

COMPARISON OF WITHINGS BODYCARDIO TO GOLD STANDARD
MEASUREMENTS OF PULSE-WAVE VELOCITY AND BODY COMPOSITON

A Thesis
by
CONNER A. MCCRAW

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CONNER A. MCCRAW
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APPROVED BY:

Scott Collier, Ph.D
Chairperson, Thesis Committee

Marco Meucci, Ph.D
Member, Thesis Committee

Joe Morgan, MD
Member, Thesis Committee

Michael J. McKenzie, Ph.D.
Dean, Cratis D. Williams School of Graduate Studies

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Abstract

COMPARISON OF WITHINGS BODYCARDIO TO GOLD STANDARD MEASUREMENTS OF PULSE-WAVE VELOCITY AND BODY COMPOSITION

Conner A. McCraw
B.S., Appalachian State University
M.S., Appalachian State University

Chairperson: Scott R. Collier, Ph.D.

Introduction: General Wellness Products (GWP) are widely used by consumers, human physiology scientists, and healthcare practitioners. However, current research on GWP accuracy is limited and often reports large inaccuracies. **Purpose:** The purpose of this study was to assess the Withings BodyCardio for accuracy in the measurement of body composition and arterial health when compared against gold standard laboratory measurements. **Methods:** Healthy, young males (N=10) and females (N=10) were assessed for measures of body composition and pulse-wave velocity (PWV) in a randomized order utilizing air displacement plethysmography (BodPod), applanation tonometry (SphygmoCor), and the Withings BodyCardio. Measures of body composition and PWV were compared with criterion measures using the Bland-Altman analysis and mean absolute percent error (MAPE). **Results:** Data is reported as Bias (95% Confidence Interval). The BodyCardio overestimated PWV by 0.68 m/s (-0.16, 1.51) and fat mass by 2.91 kg (-2.91, 8.73). BodyCardio PWV and fat mass estimations had a MAPE of 9.7% and 25.8%, respectively. The BodyCardio underestimated body mass and fat-free mass by 0.11 kg (-0.41,

0.18) and 2.87 kg (-9.04, 3.30), respectively. BodyCardio body mass and fat-free mass estimations had a MAPE of 0.15% and 5.6%, respectively. **Discussion:** The Withings BodyCardio should be used cautiously for measures of fat mass and fat-free mass, although it provides accurate measures of body mass and PWV.

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Dedication

I would like to dedicate this project to my parents Joe and Kerry Stewart. They have given me an endless amount of support and encouragement throughout my entire academic career of which I am eternally grateful.

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Chapter 1

Introduction

Background

General Wellness Products (GWP) are increasingly made available to consumers by companies like Withings, Apple, and Fitbit. These sensory-based devices aim to objectively quantify a myriad of health-related measures such as physical activity, sleep, body composition, heart rate and derivative measures such as heart rate variability as well as pulse-wave velocity (PWV). Technological and engineering advancements in accelerometry, photo-plethysmography, ballistocardiography, and bioelectric impedance analysis (BIA) are primarily responsible for the development of General Wellness Products, however the validity of these technologies have been questioned.

Digital bathroom scales, physical activity monitors and bedside sleep devices are commercially sold and were recently classified as “General Wellness Products” by the U.S. Food and Drug Administration’s amendment to the 21st Century Cures Act (FDA Digital Health, 2018). Their presence in the consumer market place is evident. A survey of 5,000 U.S. adults reported that one out of ten owns a GWP with an expected 11% increase in use by the end of 2016” (Live Science, 2015). Research scientists in human physiology and behavioral sciences frequently use GWP’s as well. Analysis of clinicaltrials.gov in 2016 revealed that Fitbit, the leading producer of GWP’s, was involved in one hundred and twenty-seven clinical studies (Wright, Hall Brown, Collier, & Sandberg, 2017). Research applications are outside of this study’s scope, however, Wright et al has provided an extensive review on how some GWP’s are transforming human physiology research (Wright et al., 2017). Additionally, data from GWP’s are being integrated into electronic medical

records and could be used to inform medical decisions which adds to the demand of validity assessment (Waggott, Singh, Batra, Wright, Ashley, 2016).

Consumers, researchers, and healthcare practitioners could assume GWP's are accurate, however, validation studies are often unavailable (Bassett, Rowlands, & Trost, 2012). An issue with validating GWP's is that new device models are increasingly available making it difficult for researchers to design, fund, and implement a validation study with the device still relevant. The validation studies that do exist often report large disagreements when GWP measurements are compared against gold-standard research laboratory measurements (Baroni, Bruzzese, Di Bartolo, & Shatkin, 2016; Nelson, Kaminsky, Dickin, & Montoye et al., 2016; Shcherbina et al., 2017).

Chapter 2

Review of Literature

Measurement of Body Composition

According to data from the National Health and Nutrition Examination Survey (NHANES) more than 2 in 3 U.S. adults are considered to be overweight or obese ($\text{BMI} \geq 25 \text{ kg} \cdot \text{m}^{-2}$) (Flegal, Kruszon-Moran, Carroll, Fryar, & Ogden, 2016). It is estimated that if the current rate of prevalence continues, then 86.3% of US adults will be overweight or obese by the year 2030 (Wang, Beydoun, Liang, Caballero, & Kumanyika, 2008). Overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health (CDC, 2017). In normal, healthy individuals total body fat content is about 80-90% subcutaneous adipose tissue, about 6-20% visceral adipose tissue, and 7% adipose tissue compartmentalized in the retroperitoneal area. Health concerns particularly arise with excessive visceral adipose tissue which is an independent risk factor for diabetes, hypertension, and all-cause mortality (Bhupathiraju & Hu, 2016; Hayashi et al., 2004; Kuk et al., 2006; Nicklas et al., 2004). Additionally, a sexual dimorphism exists in fat distribution which affects cardio-metabolic disease risk. Males typically have an android phenotype characterized by a greater accumulation of visceral fat (Palmer & Clegg, 2015). Females generally have a gynoid phenotype with subcutaneous adipose tissue accrual around the gluteo-femoral region greater than visceral/abdominal adipose deposition. Increased lipoprotein lipase activity in the visceral region and its suppression by testosterone in the femoral region of men partially describe these sex differences in fat deposition (Arner, Lithell, Wahrenberg, & Bronnegard, 1991; Ramirez et al., 1997). Growth of fat mass can occur either by growth in volume of preexisting adipocytes, i.e. hypertrophy, or through

