5-2006

Validation of the ParvoMedics TrueOne® 2400 Metabolic Measurement System for measuring resting metabolic rate in a heterogeneous adult population

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To the Graduate Council:

I am submitting herewith a thesis written by Tracie M. Weinheimer entitled "Validation of the ParvoMedics TrueOne® 2400 Metabolic Measurement System for measuring resting metabolic rate in a heterogeneous adult population." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Exercise Science.

Edward T. Howley, Major Professor

We have read this thesis and recommend its acceptance:

David R. Bassett, Jr., Eugene Fitzhugh

Accepted for the Council:
Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

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Eugene C. Fitzhugh

Accepted for the Council:

Vice Chancellor and
Dean of Graduate Studies

Validation of the ParvoMedics TrueOne® 2400 Metabolic Measurement System for measuring resting metabolic rate in a heterogeneous adult population

A Thesis

Presented for the Master of Science

Degree

The University of Tennessee, Knoxville

Tracie M. Weinheimer

May 2006

Dedication

This thesis is dedicated to my father, Robert S. Weinheimer, Jr., who always encouraged me to reach for dreams I never considered possible; and to my mother, Nancy Weinheimer, my brother Brian, sister Laura, and nephew J.R. for continual love and support. Thank you all.

Acknowledgments

I would like to thank the members of my graduate committee. Thank you Dr. Edward Howley for your patience, and constant guidance and mentorship throughout this project. Thank you Dr. David Bassett and Dr. Eugene Fitzhugh for your insight, and for serving as members of my thesis committee. A special thanks is extended to Dr. Patsy Boyce for all of her help and early mornings in pilot studies. I greatly appreciate the time and effort you all have given to me and to this project.

Abstract

The primary purpose of this study was to validate and compare the accuracy of the ParvoMedics TrueOne® 2400 Metabolic Measurement System in measuring resting VO_2 against the criterion Douglas bag method, and secondarily to compare the Douglas bag measures of VO_2 to those from the ParvoMedics TrueMax® 2400 Metabolic Measurement System, which has been previously validated up to near maximal metabolic rates (3). Resting metabolic rate (RMR) is determined by measuring the oxygen consumption (VO_2) of the subject lying in the supine position in the early morning following an overnight fast. The TrueOne® system uses a "flow-through" methodology, with the subject under a plexiglass canopy; the TrueMax® system measures gas exchange in a conventional manner. Seven males and thirteen females underwent a 30-minute RMR test on each machine; test order was randomly assigned. In addition, expired air was collected into either a Douglas bag or a non-diffusing gas collection bag from the back of the mixing chamber of each system. This allowed a simultaneous measurement of the resting VO_2 to compare the systems to the criterion method. Expired gas volume was determined using a Collins 120 liter gasometer, and O_2 and CO_2 fractions were determined using calibrated gas analyzers. The TrueOne® 2400 systematically underestimated VO_2 compared to the external Douglas bag method by approximately 22% (0.18 L/min and 0.24 L/min, respectively). The TrueMax® 2400 yielded VO_2 values nearly identical to the criterion Douglas bag method (VO_2 = 0.24 L/min and 0.23 L/min, respectively). The systematic underestimation of resting VO_2 by the ParvoMedics TrueOne® 2400 Metabolic Measurement System indicates it is not an

accurate device for measuring resting VO_2. The ParvoMedics TrueMax® 2400 is capable of accurately measuring resting VO_2.

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CHAPTER I

INTRODUCTION

According to the National Health and Nutrition Examination Survey (NHANES), a program of the Centers of Disease Control and Prevention, nearly 65% of the population, or about 60 million American adults are either overweight or obese (11). In addition, data collected up to the year 2002 indicate that this "obesity epidemic" shows no sign of decreasing (15).

This obesity trend is attributed to many factors, which generally fit into one of two categories: physical inactivity and poor nutrition. With decreased energy expenditure from continuous societal automation upgrades and increased energy intake from ever growing portion sizes, the prevalence of obesity is rising exponentially. In order to help individuals develop a weight management plan to lose the excess weight, we must have an accurate measure of some basic metabolic information. Total daily energy expenditure (TDEE) is the amount of energy a free-living body uses in a 24-hour period. It is comprised of three parts: physical activity, the thermic effect of food, and resting metabolic rate.

Resting metabolic rate (RMR) is a measure of the amount of energy expended daily in order to maintain normal bodily functions at rest, and accounts for 60-75% of TDEE (19). Measurement of RMR can provide a baseline value for nutrition and weight management plans. RMR is normally reported as either the volume of oxygen consumed (VO_2) or as kilocalories per day. One kilocalorie is the amount of energy required to raise 1 liter of water 1 degree Celsius. Metabolic rate can be measured by direct calorimetry, a procedure requiring a specialized room and technology to measure heat

production directly, as well as that associated with evaporation. However, the most common method for measuring metabolic rate, including the RMR, is by indirect calorimetry. This technique calculates energy production by measuring the volumes of oxygen consumed (VO_2) and carbon dioxide produced (VCO_2), and grams of nitrogen excreted (17). Based on constants determined by completely oxidizing carbohydrate, protein, and fat in a bomb calorimeter, VO_2 can be converted into kilocalories. In most applications, nitrogen excretion is not measured, with little loss in precision (17).

Open-circuit spirometry is the most widely used method of indirect calorimetry. In this procedure the individual breathes room air, which has a known composition of 20.93% oxygen, 0.03% carbon dioxide, and 79.04% nitrogen. The product of the ventilation and the differences between the expired gas fractions and these known O_2 and CO_2 values yields the rates of oxygen consumption and CO_2 production.

Many procedures exist to measure oxygen consumption using open-circuit spirometry. The criterion or "gold standard" method is considered to be the Douglas bag method (9). This basic technique does not provide many outlets for error. The subject inhales ambient air and expired gases are collected in a large non-diffusing canvas bag (named after the pioneer Claude G. Douglas [1882-1963]) for a specific amount of time. The gas fractions are analyzed and the volume of expired gas is then measured. This technique can be somewhat cumbersome and requires the investigator to perform all measurements by hand. However, because of the straightforward design, there is little room for introducing error and is therefore seen as a criterion standard to measure VO_2.

Advancements in technology have produced computerized metabolic gas analysis systems capable of measuring V_E, VO_2, and VCO_2. These systems continuously measure

the volume of expired air with a flow-sensing device (e.g. pneumotachometer), as well as expired gas fractions by O_2 and CO_2 analyzers. There are currently more than 30 commercially available metabolic gas analysis systems (18). They range in price from around $10,000 to more than $40,000. With an investment of many thousands of dollars, it is imperative to know if these systems are accurate and precise. Many validation and reliability studies have been done on commercially available metabolic systems (5, 18, 21, 23, 24, 29, 32). A new system for measuring RMR is the ParvoMedics TrueOne2400® Metabolic Measurement System, which uses a flow-through design, eliminating the need for mouthpieces and respiratory valves found with most systems.

The primary purpose of this study was to validate the ParvoMedics TrueOne® 2400 Metabolic Measurement System by comparing its resting VO_2 measure to that obtained by a non-simultaneous measurement via the criterion Douglas bag method. A secondary purpose was to compare the Douglas bag measures of VO_2 to those from the ParvoMedics TrueMax® 2400 Metabolic Measurement System, which has been previously validated up to near maximal metabolic rates (3).

We hypothesize that there will be no statistical difference between resting VO_2 values measured by the TrueOne® 2400 and the criterion external Douglas bag method. The TrueMax® 2400 will provide similar measures of resting VO_2 compared to the simultaneous Douglas bag collection.

CHAPTER II

REVIEW OF LITERATURE

Background

According to the Centers for Disease Control and Prevention, over 60 million people in the United States are overweight or obese, and if trends continue as they have the past 20 years, this number will continue to grow (15). The significance of this "epidemic" is highlighted by a 2005 publication in the New England Journal of Medicine which predicts that life expectancy in the U.S. could possibly decrease if obesity rates continue to rise (26). This would mean that the current generation of our youth would not be expected to live as long as their parents.

