VALIDATION OF HEAT FLUX TECHNOLOGY TO ASSESS ENERGY EXPENDITURE DURING EXERCISE

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There are limitations to current portable technology to estimate energy expenditure (EE), which may limit the accuracy when applied to free-living individuals. The KAL-X Sensor™ (Lifechek, LLC, Pittsburgh, PA) uses heat flux technology to estimate EE. The accuracy of this device has not been assessed across levels of body mass index (BMI). The purpose of this study was to examine the validity of the KAL-X Sensor™ to measure EE across different modes and intensities of physical activity. Twenty-four subjects (age = 33.8 ± 8.5 yr, BMI = 27.55 ± 3.9 kg/m^2) performed two exercise (treadmill walking, stationary cycling) sessions with each lasting 30 minutes. Walking included three 10-minute progressive intervals of 2.5 mph, 0%; 3.0 mph, 0%; and 3.0 mph, 5%. Cycling included three 10-minute progressive intervals of 50 rev/min, 0.5 kg; 60 rev/min, 0.5 kg; and 60 rev/min, 1.0 kg. The criterion measure of EE was indirect calorimetry (IC). A KAL-X Sensor™ was placed on the upper arm and at the level of the xyphoid process. EE during 30 minutes of walking for the KAL-X Sensor™ (arm sensor = 94.5 kcal, chest sensor = 100.9 kcal) was significantly lower than EE measured using IC (166.5 kcal) ($p<0.05$). EE during 30 minutes of cycling for the KAL-X Sensor™ (arm sensor = 76.4

kcal, chest sensor = 90.1 kcal) was significantly lower than EE measured using IC (138.0 kcal) ($p<0.05$). The level of BMI did not affect the pattern of results, nor did arm circumference or skinfold measured at the bicep or tricep. These results indicate that there are limitations of the KAL-X Sensor™ to provide an accurate estimate of EE during walking and cycling exercise. Additional research is needed to determine the accuracy of the KAL-X Sensor™ to estimate EE during other forms of exercise, lifestyle activity, and free-living activity.

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1 Introduction and Rationale

1.1 Introduction

Obesity is an epidemic that impacts a significant number of American adults. The most recent NHANES data, collected between 2001 through 2002, reported the prevalence of overweight in adults aged at least 20 years in the United States is 65.7%, while the prevalence of obesity has risen to more than 30% (Hedley et al., 2004). Overweight is defined as a body mass index (BMI) of 25 to 29.9 kg/m^2, while obesity is defined as a BMI of $\geq$ 30.0 kg/m^2. Data collected from NHANES III (1988-1994), collected approximately one decade earlier reported the prevalence of overweight for American adults was 55.9% and the age adjusted prevalence of obesity was 22.9% (Flegal et al., 1998). NHANES II (1976-1980) showed that 31.5% of US adults aged 20-74 years were classified as overweight, with 14.5% classified as obese (Flegal et al., 1998). These data offer support that overweight and obesity in the United States continues to increase.

The prevalence of overweight is a concern because of the link with an increased risk for developing multiple chronic diseases. Obesity and overweight may lead to diseases such as cardiovascular disease, type II diabetes mellitus, sleep apnea, osteoarthritis, and increased risk of some forms of cancer (Lawrence and Kopelman, 2004). Obesity is related to heart disease and stroke (Eckel et al., 2004) as well as hypertension, gall bladder disease, and dyslipidemia (Pi-Sunyer, 1996). Obesity may also contribute to changes in psychological health such as

depression, lead to decreased quality of life (Lawrence and Kopelman, 2004), decreased self-esteem, eating disorders and distorted body-image (NIH 1998). Because of these health concerns, it is important to continue to examine factors that impact the prevention and treatment of overweight and obesity.

Obesity occurs when there is an imbalance between energy intake and energy expenditure. Energy expenditure is a critical component for body weight control and achieving energy balance. Energy expenditure is comprised of three components; resting metabolic rate (RMR), thermic effect of food also called dietary thermogenesis, and physical activity energy expenditure. Physical activity is the most variable component of total energy expenditure and accounts for approximately 20 to 30% of daily energy expenditure; and is the most modifiable component (Keim et al., 2004).

Though assessment tools have been developed and used to assess energy expenditure, many of these techniques have limitations which may impact the accuracy of the estimate of energy expenditure or are not feasible for use in various clinical or research environments. Development of a portable monitor to accurately assess energy expenditure in free-living individuals may clarify the role energy expenditure has in energy balance, help to further explain the relationship between physical activity and health outcomes, as well as clarify exercise recommendations to the public for additional health benefits. This study will examine the accuracy of a newly developed portable device for assessing energy expenditure.

1.2 Rationale

To date, numerous physical activity monitoring devices have been studied however, each of these methods is not without disadvantages. The disadvantages in these techniques limit the ability to accurately measure energy expenditure in free-living adults. Free-living can be defined as individuals who are not in a controlled laboratory environment. These disadvantages will be discussed in detail below according to device, and provide the rationale for the need for a valid portable device to assess energy expenditure.

The gold standards or criterion measures for measuring energy expenditure include doubly labeled water (DLW) or indirect calorimetry (IC). DLW can accurately assess total energy expenditure across a 7 to 14 day period, and is not negatively affected by mode or intensity of activity. However, DLW requires expensive method instrumentation and stable isotopes, requires trained technicians, and may not be practical for use when testing numerous individuals (Starling et al., 1999, Macfarlane, 2001). Indirect calorimetry, although a frequently used reliable method, has disadvantages such as expense, required laboratory equipment, trained technicians, required time for calibration, and due to limited mobility may not feasible for field use (Macfarlane, 2001). Although most metabolic carts are not feasible for field use, portable systems are available that can be used in a free living environment. However, these systems are expensive ($20,000-$30,000), may only be used for a few hours, and may not be practical to wear to places such as work or public functions.

A commonly used method to estimate energy expenditure is self-report which involves the use of questionnaires, interviews, or physical activity diaries. Although self-report measures have been praised for their low cost and minimal subject burden, there are numerous limitations. Because self-report is a subjective measure of physical activity, this may result in

misinterpretation of instructions, inaccurate recall, deliberate misreporting, and failure to capture aspects of physical activity such as frequency, intensity and duration (Pereira et al., 1997, Montoye, 1996). Self-report measures have wide ranges in both validity and reliability, with commonly used questionnaires having correlation coefficients ranging from 0.30 to 0.39 when compared to DLW, with reliability coefficients ranging from 0.33 to 0.84 (Montoye et al., 1996).

Physiological measurements and motion sensor devices are also used to assess energy expenditure. Motion sensor devices such as pedometers and accelerometers are helpful because they limit subjectivity in measuring physical activity. Pedometers, in addition to being an objective measure of physical activity, have become popular because of their low cost, minimal burden and their ability to provide feedback to the user (Schneider et al., 2004, Tudor-Locke et al., 2001). However, pedometers are limited when assessing some ambulatory activities, are not sensitive to gait differences in people, accuracy varies in different models, fail to capture intensity and rate of activity, and are less accurate for assessing distance and kilocalories (Crouter et al., 2004, Crouter et al., 2003, Schneider et al., 2004, Tudor-Locke et al., 2001).

Because of the linear relationship between heart rate and energy expenditure during periods of exercise, heart rate monitors have been used to provide an estimate of energy expenditure during physical activity (Janz, 2002). However, heart rate response may be due to non-related physical activity events, heart rate monitors may also be uncomfortable to wear, require calibration with an exercise test, and may not be useful for capturing energy expenditure of anaerobic activity (Janz, 2002). A recent study demonstrated that a heart rate monitor was limited in the accuracy of estimating energy expenditure during running, rowing and cycling activities (Crouter et al., 2004). Heart rate monitors may also require the use of regression

equations to predict energy expenditure (Strath et al., 2000) and may be less accurate in detecting lower intensity activities (Crouter et al., 2004).

Accelerometers have been used to measure body movement and energy expenditure, with both uniaxial (i.e. MTI, Biotrainer) and triaxial (RT3, Tritrac-R3D) commercially available. Accelerometers can quantify time and intensity of activity (Westerterp, 1999), and have been shown to provide accurate and reliable estimates of energy expenditure in adults in various forms of activities (Pambianco et al., 1990, Montoye et al., 1983, Kleges et al., 1985, Balogun et al., 1989). However, they are inaccurate at predicting energy cost of activities such as cycling, swimming, rowing, upper body exercise, and walking/running up an incline (Fehling et al., 1999, Haymes et al., 1993, Jakicic et al., 1999, Melanson et al., 1995, Montoye et al., 1983, Swan et al., 1997, Crouter et al., 2004, King et al., 2004, Bassett, 2000, Welk et al., 2000). This may limit the utility of accelerometers for estimating energy expenditure in certain applications.

Technology has been developed in an attempt to increase the accuracy of estimating energy expenditure by combining measurement systems. Energy expenditure has been assessed through the combinations of systems. One of the newer devices that incorporates a combination of measurements is the SenseWear Pro Armband™ (BodyMedia, Inc, Pittsburgh, PA) which uses accelerometry, galvanic skin response, skin temperature and heat flux. Three recent peer reviewed studies have been published on the SenseWear Pro Armband™. Although these initial studies found the SenseWear Pro armband™ has the potential to accurately measure energy expenditure, it may underestimate or overestimate energy expenditure for some activities (Fruin et al., 2004, King et al., 2004, Jakicic et al., 2004). This device may be dependent on algorithms which are population or activity specific, and therefore are associated with measurement error.

The KAL-X Sensor™ (Lifechek, LLC, Pittsburgh, PA), has been developed and may address the limitations of other portable energy expenditure devices. The KAL-X Sensor™ is a wireless sensor that measures heat flux from conductive, radiant, convective, and evaporative components of heat loss, and this information is used to estimate energy expenditure. The first application of the calculation of heat balance of the human body dates back to 1932 (Buttner, 1932), with the use of heat flux appearing in peer-reviewed journals starting in the early 1980's (Layton et al., 1983). Heat flux transducers were originally used to examine heat loss in various populations such as surgical patients (English et al., 1990) and in divers (Layton et al., 1983). Heat flux transducers are the backbone of the KAL-X Sensor™, which has been developed for the assessment of energy expenditure. The KAL-X Sensor™ uses heat flux transducers to measure all four forms of heat loss, which may provide an accurate estimate of energy expenditure. Although no peer reviewed studies have been published on the KAL-X Sensor™, data are available from published abstracts. Winters et al. (1998) and Jakicic et al. (1993) found that the KAL-X Sensor™ was able to provide accurate estimates of energy expenditure for activities such as slideboard, stepping, cycling and for some speeds and grades of walking. Although these abstracts provide positive preliminary data, the subjects in the studies were young, normal weight, the sample size of the studies was small, and one of the studies only included males. These initial studies provide support for use of heat flux transducers in the assessment of energy expenditure, but also show the need for a formal validation of the KAL-X sensor.

1.3 Specific Aims

This investigation was conducted as a sub-investigation of an ongoing validation trial being performed at the Physical Activity and Weight Management Research Center at the University of Pittsburgh.

The primary aims of this study were to:

1. Examine the validity of the KAL-X Sensor^{TM} to estimate energy expenditure during motorized treadmill walking.
2. Examine the validity of the KAL-X Sensor^{TM} to estimate energy expenditure during stationary cycling.