recruitment of new preadipocytes, i.e. hyperplasia (Tchoukalova et al., 2010). Studies in rodents suggest that subcutaneous depot increases by adipocyte hyperplasia while visceral fat accumulates by adipocyte hypertrophy (Wang, Tao, Gupta, & Scherer, 2013). These differences in adipose tissue expansion and sex differences in adipocyte deposition may affect certain body composition analysis techniques like bioelectrical impedance analysis.

Air displacement plethysmography (ADP) is a body composition measurement technique that is less invasive than the gold standard Dual X-ray Absorptiometry (DXA). This system uses a measuring chamber of a known pressure and volume to calculate the volume of the subject. Poisson's Law, the pressure-volume relationship at a constant temperature and humidity, and adjustments for thoracic lung volume are used to measure the volumetric displacement the subject imposes on the chamber (Ackland et al., 2012). Body density is then derived using other demographic measures like height and body mass in addition to body volume. Like hydro-densitometry, body density is then used to estimate a two-compartment body composition model consisting of fat-mass (FM) and fat-free mass (FFM). The BodPod made by Cosmed is a device utilizing ADP technology for measurements of body composition. The BodPod has been validated when compared to DXA and for test-retest reliability (Dewit, Fuller, Fewtrell, Elia, & Wells, 2000; Tucker, Lecheminant, & Bailey, 2014). Despite its validity in measurement of body composition, the BodPod is not commonly available for consumers because the procedure is often costly and takes time to endure.

Bioelectrical impedance analysis (BIA) technology is widely used for body composition assessment because the equipment is normally portable, safe, and easy to use while less expensive than other techniques like DXA or ADP. BIA aims to derive fat mass

(FM) and fat-free mass (FFM) values from an estimation of body volume (B_v) by sending an electrical current through the body (Ackland et al., 2012). Returning to the analyzer, the impedance of the electrical current can be determined.

A principle the BIA uses is that of a cylinder's volume where volume equals length multiplied by the cross-sectional area and impedance is inversely proportional to its cross-sectional area. This principle also assumes the cylinder's material is homogeneously conductive. However, the human body is not cylindrical, and tissues vary in conductivity (Kyle et al., 2004). To address this issue, engineers developed a multi-frequency BIA. Using both high and low frequencies allow the current to penetrate the cell membrane and consequentially account for both the extracellular fluid and intracellular fluid conductance from which an estimation of total body water (TBW) is determined. FFM can then be predicted from TBW due to FM only consisting of about 7% water (Kyle et al., 2004). However, as previously mentioned, adipocytes vary in number and size, thus the amount of water within FM varies and extrapolations present inherent error. Additionally, the deposition of insulated tissues within the body such as adipose tissues affects the impedance of surrounding conductive tissues according to the mixing theory (De Lorenzo, Andreoli, Matthie, & Withers, 1997).

BIA technology has progressed over the last decade, however, a more recent study showed when compared to DXA percent error between methods was near 9% (Buffa, Mereu, Comandini, Ibanez, & Marini, 2014). Withings has developed a home bathroom scale called the BodyCardio that utilizes multi-frequency BIA technology to measure BM, FFM, and FM. The scale also wirelessly connects to a smart phone application where changes in body composition and weight can be tracked over time. While regular self-weighing and the use of

smartphone health applications can improve health outcomes, the Body Cardio has not been compared to gold standard measurement methods of body composition nor validated by an independent laboratory (Higgins, 2016; Zheng et al., 2015).

Measurements of Arterial Health

Arterial stiffness relates to the mechanical properties of arteries that subsequently affect cardiovascular health. In a healthy or young population arteries are more distensible when compared to an unhealthy or older population (Butlin et al., 2013). Arterial distensibility is important for health because it helps attenuate pulsatile flow and aligns timing of pressure waves returning to the heart for optimal coronary perfusion.

The heterogeneity of the arterial tree, meaning the diminishing of elastic properties from the central to peripheral arteries, creates an increase in amplitude of the pressure wave known as pressure amplification. Frank, Bramwell, and Hill derived this propagative model of the circulatory system in the early 20th century. Their equation concluded that pressure amplification and the pulse wave's velocity is inversely related to the distensibility and gave scientists a theoretical model to develop technology for measurement of pulse wave velocity. These studies created a large base of support and subsequently an expert consensus establishing carotid-to-femoral PWV (cf-PWV) as the gold standard for measurement of arterial stiffness (Mitchell et al., 2010; Townsend et al., 2015; Van Bortel et al., 2012). Also, multiple meta-analyses have elucidated that measurement of cf-PWV improves CVD event and mortality prediction, independent of standard risk factors like hypertension, dyslipidemia, or high blood glucose (Ben-Shlomo et al., 2014; Mitchell et al., 2010; Vlachopoulos, Aznaouridis, & Stefanadis, 2010).

