plot (68) in Figure 4, where the difference between methods in D_b (calculated as UWW D_b – BodPod D_b) is plotted against the mean D_b of the two methods. This plot was also used to identify any outliers or systematic bias. The dashed horizontal line represents the mean difference while the solid horizontal lines represent 1.96 times the standard deviation of the differences (69). It should be noted that the dashed mean difference line, while represented at zero (suggesting that the average difference between values is zero g/cm^3), was in actuality

the average difference between values (0.0007 g/cm^3).

Figure 4. *Bland-Altman Plot of Agreement between Methods.*



Although there is good overall agreement between D_b by UWW and D_b by the Bod Pod® in the present study and the paired %BF scatter plots exhibiting perfect correlations, the Bland-Altman plot depicts that the difference between methods was greater than 0.020 g/cm^3, or 1.96 times the standard deviation from the mean in four subjects.

Age Influence

Because the subjects' ages spanned two decades, it seemed prudent to determine if aging was a potential confounding factor in the results. Therefore, another simple linear regression was run (Tables 9-12), with age included as an independent variable and entered in the first block. Body density for UWW was entered as the second independent variable. The Bod

Pod® D_b was entered as the dependent variable for all analyses. The bivariate correlation showed no significant relationship to either UWW D_b ($r = -0.219$, $p > 0.19$) or BodPod® D_b ($r = 0.019$, $p > 0.90$) and the partial correlation that excluded age showed only a slight improvement in the correlation (Table 12, R partial = 0.807) versus the bivariate correlation in Table 6 that did not exclude age (R= 0.783). Thus, there appeared to be no significant relationship between aging and D_b in this subject sample of 19-38 year old Black women.

Table 9. *Aging Influence on Model Summary.*

Model	R	R Square	Adjusted R Square	df	SEE	F Δ	F Δ p-value
1[a]	0.019	0.000	-0.029	34	0.018	0.012	0.915
2[b]	0.807	0.651	0.630	33	0.011	61.637	< 0.001

Notes: [a] Independent variable: age; [b] Independent variables: age + body density by UWW; Δ = change.

Table 10. *Aging Influence on ANOVA.*

Model		Sum of Squares	df	Mean Square	F	p-value
1[a]	Regression	0.000	1	0.000	0.012	0.915
	Residual	0.011	34	0.000	--	--
	Total	0.011	35	--	--	--
2[b]	Regression	0.007	2	0.004	30.835	< 0.001
	Residual	0.004	33	0.000	--	--
	Total	0.011	35	--	--	--

Notes: [a] Independent variable: age; [b] Independent variables: age + body density by UWW.

Table 11. *Aging Influence on Coefficients.*

Model		B[a]	SE[a]	Beta[b]	t[c]	p-value
1	(Constant)	1.032	0.015	--	68.204	< 0.001
	Age	0.000	0.001	0.019	0.108	0.915
2	(Constant)	-0.182	0.155	--	-1.173	0.249
	Age	0.001	0.000	0.200	1.899	0.066
	UWW D_b	1.158	0.148	0.827	7.851	< 0.001

Notes: [a] Unstandardized coefficients; [b] Standardized coefficients; [c] degrees of freedom = 35.

Table 12. *Aging Influence on Excluded Variables*[a].

	Beta	T[b]	p-value	Partial Correlation	Tolerance
UWW D_b	0.827	7.851	< 0.001	0.807	0.952

Note: [a] Age removed for partial; [b] degrees of freedom = 35.

Power Analyses

The power analyses performed a-priori, based on published literature data, suggested that a sample of 36 women would yield 70% power for detecting significant differences for the current study (18,19,24,27,30). While this study did detect statistically significant differences between the %BF pairwise comparisons, it did not find a significant difference between the D_b results. Therefore, a post-hoc power analyses was performed using the actual D_b data to determine the true power of the D_b comparison. Using an alpha level of 0.05, a 0.001 value as the change to be detected, and the actual standard deviation of change (0.0025), the power to detect a significant difference for D_b with 36 subjects was 64.6% (18). Using these same power analyses input values, it was calculated that a minimum of 41 subjects would be required to obtain 70% power (18).