The continual growth of obesity has been attributed to an increase in physical inactivity and poor nutrition, among other factors. Physical activity directly affects total daily energy expenditure (TDEE) and overconsumption from poor nutrition can upset the body's energy balance. TDEE, the total amount of energy the body uses each day to function, is the sum of the resting metabolic rate (RMR), physical activity energy expenditure, and the thermic effect of food. RMR, the amount of energy the body uses to carry out normal functions while at rest, accounts for 60-75% of TDEE, physical activity accounts for 15-30%, and the thermic effect of food approximately 10% (19). The energy balance equation states that a stable body weight is achieved when caloric intake is equal to caloric expenditure. To lose weight, one would need to be in negative energy balance, and conversely, to gain weight, a positive energy balance is necessary. In order to combat obesity, it would be helpful to know a person's TDEE so that caloric intake needs could be addressed. Because RMR accounts for the majority of the TDEE, it

follows that an accurate measure of RMR would be helpful when designing an individual's weight management plan.

Metabolic Measurements: Direct Calorimetry

RMR can be measured two ways, through direct or indirect calorimetry. Every energy utilizing process in the body releases heat. The rate at which heat is produced is a direct reflection of the metabolic rate. Therefore, measuring a body's heat production (the process of calorimetry) gives a direct measure of metabolism (28).

Direct calorimetry involves placing a subject in a chamber insulated by flowing water and determining the change in the water's temperature over time. Heat production is measured in kilocalories (kcal), a unit of measure equal to the amount of energy required to raise one kilogram of water one degree Celsius. If the flow rate, and change in water temperature are known, then the subject's heat production can be calculated. Heat lost through respiration and evaporation can be chemically captured and added to obtain the total heat production. This process was validated in the late 1890's by Atwater and Benedict who constructed a human calorimeter capable of measuring values from rest to intense exercise (2). Although direct calorimetry is theoretically the most accurate way to measure human energy expenditure, practically it can only be used in a small number of situations. The equipment needed is large, extremely intricate and expensive, and the time required for the measurement is substantial.

Metabolic Measurements: Indirect Calorimetry

Indirect calorimetry provides an alternative means of determining heat production. Since heat production is ultimately dependent on oxygen utilization, measurement of oxygen consumption can be used to estimate energy expenditure (6).

Conversion from the volume of O_2 consumed to kilocalories of energy expenditure produced is dependent on information gained through complete combustion of foodstuffs in a bomb calorimeter. The average heat of combustion of carbohydrate is 4.1 kcal/gm; fat is 9.3 kcal/gm; and protein (in vivo) is 4.3 kcal/gm (17). In order to relate the heat of combustion to the amount of oxygen used during oxidation of these substances in the body, the energy equivalent of oxygen must be known. The energy equivalent of oxygen is the number of kilocalories produced when one liter of oxygen is used to oxidize a substance (17). It is known from the stoichiometric equation for carbohydrate oxidation that 0.75 liters O_2 is needed to oxidize 1 gram of a typical carbohydrate, glucose, and this reaction releases 3.7 kcal. If 3.7 kcal/gm is divided by 0.75 liters O_2/gm the resulting energy equivalent of oxygen is 5 kcal/liter O_2. The same process can be carried out for a typical fat yielding an energy equivalent of oxygen of 4.7 kcal/liter O_2. Proteins are not completely oxidized in the body due to its complex structure. It is possible to calculate the energy equivalent of oxygen for protein, taking into account the amount of urea that would be formed during oxidation. The energy equivalent of oxygen for protein is equal to 4.5 kcal/liter O_2 (17).

The respiratory quotient (RQ), or respiratory exchange ratio (RER), is the ratio of the volume of CO_2 produced to the volume of O_2 consumed. Knowledge of RER provides the necessary information to determine the amount and type of substrate used. The RER varies depending on the type or combination of substances being oxidized. Oxidation of only carbohydrate yields an RER of 1.0; if only fat is oxidized RER is equal to 0.70. The RER for an ordinary mixed diet is approximately 0.85, and when in the fasted state RER equals 0.82 (17). If the RER and volume of O_2 consumed during a

specific amount of time is known, the amount of energy expended during that time can be calculated by multiplying the volume of O_2 per unit time by the energy equivalent of oxygen at that RER.

The measurement of resting metabolic rate can be simplified to a single measurement, O_2 consumption, if the assumption is accepted that RER is equal to 0.82 when in a resting, fasted condition. RMR is calculated by measuring O_2 consumption for an exact amount of time, converting this to 24-hour values, and multiplying it by 4.825 kcal/liter O_2 (the energy equivalent of oxygen for RER=0.82).

Indirect Calorimetry Techniques

Two different techniques are employed for measuring metabolic rate by indirect calorimetry. Closed-circuit spirometry, developed in the 1800's, requires the subject to breathe 100% O_2 from tubing connected to a container called a spirometer. The subject's expired air is directed into another tube, which passes the gas through soda lime to absorb the carbon dioxide, while the remaining O_2 returns to the spirometer to be rebreathed by the subject. The rate of decrease from the initial to final volume of oxygen in the spirometer is equal to the subject's oxygen consumption (22). This technique is somewhat cumbersome and requires the subject to stay close to the spirometer. Furthermore, CO_2 absorption becomes a problem at exercising metabolic rates (19, 22).

The most widely used technique is open-circuit spirometry. This technique allows the subject to breathe ambient air which has a known composition of 20.93% O_2, 0.03% CO_2, and 79.04% nitrogen. Expired gas is collected over a specific amount of time, gas fractions are determined, and volume is measured. The product of the gas volume and the difference in the amounts of O_2 and CO_2 in the expired air compared to

room air reveals the amount of oxygen consumed (VO_2) and carbon dioxide produced (VCO_2) (19). Calculating an RER and multiplying by the energy equivalent of oxygen provides an indirect measure of energy metabolism.

Many open-circuit spirometry methods exist to measure oxygen consumption. The criterion, or "gold standard", is the Douglas bag method developed by Claude G. Douglas in 1911 (9). This procedure involves the subject inhaling ambient air while expired air is collected into a canvas non-diffusing gas bag. After collection over a specific amount of time, concentrations of O_2 and CO_2 are determined, traditionally by using chemical absorption methods like those by Scholander or Haldane (13, 31), and volume is measured by gasometer. Although precise, this technique can take a significant amount of time and is therefore not ideal for testing large numbers of subjects.

Technological Advancements

The Douglas Bag method was simplified with the development of electronic O_2 and CO_2 gas analyzers. CO_2 analysis is based on the fact that CO_2 absorbs infrared radiation. Infrared light is passed through a stream of expired gas moving at a constant flow rate. The stream is disrupted and a detector cell measures the difference in CO_2 concentrations between the infrared light and the original test gas. This difference is a measure of the CO_2 gas fraction of expired air ($FECO_2$). There is a small array of oxygen gas analyzers, but the most commonly used O_2 analyzers are paramagnetic analyzers. These analyzers make use of the tendency of O_2 atoms to align with magnetic fields to cause rotation of a nitrogen-filled glass dumbbell (27). O_2 concentration is directly proportional to the amount of dumbbell rotation.

To further expedite metabolic testing, rapid responding electronic gas analyzers were linked to real-time ventilation measurements. Early semiautomated systems employed the use of basic computerized systems which measured expiratory gases by mass spectrometry 20 times per second. A programmable calculator was used for data reduction and digital value display (34). This innovation decreased the time from the end of testing to acquisition of values from hours to only seconds.

Current technology allowed the creation of computerized systems capable of continuously measuring the ventilation, and O_2, and CO_2 gas fractions. Computerized systems are capable of matching volume and gas fractions breath-by-breath in time. In order to determine the volume of oxygen consumed (VO_2), a measure of expired gas volume (V_E), expired O_2 (FEO_2), and expired CO_2 ($FECO_2$) are needed. The computerized system includes a device that senses gas flow (e.g. pneumotachometer) and analyzers for both O_2 and CO_2.