While multiple methods of cf-PWV measurement exist, the SphygmoCor devices by AtCor Medical are cited over 1000 times in peer-reviewed research articles and are validated against the ARTERY Society's PWV validation guidelines (Butlin & Qasem, 2017; Butlin et al., 2013). The SphygmoCor XCEL uses applanation tonometry for high-frequency arterial wave form acquisition and volumetric displacement within a cuff for femoral pulse. The cf-PWV can then be calculated by measuring the transit time between carotid and femoral pulse and dividing it by the pulse wave's travel distance. This travel distance is estimated by measurement of several surface points along the body to most accurately determine carotid-femoral length (Butlin & Qasem, 2017).

Recently, Withings developed an advanced bathroom scale called the Body Cardio as a more convenient and less expensive alternative to devices like the SphygmoCor in measuring arterial stiffness. The BodyCardio uses ballistocardiography (BCG) and impedance plethysmography (IPG) to determine an aortic-leg pulse wave velocity (al-PWV) (Campo et al., 2017a). BCG measures slight weight variations due to left-ventricle ejection of blood and corresponds well to the opening of the aortic valve (Campo et al., 2017b). IPG measures blood volume changes at the measurement site and is used in the consumer scale to determine the arrival time of the pulse wave to the feet from the aortic valve. Subtracting the arrival time from the left ventricle ejection of blood and the pulse wave's arrival time at the feet determination of al-PWV is possible. Comparison between SphymoCor XCEL and Body Cardio for PWV has already been completed and resulted in an "acceptable" agreement between devices according to the ARTERY society's standards (Campo et al., 2017b; Van Bortel et al., 2012). However, no study has accounted for the gravitational effect by standing on a scale on al-PWV. Thus, the Body Cardio needs to be validated using this methodology.

Summary

The purpose of this study was to assess the accuracy of a commercially available General Wellness Product for measures of body composition and arterial health when compared to laboratory gold standard measurements.

It was hypothesized that there would be significant differences between devices for all measures of body composition and pulse-wave velocity. It was also hypothesized that there would be differences between devices attributable to sex.

Chapter 3

Methods

Participants

Following approval of the study from Appalachian State University Institutional Review Board (IRB# 17-0023), twenty male and female adults 18-25 years of age were recruited. Prospective participants were contacted via face to face conversation or through an IRB approved email blurb. All subjects were apparently healthy, normotensive, and had no known cardiovascular, metabolic, or renal disease. Participants had a personal (iOS or Android) smartphone and service plan which they were able to use for this study. Exclusion criteria included chronic disease that might limit physical activity (e.g., peripheral arterial disease, effort angina, heart failure, and rheumatologic disorders), laboratory measurements, the use of the Withings devices (e.g. vision inadequate to read watch or smartphone displays, lack of dexterity required to use the devices) or receiving any antihypertensive medication. All participants were students from Appalachian State University. Descriptive statistics of the subjects included in this study are provided in Table 1.

	N	Min	Max	Mean	SD
Age (yrs.)	20	18	25	21.8	2.0
Height (cm)	20	160.0	187.3	172.8	7.5
Weight (kg)	20	51.0	94.5	66.8	12.2

Table 1. Subject Descriptive Statistics

Study Procedures

Subjects were instructed to report to the Vascular Biology and Autonomic Systems Laboratory (VBASL) at Appalachian State University well-rested, fasted, and without having any stimulants twelve hours prior to testing. The investigator and subject reviewed an informed consent form which resulted in the subject's signature if they agreed to the terms and procedures of the study. Anthropometric and demographic data, i.e. sex, date-of-birth, height and weight, was collected via medical history form and a calibrated scale and stadiometer. Next, subjects rested while seated for five minutes before blood pressure was manually and automatically recorded by a medical grade stethoscope and SphygmoCor, respectively. Manual auscultation was performed to ensure no technological discrepancies were present with the SphygmoCor. Subjects were subsequently assigned to either a body composition assessment by the Bod Pod or pulse-wave velocity measurement by the SphygmoCor in a random order. Before all weight and body composition measurements, the subject was required to remove all jewelry and excess clothing and additionally required to wear compression clothing such as spandex, compression shorts, or a sports bra. Subjects were instructed to wear a swim cap, breathe normally and to sit still while in the Bod Pod. Thoracic gas volumes were predicted using the BodPod software for body volume corrections. Two measurements were completed using the Bod Pod and unless the two were significantly different, i.e. more than one standard deviation, then no third measurement was made.

The subject was instructed to stand up next to the SphygmoCor with the Body Cardio in proximal distance. The researcher measured standing blood pressure after the subject had rested in the standing position for three minutes. Next, the femoral cuff was placed on the

subject and carotid to femoral artery distance was measured using a tape measuring device. Next the researcher began assessment of pulse wave velocity by placing a doppler pen via applanation tonometry on the subject's carotid artery. Pulse wave velocity was measured three times and in between measurements the subject was instructed to stand onto the BodyCardio until successful measurement of body composition and pulse wave velocity were garnered. The BodyCardio was properly cleaned between subjects.

Chapter 4

Results

Statistical Analysis

Data was collected from each device's particular software and the Withings' "Healthmate" website and compiled into a secure database. The average of three pulse-wave velocity measurements and two of each body composition measurements were used for analysis. A Bland-Altman analysis was conducted for measures of pulse-wave velocity and body composition. Bias was calculated as the criterion-reference measurement minus the General Wellness Product measurement. A one-sample t-test was performed to acquire the mean difference and 95% confidence intervals for the Bland-Altman plots. Furthermore, regression analysis was performed to evaluate for proportional bias and Pearson correlation coefficient. Mean Absolute Percent Error (MAPE) presents the error as a percentage of the overall mean and indicates the degree of error. Additionally, a repeated measures ANOVA was conducted to analyze variance attributable to sex between devices.