CHAPTER FIVE

Discussion

The primary purpose of this study was to validate the Bod Pod®, using UWW as the gold standard criterion, in adult Black women for the determination of body density (D_b). A secondary purpose of this study was to evaluate the race/ethnicity-specific percent body fat (%BF) equations of Siri vs. Ortiz to determine which would be most accurate for use in Black women when estimating %BF from measured D_b. The results indicated there was no significant difference ($p = 0.715$) found between the Bod Pod® and UWW for D_b results in adult Black women. Significant differences ($p < 0.001$) were found between the general Siri formula and the race/ethnicity-specific Ortiz formula for estimating %BF from D_b. The following discussion focuses on the aforementioned results followed by a review of limitations in the study.

Validity of the Bod Pod® in Adult Black Women for Determination of D_b

The present study found that there was no significant difference between the Bod Pod® and a criterion "gold standard" method, UWW, for determination of D_b in adult Black women. This suggests that the Bod Pod® is a valid alternative for determining D_b in adult Black women. These findings compare favorably with those of Fields, Hunter, and Goran (23) and McCrory et al. (19), both of whom reported that the Bod Pod® was indeed a valid alternative to UWW for D_b determination and resultant %BF determinations. Although

those conclusions appear to be contrary to that of Millard-Stafford et al. (34), who reported that the Bod Pod® significantly overestimated ($p < 0.05$) D_b and underestimated %BF when compared to a four-compartment (4C) model, that study's recommendation was specific to young adults and not the current study's population sample of adult Black females.

Findings from the present study indicate that the Bod Pod® is a valid method for determining D_b in adult Black women as compared to UWW. It therefore can be used in lieu of UWW for estimating %BF as long as one is comfortable with the known under/over-estimation error, which results from the various %BF estimation formula(s). The mean difference between methods for D_b was 0.0007 ± 0.0112 g/cm^3. These results are important from both a research and (practical) clinical perspective, because unlike UWW, DXA or other D_b determination methods, the Bod Pod® does not require water submersion, affords no exposure to x-rays, and offers a quick, convenient method for D_b determination. Considering that Black women are at major risk for the development of obesity and obesity-related diseases, it is crucial to identify and promote a valid, easy-to-use technique for determination of D_b and estimation of %BF.

Use of Race/Ethnicity-Specific Equations for Determination of Percent Body Fat

There are a number of differences in body composition between ethnicities, specifically Blacks as compared to Whites. Blacks have been shown to have a greater muscularity, bone density, bone mineral mass, total body potassium, and body protein content than Whites, all of which should contribute to a higher density of fat free mass (D_{ffm}) (7–11) and presumably higher total D_b. Therefore, in order to obtain accurate D_b results from any instrument

measuring D_b and resultant %BF estimations, it is suggested that race/ethnicity must be taken into account.

Determining the multiple components that contribute to D_b was not feasible for the current study. More elaborate D_b methodologies while desirable, was not possible. A matched comparison group of similarly aged White women would also have been helpful for determining over- or underestimation issues with the D_b methodology used. Therefore, it is not possible to state with certainty that the lower %BF estimations found per the Siri equation were truly biological underestimations attributable to being non-ethnic specific as has been documented in the literature (45) .

The present study confirmed that a significant difference exists between the general Siri formula and the race/ethnicity-specific Ortiz formula (7) for estimated %BF values derived from D_b in adult Black women. Using D_b data from UWW, the mean difference for $\%BF_{Siri}$ was 1.33 ($\pm$ 0.12), approximately 1% lower than $\%BF_{Ortiz}$. Using the D_b data from the Bod Pod®, the mean difference for $\%BF_{Siri}$ was 1.32 ($\pm$ 0.17). Again, this was approximately 1% lower than $\%BF_{Ortiz}$. Since the standard error of the estimate using UWW is about 2.5% (45), this 1.33% error is well within the known error inherent in the UWW methodology. These numbers, while statistically significant, are relatively small and therefore the clinical practical relevance or impact is potentially negligible. This suggests that the use of race/ethnicity-specific equations may be unnecessary when estimating %BF from D_b measured via UWW or the Bod Pod® in adult Black women. Similar conclusions were reached by other studies (19,23,26,32,33).

Given our study found no significant differences in D_b values obtained via UWW versus the Bod Pod®, our results are potentially in disagreement with Wagner et al. (9) and

Buchholz at el. (32), who reported that the use of race/ethnicity-specific equations in the Bod Pod® were necessary to provide accurate results in Blacks when using either a 4C model and DXA as the criterion measures.