The secondary aims of this study were to:

3. Examine the accuracy of energy expenditure measured using the KAL-X Sensor^{TM} for different BMI classifications (normal 20-24.9, overweight 25-29.9, and obese 30-35 kg/m^2).
4. Examine the accuracy of the KAL-X Sensor^{TM} according to the anatomical placement site of the sensor (chest vs. arm).

1.4 Research Hypotheses

The primary hypotheses of this study were the following:

1. Energy expenditure measured by the KAL-X Sensor^{TM} will not be significantly different from energy expenditure measured by the criterion measure indirect calorimetry for motorized treadmill walking.
2. Energy expenditure measured by the KAL-X Sensor^{TM} will not be significantly

different from energy expenditure measured by the criterion measure indirect calorimetry for stationary cycling.

The secondary hypotheses:

3. There will be no significant difference between energy expenditure estimated by the KAL-X Sensor™ and the criterion measure across levels of body mass index (normal 20-24.9, overweight 25-29.9, and obese 30-35 kg/m^2).
4. There will be no significant differences between energy expenditure data collected at the sensor site of the chest and energy expenditure data from the sensor site of the left arm.

1.5 Significance of the Study

There is a need to accurately measure energy expenditure in free-living individuals. Criterion measures of energy expenditure such as DLW and IC are expensive and are limited by methodological factors such as time, training, and mobility. Cost effective methods such as pedometers are often used in large populations, however, these methods have limitations that affect their accuracy. Promising advances in technology have led to the use of heat flux transducers to estimate energy expenditure. Data from studies examining these devices have been positive and have led to newer technological advances in the use of heat flux to estimate energy expenditure. If it is determined that the KAL-X Sensor™ is a valid method to assess energy expenditure in free-living adults, this device may be used in both research and clinical applications.

2 Review of Literature

2.1 Introduction

The purpose of this study was to examine the validity of the KAL-X Sensor^{TM} to measure energy expenditure across different modes and intensities of activities. Energy expenditure is comprised of three components; resting metabolic rate (RMR), thermic effect of food also called dietary thermogenesis, and physical activity energy expenditure. Physical activity is the most variable component of total energy expenditure and accounts for approximately 20 to 30% of daily energy expenditure; and is the most modifiable component (Keim et al., 2004). Since physical activity is the most variable component of energy expenditure, this may be the most responsive to interventions and have the greatest impact on health-related outcomes.

Levine et al. (2002) has reviewed "NEAT", non-exercise activity thermogenesis, which makes up a portion of activity thermogenesis. NEAT can be defined as energy expenditure for everything we do that is not sleeping, eating or sports-like exercise. Since many Americans do not engage in regular physical activity most of their time is likely spent performing NEAT activities. Difficulties in measuring NEAT and the variability in NEAT make it hard to understand how these activities contribute to health-related variables. A valid portable device for measuring energy expenditure may help to accurately measure activities occurring in the free-living environment as well as explain how NEAT activities may contribute to energy balance and weight change.

Methods of assessing physical activity energy expenditure include self-report, pedometers, heart rate monitors, and accelerometers, as well as by more sophisticated and valid techniques such as indirect calorimetry and doubly-labeled water. Each of these techniques has problems that limit either their practicality or validity when assessing physical activity energy expenditure in free-living adults. This literature review will focus on techniques currently available to assess physical activity energy expenditure, and will support the need for a portable device that will provide a valid estimate of physical activity energy expenditure in free-living individuals.

2.2 Criterion Measures of Energy Expenditure

2.2.1 Doubly Labeled Water (DLW)

Doubly-labeled water (DLW) is typically considered the "gold standard" for the assessment of energy expenditure in free-living individuals. DLW requires that an individual consume a known volume, based on body weight, and concentration of stable isotopes $^{18}0$ and hydrogen ^{2}H. Urine is measured over a 7 to 14 day period to determine the elimination rates of these two isotopes, from which carbon dioxide and the respiratory quotient can be estimated and energy expenditure determined (Montoye et al., 1996).

The ability of DLW to assess energy expenditure was initially examined for use in laboratory animals in the 1950's (Lifson et al., 1995), and has since been applied to humans. DLW has been shown to be accurate to within ± 8% of known values when used in laboratory animals (Roberts, 1989, Nagy, 1980), whereas DLW has been shown to be accurate to within ± 5% in humans when compared to a respiratory chamber (Schoeller et al., 1986, Seale et al., 1993, Westerterp et al., 1988) or other continuous methods of measuring respiratory gas exchange

(Schoeller and van Santen, 1982). When applied to free-living environments, it has been suggested that there is most likely a slight increase in the error of measurement with DLW (Montoye et al., 1996). Thus, DLW is typically considered as the most accurate technique for assessing energy expenditure in free-living individuals.

Despite the potential accuracy of DLW for assessing energy expenditure in free-living environments, there are disadvantages that limit the wide use of this technique in research and clinical situations. DLW requires the use of water containing stable isotopes (^{18}O and ^{2}H), and this can be expensive with cost ranging from $500 to $1500 per subject for each measurement period, with additional costs for laboratory equipment and well-trained technicians. DLW also requires that subjects collect urine over a 7 to 14 day period and transport this urine to a laboratory for analysis, which may create a significant burden and barrier for subjects. These factors may limit the practical utility of assessing energy expenditure using DLW in many research and clinical settings (Starling et al., 1999, Macfarlane, 2001).

While DLW may provide an accurate representation of energy expenditure in free-living individuals, this method provides little information about the pattern of physical activity behavior that influences energy expenditure. Because of the need to collect excreted urine over a 7 to 14 day period, DLW can only provide a representation of the average total energy expenditure per day during this period of time, rather than information with regard to more acute periods of physical activity. Thus, this may limit the utility of DLW if the desire is to obtain information about acute periods of physical activity or how patterns of activity contribute to total energy expenditure and health-related outcomes.

2.2.2 Indirect Calorimetry (IC)

Open-circuit indirect calorimetry (IC) is commonly used as a criterion measure when assessing energy expenditure. Montoye et al. (1996) reported that indirect calorimetry is accurate to within 2% of energy expenditure measurements of doubly-labeled water (DLW). Despite the potential accuracy of IC, there are numerous disadvantages of this method for the assessment of energy expenditure including expense, the need for trained technicians, and due to limited mobility this method may not feasible for use outside of controlled laboratory conditions (Macfarlane, 2001). While there are portable IC systems commercially available that can be used in field settings, these systems can be expensive (i.e. $20,000-$30,000), may only be used continuously for a few hours before recharging is necessary, and may not be practical to wear in many settings (i.e., work, home, social setting, etc.). These limitations of IC negatively impact the utility of this method of assessing energy expenditure in free-living adults.

2.3 Methods of Estimating Energy Expenditure

2.3.1 Self-Report Methods

A commonly used method to estimate energy expenditure is self-report of physical activity, which can include the use of questionnaires, interviews, or physical activity diaries. These techniques typically involve the assignment of a score or value to a reported physical activity, which are then summed over the measurement period and converted to energy expenditure (Keim et al., 2004). Self-report measures have advantages of being low cost and require relatively minimal participant burden. However, the accuracy of self report techniques for estimating energy expenditure has been questioned. This may be a result of these techniques being prone to misinterpretation of instructions by respondents, inaccurate recall of activity

behaviors, deliberate misreporting of information, or the inability of these techniques to accurately capture all forms and components of physical activity (Pereira et al., 1997, Montoye, 1996).

The 7-day Physical Activity Recall (PAR) is commonly used in intervention research to assess physical activity and estimate energy expenditure. Leenders et al. (2001) compared energy expenditure estimated from the PAR to DLW and reported no significant difference in the group mean when represented using either of these techniques. However, further examination of the data reveal rather larger individual differences between the PAR and DLW for individuals with relatively low or high levels of energy expenditure. Individuals with the lowest levels of energy expenditure tended to overestimate energy expenditure by 137 kcal/d, with individuals with the highest energy expenditure tended to underestimate by 287 kcal/d. Moreover, Irwin et al. (2001) reported that the PAR differed from DLW by 30.6 ± 9.9%. These discrepancies in energy expenditure estimated from the PAR may indicate that this method is unable to accurately capture individual differences in physical activity, which may limit the utility of this questionnaire.

The inability of questionnaires to accurately estimate energy expenditure is not limited to the PAR. Startling et al. (1999) compared the Minnesota Leisure Time Activity Physical Activity Questionnaire (LTA) and the Yale Physical Activity Questionnaire (YPAS) to DLW in older men and women (45 to 84 years). Results showed the LTA underestimated physical activity by approximately 50% to 60% compared with DLW, with no significant difference reported between YPAS and DLW. Jacobs et al. (1993) examined 10 commonly used physical activity questionnaires and reported that most questionnaires may not be suitable for accurately estimating energy expenditure during moderate and light intensity activity, but may be more

accurate for estimating energy expenditure during periods of more vigorous intensity activity. Moreover, Montoye et al. (1996) reviewed the reliability and validity of various physical activity questionnaires and concluded that there is a wide range of validity and reliability that may be questionnaire specific. Thus, it appears that there is variability in the accuracy of questionnaires for estimating energy expenditure, and this should be considered when selecting a questionnaire to assess physical activity in free-living adults.

2.3.2 Pedometers

Pedometers, which assess number of steps of locomotion, have been used to measure physical activity. Advantages may include objective measuring of physical activity, low cost, minimal burden, and the ability to provide feedback to the user (Schneider et al., 2004, Tudor-Locke et al., 2001). However, inherent disadvantages of pedometers may make these devices less viable in the assessment of energy expenditure. One major disadvantage of pedometers is that the accuracy varies in different models. A recent study by Schneider et al. (2004) compared the step values of 13 models of pedometers over a 24 hour period, with the Yamax Digi-Walker SW-200 (YX200) model used as the criterion measure. Results showed five of the pedometers (Freestyle Pacer Pro, Accusplit Alliance 1510, Yamax Skeleton EM 180, Colorado on the Move, and Sportline 345) significantly underestimated steps ($p \leq 0.05$), while three pedometers (Walk4 Life LS 2525, Omron HJ-105, and Oregon Scientific PE316CA) significantly overestimated steps ($p \leq 0.05$). Underestimations were as high as 25% while overestimations reached 45% in some models of pedometers. Thus, these results indicate that the accuracy of steps taken and energy expenditure estimation may depend on the brand of pedometer.

Accuracy of pedometers can also be impacted by the intensity and rate of the activity. When comparing pedometers to hand counted steps, during slow treadmill walking of 54 m/min many pedometers (Sportline 345, Yamasa Skeletone, Sportline 330, and Freestyle Pacer Pro) significantly ($p \leq 0.05$) underestimated steps, while during fast treadmill walking (107 m/min) pedometers (Yamasa Skeleton, Omron, Kenz Lifecorder, New Lifestyles 2000, Oregon Scientific and Walk4Life LS 2525) significantly overestimated steps (Crouter et al., 2003). There is some evidence that pedometers may be most accurate for assessing steps at the speed of 80 m/min, with some pedometers (Yamax, Omron, New Lifestyles, Yamasa Skeletone, Kenz Lifecorder, Walk4Life LS 2525) measuring steps within ± 1% of actual steps when walking at this pace (Crouter et al., 2003, Le Masurier et al., 2004).