Pulse-Wave Velocity

The mean PWV and standard error for each device and sex are displayed in Table 2 as well as graphically displayed in Figure 1. The mean difference between devices was 0.68m/s and their respective 95% confidence intervals were (-0.16, 1.51) as shown in Figure 2. Regression analysis resulted in a Pearson correlation coefficient of 0.49 and evidence of proportional bias ($p < 0.05$). Analysis of variance showed no effect of sex on PWV measurement between devices. MAPE was calculated to be 9.7%.

	PWV (w)	PWV (r)
Male	6.2±0.2	7.0±0.2
Female	5.9±0.2	6.6±0.2
Total	6.1±0.1	6.8±0.1

Table 2. Pulse-Wave Velocity ± SE (m/s)

* “r” = reference device “w” = Withings BodyCardio

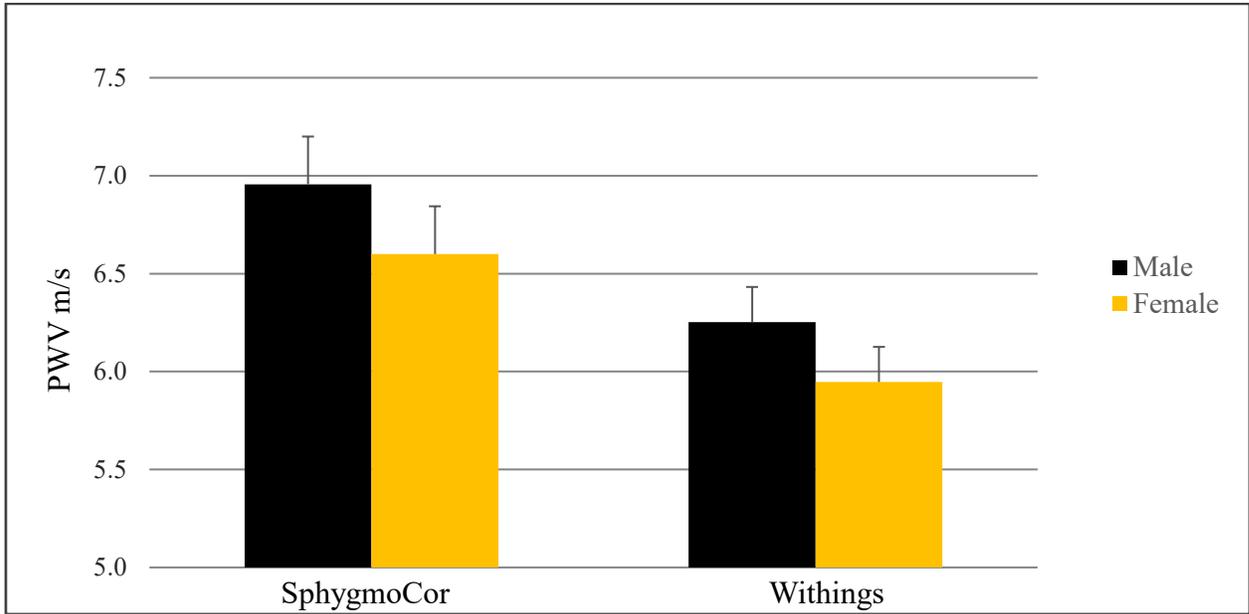


Figure 2. Pulse-Wave Velocity by Device and Sex

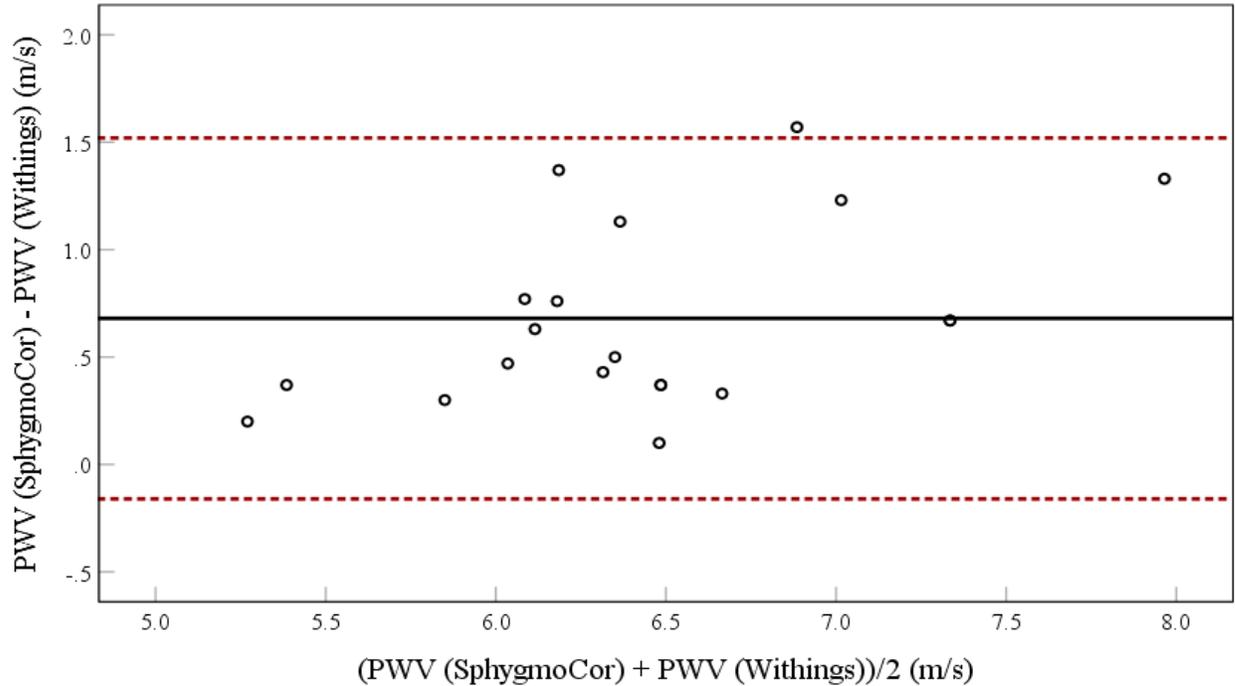


Figure 2. Mean Difference and 95% confidence intervals of PWV between devices.