It cannot be determined, however, which %BF equation is more appropriate for estimating %BF in this population, as there was no comparison group to determine over- or underestimating issues. It can only be noted that the equations produce different results, suggesting that either the race/ethnicity Ortiz formula overpredicts %BF or that the general Siri formula truly underpredicts %BF in Blacks as reported in other research studies (58).

Given these results, it can be argued that the Siri equation underestimated %BF in this Black female population. This may be a result of D_{ffm} assumptions used with the Siri equation, which was derived from a theoretical population using White male cadavers with an assumed a D_{ffm} of 1.100 g/ml. If the D_{ffm} of adult Black women is greater than 1.100 g/ml then we would expect to see an underestimation of %BF using the Siri formula (9). Alternatively, it could also be argued that the Ortiz equation overestimated %BF, which suggests that actual D_{ffm} for adult Black women is somewhere between the 1.100 g/ml, assumed by Siri, and the 1.106 g/ml assumed by Ortiz.

Despite the good overall agreement between D_b determined by UWW and D_b by the Bod Pod® in the present study, the difference between methods was greater than 0.020 g/cm^3, or 1.96 times the standard deviation from the mean, in four subjects. This suggests that the Bod Pod® may not be valid at the individual level. This slightly disagrees with results found by Biaggi et al. (42) who found accurate group and individual assessment of D_b and %BF when compared against UWW. Future research needs to better elucidate these observations.

Limitations

While the utmost care was taken for recruiting and testing per our stated methodology, there remains the possibility that the results of this study may have been influenced due to known limitations in our study design as well as potential unknown non-compliance issues as detailed below.

1. Pre-Test Compliance. Non-compliance to the diet and exercise pre-test could produce errors in D_b and %BF calculations. To minimize these known potential errors, adherence to the medical exclusions and pre-test guidelines were verified via completion of several questionnaires upon lab arrival. However, these all relied on accurate, truthful self-reporting. With the exception of the hydration status via urinalysis screening, there were few objective mechanisms in place to verify accuracy of subjects' self-reports. Therefore, it is possible that some individuals did not comply with the pre-test guidelines and were not accurate in completing the questionnaires.

2. Predicted Lung Volumes. The use of estimated RV could have resulted in an overestimation of %BF between 2.0 – 3.5% (44–46), but since this estimation formula was applied equally across the entire subject sample, the same degree of overestimation error would likely be systematically present throughout the enitre study sample (46). In addition, this degree of over-predicition is also within the known error range of the Bod Pod® (5).

3. UWW as Criterion Method. Previous studies have shown UWW to contribute varied differences in D_b and %BF measurements between the Bod Pod® and UWW (42). While no significant differences were found between the aforementioned variables in the present study, the presence of multiple measurements including water temperature, sensor calibrations,

residual volume, and UWW measurements may have lead to unintentional technical measurement errors which could have contributed to increased error in the estimations of D_b and %BF (42). Also, the use of UWW to determine body density does not directly result in D_{ffm} or bone mass measurements, thus the D_b calculation cannot be as precise as a DXA or other advanced imaging techniques.

4. UWW Procedure - Subject Compliance. There is also a degree of subject compliance that impacts the UWW result. Because exhaling all one's air prior to submerging underwater is deemed "unnatural" and potentially frightening for the subject, subjects first practiced the exhalation component outside of the tank in order to learn how to perform this technique. Once in the tank, subjects engaged in several UWW trials in order to account for learning and fatigue effects of this exhalation technique. Still, some subjects may have found this technique difficult to perform, and therefore their best efforts may still have been inadequate, resulting in an overestimation of %BF (47).

5. Age Range. A further limitation to this study is the age of the samples used for development of the D_b equations and the age range for this study sample. There is no published D_b formula for 19-23 year old women for the Ortiz formula that estimates %BF. The study sample of Black women for the Ortiz %BF formula ranged from 24-79. Because the population in this study included those between the ages of 19 and 23, the Ortiz %BF formula used may not be accurate for younger adult Black women. Future research should examine the accuracy of the Ortiz %BF formula in this particular age group by comparing results with more precise body composition imaging techniques.

6. Sample Size. As acknowledged in the results, the sample size for the present study yielded a power between 65-70%, depending upon the variable. Thus, it is possible that if the power was higher, the non-significant findings may have been more trustworthy.