Flow sensing devices create a signal that is proportional to gas flow. This signal is integrated over time and the area under the curve is equal to the gas volume. There are a variety of flow sensing devices, but two of the most common are pressure differential pneumotachometers and turbine flowmeters. Pressure differential pneumotachometers measure the pressure drop across resistive membranes, which is proportional to gas flow (10). Turbine flowmeters use the number of rotations of an internal vane to determine the flow of gas. These flowmeters were found to have problematic linearity at the beginning of low flow rate testing, referred to as the "lag-before-start" effect, and also at high flow rates, referred to as "spin-after-stop" effect (35). But initial troubles were resolved and turbine flowmeters are currently used in validated equipment (20).

Computerized systems were produced to make metabolic measuring easier and simpler for tests ranging from rest to maximal exercise. However, a system is useless if it does not accurately assess energy expenditure. Many of the commercially available computerized metabolic systems, have been tested against the Douglas bag standard to determine the validity of the computer's returned resting VO_2 or RMR values (5, 18, 21, 23, 24, 29).

Computerized Systems Validations

Three such systems, the COSMED K4 b^2, the Aerosport KB1-C, and the BodyGem, are newer portable devices. These units are light weight and are either handheld or attached to the subject via a harness to allow for comfort and free movement. McLaughlin et al. validated the COSMED K4 b^2, a portable system worn on the subject's chest attached by a harness, against the criterion Douglas bag at rest and during exercise (20). The rest period consisted of 10 minutes in a seated position with gas collection during the last five minutes before onset of exercise. Results showed no significant differences in resting VO_2 between the K4 b^2 and the Douglas bag (0.33 ± 0.02 vs. 0.38 ± 0.02, respectively). Similar results found at the highest work rate led the authors to conclude that this portable system is accurate for measuring oxygen uptake over a wide range from rest to heavy exercise (20).

The Aerosport KB1-C, another example of a portable harness-mounted system, was validated in much the same way as the COSMED K4 b^2 from rest to 250 W of exercise. The KB1-C pneumotach was set on the medium-flow setting, which manufacturers claimed corresponded to flow rates between 10-120 L/min. The rest period again lasted 10 minutes with gas collection occurring in the last five minutes.

Results of this validation showed that the KB1-C values for VO_2, VCO_2, and V_E were all significantly higher at rest than Douglas bag values ($P < 0.01$) (16). The KB1-C also overestimated values at the work rates of 50 W and 200 W, but no significant differences were found at other intensities. The investigators believed the KB1-C was a valid instrument for measuring metabolic variables at a variety of exercise intensities, and even at rest, if appropriate pneumotach flow settings were used.

The BodyGem is a handheld unit manufactured specifically for quick and easy measurement of RMR. Sixty-three adults participated in this study designed to compare the BodyGem unit to the Douglas bag method. Subjects were tested on two different occasions, and during each session, measurements were made with both the BodyGem and the Douglas bag in random, balanced order. In order to make direct comparisons between the two methods, the BodyGem was connected to a computer to retrieve information on oxygen consumption as the BodyGem only displays RMR in kcal/day. Mean VO_2 and RMR values from all 4 tests showed extremely close agreement between the BodyGem and Douglas bag (241 ± 46 and 240 ± 45 ml/min; 1657 ± 324 and 1650 ± 307 kcal/day, respectively) (23). The authors concluded that the BodyGem is accurate and reliable in measuring resting VO_2 and RMR in a heterogeneous adult population.

ParvoMedics, of Sandy, Utah, manufactures a laboratory based metabolic measuring system capable of measuring VO_2 values from rest to maximal exercise. This system, the TrueMax® 2400 Metabolic Measurement System, uses a pressure differential pneumotachometer, a paramagnetic O_2 analyzer, and an infrared CO_2 analyzer. Bassett, et al validated this system in both the inspiratory and expiratory modes with a simultaneous Douglas bag collection. Results showed that the TrueMax® 2400 performed similarly to

the Douglas bag method for all gas exchange variables from rest to 250 W of cycle ergometer work (3).

CHAPTER III

MANUSCRIPT

Abstract

Purpose: The primary purpose of this study was to validate and compare the accuracy of the ParvoMedics TrueOne® 2400 Metabolic Measurement System in measuring resting VO_2 against the criterion Douglas bag method, and secondarily to compare the Douglas bag measures of VO_2 to those from the ParvoMedics TrueMax® 2400 Metabolic Measurement System, which has been previously validated up to near maximal metabolic rates (3). Resting metabolic rate (RMR) is determined by measuring the oxygen consumption (VO_2) of the subject lying in the supine position in the early morning following an overnight fast. The TrueOne® system uses a "flow-through" methodology, with the subject under a plexiglass canopy; the TrueMax® system measures gas exchange in a conventional manner. **Methods:** Seven males and thirteen females underwent a 30-minute RMR test on each machine; test order was randomly assigned. In addition, expired air was collected into either a Douglas bag, or a non-diffusing gas collection bag from the back of the mixing chamber of each system. This allowed for a simultaneous measurement of resting VO_2 to compare each system to the criterion method. Expired gas volume was determined using a Collins 120 liter gasometer, and O_2 and CO_2 fractions were determined using calibrated gas analyzers. **Results:** The TrueOne® 2400 systematically underestimated VO_2 compared to the external Douglas bag collection by approximately 22% (0.18 L/min and 0.23 L/min, respectively). The TrueMax® 2400 yielded values identical to the criterion Douglas bag method (VO_2 = 0.24 L/min and 0.23 L/min, respectively). **Conclusion:** The systematic

underestimation of resting VO_2 by the ParvoMedics TrueOne® 2400 Metabolic Measurement System indicates it is not an accurate device for measuring resting VO_2. The ParvoMedics TrueMax® 2400 is capable of accurately measuring resting VO_2.

Key Words: INDIRECTCALORIMETRY, DOUGLAS BAG, VALIDATION, OXYGEN UPTAKE

Introduction

According to the National Health and Nutrition Examination Survey (NHANES), a program of the Centers of Disease Control and Prevention, nearly 65% of the population, or about 60 million American adults are either overweight or obese (11). In addition, data collected up to the year 2002 indicate that this "obesity epidemic" shows no sign of decreasing (15).

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Advancements in technology have produced computerized metabolic gas analysis systems capable of measuring V_E, VO_2, and VCO_2. These systems continuously measure

the volume of expired air with a flow-sensing device (e.g. pneumotachometer), as well as expired gas fractions by O_2 and CO_2 analyzers. There are currently more than 30 commercially available metabolic gas analysis systems (18). They range in price from around $10,000 to more than $40,000. With an investment of many thousands of dollars, it is imperative to know these systems are accurate and precise. Many validation and reliability studies have been done on commercially produced metabolic systems (5, 18, 21, 23-25, 29, 32). A new system for measuring RMR is the ParvoMedics TrueOne2400® Metabolic Measurement System, which uses a flow-through design and eliminates the need for mouthpieces and valves found in most systems.

The primary purpose of this study was to validate the ParvoMedics TrueOne® 2400 Metabolic Measurement System by comparing its resting VO_2 measure to that obtained by a non-simultaneous measurement via the criterion Douglas bag method. A secondary purpose was to compare the Douglas bag measures of VO_2 to those from the ParvoMedics TrueMax® 2400 Metabolic Measurement System, which has been previously validated up to near maximal metabolic rates (3).

Methods

Participants

Twenty men and women were involved with the study. Participants' heights (without shoes) were measured using a stadiometer (Seca Corp., Columbia, Maryland). Weight (in light clothing, without shoes) was measured using a physician's scale (Health-o-meter, Inc. Bridgeview, Illinois). The men (n=7) were 30±10.4 (mean ± SD) years old with body height of 184.5 ± 6.8 centimeters, and body weight of 82.2 ± 10.4 kilograms.