Body Mass

The mean BM and standard error for each device and sex are displayed in Table 3 as well as graphically displayed in Figure 3. The mean difference between devices was -0.11 kg and their respective 95% confidence intervals were (-0.41, 0.18) as shown in Figure 4. Regression analysis resulted in a Pearson correlation coefficient of 0.47 and evidence of proportional bias ($p < 0.05$). Analysis of variance showed no effect of sex on BM measurement between devices. MAPE was calculated to be 0.15%.

	BM (w)	BM (r)	FM (w)	FM (r)	FFM (w)	FFM (r)
Male	75.7±2.5	75.5±2.4	7.3±1.5	10.6±1.4	68.2±1.8	64.9±1.9
Female	57.8±2.5	57.8±2.4	10.2±1.5	12.8±1.4	47.6±1.8	45.1±1.9
Total	66.8±2.7	66.6±2.6	11.7±1.0	8.8±1.1	55.0±2.6	57.9±2.7

Table 3. Body Mass, Fat Mass, and Fat-Free Mass ± SE (kg).

* “r” = reference device “w” = Withings BodyCardio

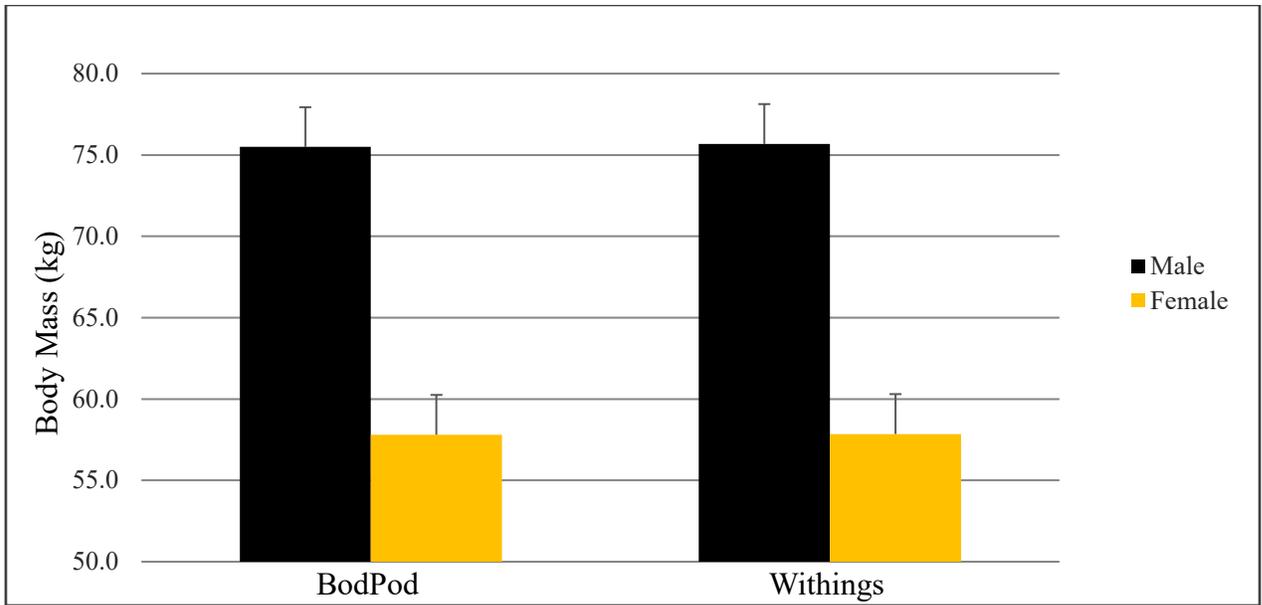


Figure 3. Body Mass by Device and Sex.