7. Generalizability. This study's findings are limited to adult Black women between 19-38 years of age. Results may not be applicable to those under or over this age range or of other ethnicities. Furthermore, due to the broad biological definition of who was considered "Black", it is possible that the results may have been different if stricter biological requirements were instituted. As such, those with different degrees of biological Black heritage (e.g., all biological parents and grandparents from Africa, all Caribbean, etc.) may have different %BF test results.

CHAPTER SIX

Summary and Conclusions

Summary

The purpose of this study was to validate the Bod Pod® against UWW in adult Black women (aged 19-38 years) for the determination of D_b and %BF. A secondary purpose of this study was to evaluate the race/ethnicity-specific equations of the Bod Pod® to determine which equation is most accurate for use in Black women when determining %BF.

Results showed no significant difference between D_b as measured by the Bod Pod® and UWW in adult Black women. This suggests that the Bod Pod® is valid in determining D_b in adult Black women and compares favorably to other published research reports (19,23). From a practical perspective these results are important because unlike UWW or DXA, the Bod Pod® does not require water submersion, affords no exposure to x-rays, and offers a quick and convenient method for determination of D_b in this population. Considering that Black women are at major risk for the development of obesity and obesity-related diseases, it is crucial to identify and promote the use of a valid and easy-to-use technique (such as the Bod Pod®) for determination of D_b and %BF.

There was no significant difference between the Bod Pod® D_b versus UWW D_b determinations. However, a statistically significant difference (but clinically small, only a mean of 1%) was found between the general Siri %BF estimation formula and the race/ethnicity-specific Ortiz %BF estimation. Age did not appear to be a factor. This

difference in %BF estimation between the two methods is well documented in the literature, with the Siri formula consistently underpredicting %BF in Blacks when compared to the Ortiz Black-specific formula. Therefore, it is not surprising to have this occur in the current study. Even so, this difference may be explained by the known differences in body composition between ethnicities, wherein Blacks tend to have a greater muscularity, higher bone density and bone mineral mass greater total body potassium, and greater body protein content collectively resulting in a D_{ffm} than Whites. This suggests that the use of race/ethnicity-specific equations are necessary when an accurate determination of %BF from D_b is required in adult Blacks (9,32).

Conclusions

Based on the results of the present study, the following research question and hypotheses were addressed:

Research Question: *Will body density (D_b) measurements and consequent percent body fat (%BF) estimations differ when measured in the Bod Pod® versus underwater weighing for adult Black women?*

Hypothesis One. There will not be a significant difference between the Bod Pod® and underwater weighing determination of D_b for adult Black women subjects.

This hypothesis was accepted because paired t-tests showed no significant difference between D_b determinations using these two methods. This finding was also corroborated by the D_b values being highly correlated with each other.

Hypothesis Two. There will be a significant difference in percent body fat (%BF) estimations between the race/ethnicity-specific equations of Siri versus Ortiz.

This hypothesis was accepted because a statistically significant difference was found between $\%BF_{Siri}$ and $\%BF_{Ortiz}$ estimations. The $\%BF_{Siri}$ equation resulted in a lower %BF estimation in comparison to the %BF estimation calculated by the Ortiz equation.

Practical Application and Suggestions for Future Research

To the knowledge of the investigators, this was the first study aimed at validating the Bod Pod® for use specifically in a relatively larger population of adult Black women. The findings of the present study suggest that the Bod Pod® is valid in determining D_b in adult Black women. These results are significant because unlike UWW or DXA, the Bod Pod® does not require water submersion, affords no exposure to x-rays, and offers a quick and convenient method for determination of D_b and subsequent estimation of %BF in this population. Considering that Black women are at major risk for the development of obesity and obesity-related diseases, it is crucial to maintain valid and easy-to-use techniques for determination of D_b and %BF.

Additional future research may increase the age range to include menopausal and post-menopausal women and could also aim to validate the Bod Pod® for use in other underrepresented populations in body composition research.

APPENDIX A

TELEPHONE HEALTH/INFO SCREENING

Caller Name:_____ **AGE____** Phone:_____ E-mail:_____
Approximate Weight: _____ **(300 lb. limit).** INTERVIEWER: _____

1. Have you ever been diagnosed with an eating disorder? Y N
   If YES, stop screening and thank the caller for their interest but explain we do not have permission to conduct body comp testing on ED patients.