The women (n=13) had mean age of 29 ± 10.2 years, body height of 70.2 ± 19 cm, and body weight of 74.4 ± 17.3 kg. Participants were recruited from the University of Tennessee staff and student body, as well as the surrounding community. Prior to participation, the participants read and signed an informed consent form approved by the University of Tennessee's Institutional Review Board. Participants were also asked to fill out a health history questionnaire to determine if any were taking medications that might affect the RMR.

Procedures

Pilot trials were conducted on three participants to examine the effect of simultaneous gas collection with the Douglas bag connected in series with the TrueOne® 2400. The pilot trials revealed that the resistance offered by the conventional Douglas bag caused a dramatic drop in flow rate. It was determined that a 170 liter mylar-type non-diffusing gas bag (Hans Rudolph, Inc., Kansas City, Missouri) could be used instead, without causing a change in flow rate. This was used to evaluate the internal validity of the TrueOne® 2400 system.

The participants were tested in the morning after abstaining from food, caffeine, and exercise for a minimum of eight hours. Participants rested for approximately 20 minutes in a reclined position before testing began. The participants were randomly assigned to either Condition 1 or Condition 2. Those assigned to Condition 1 were first tested with the TrueOne® 2400 Metabolic Measurement System (ParvoMedics, Inc., Sandy, Utah) followed by the Douglas bag, which was connected in series with the TrueMax® 2400 Metabolic Measurement System (ParvoMedics, Inc., Sandy, Utah).

Condition 2 tested in reverse order. Individuals were given at least 10 minutes between tests to become adapted to the new equipment.

TrueOne® 2400 Metabolic Measurement System

The primary system evaluated in this study, the ParvoMedics TrueOne® 2400 metabolic measurement system, is an example of an open-circuit flow-through computerized indirect calorimeter. This method, which has been used by other investigators (33), involves placing a transparent plastic hood, which has a continuous stream of room air flowing through it, over the subject's head. The stream of ambient air (20.93% O_2 and 0.03% CO_2) dilutes the subject's expired gas which is directed to gas analyzers for analysis. The volume of the expired gas (V_E) is measured by a pneumotachometer using pressure differentials, and concentrations of both O_2 and CO_2 are continuously measured by paramagnetic O_2 and infrared CO_2 analyzers, respectively. VO_2 is calculated by conventional equations (28). Therefore it is imperative that accurate and precise measures of V_E, expired O_2 (FEO_2), and expired CO_2 ($FECO_2$) are made by the computerized analytical system. Since the TrueOne® 2400 system uses a fairly high flow rate (around 20 l/min) the FEO_2 values are diluted and become similar to the FIO_2 values (e.g. about 20%). Thus, the O_2 analyzers must be capable of detecting small differences in gas concentrations, and the CO_2 analyzers must be sensitive enough to measure similarly low gas fractions (e.g. < 1.0%). Even minor errors in either of these measurements will lead to major errors after calculation. For example, an error of 0.05 in the $FIO_2 - FEO_2$ difference would lead to approximately 5% difference in calculated VO_2. It was therefore essential to frequently calibrate both the pneumotachometer and gas analyzers, and this was done before every test in this study.

The TrueOne®2400 Metabolic Measurement System pneumotach was calibrated with a series 5530 3-Liter calibration syringe (Hans Rudolph, Inc., Kansas City, Missouri) according to manufacturer's instructions. The gas analyzers were calibrated using room air and a standard gas consisting of 19.51% O_2, and 1.01% CO_2. Both calibrations were completed before each participant's test. Ambient room temperature, relative humidity, and barometric pressure were determined at the start of every test, and this information was entered into the computer.

While in a reclined position, a clear, plastic hood was placed over the subject's head and neck with the attached vinyl sheet secured over the torso. Room air was pulled in through an opening in the plastic hood and the canopy air was pulled out another opening where tubing carried it to the pneumotach and mixing chamber of the TrueOne® system. Flow rate and the downstream O_2 and CO_2 percentages were measured by the ParvoMedics TrueOne® 2400system to determine the VO_2 and the resting metabolic rate. The subjects rested for an additional 10 minutes to become accustomed to the apparatus, and testing began when CO_2 readings stabilized between 0.90 and 1.1%, which was accomplished by manually adjusting the Dilution Pump Controller's flow rate. A thirty-minute period of RMR measurement followed. Expired gases were continuously sampled from the mixing chamber through a Nafion Dryer (Permapure, Toms River, NJ) catheter into paramagnetic O_2 and infrared CO_2 analyzers. After the initial 30-minute test, an additional 6 minutes of air was simultaneously measured by the TrueOne® 2400 and collected into the 170-liter non-diffusing mylar bag through a hose attached to the back of the mixing chamber. The gas fractions of the expired gas were determined by directly attaching the Nafion Dryer catheter from the TrueOne® 2400 system to the mylar bag

and running the system's Signal Display program for one minute. Volume was measured using a 120-liter Tissot gasometer (Warren E. Collins Inc., Braintree, Massachusetts) and ventilation rate, VO_2, VCO_2, RQ, and RMR were calculated taking into account the volume of air removed by the mixing chamber during testing, and the volume of air removed during the one-minute gas bag analysis. These calculated values were then compared against the system's report in order to confirm the internal validity of the TrueOne® 2400 system.

TrueMax® 2400 Metabolic Measurement System

The TrueMax® 2400 Metabolic Measurement System's pneumotach was also calibrated with series 5530 3-Liter calibration syringe (Hans Rudolph, Inc., Kansas City, Missouri) according to manufacturer's protocol. The gas analyzers were calibrated using room air and a standard gas consisting of 16.03% O_2, and 3.98% CO_2. Both calibrations were performed before every test. Ambient room temperature, relative humidity, and barometric pressure were determined at the start of each test, and this information was entered into the computer.

While in a reclined position, a two-way non-rebreathing face mask (Hans Rudolph, Inc., Kansas City, Missouri) was fitted over the participant's nose and mouth and was secured with an adjustable head cap (Hans Rudolph, Inc., Kansas City, Missouri). A hydrogel Ultimate Seal™ (Hans Rudolph, Inc., Kansas City, Missouri) was placed between the subject's skin and face mask to prevent air leakage. Leaks were checked by having the subject exhale while covering the expired air port of the two-way non-rebreathing face mask. Expired air was directed through a hose to sensors in the TrueMax® that monitor the flow and the percentages of O_2 and CO_2 in the air. Once the

face mask was in place, each subject completed an additional ten minutes of rest to assure a steady baseline value. During the following 20-minute test period, expired gases were simultaneously collected into a Douglas bag placed in series with the mixing chamber used by the metabolic system. The gas fractions were analyzed by drawing a continuous sample of expired gases from the mixing chamber through a Nafion Dryer (Permapure, Toms River, NJ) catheter into a paramagnetic O_2 and infrared CO_2 analyzers. Douglas bag gas fractions were determined post collection by drawing a one-minute sample through the Nafion Dryer catheter attached directly to the Douglas bag. Volume was measured using a 120-liter Tissot gasometer (Warren E. Collins Inc., Braintree, Massachusetts) and ventilation rate, VO_2, VCO_2, RQ, and RMR were calculated accounting for the volume of air removed by the mixing chamber during testing and the amount used during the one-minute analysis.

Statistics

The participants were tested with both systems and testing order was randomly assigned. The reported values are expressed as the mean and standard deviation. A paired sample t-test was used to examine differences in VO_2, VCO_2, and RQ between the TrueOne® system and the independent, non-simultaneous Douglas bag collection. Paired sample t-tests were also used to compare differences in the variables examined by the TrueOne® versus the mylar gas bag for the additional six minute test to evaluate internal validity. A Bland-Altman plot was used to show the difference between the measured VO_2 of the TrueOne® and independent Douglas bag collection. The data were analyzed using SPSS 13.0 for Windows (SPSS Inc., Chicago, Illinois). An alpha level of 0.05 was selected to indicate statistical significance.

Results

Table 1 presents the gas exchange variables for the 6-minute post-test collection from the TrueOne® 2400 and attached non-diffusing mylar bag. All variables except down stream $\%O_2$ ($DS\%O_2$) and flow rate were found to be statistically different at the $P<0.01$. However, the differences, with the exception of RER, were so small they were not physiologically meaningful.