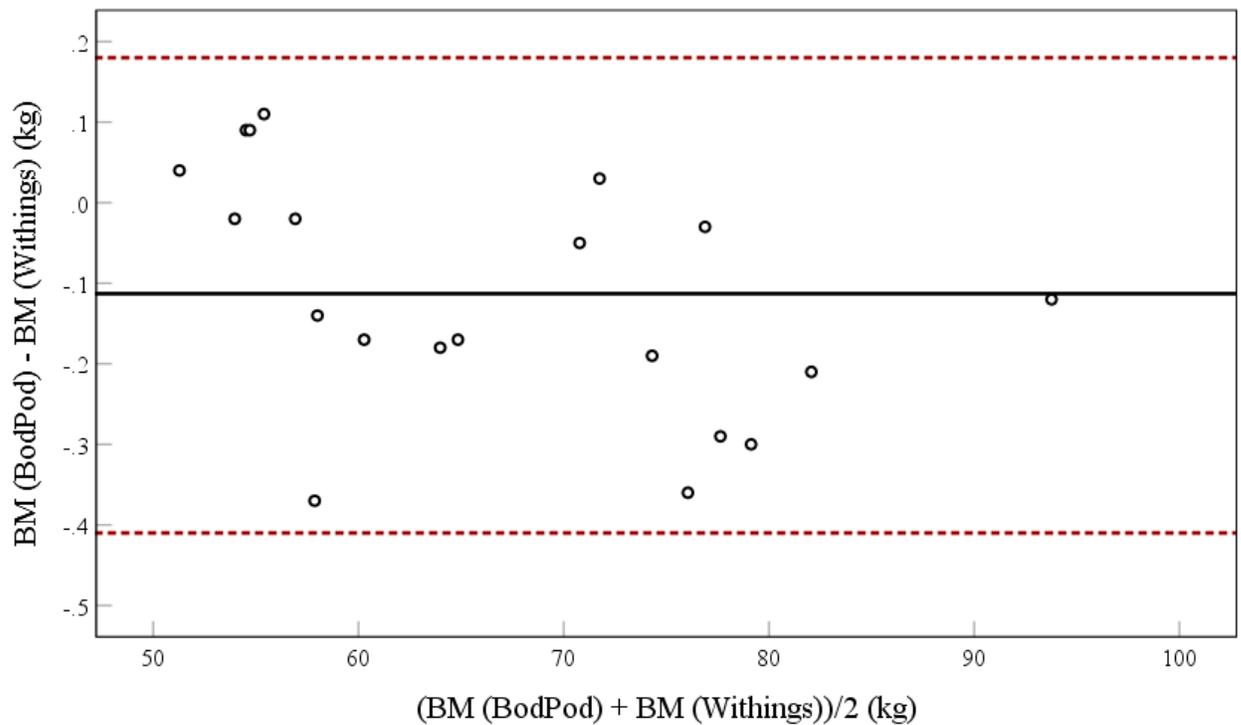


Figure 4. Mean difference and 95% confidence intervals of BM between devices.

Fat Mass

The mean FM and standard error for each device and sex are displayed in Table 3 as well as graphically displayed in Figure 5. The mean difference between devices was 2.91kg and their respective 95% confidence intervals were (-2.91, 8.73) as shown in Figure-6. Regression analysis resulted in a Pearson correlation coefficient of 0.16 and no evidence of proportional bias. Analysis of variance showed no effect of sex on PWV measurement between devices. MAPE was calculated to be 25.8%.

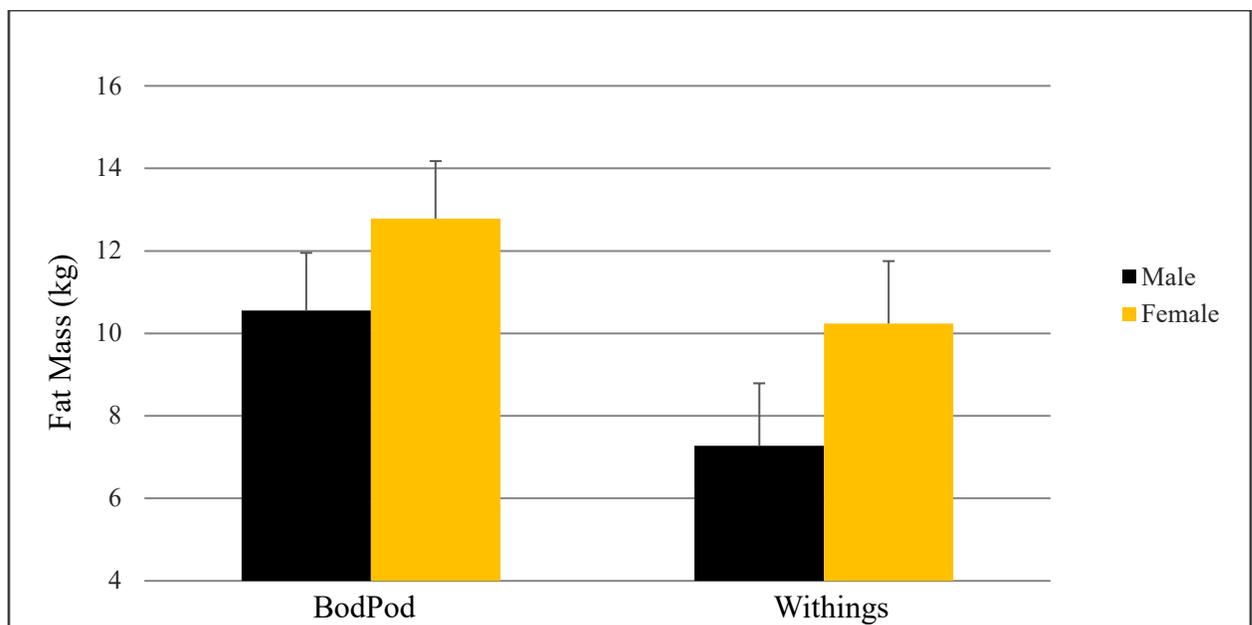


Figure 5. Fat Mass by Device and Sex.