Although some pedometers are accurate in assessing steps they are less accurate in assessing distance and kilocalories. Crouter et al. (2003) found most pedometers estimated distance within 10% at 80 m/min, but overestimated distance at slower speeds (54 m/min) and underestimated distance at faster speeds (107 m/min). When the investigators compared energy expenditure of pedometers to indirect calorimetry, net kilocalories were overestimated at every speed (54, 67, 80, 94, and 107 m/min), while gross kilocalories were within 30% accuracy for all speeds. This study found that at slower speeds, the accuracy of the pedometers was compromised for step counting, kilocalorie estimates, and distance traveled. Thus, these results indicate pedometers may not be suitable for use in populations with a slow gait, such as the elderly or obese, and may be more accurate for counting steps rather than estimating energy expenditure.

Studies of pedometers have shown that these devices may not provide a comparable estimate of physical activity when compared to questionnaires or accelerometers. When comparing pedometers to the 7 day PAR, low ($r = 0.34$) to

moderate correlations ($r = 0.49$) have been reported between step counts and average energy expenditure (Welk et al., 2000). Moreover, when compared to a CSA accelerometer in laboratory or field settings, the Yamax pedometer detected significantly lower steps than the CSA during treadmill walking at 54 m/min (75.4% versus 98.9%, $p< 0.05$) (Le Masurier and Tudor-Locke 2003), whereas the Sportline 330 detected fewer steps than the CSA ($p< 0.05$) (Le Masurier et al., 2004). Thus, these results show some pedometers may be less accurate than others for assessing energy expenditure and lower intensity activities.

Reliability and validity of pedometers has improved as this technology has evolved. Earlier models of pedometers had poor reliability across models and errors in the estimation of steps and distance walked (Washburn et al., 1980, Gayle et al., 1977); however, newer models have shown improvements in reliability and validity with the Yamax Digi-walker measuring steps and distance to within 1% of actual values (Bassett et al., 1996) and correlations of 0.76 between the Tritrac accelerometer and the Yamax Digi-Walker (Differding et al., 1998). However, pedometers continue to have difficulty in accurately detecting changes in speed of walking and can not accurately estimate the intensity or duration of an activity (Welk et al., 2000).

In summary, while pedometers may be appealing because of their low cost and ease of use, the ability of the devices to accurately estimate energy expenditure across a variety of activities is limited. This may limit the use of pedometers in some populations and when performing certain forms of activities.

2.3.3. Heart Rate Method to Estimate Energy Expenditure

Heart rate monitors have been used to estimate energy expenditure, and is a result of these devices providing an objective measurement, having the ability to measure different intensities of physical activity, and because heart rate is significantly correlated with energy expenditure during aerobic physical activity (Janz, 2002). However, there are numerous disadvantages of this method of estimating energy expenditure. For example, heart rate response may be due to non-related physical activity events such as emotions, room temperature, and training state (Janz, 2002), which can typically result in an overestimation of energy expenditure. Disadvantages of heart rate monitors include comfort level when being worn and some are not useful for capturing energy expenditure of anaerobic activity (Janz, 2002).

To improve the accuracy of heart rate to estimate energy expenditure, a calibration test is necessary to determine the relationship between heart rate and energy expenditure for each individual. Strath et al. (2000) examined the relationship between heart rate (beats/min) and oxygen consumption (VO_2 = ml/kg/min) during both laboratory and field-based moderate intensity activities. A moderate correlation was found between heart rate and VO_2 ($r = 0.68$); however, adjustments for age and fitness level increased the accuracy of predicted energy expenditure to $r = 0.87$.

In a review of the literature, Montoye et al. (1996) reported similar correlations for energy expenditure between heart rate and DLW ($r = 0.73$) or VO_2 ($r = 0.55$), with the inaccuracy of heart rate to estimate energy expenditure ranging from 2% to 22%.

2.3.4. Accelerometry

Accelerometry is a method of detecting body motion using either uniaxial (i.e., Caltrac or CSA/MTI) or multi-axial (i.e., RT3 or TriTrac-R3D) devices. These devices use electronic sensors to monitor body movement, and these movement counts can be used to estimate energy expenditure. Accelerometers are typically worn at the level of the waist, and there is the ability to capture and store minute-by-minute data for periods of up to 4 weeks. Thus, accelerometry may have utility for monitoring energy expenditure in free-living individuals.

It appears that accelerometers may provide the most accurate estimate of energy expenditure during periods of level walking. When compared to a criterion measure of energy expenditure, significant correlations have been shown for uniaxial ($r = 0.94$) (Pambianco et al., 1990) and triaxial accelerometers ($r = 0.99$) (Levine et al., 2001) during periods of level walking, with consistency during steady state walking ranging from 0.86 to 0.96 (Jakicic et al., 1999). Despite these significant correlations, Pambianco et al. (1990) reported that accelerometry may overestimate energy expenditure by an average of 9-13% compared to indirect calorimetry, with significant differences of 13.5 kcal, 19 kcal, 25.5 kcal shown between accelerometry and the criterion measure for speeds of 3.2, 4.8 and 6.4 km/h, respectively. Haymes et al. (1993) reported that accelerometry significantly overestimated energy expenditure at walking speeds above 2mph (~3.6 kcal/min) and could not discriminate between running speeds of 5-8mph (overestimated ~2.6 kcal/min), while Balogun et al. (1989) reported that accelerometry significantly ($p< 0.001$) overestimated energy expenditure by 13.3 to 52.9% during level walking at various walking speeds (54, 81, 104, 130 m/min).

A disadvantage of accelerometers is that these devices may not be sensitive to changes in work rate during walking resulting from changes in grade or speed, which may result in the over-

or underestimation of energy expenditure. Fehling et al. (1999) reported that the Caltrac accelerometer significantly overestimated energy expenditure 10% during walking on a flat surface; however, when the grade was increased the error in estimate increased to 52%. Examination of the Tritrac accelerometer indicated that energy expenditure was significantly underestimated by 19% during level walking and by 28% when walking grade was increased.

It has also been demonstrated that accelerometry may not be accurate for all forms of activity. Montoye et al. (1983) found accelerometry compared with indirect calorimetry had a standard error of estimate of 6.6 ml/kg/min for activities such as stepping, half knee-bends, flour touches, as well as walking and running on flat and incline surfaces. Jakicic et al. (1999) found accelerometry significantly overestimated ($p < 0.05$) energy expenditure at the lowest walking and running speeds by 1 kcal/min, however significant underestimations were found for all other walking and running workloads, stepping, slideboard and cycling activities (29.8 to 50.0 kcal). Thus, these studies indicate the accuracy of accelerometry is activity specific.

Inter-unit variability may impact the accuracy of accelerometry and inter-unit correlations may be affected by change in work rate. Jakicic et al. (1999) found there was a significant difference ($p \leq 0.05$) between two accelerometry units during walking, stepping, and slideboard exercises, with the difference between these two units being 0.5 to 0.8 kcal/min. Nichols et al. (1999) reported inter-unit correlations of 0.87 during walking ($r = 0.87$), however the inter-unit correlations were 0.84 during jogging and 0.73 during fast running. These results illustrate there may be inter-unit variability among accelerometers, which may suggest the need to using the same unit when assessing energy expenditure within an individual over a period of time.

The accuracy of accelerometry may be dependent on the unit type (i.e. Caltrac versus Tritrac versus CSA, etc). When comparing the accuracy of accelerometry units during

laboratory conditions, Welk et al. (2000) reported that the CSA provided accurate estimates of energy expenditure, while the Tritrac and Biotrainer overestimated energy expenditure (101 to 136%). However, during field activities the CSA, Tritrac and Biotrainer all underestimated energy expenditure (42 to 67%). These results demonstrate that variability may exist between different models of accelerometers, and this should be considered when these devices are used in clinical and research applications.

In summary, while accelerometers detect motion and provide minute-by-minute data these devices exhibit large over- and under estimations of energy expenditure particularly during activities of increased work rate due to changes in speed or grade. Both inter-unit variability and model of the accelerometer may play a role in the accuracy of estimated energy expenditure. Thus, the use of accelerometry to estimate energy expenditure may not be applicable for many forms of activities that occur in the free-living environment.

2.3.5. Intelligent Device for Energy Expenditure and Activity (IDEEA)

A newer portable device called the Intelligent Device for Energy Expenditure and Activity (IDEEA, MiniSun, CA) has been developed to estimate energy expenditure of physical activity. The IDEEA system estimates energy expenditure through body and limb motions, which are collected through five sensors attached to the chest, thighs and feet. Signals from the sensors are recoded to the device and later downloaded to a computer for analysis. Few studies have been published examining the validity of this device. A study by Zhang et al. (2004) was performed to examine the validity of IDEEA, compared to estimated energy expenditure from a non-portable mask calorimeter (Hans Rudolph, Kansas City, MO) and a respiratory chamber with open air circuits. One of the experimental protocols included performing activities such as

sitting, standing, lying down, level treadmill walking and running at different speeds for 50 minute durations while wearing the mask calorimeter, while the other protocols consisted of subjects living in a metabolic chamber for 23 hours during which time they completed three exercise sessions on a motorized treadmill (walk for 15 minutes, run for 10 minutes or walk for 15 minutes, and walk for 15 minutes). Analysis of data showed the overall accuracy for estimated energy expenditure of IDEEA and the calorimeters was 95.1 ± 2.3%. However, it was also found that IDEEA underestimated energy expenditure for certain subjects and overestimated energy expenditure for others up to 10%. The errors in the estimation of energy expenditure using IDEEA may limit the use of this device for estimating energy expenditure in free-living individuals.

IDEEA may have limitations related to wearability of this device in free-living individuals. For example, IDEEA sensors are attached to the body using medical tape and must be removed during bathing (Zhang et al., 2004). Moreover, the sensors are taped on the chest, the frontal part of the thigh and under each foot, and these placements may potentially make the device uncomfortable or less appealing to some individuals. IDEEA sensors are also connected by thin flexible wires which may be cumbersome or limit the willingness of individuals to wear this device. Zhang et al. (2003) also noted that the anatomical positions or angle of the sensors may be impacted by the shape of the body (i.e. lean versus obese, male versus female shape), and the variability in site location may affect the accuracy of this device. Zhang et al. (2004) reported that the IDEEA may also have limitations when detecting arm movements and the transition from one activity to another (i.e. from running to walking). These factors appear to impact the accuracy of IDEEA, which may limit the utility in research and clinical environments for the estimation of energy expenditure.

2.3.6. SenseWear Pro Armband™

The SenseWear Pro Armband™ (SWA) is a portable sensor that gathers information on movement, heat flux, skin temperature, near-body temperature, and galvanic skin response, which are used to estimate energy expenditure. The SWA is worn on the right arm over the belly of the bicep muscle, and has the capability of capturing and storing minute-by-minute data.

It appears the SWA exhibits errors in estimation of energy expenditure, which vary according to exercise modality. Fruin et al. (2004) found during cycling exercise the SWA underestimated energy expenditure compared to indirect calorimetry, with the most pronounced difference during early exercise (minute 1-10, % difference = 8%). When examining walking, King et al. (2004) found that the SWA underestimated total energy expenditure during various speeds of walking and running compared to indirect calorimetry ($p \leq 0.001$), while Fruin et al. (2004) found the SWA overestimated energy expenditure while walking on a flat surface (14-38%) and underestimated energy expenditure during walking on an incline (22%).

Jakicic et al. (2004) examined the ability of the SWA to estimate energy expenditure, which incorporated the use of both exercise-specific and general algorithms. Use of the exercise specific algorithms resulted in non-significant differences between energy expenditure estimated by the SWA compared with indirect calorimetry. However, when the general algorithm was used the SWA significantly ($p \leq 0.001$) underestimated energy expenditure during walking (6.9%), cycling (28.9%), and stepping (17.7%) and overestimated energy expenditure during arm ergometry (29.3%). Thus, these results indicate the SWA may be less accurate when using the manufacturer's general algorithm and may require the use of exercise specific algorithms, which would limit the use of this device in free-living individuals.