Figure 1 reveals the relationship of all metabolic values (downstream $\%O_2$ [$DS\%O_2$], downstream $\%CO_2$ [$DS\%CO_2$], VO_2, VCO_2, RER, and flow rate) from the TrueOne® 2400 system and the non-diffusing mylar bag connected in series. The similarities are clearly defined by the reference lines. However, small differences in VO_2 and VCO_2 led to relatively large differences in RER.

Table 2 shows the gas exchange variables for both machines and the Douglas bag. Data are presented as means ± SD. Near perfect agreement, with no significant differences, was found between the TrueMax® 2400 metabolic system and the Douglas bag during the simultaneous collection for all variables. When comparing the TrueOne® 2400 to the non-simultaneous external Douglas bag method, all comparable variables were significantly different at $P\leq0.01$. The TrueOne® 2400 system reported VO_2 values an average of 0.05 l/min lower than the criterion Douglas bag method, a 22% difference.

Figure 2 shows the relationship of all relevant metabolic values reported from the TrueOne® 2400 system compared to the external Douglas bag collection. It is clear from the scatter plots that the TrueOne® 2400 underestimated both VO_2 and VCO_2 compared to the Douglas bag resulting in a very scattered plot for the RER comparison.

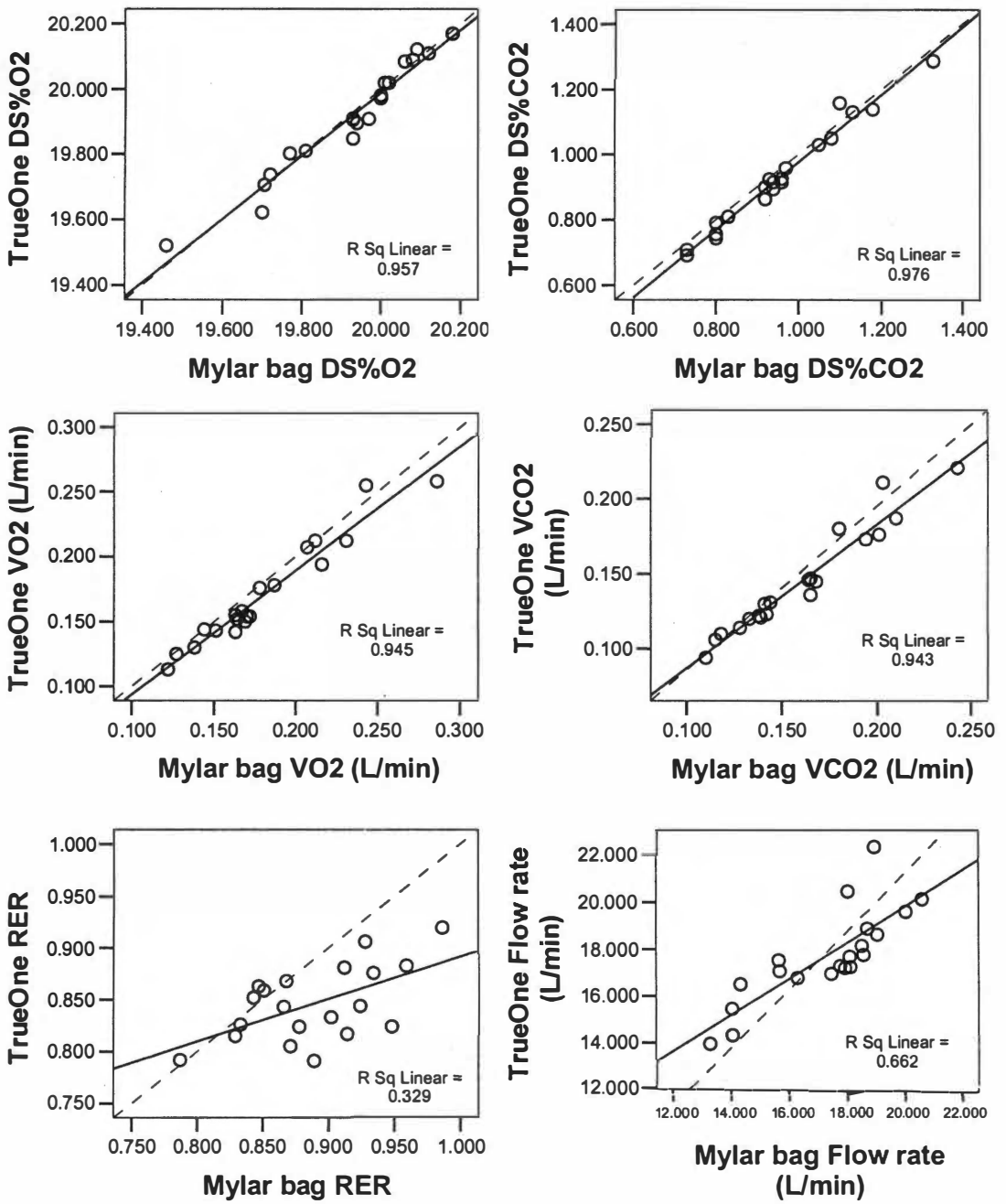


Figure 1 Scatter plots with reference lines illustrating the relationship between the metabolic values reported by the TrueOne 2400 and the mylar bag during the 6-minute post test collection

Table 1 Values of relevant metabolic variables for the TrueOne® 2400 six minute post-test collection

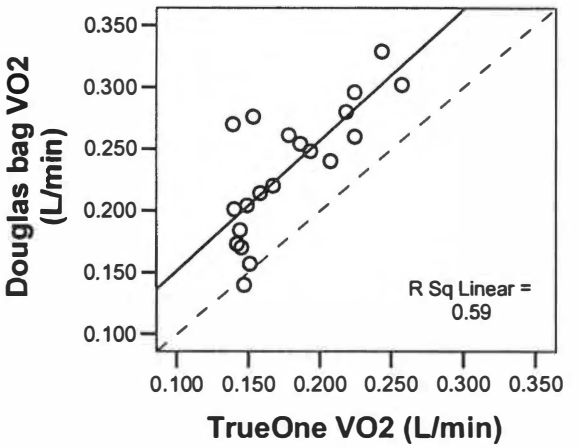
	TrueOne	Mylar bag
$DS\%O_2$	19.91±0.175	19.92±0.177
$DS\%CO_2$	0.93±0.163	0.96±0.156 *
Flow l/min	16.53±1.899	17.26±2.095 ¶
VO_2 l/min	0.17±0.041	0.18±0.041 *
VCO_2 l/min	0.15±0.035	0.16±0.036 *
RER	0.85±0.036	0.89±0.050 *

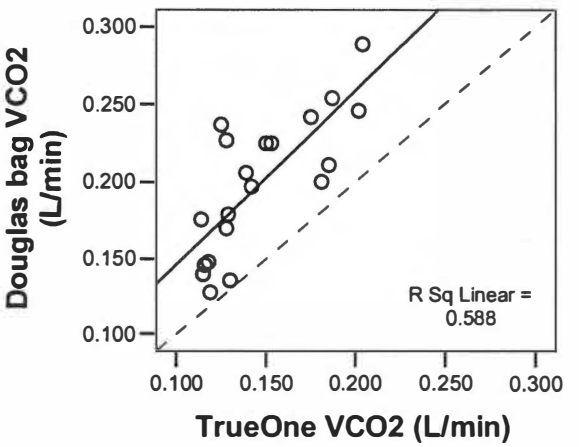
* $p \leq 0.01$ vs. TrueOne; ¶ $p \leq 0.05$ vs. TrueOne

Table 2 Values of relevant metabolic variables for the TrueMax® 2400, TrueOne® 2400, and Douglas bag

	TrueMax	Douglas Bag	TrueOne
VO_2 l/min	0.24±0.056	0.23±0.053	0.18±0.038 *
VCO_2 l/min	0.20±0.049	0.20±0.045	0.15±0.031 *
RER	0.85±0.037	0.85±0.033	0.82±0.037 *