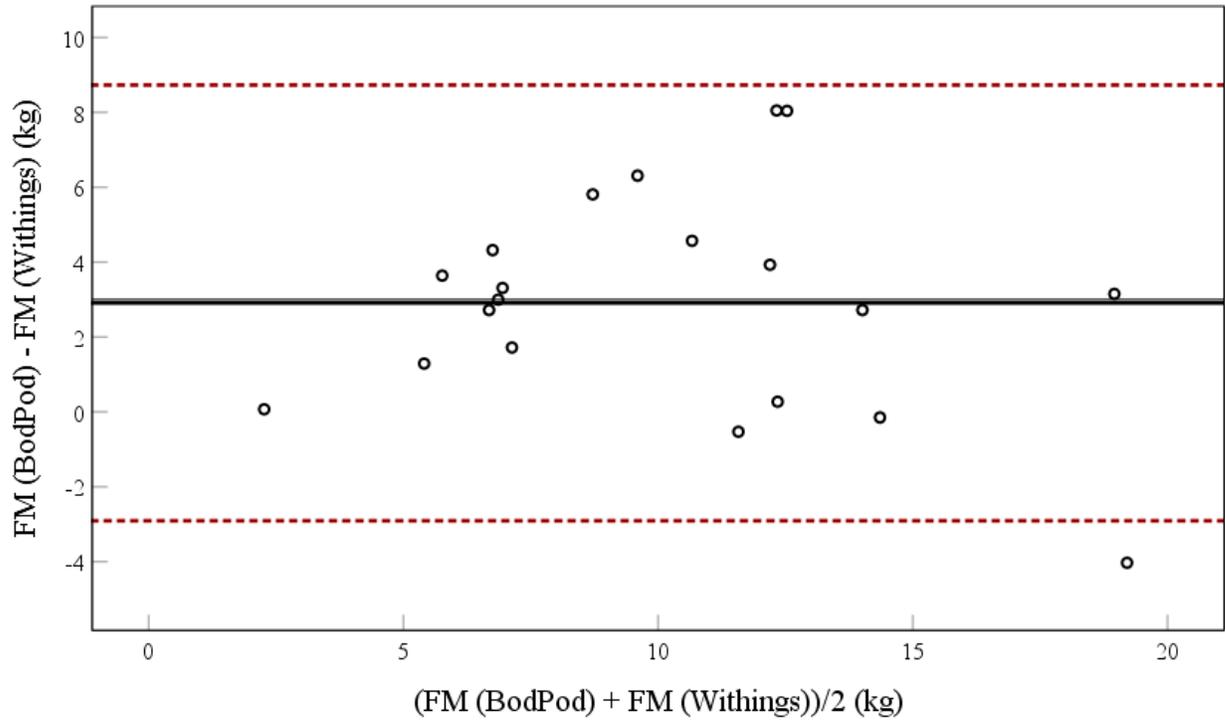


Figure 6. Mean difference and 95% confidence intervals of FM between devices

Fat-Free Mass

The mean BM and standard error for each device and sex are displayed in Table 3 as well as graphically displayed in Figure 7. The mean difference between devices was -2.87kg and their respective 95% confidence intervals were (-9.04, 3.30) as shown in Figure 8. Regression analysis resulted in a Pearson correlation coefficient is 0.06 and no evidence of proportional bias. Analysis of variance showed no effect of sex on PWV measurement between devices. MAPE was calculated to 5.6%.

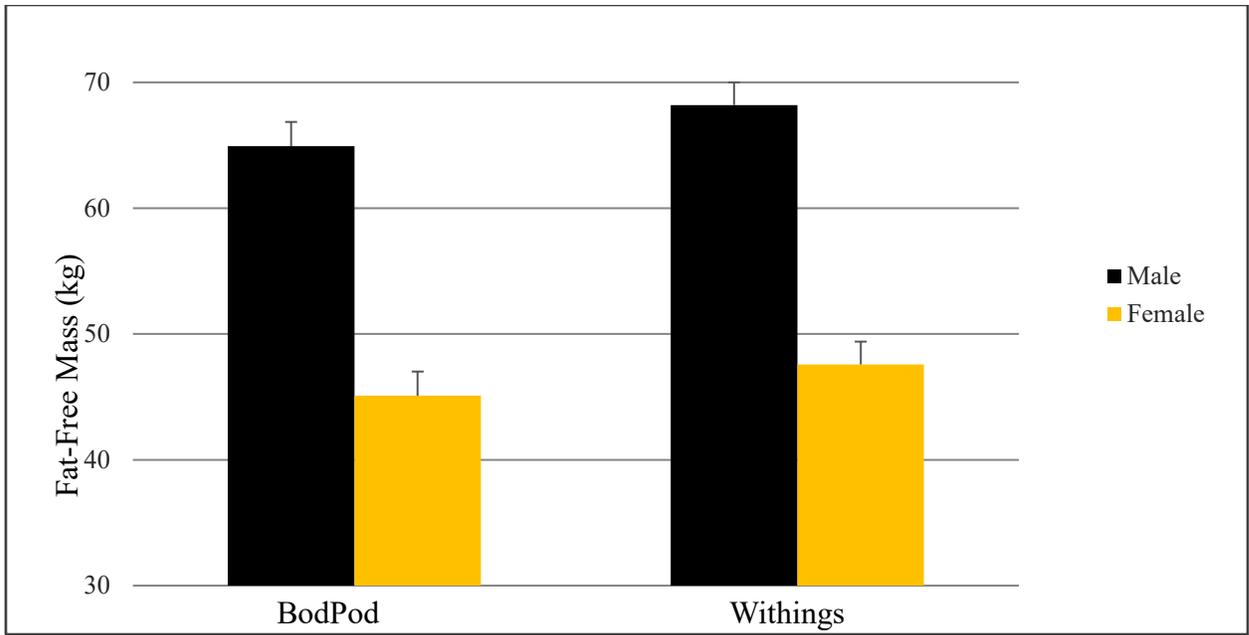


Figure 7. Fat-Free Mass by Device and Sex.