Although armbands such as the SWA appear to be inaccurate for some forms of acute periods of activity, they may be more useful in capturing longer periods of activity. Mignault et al. (2005) found no significant differences in mean energy expenditure between the SWA (2,237 ± 568 kcal/day), which is marketed as the HealthWear armband (Roche Diagnostics, Indianapolis, IN), compared with doubly-labeled water (2,315 ± 625 kcal/day) during a 10 day period. Although no significant differences were found, the range of under-and over- estimation of the armband versus DLW was -243 to 176 kcal/day. Thus, while there are limitations in the accuracy of the SWA for estimating energy expenditure during acute periods of physical activity, the accuracy of this device may be improved when energy expenditure is estimated over longer periods of time.

2.3.7. Heat Flux to Estimate Energy Expenditure

The first model of the calculation of heat balance of the human body dates back to 1932 (Buttner 1932) while the first peer reviewed journals to publish studies on heat flux appeared in the early 1980's. Heat balance is defined as the balance between heat produced and the heat lost (English et al., 1990). Original studies that incorporated the use of heat flux transducers were used to examine heat loss in populations including divers and surgical patients. The validity of heat flux transducers to measure heat loss has shown positive findings. A study by Layton et al. (1983) was performed to examine the validity of heat flux transducers by comparison to a suit calorimeter, which served as the criterion measure or direct calorimetry. Subjects underwent 2 days of testing, each consisting of a series of cooling and warming cycles, with the entire testing period lasting approximately 6 hours. Subjects rested in a seated position with their legs and feet resting on a hassock. Water in the suit calorimeter was cooled and heated to allow for changes in

body temperature, which included heat loss. Temperatures used for the testing cycle included 28, 23, 18, 10 and 5 degrees Celsius, with 35 degrees Celsius used to warm subjects after the coolest conditions. During the testing cycles both the heat flux transducers and suit calorimeter were worn for all testing. Fourteen heat flux transducers were worn to provide heat loss information for 6 different segments of the body. Data analysis showed a correlation between heat loss rates measured using the heat flux transducers and a suit calorimeter. While heat loss measured between both measures was similar for the torso and legs, the transducers measured less heat from the head and arms than the suit calorimeter. Based on the results it appears heat flux transducers may provide a reasonable measurement of relative regional and total heat in human subjects during rest in a supine position.

A more recent study examined the ability of heat flux transducers to measure heat exchange in subjects who were exposed to four different temperatures (30, 33, 37 band 40 degrees Celsius) (English et al., 1990). Each temperature remained constant for twenty minutes and heat flux data was recorded every minute. Heat exchange was measured using six heat flux transducers, with three worn on the back and three worn on the chest. Heat exchange values obtained from the heat flux transducers were used to compute heat exchange coefficients (radiant, convection, combined radiant and conduction, and conductance) from pre-existing formulas. Coefficients for radiation (6.4), convection (8.7), combined radiation and conduction (9.7), and conductance (41) were within accepted ranges (Allan, 1987 and Kerslake, 1972). The results indicate the direct measurement of heat exchange with heat flux transducers may improve the understanding of the body's thermal balance.

The ability of heat flux transducers to measure heat loss during varying conditions has led to the use of heat flux transducers for the assessment of energy expenditure. The KAL-X

Sensor™ is a wireless sensor that uses heat flux technology to measure conductive, radiant, convective and evaporative heat loss, to estimate energy expenditure (EE). There is limited published data on the validity of the KAL-X Sensor™ for estimating energy expenditure. However, two pilot studies published as abstracts have been conducted to assess the accuracy of the KAL-X Sensor™.

Jakicic et al. (1993) examined the validity of a KAL-X prototype to measure energy expenditure. Subjects were seven healthy males (age = 21.57 ± 5.06 years, BMI = 22.37 ± 1.91 kg/m^2) recruited to participate in three exercise trails (walking, cycling and stepping). The trials were each five minutes in length with both the KAL-X Sensor™ and indirect calorimetry worn to measure energy expenditure at rest, during exercise and post exercise. Four KAL-X Sensors™ were worn on the upper arm, chest, back and thigh during each trial. Protocols for the exercise trials included the following treadmill walking at 3.0 mph at 0% grade, stepping on an 8 inch bench at 80 cycles per minute and cycling at 1 kg resistance at 50 rpm. Comparison of energy expenditure measured by indirect calorimetry and by the KAL-X Sensor™ showed no significant differences ($p \leq 0.05$) for walking (44.42 ± 6.12 (IC) vs. 42.46 ± 16.89 kcal (KAL-X), stepping (47.26 ± 5.61 (IC) vs. 43.23 ± 18.48 kcal (KAL-X), and cycling (43.06 ± 4.65 (IC) vs. 43.08 ± 25.85 kcal (KAL-X). Although the sample size was small and the exercise duration was short, it appears that the initial tests of the KAL-X system provide valid estimates of energy expenditure of selected moderate intensity activities.

Winters et al. (1998) examined the validity of a KAL-X prototype to measure energy expenditure during walking, cycling, stepping and slideboard exercises. Twenty subjects (age = 21.5 ± 3.38 years; BMI = 23.3 ± 3.55 kg/m^2) were recruited to participate in four exercise trials lasting 20-30 minutes. The treadmill walking protocol was 30 minutes in length and consisted of

walking at 3.5 mph at 0, 5, and 10% grades (each grade was a 10 minute bout). Cycling, stepping and slideboard exercises were all 20 minutes in length with the rate increasing at 10 minutes from 50 to 65 rpm, 17 to 21 cycles and 20 to 30 cycles for the three exercises respectively. The KAL-X Sensors^{TM} were worn for all trials and were placed on the chest, back, right upper arm, and calf. Heat flux data was recorded by the KAL-X Sensor^{TM} during each minute of the exercise session and this data was downloaded to a computer for analysis. Indirect calorimetry served as the criterion measure for all trials. No significant differences ($p \leq 0.05$) were found between energy expenditure measured from indirect calorimetry and from the KAL-X Sensor^{TM} for any of the exercise trials except for level walking. Results for energy expenditure estimates for the KAL-X, although not significantly different from indirect calorimetry, were based on a proprietary non-linear regression from the walking data.

Based on the review of literature it appears the use of heat flux to measure energy expenditure during physical activity shows promising results, however these results were based on a prototype instrument, subjects in the studies were young, lean individuals and the sample size of the studies was small, with one of the studies limiting the testing to males. These initial studies provide support for use of heat flux transducers in the assessment of energy expenditure, but also show the need for a formal validation of the KAL-X Sensor^{TM}. Therefore, studies are needed to establish the validity of the KAL-X Sensor^{TM} to measure energy expenditure.

2.4 Significance

The ability to assess energy expenditure in free-living individuals is important because of the need to better understand the association between energy expenditure and chronic disease. Currently, criterion measures such as DLW and IC are not feasible for use in free-living adults, and may provide limited information with regard to patterns of physical activity. An alternative approach would be the use of portable devices such as accelerometers, heart rate monitors, pedometers, or the use of self-reported physical activity using questionnaires. However, these methods have also been show to have limitations which limit the accuracy to estimate energy expenditure. Alternative technology includes the use of heat flux, and this has been integrated into the KAL-X Sensor^{TM}. Despite promising initial results from studies of prototypes of this unit, further validation of the KAL-X Sensor^{TM} is necessary prior to use in research and clinical settings. The primary focus of this current study was to examine the validity of the KAL-X Sensor^{TM}.

3 Methods

3.1. Introduction

Adequate levels of physical activity and energy expenditure are important for optimal health, which may result in risk reduction for numerous diseases. Thus, it is important to accurately quantify levels of activity and corresponding energy expenditure to better understand the association with health-related outcomes. However, many of the current techniques for assessing energy expenditure have limitations which affect their utility in clinical or research settings. These limitations include, but are not limited to, expense, subjectivity, validity and reliability, or portability of the available technologies. The KAL-X Sensor^{TM} (LifeChek, LLC, Pittsburgh, PA) is a portable device that may be used to assess energy expenditure and physical activity. However, to date no independent studies have been published on the validity of the KAL-X Sensor^{TM} to assess energy expenditure. Therefore, the purpose of this study was to examine the validity of the KAL-X Sensor^{TM} to measure energy expenditure across different modes and intensities of physical activity.

3.2 Subjects

Twenty-four adult men (n=12) and women (n=12) were recruited to participate in this study. Individuals were considered eligible if they were 18-50 years of age for women or 18-40 years of age for men with a body mass index (BMI) of 20 to 35 kg/m^2. The age range used for

this study was chosen based on the American College of Sports Medicine guidelines for selecting subjects with minimal risk. Subjects were recruited through various methods such as newspaper advertisements, radio advertisements, mailings and other techniques. The subjects for this study are part of a sub-investigation of an ongoing validation trial. The following criteria were used to determine individuals who were eligible to participate in this study.

3.3 Inclusion Criteria

1. Not currently pregnant or planning on becoming pregnant during their participation in this study.
2. Not being treated for a medical condition that could impact exercise participation or increase health risk when participating in vigorous exercise (i.e., heart disease, diabetes mellitus, cancer, etc.).
3. No history of myocardial infarction or history of undergoing heart surgery (e.g., bypass or angioplasty).
4. Not taking medication that would affect heart rate or blood pressure responses to exercise (e.g., beta blockers).
5. A non-medicated resting blood pressure less than 140/90 mmHg.
6. No musculoskeletal conditions that could be aggravated with vigorous exercise or prevent participation in vigorous exercise.

3.4 Experimental Design

This investigation was conducted as a sub-investigation of an ongoing multiphase validation trial being conducted through the Physical Activity and Weight Management Research Center at the University of Pittsburgh. This sub-investigation was a cross-sectional study where subjects participated in laboratory validation trials; the larger trial will consist of additional phases that will include outdoor validation trials and trials of wearability and integrity of the sensor.

Table 3.1 Timeline of the Sub-investigation

Day 1	Week 1	Weeks 2-4	Months 2-4
Phone screening	Orientation	Graded Exercise Test Activity Sessions	Main Study Outdoor trials and trials of wearability and integrity

Twenty-four subjects were recruited to participate in this study, consisting of 12 males and 12 females. An attempt was made for there to be four males and four females in each BMI category, however subject availability prevented this from occurring for the male subjects. Subjects were divided by BMI category (20-24.9 kg/m^2, 25-29.9 kg/m^2, and 30-35 kg/m^2), with four females and four, five, and three males in each category, respectively. Randomization was based on a counterbalanced design to two experimental trials (treadmill walking and stationary cycling), with all subjects participating in both modes of activity.

Prior to the experimental physical activity sessions, subjects were invited to an orientation session if their self reported demographic information (age, height, weight) and

preliminary screening information indicated they may be eligible. This orientation session lasted approximately thirty minutes and was used to explain the purpose and procedures of the study. Subjects were encouraged to ask any questions they may have had regarding their participation in this study. At the conclusion of the orientation, subjects who were interested in participating in the study were provided written informed consent (See Appendix A), with height and weight verified. Subjects also completed the Physical Activity Readiness Questionnaire (PAR-Q) and a detailed medical history form.