* $p \leq 0.01$ vs. both TrueMax and Douglas Bag





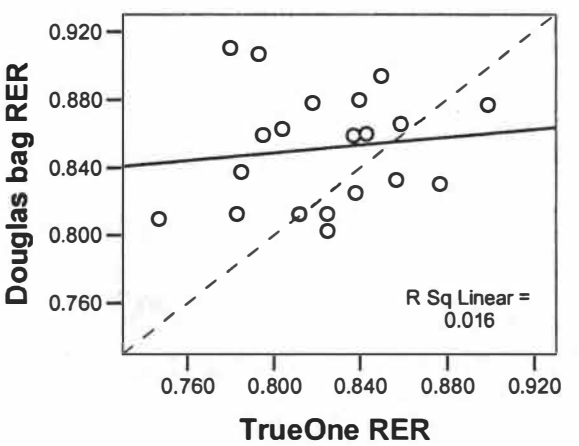


Figure 2 Scatter plots with reference lines illustrating the relationship of metabolic values between the TrueOne 2400 and the non-simultaneous Douglas bag collection

The Bland-Altman plot in Figure 3 reveals the differences between techniques (non-simultaneous external Douglas bag minus TrueOne® 2400) for individual VO_2 scores (4). The difference scores (expressed as mean and 95% CI) were all above the zero line (except for one subject) showing the TrueOne® 2400 systematically underestimated VO_2. The widely scattered distribution of data points above zero also clearly portrays the vast disagreement between systems.

Figure 4 shows scatter plots with reference lines comparing the TrueMax® 2400 system to the Douglas bag collection in series. All plots are in near perfect alignment with the reference line showing the consistently similar results from the TrueMax® 2400 and Douglas bag.

Discussion

The major finding of this study was that the ParvoMedics TrueOne® 2400 with attached canopy systematically underestimated resting VO_2 when compared to both the criterion external Douglas bag method and validated TrueMax® 2400 metabolic system (9). The 22% difference in reported VO_2 values from the TrueOne® 2400 to the external non-simultaneous Douglas bag collection (0.18 L/min and 0.23 L/min, respectively) is a major error. The 22% error equated to a daily caloric difference of 437 calories (1236 kcal/day TrueOne® 2400 vs.1673 kcal/day Douglas bag). This discrepancy could have a major impact on planning weight management programs.

The results of this study further validate the performance of the TrueMax® 2400 even at low flow rates associated with resting conditions. Bassett et al. first validated this system in 2001. Eight males participated in the study which showed that the TrueMax® 2400 produced results similar to the Douglas bag ranging from rest to 250W of exercise

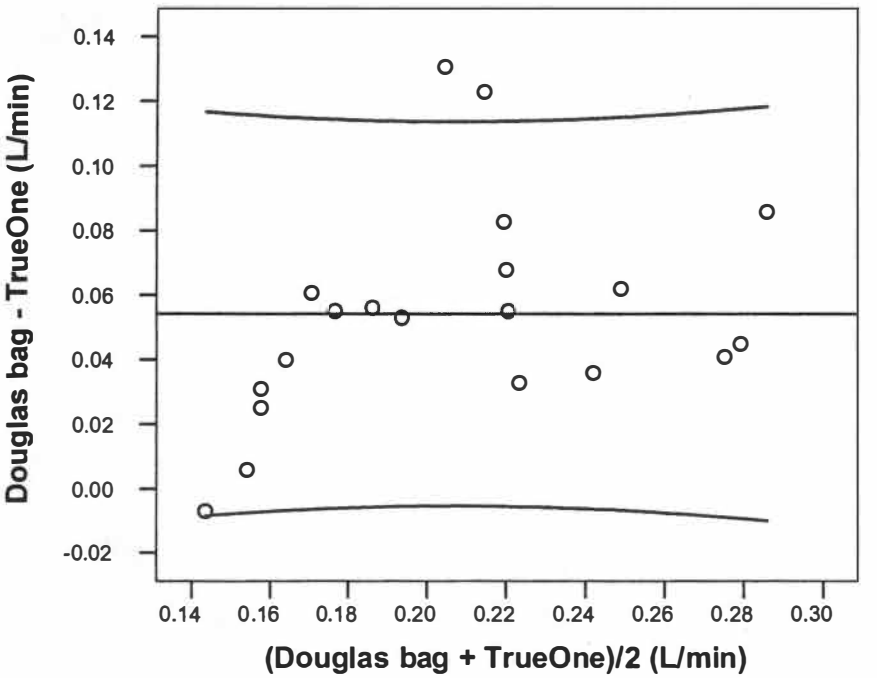


Figure 3 Bland-Altman plot comparing VO2 values from the criterion Douglas bag external collection to the TrueOne 2400 system. Solid straight line is placed at the mean of Y; other two lines represent 95% CI

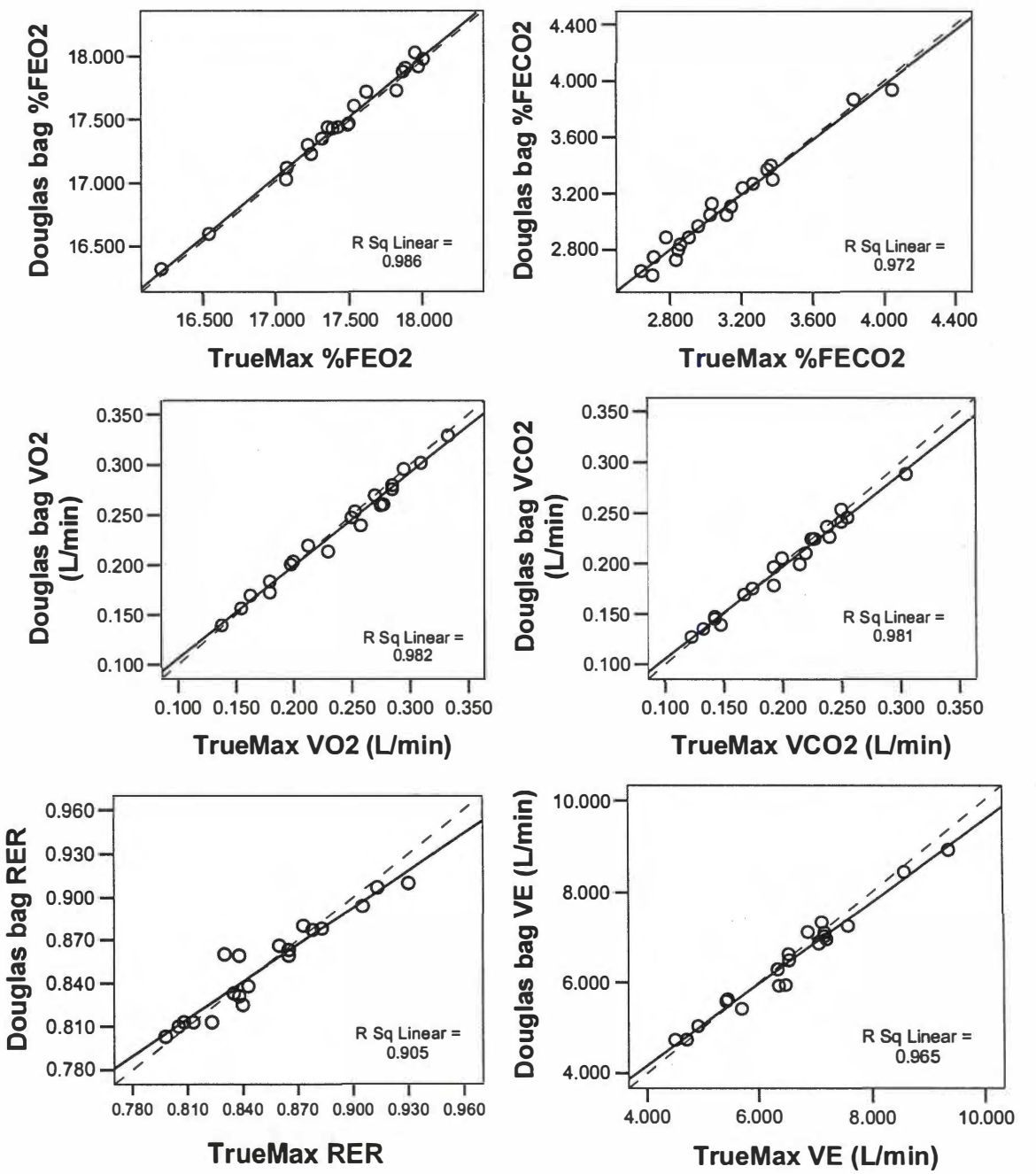


Figure 4 Scatter plots with reference lines illustrating the similarities of metabolic values between the TrueMax 2400 system and Douglas bag collection in series