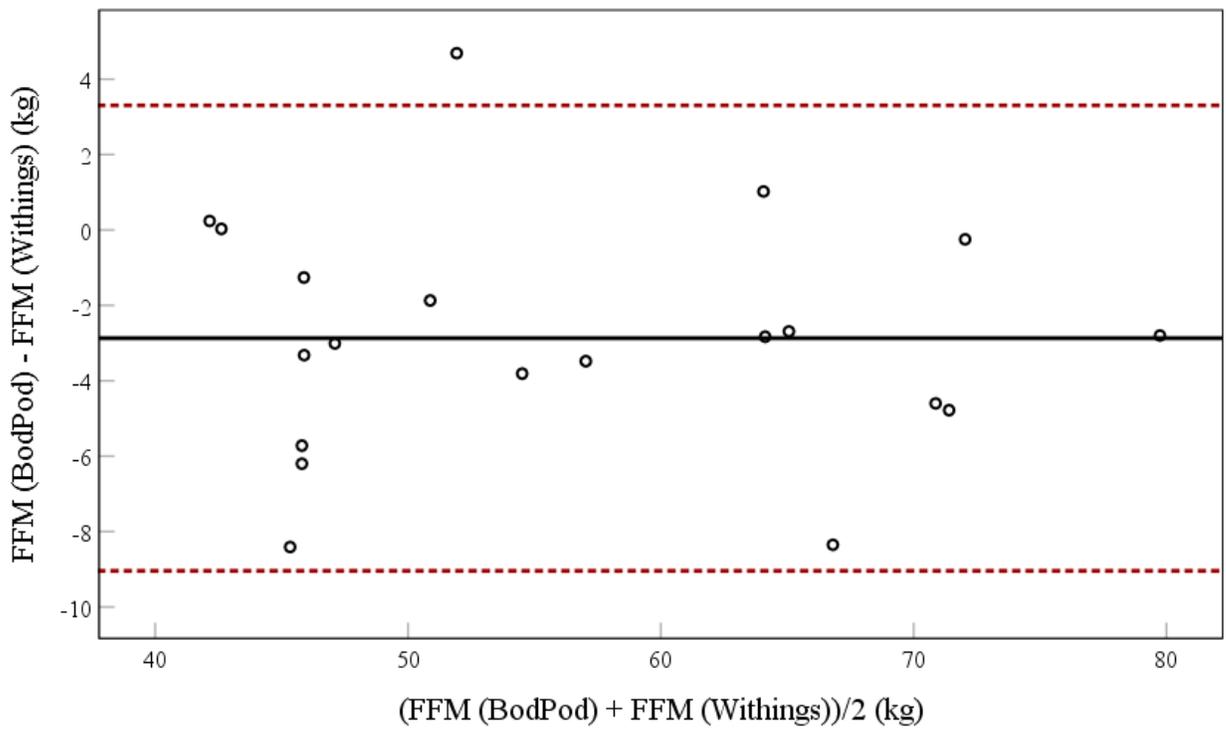


Figure 8. Mean difference and 95% confidence intervals of FFM between devices.

Chapter 5

Discussion

The present study assessed the agreement between a consumer-based General Wellness Product and gold-standard laboratory measurements of arterial health and body composition. Body mass showed the strongest agreement between devices with a MAPE of 0.15% whereas fat mass had the weakest agreement with a MAPE of 25.8%. Digital scales typically utilize a strain gauge to measure body mass instead of bioelectric impedance analysis which may explain the strength of agreement for body mass between devices. While there is not a consensus on an acceptable limit of error for body composition in comparison to gold-standard measurements this study's findings beckon for further investigation into an acceptable range. One study has suggested that 1.5% or less percent error for body composition measures is acceptable when comparing the BodPod to DXA (Ball & Altona, 2004). According to these guidelines, none of the body composition measurements from this study other than body mass would be deemed acceptable.

According to the ARTERY society's expert consensus for accuracy of pulse-wave velocity measurement, an "acceptable" accuracy rating is a mean difference of less than or equal to 1.0 m/s and a standard deviation of less than or equal to 1.5 m/s. The present study found the Withings BodyCardio to be in "acceptable" agreement with the AtCor Medical SphygmoCor for measurement of pulse-wave velocity with a mean difference of 0.68 m/s and a standard deviation of 0.57 m/s in respect to the ARTERY society's guidelines. A previous study had already demonstrated an "acceptable" accuracy between the BodyCardio and SphygmoCor but relied on self-reported height and did not account for the gravitational effects of standing upright on the cardiovascular system and pulse wave

velocity. This study was the first to show an “acceptable” accuracy between the devices while measuring subject height and accounting for the gravitational effects of standing upright while measuring pulse-wave velocity. The impact of these results are bolstered considering that pulse-wave velocity improves prediction of cardiovascular disease event and mortality independent of lifestyle and standard risk factors. Implications of having an affordable, portable, and accurate scale for measurement of pulse-wave velocity that can be monitored over time may include better cardiovascular health outcomes.

The number of subjects recruited was a limitation of this study. While the number of males and females were equivalent this study’s small sample size may provide explanation for the lack of observation of variance attributable to sex for pulse-wave velocity and body composition measures. Additionally, this small sample size may have hidden any proportional bias that would be pertinent to determining sensitivity. Another limitation of this study was the lack of control for hydration. Hydration status largely impacts measurement of body composition by bioelectrical impedance analysis (Buffa et al., 2014).

This study presented inaccuracies for fat mass and fat-free mass in the Withings BodyCardio when compared to gold-standard laboratory measurements in a young and healthy population. Furthermore, pulse-wave velocity was found to have an “acceptable” accuracy with the ARTERY societies guidelines. Moreover, the communication around these measurements of arterial health and body composition is important. While there are optimal ranges of body composition and pulse wave velocity for health, the dialogue between consumers and device manufactures needs to include information about device accuracy. Investigation to determine whether use of the BodyCardio’s corresponding phone application

“Healthmate” leads to prevention of cardiovascular disease or reduction of risk factors is needed.

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Vita

Conner Anson McCraw was born in Hendersonville, North Carolina. He graduated from Appalachian State University in Boone, North Carolina in December, 2016, with a Bachelor of Science in Exercise Science and a concentration in Clinical Exercise Physiology. The following Spring, he accepted a research assistantship with Appalachian State University and began study toward a Master of Science degree which was completed in December of 2018. In November of 2018, Mr. McCraw accepted a position as a certified Clinical Exercise Physiologist at a cardiac-rehabilitation center.

Mr. McCraw currently resides in Seattle, Washington. During his free time, he enjoys riding his bike and spending time with family and friends.