Subjects underwent a graded exercise test (GXT) to ensure it was safe to perform the experimental physical activity sessions and to minimize the risks to the subjects. This test was reviewed by a cardiologist prior to participation in the activity sessions. If a subject had a positive stress test they then were ineligible for the study and were referred to their personal physician for follow-up and appropriate medical care. If the subject was cleared to continue in the study they were scheduled for the physical activity sessions.

The experimental sessions included a treadmill walking session and a stationary cycling session, which occurred on two separate occasions. Each of these activity sessions were thirty minutes in length. The KAL-X Sensor^{TM} was worn for both of these activity sessions, with indirect calorimetry used as the criterion measure of energy expenditure. These sessions are described in detail below in the Experimental Procedures section.

3.5 Screening Procedures

3.5.1 Weight

Body weight was assessed at screening and prior to each experimental session. Subjects were wearing light weight clothing (such as shorts and a t-shirt) at the time of this measurement. Weight was measured to the nearest 0.25 lbs using a calibrated medical balance beam scale (Health-O-Meter Inc., Bridgeview, IL).

3.5.2 Height

Height was measured at screening using a calibrated, wall mounted stadiometer (Perspective Enterprises, Inc., Kalamazoo, MI). Subjects removed their shoes, with height measured to the nearest 0.1 cm.

3.5.3 PAR-Q

The Physical Activity Readiness Questionnaire (PAR-Q) was used to assess a subject's ability to safely participate in physical activity (American Medical Association: Guides to the Evaluation of Permanent Impairment. AMA, Chicago, 1990). The PAR-Q is shown in Appendix B. An affirmative response to any question indicated that the subject was ineligible to participate in this study.

3.5.4. Medical History

All subjects completed a detailed medical history form at screening. The medical history form is shown in Appendix C. Information from this form was used to determine eligibility.

3.5.5 Graded Exercise Test

Subjects underwent a graded exercise test (GXT) to determine if they had contraindications to exercise. Subjects with contraindications were ineligible for this study. All exercise tests were performed at the Physical Activity and Weight Management Research Center under the supervision of Dr. Jakicic, who is certified by the American College of Sports Medicine as an exercise specialist. Subjects were instructed to abstain from vigorous exercise 24 hours prior to their GXT. Prior to the GXT, subjects rested in a seated position for 10 minutes which was followed by the assessment of resting blood pressure and heart rate.

The GXT was a sub-maximal exercise test that was performed on a motorized treadmill using a modified Stanford treadmill protocol. This protocol consisted of a constant speed of 3.0 mph with the initial grade being 0%. The grade of the treadmill increased 2.5% every three minutes until termination of the test. A 12-lead ECG (GE Medical, Milwaukee, WI) was used to measure heart rate at one minute intervals during the test and at the termination of the test. The test was terminated at the point that a subject achieved 85% of their age-predicted maximal heart rate or if any of the American College of Sports Medicine (ACSM) criteria for test termination were met. The ACSM termination criteria include the onset of angina or angina-like symptoms, significant drop in systolic blood pressure or a failure of systolic blood pressure to increase with an increase in exercise intensity, excessive rise in blood pressure (Systolic >260 mmHg or diastolic pressure >115 mmHg), signs of poor perfusion (light-headedness, confusion, nausea, pallor, etc.), failure of heart rate to increase with increased exercise intensity, noticeable change in heart rhythm, subject requests to stop, physical or verbal manifestations of severe fatigue, or failure of testing equipment (ACSM's Guidelines for Exercise Testing and Prescription, 6th edition). At test termination, the subjects were seated until heart rate and blood pressure returned

to pre-testing levels. The results of this exercise test were evaluated by a physician to assess eligibility for each subject.

3.6 Experimental Procedures

Subjects performed experimental trials including walking and stationary cycling, and these activity sessions were performed based on random assignment in a counterbalanced order. The experimental activity sessions were performed on separate days, with at least 2 days between the testing sessions. Both the KAL-X Sensor^{TM} and indirect calorimetry were used during each session, with indirect calorimetry used as the criterion measure.

Prior to participation in these activity sessions, subjects were asked to abstain from food and caffeine intake for 4 hours, and vigorous exercise and alcohol for 24 hours. All subjects wore standardized clothing for the physical activity sessions. The Physical Activity and Weight Management Research Center provided subjects with a short sleeve t-shirt to wear during both the walking and cycling sessions.

3.6.1. Activity Sessions

Walking Subjects performed a 30-minute walking session on a motorized treadmill. Subjects were in a seated position prior to the test, and 10 minutes of resting energy expenditure was collected. The exercise protocol consisted of subjects walking at 2.5 mph at 0% grade (10 minutes), 3.0 mph at 0% grade (10 minutes), and 3.0 mph at 5% grade (10 minutes). This protocol was selected because it is similar to a treadmill walking protocol used by Winters et al. (1998), who tested a KAL-X prototype. Termination of this test occurred if a subject exceeded 85% of their age-predicted maximal heart rate computed as the following [.85 x (220-age)].

Following this walking session, subjects remained in a seated position for 10 minutes to collect additional recovery energy expenditure data.

Table 3.2 Walking Protocol for Experimental Session

Walking Protocol	**Length of Stage**	**Speed**	**Grade**
Stage 1	10 minutes	2.5 mph	0%
Stage 2	10 minutes	3.0 mph	0%
Stage 3	10 minutes	3.0 mph	5%

Stationary Cycling Subjects performed a 30-minute session on a stationary cycle ergometer (Monarch 818e). Subjects pedaled at 50 rev/min and 0.5 kg resistance (10 minutes), 60 rev/min and 0.5 kg resistance (10 minutes) and 60 rev/min and 1.0 kg resistance (10 minutes). The stationary cycling protocol was selected because it is similar to a previously used protocol by Winters et al. (1998). Subjects were paced using a metronome, and if the subject was unable to maintain the desired cadence the test was terminated. The test was also terminated if the subject exceeded 85% of their age-predicted maximal heart rate. Prior to and following the activity session energy expenditure was collected in a seated position for 10 minutes.

Table 3.3 Cycling Protocol for Experimental Session

Cycling Protocol	**Length of Stage**	**Speed**	**Resistance**
Stage 1	10 minutes	50 rev/min	0.5 kg
Stage 2	10 minutes	60 rev/min	0.5 kg
Stage 3	10 minutes	60 rev/min	1.0 kg

3.6.2 Heart Rate

Heart rate was measured during all activity sessions. Minute-by-minute heart rate data was collected using a Polar Vantage NV (Kempele, Finland) portable heart rate monitor. Heart rate data was used to estimate the intensity of the activity sessions, with exercise terminated if the subject exceeded 85% of their age-predicted maximal heart rate. The Polar Vantage NV was positioned at the level of the inferior sternum just superior to the KAL-X chest Sensor^{TM}.

3.6.3 Indirect Calorimetry Assessment of Energy Expenditure

Indirect calorimetry was used as the criterion measure of energy expenditure. Minute-by-minute data was collected using an open circuit respiratory metabolic system (SensorMedics Oxycon Mobile Metabolic Measuring System, Yorba Linda, CA). This system was calibrated prior to each activity session. Oxygen uptake recorded at one minute intervals was converted to kcal/min based on respiratory exchange ratio (RER) and was used to represent energy expenditure.

3.6.4 KAL-X Sensor^{TM}

KAL-X Sensors^{TM} (LifeChek, LLC; Pittsburgh, PA) were used to estimate energy expenditure. Data from the KAL-X Sensor^{TM} was transmitted by a radio signal to a free standing data logger that was hard wired to a laptop computer. Data was transmitted to the data logger at least 5 times per minute and the values were averaged and converted to kcals at one minute intervals.

The KAL-X Sensor™ consists of 18 thermocouples designed to detect small changes in body temperature across both small and thick layers of membranes. Energy expenditure was estimated using the following equation: kcal/min = (heat flux * body surface area) / 0.80.

Participants wore a KAL-X Sensor™ on their left arm and on the chest just inferior to the sternum. Based on pilot data it appeared the KAL-X Sensor™ may be more responsive to changes in heat flux when the sensor is placed on the chest, which may be a result of the sensor located near the body's core heat. Thus, this study examined sensor site placement as a secondary aim. A measure of fit was performed in order to correctly position the armband at the midpoint of the upper arm, with arm circumference used to locate this position. Arm circumference was measured according to procedures by Lohman et al. (1991). Subjects stood with their elbow flexed at 90º and the palm facing superiorly. The acromion process was identified with the most distal part marked, and the inferior olecranon process was located and marked. A tape was placed so that is passed these two marks, and the midpoint was located between them and marked. Subjects relaxed their arm, extended the elbow and a Gullick tape measure was placed perpendicular to the long axis of the arm at the marked midpoint and circumference was recorded to the nearest 0.1 cm. In addition, bicep and tricep skinfolds were taken according to the recommended technique by Lohman et al. (1991). The biceps skinfold is a vertical fold taken on the anterior aspect of the arm over the belly of the biceps muscle. The triceps skinfold was measured in the midline of the posterior aspect of the arm, over the triceps muscle, midway between the lateral portion of the acromion process and the inferior olecranon process. These skinfold measurements were also used to correctly position the KAL-X Sensor™ at the midpoint of the arm, with the sensor placed between the bicep and tricep skinfold locations.

3.7 Statistical Analysis

All data analysis performed was conducted using SPSS software version 13.0 with statistical significance defined as $p \leq 0.05$. Descriptive characteristics (age, body weight, BMI, etc.) of the subjects are presented. Energy expenditure was analyzed separately for each physical activity session (walking and cycling). Energy expenditure data from both the KAL-X Sensor^{TM} and indirect calorimetry were averaged from the last five minutes of each stage and compared, this analysis was selected because it was previously used by Jakicic et al. (1999).

A three way ANOVA was used to assess the differences in body mass index classification (20-24.9, 25-29.9, and 30-35 kg/m^2) across measurement technique (indirect calorimetry vs. KAL-X sensor) and workload. Body mass index was considered a between subject variable, while measurement technique and workload were considered within subject variables. Post-hoc analyses were performed to probe main effects, with the p-value adjusted using the Bonferroni technique. A two way ANOVA was used to assess differences in energy expenditure between sensor site (chest vs. arm), with time and sensor site considered within subject variables.

3.8 Statistical Analysis Power

Pilot data using the KAL-X Sensor^{TM} were used to estimate the sample size for the validation study included in this application. Based on these studies, when compared to indirect calorimetry during periods of exercise, the standard deviation of the mean difference was ± 1.2 kcal/min. Considering this standard deviation, it was proposed that 24 subjects be recruited to participate in this study. This allowed a mean difference of 2.0 ± 1.2 kcal/min to be detected between the KAL-X Sensor^{TM} and indirect calorimetry for an effect size of 1.67. This effect size was detectable at $p \leq 0.05$ with statistical power of 0.95. Thus, this study was adequately powered to test hypotheses 1 and 2, which specifically compared energy expenditure estimated using the KAL-X Sensor^{TM} versus the criterion measure during walking and cycling exercise.

4 RESULTS

4.1 Introduction

The purpose of this study was to examine the validity of the KAL-X Sensor™ to measure energy expenditure across different modes and intensities of activity. A repeated measures design was utilized for this study. The independent variable was measurement technique (KAL-X Sensor™ and Indirect Calorimetry). The primary dependent variable was energy expenditure (kcal/min and kcal/session). Secondary analyses examined the effect of body mass index (BMI) classification (20-24.9, 25-29.9, and 30-35 kg/m^2) and KAL-X Sensor™ location (chest or arm) on the validity of the KAL-X Sensor™ to estimate energy expenditure. Additional analyses were performed to examine the effect of anthropometric measures (bicep skinfold, tricep skinfold, and arm circumference) on the estimate of energy expenditure using the KAL-X Sensor™.