2. Do you currently have a cold, chronic bronchitis, emphysema, or moderate to severe asthma? Y N
   If YES, stop screening and thank the caller; If it's just a 'temporary cold, tell him to call back when the cold is gone. Tell him/her we will be conducting the study for a few more weeks.

3. Race/Ethnicity
   Do you classify yourself as Black? This includes but is not limited to African American, Sub-Saharan African, and Afro-Caribbean. Y N
   If NO, stop screening and thank the caller. **If YES, continue:**

   a. Are both of your parents Black? This includes but is not limited to African American, Sub-Saharan Africa, and Afro-Caribbean. Y N

   b. To your knowledge are all of your grandparents Black? This includes but is not limited to African American, Sub-Saharan African, and Afro-Caribbean. Y N

   If NO for any of the above, stop screening and thank the caller. **If YES, continue:**

4. Bathing Suit: Are you willing to wear a tight fitting bathing suit? Y N
   If NO, stop screening and thank the caller. **If YES, continue:**

   Do you have a 1 or 2 piece lycra-style bathing suit? Y N
   a. If yes, is it without bra padding? Y N
   b. If yes, is it without 'ornamentation' (no frills, belts, ruffles, etc.) Y N
   If NO to "a or b", ask: "Can the padding/frills/belts etc. be removed?" Y N

5. Underwater Weighing: Are you willing and able to completely submerge your head underwater? Y N

6. Pregnancy: Are you pregnant or think you might be pregnant? Y N
   If NO to any of the above, stop screening and thank the caller.

APPROVAL STATUS: YES NO PENDING

If yes, thank them and tell them you will be e-mailing them an appointment reminder and sending them pre-test day instructions regarding eating, drinking, and exercise.

APPT: Day_____Date:_____Time: _____ ID#: _____ **OR,**
CALL-BACK: Best Day(s) and Times: _____
E-Mail Address: _____

APPENDIX B

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: January 22, 2013
IRB Study # 13-0800
Title of Study: Measurement of fat mass using the Bod Pod®: a validation study in adult Black women
Principal Investigator: Dangaia Sims
Principal Investigator Department: Exercise and Sport Science
Principal Investigator Phone number: 757-784-3694
Principal Investigator Email Address: dasims@live.unc.edu
Faculty Advisor: Bonita L. Marks, Ph.D.
Faculty Advisor Contact Information: marks@email.unc.edu
Co-Investigators: Dr. Edgar Shields (shields@email.unc.edu)
Dr. Deborah Stroman (dstro@unc.edu)

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to assist in determining whether or not the Bod Pod® is an appropriate means of body composition measurement in Black women, when a race-specific equation is used. Considering that Black women are at major risk for the development of obesity and obesity-related diseases and that Black women are under-represented in body composition research, determining whether the Bod Pod® is a valid body composition assessment method for this specific population may facilitate wider use of air displacement plethysmography technology in community health clubs and wellness centers. Body density measurements obtained from the Bod Pod® will be compared against measurement obtained from underwater weighing, a gold standard method for body composition. Percent body fat will be determined using two different formulas. One was

developed originally for use in White adult males and the other was specifically developed for use in adult Black women.

You are being asked to be in the study because you fit the description of a Black woman between the ages of 19 and 39. For the purposes of this study "Black" is used to describe persons of whom all biological parents are of African descent, excluding Black Hispanics. This will encompass but is not limited to the following ethnicities: African-American, Sub-Saharan African, and Afro-Caribbean.

Are there any reasons you should not be in this study?
You should not be in this study if you do not fit this study's description of being of Black descent. For the purposes of this study "Black" is used to describe persons of whom all biological parents are of African descent, excluding Black Hispanics. This will encompass but is not limited to the following ethnicities: African-American, Sub-Saharan African, and Afro-Caribbean. Additionally you should not be in this study if you have any or all of the following: significant lung problems medically termed chronic obstructive pulmonary disease (COPD; e.g. asthma, bronchitis, etc.), an upper respiratory tract infection (e.g. cold, flu), are not willing or able to wear the mandatory clothing for testing which includes a tight fitting bathing suit (lycra or spandex; one- or two-piece), and/or not able to perform the appropriate techniques as required by the Bod Pod® and underwater weighing.