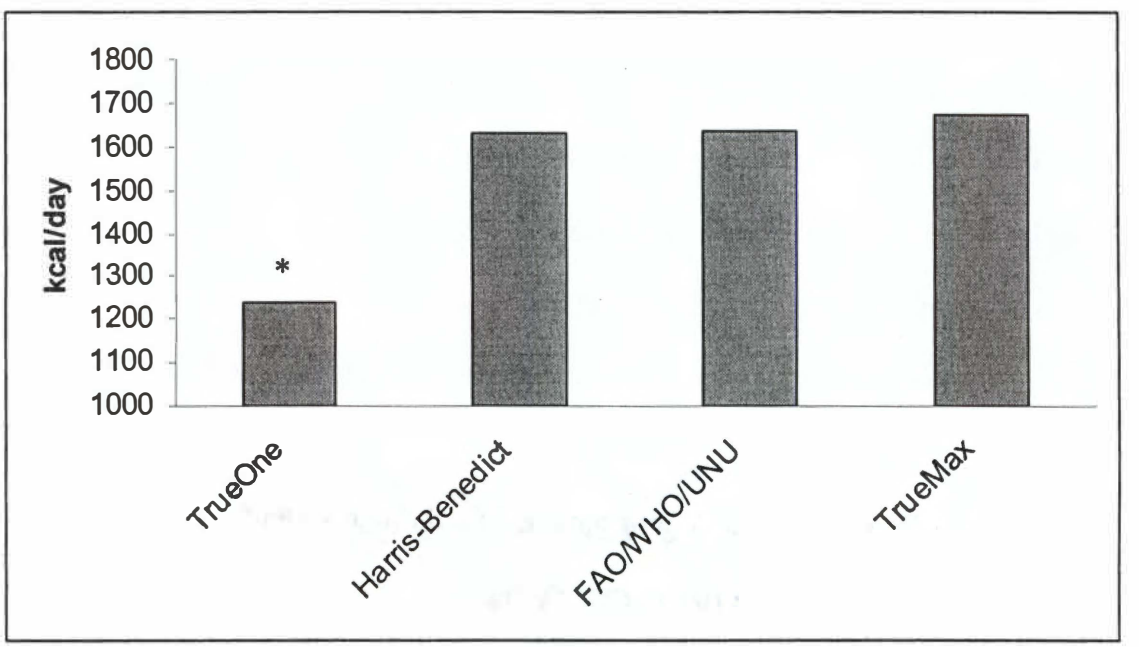
on a cycle ergometer. Mean VO_2 values, measured with the system in either expired or inspired mode, were within 0.01 L/min of the Douglas bag values at rest (0.38 ± 0.04 L/min). Figure 3 shows all metabolic values (%FEO_2, %$FECO_2$, VO_2, V_E, and RER) in near perfect agreement between the TrueMax® 2400 and the Douglas bag in this study. There was minimal scatter displayed on the plots with most points on the line of identity. The lack of scatter also reveals that the TrueMax® 2400 was consistently responding similarly to the criterion Douglas bag.

The TrueOne® 2400 showed good agreement between the computer generated values and those obtained with the non-diffusing mylar bag placed in series with the system (Figure 1). The differences that existed were very small, and for the most part physiologically insignificant, with the exception of the RER, which was 0.04 units higher in the mylar bag. This internal validity between the flow-through system and the mylar bag stands in contrast to the difference between the flow-through system and the external Douglas bag. Why this occurred is not known, and it raises questions about which system is correct. Is the TrueOne 2400 systematically underestimating VO_2, or is the TrueMax systematically overestimating the VO_2?

We addressed this question by comparing each measured value to predicted RMR values using the Harris-Benedict and FAO/WHO/UNU equations (14, 30). The average measured value (1236 ± 261 kcal/day) from the flow-through system was 395 kcal/day (32%) lower than that from the Harris-Benedict estimation (1631 ± 274 kcal/day), and 399 kcal/day (32%) lower than that from the FAO/WHO/UNU estimation (1635 ± 282 kcal/day). In contrast, the TrueMax® 2400 average measured RMR value (1673 ± 404 kcal/day) only differed from the Harris-Benedict estimation by 42 kcal/day (2.6%), and

from the FAO/WHO/UNU by 38 kcal/day (2.3%). This data is visually displayed in Figure 5. We therefore concluded that the TrueOne® 2400 was vastly underestimating VO_2, where the resting VO_2 values obtained from the TrueMax® 2400 are representative of adult RMR measurements.

Future research conducted with the TrueOne® 2400 should focus on determining the accuracy of the gas analyzers. One method to determine a flow through system's ability to accurately measure gas concentrations is known as an alcohol burn. This technique involves completely combusting a known amount of alcohol (usually methanol with RER=0.67) under the canopy of the system and determining VO_2 and underestimated resting VO_2 values compared to the criterion Douglas bag, it cannot be



* $p \leq 0.01$ vs. Harris-Benedict, FAO/WHO/UNU, and TrueMax

Figure 5 Comparison of measured RMR values from the TrueOne and TrueMax with predicted values from standard equations

VCO_2 (8). The calculated RER is then compared to the known value for the alcohol. Performing this test with the TrueOne® 2400 may help clarify the problems with this system.

The lower measured resting VO_2 found with a flow-through system are in agreement with other studies considering similar canopy or hooded metabolic systems (1, 7, 12). However, these studies primarily focused on the effect of using the same metabolic system with different ways of collecting expired gases, (e.g., comparing the canopy to a face mask or a mouthpiece. These studies were not aimed at validating the flow-through system by comparing it to a criterion. Studies validating different metabolic systems against the criterion Douglas bag method have found significant differences between the computerized system and the Douglas bag (5, 16). However, a majority of the literature supports the use of computerized metabolic systems as accurate measuring devices for VO_2 (3, 20, 21, 23-25, 29, 32). It should be noted that direct comparisons with these studies are extremely difficult since this study looked only at the systems' performance while subjects were at rest. Most other validation studies tested machine performance during exercise.

Conclusion

When evaluating a computerized system's performance, one should consider the subject population. Obviously more accurate measures would be needed in clinical laboratory settings with patients than in the fitness arena with generally healthy subjects. However, the 22% lower VO_2 values found with the TrueOne® 2400 compared to the Douglas bag (0.18 l/min and 0.23 l/min, respectively) could certainly be seen as

problematic in any situation. Because the TrueOne® 2400 flow-through system considered a valid device for measuring resting VO_2. Conversely, the TrueMax® 2400 produced accurate and valid measures of resting VO_2, even though the system was originally intended for measurements of exercise VO_2.

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APPENDICES

Appendix A

Informed Consent

INFORMED CONSENT FORM

Investigator: Tracie Weinheimer
Address:
The University of Tennessee
Department of Health and Exercise Science
1914 Andy Holt Ave.
Knoxville, TN 37966
Telephone: (865) 974-8768

Purpose
You are invited to participate in a research study. The purpose of this research study is to determine the validity of the Parvo TrueONE 2400 indirect calorimetry system in measuring resting metabolic rate. Resting metabolic rate is a measure of the number of calories required to maintain the body in a resting state. If you give your consent, you will be asked to perform the testing described below. You will first complete a health history questionnaire to determine your health status. All testing will be administered in the Applied Physiology Laboratory in the HPER building on the UT campus. You will report to the lab following an overnight fast having abstained from both food and exercise the morning of the test.