4.2 Subject Characteristics

The subjects in this sub-investigation were 24 adult men and women (12 males and 12 females) participating in a larger validation trial at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. Subjects were between 18-50 years of age for women and 18 and 40 years of age for men, with a body mass index (BMI) ranging between 20 to 35 kg/m^2. Subjects were divided by BMI category (20-24.9 kg/m^2, 25-29.9 kg/m^2 and 30-35 kg/m^2), with four females in each category and four, five, and three men in each BMI category, respectively. Descriptive statistics (mean ± standard deviation) for subjects are presented in Table 4.1.

Table 4.1 Baseline Characteristics of Subjects (mean ± standard deviation)

Variable	BMI Category	All Subjects*	Male**	Female***
Age (years)	Total	33.8 ± 8.5 (n=24)	30.2 ± 1.7 (n=12)	37.4 ± 2.7(n=12)
	20.0-24.9 kg/m^2	30.9 ± 2.8 (n=8)	29.5 ± 2.9 (n=4)	32.3 ± 5.2 (n=4)
	25.0-29.9 kg/m^2	33.8 ± 3.2 (n=9)	29.2 ± 3.0 (n=5)	39.5 ± 5.1 (n=4)
	30.0-35.0 kg/m^2	37.1 ± 2.9 (n=7)	32.7 ± 3.5 (n=3)	40.5 ± 3.9 (n=4)
Height (cm)	Total	170.41 ± 10.03	177.4 ± 2.1	163.4 ± 2.0
	20.0-24.9 kg/m^2	170.3 ± 2.5	174.8 ± 3.6	165.9 ± 2.0
	25.0-29.9 kg/m^2	172.2 ± 4.1	179.2 ± 4.4	163.4 ± 4.5
	30.0-35.0 kg/m^2	168.3 ± 4.1	178.0 ± 1.7	161.0 ± 4.0
Weight (kg)	Total	80.23 ± 14.51	87.1 ± 4.1	73.3 ± 3.3
	20.0-24.9 kg/m^2	68.5 ± 2.8^{AB}	73.1 ± 3.4^{CD}	63.8 ± 3.3^{E}
	25.0-29.9 kg/m^2	81.4 ± 4.7^{A}	90.0 ± 5.1^{C}	70.8 ± 4.4^{F}
	30.0-35.0 kg/m^2	92.1 ± 4.1^{B}	101.1 ± 5.5^{D}	85.4 ± 2.9^{EF}
Body Mass Index (kg/m^2)	Total	27.55 ± 3.9	27.6 ± 0.9	27.5 ± 1.3
	20.0-24.9 kg/m^2	23.5 ± 0.5^{A}	23.9 ± 0.2^{C}	23.1 ± 0.9^{E}
	25.0-29.9 kg/m^2	27.3 ± 0.5^{A}	27.9 ± 0.7^{C}	26.4 ± 0.5^{E}
	30.0-35.0 kg/m^2	32.5 ± 0.7^{A}	31.9 ± 1.2^{C}	33.0 ± 0.8^{E}
Arm Circumference (cm)	Total	32.18 ± 4.04	34.2 ± 0.9	30.2 ± 1.1
	20.0-24.9 kg/m^2	29.3 ± 1.1^{A}	31.9 ± 0.7	26.8 ± 1.0^{E}
	25.0-29.9 kg/m^2	32.9 ± 1.4	35.4 ± 1.7	29.7 ± 1.2^{F}
	30.0-35.0 kg/m^2	34.6 ± 1.1^{A}	35.2 ± 2.2	34.0 ± 1.2^{EF}
Tricep Skinfold (mm)	Total	20.46 ± 12.06	12.3 ± 1.9	28.7 ± 3.1
	20.0-24.9 kg/m^2	16.4 ± 2.9^{A}	11.9 ± 3.3	20.9 ± 4.0^{E}
	25.0-29.9 kg/m^2	16.4 ± 3.2^{B}	9.0 ± 1.5	25.6 ± 2.4^{F}
	30.0-35.0 kg/m^2	30.3 ± 5.3^{AB}	18.2 ± 4.7	39.5 ± 4.5^{EF}
Bicep Skinfold (mm)	Total	13.20 ± 8.92	7.5 ± 1.3	18.9 ± 2.5
	20.0-24.9 kg/m^2	8.9 ± 2.1^{A}	4.8 ± 0.5^{C}	13.1 ± 3.1^{E}
	25.0-29.9 kg/m^2	11.7 ± 2.8	6.5 ± 0.9^{D}	18.3 ± 4.5^{F}
	30.0-35.0 kg/m^2	20.0 ± 3.5^{A}	12.7 ± 3.8^{CD}	25.5 ± 3.5^{EF}
% Minority Representation	Total	29.2% (n=7/24)	16.7% (n=12)	41.7% (n=12)
	20.0-24.9 kg/m^2	0.0% (n=0/8)	0.0% (n=0/4)	0.0% (n=0/4)
	25.0-29.9 kg/m^2	16.7% (n=4/9)	40.0% (n=2/5)	50.0% (n=2/4)
	30.0-35.0 kg/m^2	12.5% (n=3/7)	0.0% (n=0/3)	75.0% (n=3/4)

* BMI groups with same letter indicate significant difference ($p \leq 0.05$) for all subjects.
** BMI groups with same letter indicate significant difference ($p \leq 0.05$) for male subjects.
*** BMI groups with same letter indicate significant difference ($p \leq 0.05$) for female subjects.

4.3 Intensity of Exercise during Walking and Cycling Exercises.

To describe the intensity of walking and cycling exercises for each workload, descriptive statistics were calculated for percent of age-predicted maximal heart rate (HRmax = 220 - age) by exercise stage. Descriptive statistics (mean ± standard deviation) for walking and cycling exercises are presented in Table 4.2. The exercise intensity was approximately 50%, 53%, and 63% across the walking exercise stages, with the exercise intensity approximately 49%, 52%, and 59% across the cycling exercise stages.

Table 4.2 Percent of age-predicted maximal heart rate for walking and cycling exercise by stage

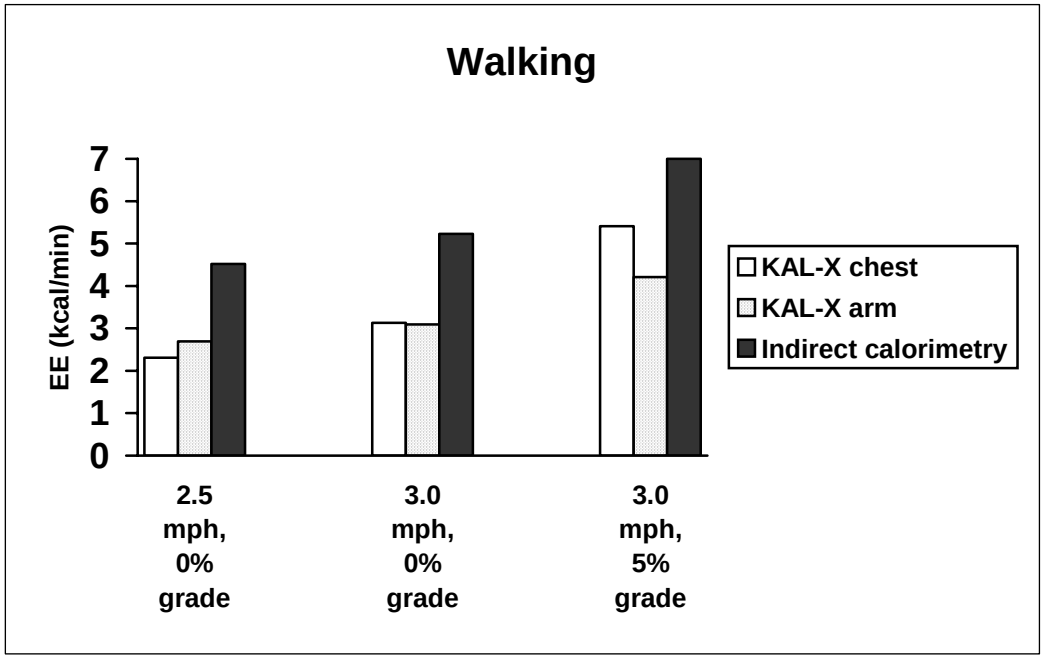
Exercise (N)	Stage	Length of Stage	Speed	Grade or Resistance	% age-predicted maximal heart rate (mean ± standard deviation)
Walk (N=23)					
	1	10 minutes	2.5 mph	0% grade	50.4 ± 8.4%
	2	10 minutes	3.0 mph	0% grade	53.3 ± 9.3%
	3	10 minutes	3.0 mph	5% grade	62.8 ± 12.0%
Cycle (N=23)					
	1	10 minutes	50 rev/min	0.5 kg	48.7 ± 8.7%
	2	10 minutes	60 rev/min	0.5 kg	51.9 ± 9.4%
	3	10 minutes	60 rev/min	1.0 kg	58.7 ± 11.4%

4.4 Comparison of Energy Expenditure by Measurement Technique (Indirect Calorimetry and KAL-X Sensors™)

A two-factor repeated measures ANOVA (device x exercise stage), with exercise stage as the repeated factor, was performed to assess the differences in measurement technique (Indirect Calorimetry vs. KAL-X Sensor™) across the workloads. Energy expenditure data measured by indirect calorimetry and estimated by the KAL-X Sensors™ (arm and chest) were analyzed across the last 5 minutes of each workload and the average energy expenditure of the 5 minutes was calculated (min 6-10, 16-20, and 26-30, labeled as stage 1, 2, and 3, respectively). Due to the failure of at least one KAL-X Sensor™, 23 subjects had complete data for treadmill walking and 23 subjects had complete data for stationary cycling. A repeated measures ANOVA (Indirect Calorimetry vs. Arm vs. Chest) was performed to examine differences in total energy expenditure (TEE) by measurement technique for walking. The ANOVA revealed a significant interaction effect ($p \leq 0.006$) (Figure 4.1). Post-hoc analyses were performed to examine significant differences between groups (Indirect Calorimetry vs. KAL-X arm Sensor™ and Indirect Calorimetry vs. KAL-X chest Sensor™). Because of multiple comparisons for each variable, the critical p-value was adjusted based on these multiple comparisons (p-value of 0.05 / 6 comparisons = 0.008) and these results are presented in Table 4.3. Significant differences were found between the KAL-X arm Sensor™ kcal/min and indirect calorimetry kcal/min during walking for all exercise stages ($p \leq 0.008$), with the KAL-X arm Sensor™ having significantly lower energy expenditure (kcal/min) than indirect calorimetry (kcal/min). Significant differences were found between the KAL-X chest Sensor™ (kcal/min) and indirect calorimetry (kcal/min) during walking for stages 1 and 2, with the KAL-X chest Sensor™ consistently underestimating energy expenditure (kcal/min).