How many people will take part in this study? Approximately 36 women will participate in this study.

How long will your part in this study last?
This study requires one total visit. This visit will take approximately 1-1.5 hours. There will be no follow-up for this study.

What will happen if you take part in the study?
This study consists of one visit, which will occur, in the Exercise Science Teaching Lab the Sports Medicine Research Lab and the Applied Physiology Lab, all of which are located on the ground floor in Fetzer Hall.

Enrollment and Pre-Testing

1. Upon arrival to the Exercise Science Teaching Lab (ESTL) you will be given private time to read the consent form, ask any questions you may have, and sign the consent form if you choose to participate.
2. You will complete a general health history form to ensure you have no health problems that may interfere with your participating.
3. You will complete a 24-hour health history form and a dietary profile questionnaire.
4. You will complete a pulmonary function (COPD) screening. If you have a score suggestive of "moderate to severe" COPD, you will be excluded from the study. Using a disposable cardboard mouthpiece, you will be asked to stand and exhale maximally into the spirometry unit, which will test your lung function. You will perform this test three times, resting one to two minutes between trials. Your 'best' score will be used as the test score.

5. If pre-screening is successful and you are admitted to the study, you will be escorted from the ESTL to the Sports Medicine Research Lab (SMRL) body composition office to complete body composition testing.
6. Upon arrival to the SMRL, you will complete a urinalysis screening to measure hydration status. You will be asked to use the private restroom in the office where you will void into a small plastic cup. Upon analysis of the urine, if you are dehydrated you will be rescheduled and additional hydration suggestions will be given. If adequately hydrated, you will be asked to change into your swimwear.

Body Composition Testing

1. You will first complete body composition testing via the Bod Pod®, then you will be escorted to a different lab to participate in underwater weighing.
2. In the SMRL private bathroom, you will put on your own swimsuit and the lab-provided lycra swim cap, remove all jewelry and put in a secure place among your personal items. You will enter the Bod Pod® testing area where your height and weight will be measured.
3. You will be instructed to sit in the Bod Pod® while staying as still as possible and breathing normally.
4. You will be given a three-minute practice/familiarization session so you can become accustomed to the unit and determine if you is able to sit in the unit without difficulty.
5. While sitting quietly in the Bod Pod®, one test will be completed, alternating use of the body fat test prediction formulas.
6. This entire testing phase will require approximately 20 minutes. At the conclusion of the Bod Pod® testing session, you will be escorted to the underwater weighing (UWW) tank area in the Applied Physiology Lab (APL). It is suggested you bring a swim/bath robe cover up for the walk in the hallway between the two testing labs (less than a 3-minute walk). You will be given instructions as to how to perform the dunking procedure outside of the UWW tank and be allowed ample time to practice before entering the UWW tank.
7. You will enter the UWW tank slowly. Once standing in the tank, you will carefully pat down your swimsuit to remove any trapped air; this will include wetting the head, as hair will also trap air.
8. You will be given instructions regarding how to sit in the chair suspended within the tank so that your head will remain above the water level during the non-measurement rest periods.
9. With minimal water movement, you will grasp one side of the PVC piping chair and slowly lower yourself into the chair, grasping the other side when seated.
10. You will be instructed to fully submerge your head underwater by bending forward slowly, so that all parts of the body are completely under water. At the same time, you will exhale maximally. This will allow you to "sink". Since muscle weighs more than fat, and excess air in your lungs will cause you to float, excess air in your lungs will be misinterpreted as fat and cause an incorrect body fat determination. Therefore, in order to make sure we get the best UWW measurement, you must learn to blow out as much air as possible as you go underwater. Your feet must not touch the bottom of the tank and you must not be floating off the seat. In the event that you "float" off of the seat, you will be required to put a weight belt on your lap and the procedure will be repeated.

11. You must remain still while seated completely submerged underwater until the electronic scale reading has minimal changes and no more exhalation bubbles are seen. While this usually requires only a few seconds, it may take up to 10 seconds to get a good reading.
12. At the completion of each trial, the tester will knock on the UWW tank to cue you to slowly come up from underneath the water. Six to ten trials of UWW will be administered and the three best, most reliable trials will be used to determine your percent body fat.
13. At the conclusion of the entire testing session, you will be given a copy of your body composition test results.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. While you will not benefit directly from being in this research study, you will receive personal information about your body composition as well as information to assist you in maintaining or improving your body composition profile.