Testing
1. We will measure your height and weight.

2. You will be asked to rest quietly in a reclined position, without sleeping, for 30 minutes.

3. Following the rest period, your resting metabolic rate will be determined by three methods:

a. Douglas bag - A face mask, similar to the standard anesthetic mask, will be placed on your face so that both your nose and mouth are encapsulated. You will be able to breathe room air with your expired air being collected in a hose running from the face mask to the Douglas bag (a large volume air-tight bag). You will be asked to rest in a comfortable reclined position attached to this apparatus for 30 minutes.

b. Parvo TrueMax – You will be fitted with a face mask as described above. Again, you will breathe room air. The hose leading out of the mask will be attached to the Parvo TrueMax computer system which will analyze your expired air. You will be asked to rest in a comfortable reclined position attached to this apparatus for 30 minutes.

c. Parvo TrueONE – While in a comfortable reclined position, a clear plastic canopy hood will be placed so that it rests over your head and neck. No part of the hood will be in contact with your face and you will be able to see and hear your surroundings from within the hood. An attached vinyl sheet will be secured around your torso. An opening in the hood will allow you to breathe room air

normally. Another opening will direct your expired air into a tube connected to the computer system where it will be analyzed.

Potential Risks

The risks associated with these lab procedures pertain to those individuals with anxiety about small enclosed spaces (such as the ParvoONE hooded test). To deal with this or any other issues that may arise, you will be able to terminate any test at any time.

Benefits of Participation

From the results of your tests, you will be told your resting metabolic rate. Resting metabolic rate can be an important tool in designing a diet and exercise program to achieve and maintain your body weight goal.

Confidentiality

The information obtained from these tests will be treated as privileged and confidential and will consequently not be released to any person without your consent. However, the information will be used in research reports and presentations; your name and other identity will not be disclosed.

Contact Information

If you have questions at any time concerning the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact Tracie. If you have questions about your rights as a participant, contact Research Compliance Services of the Office of Research at (865) 974-3466.

Right to Ask Questions and Withdraw

You are free to decide whether or not to participate in this study and are free to withdraw from the study at any time.

Before you sign this form, please ask questions about any aspects of the study which are unclear to you.

Consent

By signing, I am indicating that I understand and agree to take parting in this research study.

_____ _____

Your signature Date

_____ _____

Researcher's signature Date

By signing below, I give my permission for you to save my contact information so that I can be contacted for follow-up tests. Signing does not obligate me to return for those tests.

_____ _____

Your signature Date

Appendix B

Health History Questionnaire

HEALTH HISTORY QUESTIONNAIRE

NAME_____ DATE_____

DATE OF BIRTH_____ AGE_____

ADDRESS_____

_____

PHONE NUMBERS (HOME)_____(WORK)_____

e-mail address:_____

When is the best time to contact you?_____

MEDICAL HISTORY

Past History:
Have you ever been diagnosed with the following conditions? Please check the appropriate column.

	Yes	No	Don't Know
Rheumatic Fever	( )	( )	( )
Heart Murmur	( )	( )	( )
High Blood Pressure	( )	( )	( )
Any heart problem	( )	( )	( )
Lung Disease	( )	( )	( )
Seizures	( )	( )	( )
Irregular heart beat	( )	( )	( )
Bronchitis	( )	( )	( )
Emphysema	( )	( )	( )
Diabetes	( )	( )	( )
Asthma	( )	( )	( )
Kidney Disease	( )	( )	( )
Liver Disease	( )	( )	( )
Severe Allergies	( )	( )	( )
Orthopedic problems	( )	( )	( )
Hyper- or Hypothyroidism	( )	( )	( )
AIDS	( )	( )	( )
Heparin Sensitivity	( )	( )	( )

Present Symptom Review:
Have you recently had any of the following symptoms? Please check if so.

Chest Pain	( )	Frequent Urination	( )
Shortness of Breath	( )	Blood in Urine	( )
Heart palpitations	( )	Burning sensations	( )
Leg or ankle swelling	( )	Severe headache	( )
Coughing up blood	( )	Blurred vision	( )
Low blood sugar	( )	Difficulty walking	( )
Feeling faint or dizzy	( )	Weakness in arm	( )
Leg numbness	( )	Significant emotional problem	( )

Do you smoke? Yes/No If yes, how many per day?_____

Are you currently trying to lose weight (through diet, exercise, and/or medication)? Yes/No
If, "yes," for how long have you been trying to lose weight? _____

Are you taking any medications? Yes/No
If yes, please describe:_____

OTHER INFORMATION
Whom should we notify in case of emergency?

Name _____

Address _____

Phone # _____

I have been given the opportunity to ask questions about any of the above items that were unclear, and I have answered all questions completely and truthfully to the best of my knowledge.

SIGNATURE_____DATE_____

Appendix C

Air Collection Data Sheet

AIR COLLECTION DATA SHEET

SUBJECT: _____

DATE: _____

RM
TEMP: _____

BAROMETRIC PRESSURE: _____

VAPOR PRESSURE: _____

DOUGLAS BAG (TrueMAX)

COLLECTION TIME: _____

%O2: _____ %CO2: _____

TISSOT: END - START _____ END - START _____

TOTAL
VOLUME=

H/R MYLAR BAG (TrueONE)

COLLECTION TIME: _____

%O2: _____ %CO2: _____

TISSOT: END - START _____

TOTAL VOLUME=

Appendix D

Subject Data Sheet

SUBJECT DATA SHEET

SUBJECT #: _____

DATE: _____ TIME: _____

HEIGHT: _____ WEIGHT: _____ AGE: _____

ParvoMAX **DB**

%FEO2		%FEO2	
%FECO2		%FECO2	
VE (L/min)		VE(L/min)	
VO2(L/min)		VO2(L/min)	
VCO2 (L/min)		VCO2 (L/min)	
RER		RER	

Parvo REE (Kcal/D)

ParvoONE **DB**

	30 min	6 min		
%FEO2			%FEO2	
%FECO2			%FECO2	
VE (L/min)			VE (L/min)	
VO2(L/min)			VO2(L/min)	
VCO2 (L/min)			VCO2 (L/min)	
RER			RER	

Parvo REE (Kcal/D)

Appendix E

Test Reminder

RESTING METABOLIC RATE TEST REMINDER

Name: _____

Test Date: _____

Test Time: _____

This is a reminder that you have agreed to participate in a test of resting metabolic rate at the above day and time. The testing will be done in the Exercise Physiology Lab on the third floor of the HPER building on the campus of The University of Tennessee.

The entire experience will take almost 2 hours and will include 3 tests to measure your resting metabolic rate. When you first arrive to the lab, your height and weight will be measured then you will be asked to rest quietly in a reclined position without sleeping for 30 minutes. Next, you will be put through the testing, which will last about an hour, and requires you to rest quietly in a reclined position without sleeping. Once the testing is complete, a snack and juice will be provided, if you are hungry.

Please remember:

1. 8 hours prior to testing please refrain from: food & drink (except for water); caffeine, alcohol, or other stimulants; any heavy exercise.
2. On test day exert as little energy as possible – drive to the test lab and take the elevator to the third floor (Press button **2** in elevator).
3. Wear comfortable clothing – you will be in a resting position for approximately 2 hours and the more relaxed you are the better your results will be.

THANK YOU FOR YOUR PARTICIPATION!!

If you have any questions or need to change your test date/time, please feel free to contact Tracie at (513)236-1904 or tweinhei@utk.edu

VITA

Tracie Weinheimer was born in Cincinnati, Ohio on November 23, 1981 to Robert and Nancy Weinheimer. She received her Bachelor of Science degree in Exercise Science from The University of Dayton, in Dayton, Ohio in 2004. She attained a position as a graduate teaching associate in the Physical Education Activity Program while working toward her Master's degree. In 2006, she earned her Master of Science degree in Exercise Physiology at The University of Tennessee, Knoxville.