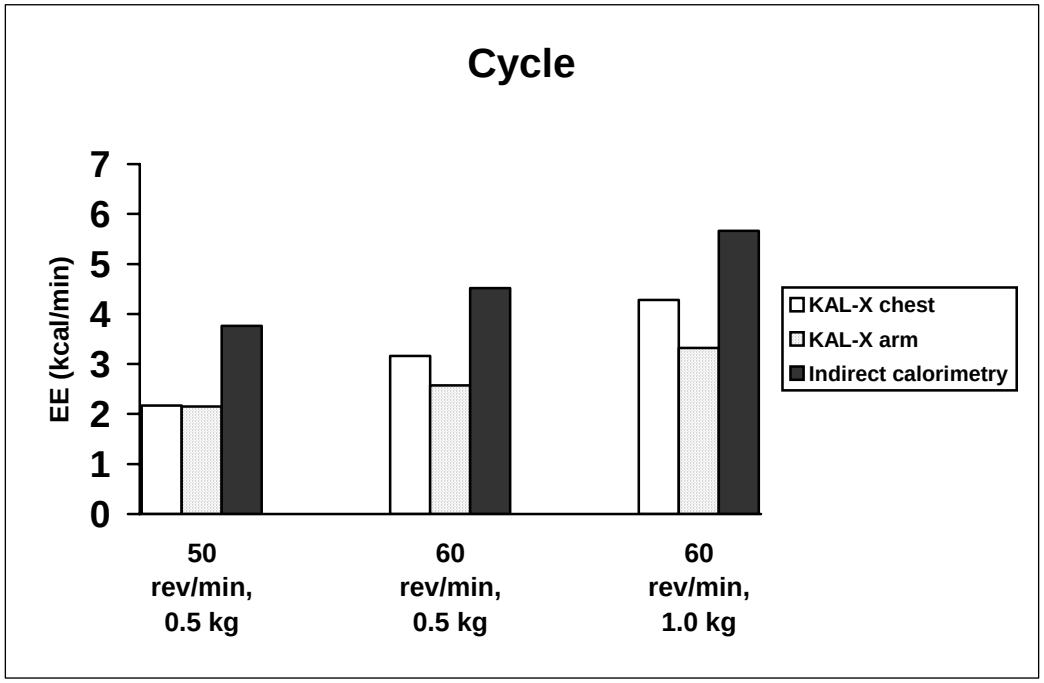
A repeated measures ANOVA (Indirect Calorimetry vs. Arm vs. Chest) was performed to examine differences in total energy expenditure (TEE) by measurement technique for cycling. The ANOVA revealed a significant interaction effect ($p \leq 0.001$) (Figure 4.2). Post-hoc analyses were performed to examine significant differences between groups (Indirect Calorimetry vs Arm and Indirect Calorimetry vs. Chest) (Table 4.3). During cycling significant differences were found between the KAL-X arm Sensor™ kcal/min and indirect calorimetry kcal/min for all exercise stages ($p \leq 0.008$), with the KAL-X arm Sensor™ underestimating energy expenditure (kcal/min). Similarly, significant differences were found between the KAL-X chest Sensor™ kcal/min and indirect calorimetry kcal/min during cycling for all exercise stages ($p \leq 0.008$), with significantly lower energy expenditure (kcal/min) reported by the KAL-X chest Sensor™.

Figure 4.1 Energy expenditure (kcal/min) during walking exercise



p-values:
exercise stage effect: $p \leq 0.001$
device effect: $p \leq 0.001$
exercise stage x device interaction: $p \leq 0.006$

Figure 4.2 Energy expenditure (kcal/min) during cycle exercise



p-values:
exercise stage effect: $p \leq 0.001$
device effect: $p \leq 0.001$
exercise stage x device interaction: $p \leq 0.001$

Table 4.3 Comparison of energy expenditure measured by indirect calorimetry (IC) and KAL-X Sensors™

Exercise (N)	Workload[a]	Units	Correlation Coefficients		Difference Scores (p≤ .005)	
			KAL-X Arm vs. IC	KAL-X Chest vs. IC	KAL-X Arm minus IC	KAL-X Chest minus IC
Walk (N=23)						
	1	kcal· min^{-1}	0.40	0.28	-1.82 ± 1.11**	-2.20 ± 1.07**
	2	kcal· min^{-1}	0.42*	0.16	-2.14 ± 1.24**	-2.09 ± 1.52**
	3	kcal· min^{-1}	0.50*	0.23	-2.79 ± 1.93**	-1.58 ± 2.69
	TEE[b]	Kcal	0.46*	0.31	-71.9 ± 38.2***	-69.2 ± 42.0***
Cycle (N=23)						
	1	kcal· min^{-1}	0.35	0.37	-1.61 ± 0.69**	-1.59 ± 0.84**
	2	kcal· min^{-1}	0.38	0.29	-1.96 ± 0.87**	-1.36 ± 1.64**
	3	kcal· min^{-1}	0.15	-0.03	-2.34 ± 1.25**	-1.38 ± 2.21**
	TEE[b]	Kcal	0.30	0.20	-60.6 ± 23.9***	-47.9 ± 23.9***

* Correlation is significant at the 0.05 level
** Difference significant at $p \leq 0.008$ (p-value of 0.05/ 6 comparisons)
*** Difference significant at $p \leq 0.05$
[a] Refer to Table 4.2
[b] Units are total kcal across 30 minute exercise session.

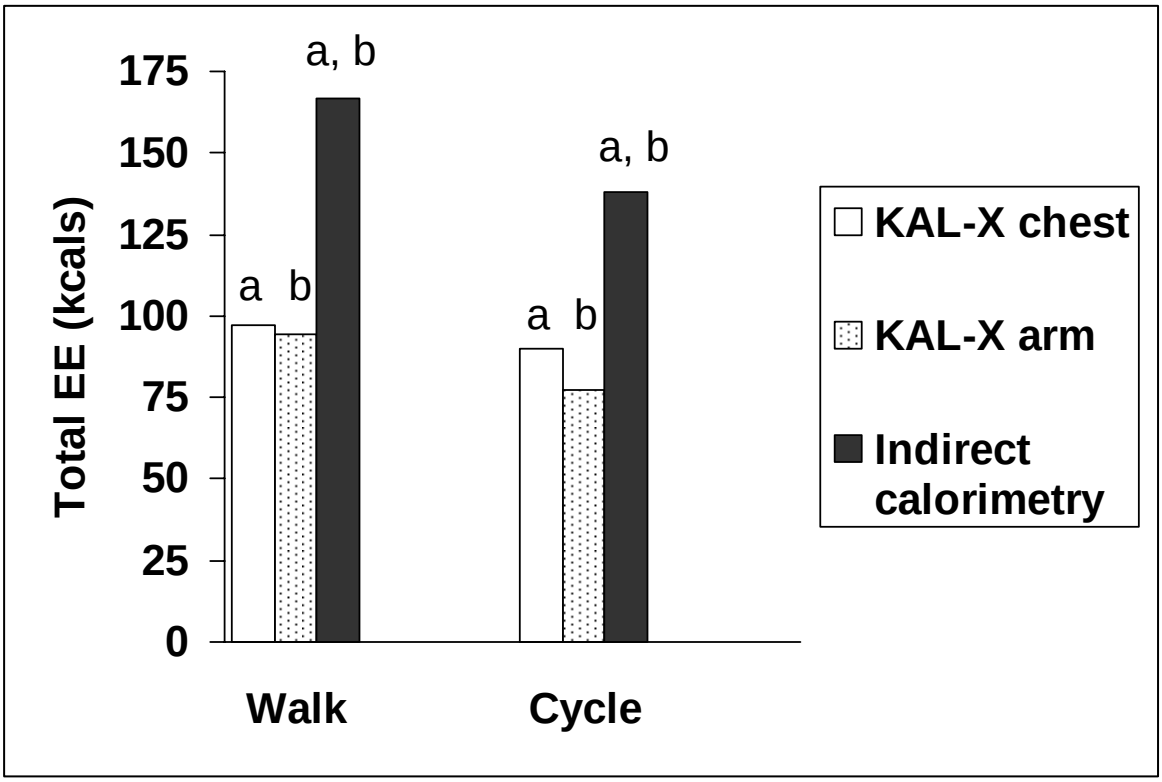
Pearson Product Moment Correlation Coefficients were calculated to determine the relationship between energy expenditure from the KAL-X Sensors™ and indirect calorimetry during each workload for walking and cycling exercises. Correlations are presented in Table 4.3. There were significant relations ($p \leq 0.05$) in energy expenditure estimated from the KAL-X arm Sensor™ and measured from indirect calorimetry during stage 2 ($r = 0.42$) and stage 3 ($r = 0.50$) of walking. The correlation ($r = 0.40$) was not significant between the energy expenditure from the KAL-X arm Sensor™ and indirect calorimetry during stage 1 of walking. Energy expenditure estimated by the KAL-X chest Sensor™ during walking was not significantly correlated with indirect calorimetry for any workload. When examining cycling exercise, the correlations were not statistically significant for relations between energy expenditure from the

KAL-X arm Sensor™ and indirect calorimetry, or relations between the KAL-X chest Sensor™ and indirect calorimetry.

Pearson Product Moment Correlation Correlations were calculated to determine the relationship between total energy expenditure across the 30 minutes of exercise from the KAL-X Sensors™ and indirect calorimetry during walking and cycling exercises. The correlation ($r = 0.46$) was statistically significant for the relation between total energy expenditure from the KAL-X arm Sensor™ and indirect calorimetry for walking (shown in Table 4.3). No other significant correlations were found for relations between total energy expenditure from the KAL-X Sensors™ and indirect calorimetry for walking or cycling (shown in Table 4.3).

Total energy expenditure summed across the exercise protocol (walking or cycling) were analyzed using dependent t-tests to compare indirect calorimetry and the KAL-X Sensor™. The critical p-value was adjusted based on these multiple comparisons (p-value of 0.05 / 3 comparisons = 0.016). Total energy expenditure during walking was significantly lower when estimated from the KAL-X chest Sensor™ (97.3 ± 36.2 kcal) and KAL-X arm Sensor™ (94.5 ± 38.2 kcal) when compared to indirect calorimetry (166.5 ± 35.2 kcal) ($p \leq 0.001$). There was a significant difference in total energy expenditure during cycling between indirect calorimetry (138.0 ± 20.8 kcal) and both the KAL-X chest Sensor™ (90.1 ± 38.1 kcal) and the KAL-X arm Sensor™ (77.5 ± 19.6 kcal) ($p \leq 0.001$), with both KAL-X Sensors™ underestimating energy expenditure. Total energy expenditure for the thirty minute exercise protocols and differences between TEE by measurement technique are shown in Figure 4.3, with difference scores presented in Table 4.3.

Figure 4.3 Total Energy Expenditure during walking and cycling



* Values with same letter indicate significant difference at p≤ 0.001

4.5 Comparison of Energy Expenditure between KAL-X Sensors™ (effect of location)

A two-way repeated measures ANOVA (exercise stage x sensor site) was used to assess differences in energy expenditure between sensor site (chest vs. arm), with exercise stage and sensor site considered within subject variables. Results revealed a significant exercise stage x sensor site interaction for both walking (p= 0.004) and cycling (p= 0.01) exercises (data shown in Figures 4.1 and 4.2). Post-hoc analyses were conducted to compare the mean energy expenditure during each stage of exercise between the two KAL-X Sensors™ (arm, chest) with data shown in Table 4.4. Based on multiple comparisons the critical p-value was adjusted (p-value of 0.05 / 3 comparisons = 0.016). Dependent t-tests revealed a significant difference (p≤

0.01) between energy expenditure from the KAL-X arm and KAL-X chest Sensor™ during the third workload of the walking exercise. No other significant differences were found between the KAL-X arm and KAL-X chest Sensor™ during walking. When examining cycling, no significant differences between energy expenditure estimated from the KAL-X arm and KAL-X chest Sensor™ were found for any workloads (Table 4.4).