What are the possible risks or discomforts involved from being in this study?
Although measurement of body composition in the Bod Pod® is relatively quick, the small chamber may cause feelings of claustrophobia in certain individuals, even with the viewing window. Additionally, you may experience mild discomfort associated with fully submerging your head and body underwater.

There is no anticipated risk of psychological harm, economic loss, or legal jeopardy associated with participation in this study. There will be two CPR-trained researchers present during all testing procedures to ensure safety throughout the testing. In the unlikely event that you sustain an injury during the study, you will be referred to the appropriate medical personnel on campus (i.e. Campus Health Services or the UNC Hospital's Emergency Room). A landline telephone is located in each lab with emergency procedures posted.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Upon enrollment in the study, you will be assigned an identification number. All written information collected will be associated with this identification number and will be stored separate from the data file in a locked file cabinet in the Exercise Science Teaching Lab (ESTL) in Fetzer Hall at UNC-Chapel Hill. Only the principle investigator (D. Sims) and primary faculty advisor (Dr. Marks) will have access to this information. During the study, all electronic files will be stored on a password protected external USB drive. Upon completion of the study, all de-identified hard copy data and the password-protected USB flash drive will be transferred from the ESTL to locked cabinets in the faculty advisor's locked office in Woollen Gym (W311). Subject data contained on the Bod Pod® and UWW tank computers will be deleted.

You will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, because you did not fit the criteria required by the study, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive anything for being in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

APPENDIX C

GENERAL HEALTH HISTORY SCREENING

ID #:_____ Age? _____ Date:_____

This questionnaire has been designed to identify those for whom body composition testing might be inappropriate or unreliable. Please read the following questions carefully and **circle YES or NO. For every "YES" answer please provide a brief explanation below the question or in the "Comments" section.** Thank you.

1. Has a doctor ever told you or your parents that you have lung trouble?	Yes	No
2. Do you have breathing difficulties or shortness of breath?	Yes	No
3. Do you frequently suffer from pain in your chest?	Yes	No
4. Do you often feel faint or have severe dizzy spells?	Yes	No
5. Do you have claustrophobia? (i.e., fear/panic in small-enclosed spaces?)	Yes	No
6. Are you pregnant or think you might be pregnant?	Yes	No
7. Can you fast (not eat or drink) for 2 hours without it adversely affecting your health?	Yes	No
8. Do you make yourself sick (vomit) when you feel uncomfortably full?	Yes	No
9. Do you ever eat in secret?	Yes	No
10. Do you often use laxative and/or colon cleaners?	Yes	No
11. Do you fast often?	Yes	No
12. Do you currently suffer with or have you ever suffered in the past with an eating disorder?	Yes	No
13. Are you allergic to lycra?	Yes	No
14. Are you taking any medications?	Yes	No
15. Is there any other condition not listed here that may affect your ability to safely participate in the body composition and lung function testing?	Yes	No
16. Are you a UNC student or employee?	Yes	No
17. (If yes to 16) Do you possess a UNC One Card to verify your information?	Yes	No

COMMENTS:

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PFT (Lung Function) SCORES:	**Trial 1**	**Trial 2**	**Trial 3**
FEV_1	_____	_____	_____
FEV_1%	_____	_____	_____

Hydration Status USG Score _____ Acceptable? Y N

APPENDIX D

24-Hour History Form

Subject ID#:_____ Date:_____ Time:_____

1. How would you rate your general state of well being today? (circle number)

   1. very, very good
   2. very good
   3. good
   4. average
   5. bad
   6. very bad
   7. very, very bad

2. Have you been sick within the past week? YES NO
   If you answered "yes", please describe the nature of your illness:

3. Did you exercise today? YES NO
   If you answered "yes":

   At what time did you exercise?

   For how long did you exercise?

   Please briefly describe what you did:

   Please rate the intensity of today's exercise by circling the appropriate number low:

   1. very, very easy
   2. very easy
   3. easy
   4. average
   5. hard
   6. very hard
   7. very, very hard

4. Describe any exercise you performed yesterday (what you did, how long, how hard):

5. How long ago did you last eat? _____ Please describe any food consumed (include quantities):

6. When did you last drink something? _____ hours/min

7. How much have you drank today? _____ cups/ounces.
   Describe:

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