Table 4.4 Comparison of energy expenditure from two KAL-X Sensors™ using correlation coefficients (Pearson) and dependent t-tests

			Energy Expenditure (kcal· min^{-1})			
Exercise (N)	Workload[c]	Total Elapsed Time (min)	KAL-X Arm	KAL-X Chest	Difference (mean ± standard deviation)	Pearson Correlation Coefficients Between the KAL-X Arm and Chest sensors
Walk (23)						
	1	6-10	2.69 ± 1.04	2.31 ± 0.78	0.38 ± 1.09	0.30
	2	16-20	3.09 ± 1.23	3.13 ± 1.28	0.04 ± 1.47	0.31
	3	26-30	4.21 ± 2.15	5.41 ± 2.56	1.20 ± 2.08[a]	0.62**
	TEE[b]	1-30	94.5 ± 38.2	97.3 ± 36.2	2.75 ± 33.4	0.60**
Cycle (23)						
	1	6-10	2.15 ± 0.55	2.17± 0.83	0.02 ± .081	0.37
	2	16-20	2.57 ± 0.75	3.16 ± 1.69	0.59 ± 1.45	0.52*
	3	26-30	3.32 ± 1.07	4.28 ± 2.03	0.96 ± 1.90	0.38
	TEE[b]	1-30	77.5 ± 19.6	90.1 ± 38.1	12.6 ± 34.6	0.43*

** Correlation coefficient is significant at p≤ 0.01
* Correlation coefficient is significant at p≤ 0.05
[a] Differences are statistically significant at adjusted p-value 0.016
[b] Units are total kcal across 30 minute exercise session
[c] Refer to Table 4.2

Pearson Product Moment Correlations were calculated to determine the relationship between energy expenditure estimated from the KAL-X arm Sensor™ and the KAL-X chest Sensor™. Correlations are presented in Table 4.4. Significant relations were observed between the KAL-X arm and chest Sensors™ during the third stage of walking ($r = .62$, $p \leq 0.01$) and during the second stage of cycling ($r = .52$, $p \leq 0.05$). No other significant relations were observed for the remaining walking and cycling stages. Significant relations were found between total energy expenditure from the KAL-X chest and KAL-X arm Sensors™ for both walking ($r = 0.60$, $p \leq 0.01$) and cycling exercises ($r = 0.43$, $p \leq 0.05$).

4.6 Effect of BMI Classification on Energy Expenditure Estimated Using KAL-X Sensor™

A three-way repeated measures ANOVA (device x BMI category x exercise stage) was used to assess the accuracy of energy expenditure measured for different body mass index classifications (20-24.9 kg/m^2, 25-29.9 kg/m^2, and 30-35 kg/m^2) for both walking (Table 4.7) and cycling exercises (Table 4.8).

Results for walking exercise revealed significant time ($p \leq 0.001$) and device effects ($p \leq 0.001$). However, there was no significant BMI effect ($p = 0.22$), exercise stage x device effect ($p \leq 0.009$), or device x exercise stage x BMI effect ($p = 0.62$) (Table 4.5). Similarly, when data were analyzed to examine differences in body mass index classification across measurement technique and workload for cycling, results revealed significant time ($p \leq 0.001$) and device effects ($p \leq 0.001$) shown in Table 4.6. There was no significant BMI effect ($p = 0.72$), exercise stage x device effect ($p \leq 0.002$), or device x exercise stage x BMI effect ($p = 0.59$) for analysis of cycling exercise data.

Table 4.5 Effect of BMI on Energy Expenditure for Walking (N=23)

Stage of Exercise	Energy Expenditure (kcal/min) KAL-X Arm Sensor (kcal/min)	KAL-X Chest Sensor (kcal/min)	Indirect Calorimetry (kcal/min)	p-values BMI Effect	Time effect	Device effect	Time x device	Device x Time x BMI effect
1	2.69 ± 1.04^{B}	2.31 ± 0.78^{A}	$4.52 \pm 0.98^{A, B}$	0.28	0.001	0.001	0.009	0.62
2	3.09 ± 1.23^{D}	3.13 ± 1.28^{C}	$5.23 \pm 1.06^{C, D}$					
3	4.21 ± 2.15^{E}	5.41 ± 2.56	7.00 ± 1.60^{E}					

* Values with same letter indicate significant difference ($p \leq 0.005$).

Table 4.6 Effect of BMI on Energy Expenditure for Cycling (N=23)

Stage of Exercise	Energy Expenditure (kcal/min) KAL-X Arm Sensor (kcal/min)	KAL-X Chest Sensor (kcal/min)	Indirect Calorimetry (kcal/min)	p-values BMI Effect	Time effect	Device effect	Time x device	Device x Time x BMI effect
1	2.15 ± 0.55^{B}	2.17 ± 0.83^{A}	$3.76 \pm 0.65^{A, B}$	0.72	0.001	0.001	0.002	0.59
2	2.57 ± 0.75^{D}	3.16 ± 1.69^{C}	$4.52 \pm 0.80^{C, D}$					
3	3.32 ± 1.07^{E}	4.28 ± 2.03	5.66 ± 0.82^{E}					

* Values with same letter indicate significant difference ($p \leq 0.005$).

4.7 Comparison of Anthropometric Data and Energy Expenditure

A three-way ANOVA (device x exercise stage x anthropometric variable) was performed separately by anthropometric measurement (bicep skinfold, tricep skinfold, and arm circumference) to assess the potential differences in energy expenditure for the devices (KAL-X Sensor^{TM} and Indirect Calorimetry) for both walking and cycling exercises. As shown in a previous table (Table 4.3), the KAL-X chest and arm Sensors^{TM} significantly underestimated energy expenditure (kcal/min) compared to indirect calorimetry during all workloads of walking and cycling exercise. An additional analysis was added to examine potential effects of anthropometric measurements on energy expenditure results. Subjects were divided into tertiles for bicep skinfold that were defined as 3.5-6.5, 6.6-17.0, and 17.1-35.5 millimeters, respectively. A repeated measures ANOVA was run, with device (Indirect Calorimetry vs. KAL-X arm Sensor^{TM} vs. KAL-X chest Sensor^{TM}) and exercise stage used as the within-subject factors and bicep skinfold tertile classification the between-subject factor. Results of this analysis indicted no significant interaction effect when bicep skinfold tertile category was included in the statistical analysis for walking exercise ($p \leq 0.57$; see Table 4.9) or cycling exercise ($p \leq 0.74$; see Table 4.12). Results revealed no significant interaction ($p = 0.74$) for time, device, and bicep category.

Subjects were divided into tertiles based on tricep skinfold (4.5-11.5 mm, 11.6-26.0 mm, and 26.1-48.5 mm). A repeated measures ANOVA was run, with device (Indirect Calorimetry vs. KAL-X arm Sensor^{TM} vs. KAL-X chest Sensor^{TM}) and exercise stage used as the within-subject factors and tricep skinfold tertile classification the between-subject factor. Results of this analysis indicted no significant interaction effect when tricep skinfold tertile category was

included in the statistical analysis for walking exercise ($p \leq 0.77$; see Table 4.10) or cycling exercise ($p \leq 0.79$; see Table 4.13).

Subjects were divided into tertiles based on arm circumference (25.0-30.1 cm, 30.2-33.3 cm, and 33.4-40.0 cm). A repeated measures ANOVA was run, with device (Indirect Calorimetry vs. KAL-X arm Sensor^{TM} vs. KAL-X chest Sensor^{TM}) and exercise stage used as the within-subject factors and arm circumference tertile classification the between-subject factor. Results of this analysis indicted no significant interaction effect when arm circumference tertile category was included in the statistical analysis for walking exercise ($p \leq 0.19$; see Table 4.11) or cycling exercise ($p \leq 0.28$; see Table 4.14).

Table 4.7 Comparison of Energy Expenditure (kcal/min) during Walking Exercise using Indirect Calorimetry and KAL-X Sensor™ by BMI category

Exercise (N)	Stage of Exercise	BMI Category (kg/m^2)	KAL-X Arm kcals by BMI category	KAL-X Chest kcals by BMI category	Indirect Calorimetry kcals by BMI category	BMI effect	Time effect	Device effect	Time x Device	Device x Time x BMI effect
Walk (23)						0.28	$p \leq 0.001$	$p \leq 0.001$	0.009	0.65
	1	20.0-24.9	2.18 ± 0.58	2.69 ± 0.72	4.12 ± 0.75					
		25.0-29.9	3.04 ± 1.40	2.11 ± 0.80	4.74 ± 0.61					
		30.0-35.0	2.85 ± 0.69	2.13 ± 0.75	4.72 ± 1.57					
	2	20.0-24.9	2.49 ± 0.79	3.16 ± 1.28	4.94 ± 1.06					
		25.0-29.9	3.43 ± 1.52	3.00 ± 0.94	5.41 ± 0.87					
		30.0-35.0	3.37 ± 1.11	3.29 ± 1.84	5.34 ± 1.40					
	3	20.0-24.9	3.12 ± 1.29	4.48 ± 1.61	6.20 ± 1.46					
		25.0-29.9	4.91 ± 2.72	5.42 ± 2.53	7.33 ± 1.36					
		30.0-35.0	4.61 ± 1.80	6.64 ± 3.42	7.56 ± 1.90					

Table 4.8 Comparison of Energy Expenditure (kcal/min) during Cycle Exercise using Indirect Calorimetry and KAL-X Sensor^{TM} by BMI category

Exercise (N)	Stage of Exercise	BMI Category (kg/m^2)	KAL-X Arm kcals by BMI category	KAL-X Chest kcals by BMI category	Indirect Calorimetry kcals by BMI category	BMI effect	Time effect	Device effect	Time x Device	Device x Time x BMI effect
Cycle (23)						0.72	$p \leq 0.001$	$p \leq 0.001$	0.002	0.59
	1	20.0-24.9	2.02 ± 0.54	2.06 ± 0.57	3.55 ± 0.59					
		25.0-29.9	2.07 ± 0.52	2.27 ± 0.80	3.77 ± 0.57					
		30.0-35.0	2.46 ± 0.58	2.18 ± 1.22	4.05 ± 0.84					
	2	20.0-24.9	2.27 ± 0.66	3.06 ± 1.33	4.19 ± 0.84					
		25.0-29.9	2.51 ± 0.54	3.27 ± 1.69	4.64 ± 0.50					
		30.0-35.0	3.05 ± 1.00	3.14 ± 2.33	4.80 ± 1.06					
	3	20.0-24.9	3.18 ± 1.29	4.65 ± 1.68	5.28 ± 0.75					
		25.0-29.9	3.36 ± 0.98	4.23 ± 1.90	5.62 ± 0.71					
		30.0-35.0	3.45 ± 1.09	3.86 ± 2.81	6.22 ± 0.86					

Table 4.9 Examination of Energy Expenditure Measured by Device and Bicep Category during Walking

Exercise (N)	Stage of Exercise	Bicep Category (mm)	KAL-X Arm kcals by bicep category	KAL-X Chest kcals by bicep category	Indirect Calorimetry kcals by bicep category	Bicep effect	Time effect	Device effect	Time x Device	Device x Time x Bicep effect
Walk (23)						0.67	$p \leq 0.001$	$p \leq 0.001$	0.008	0.57
	1	3.5-6.5	2.45 ± 0.62	2.55 ± 0.77	4.61 ± 0.75					
		7.0-17.0	3.03 ± 1.65	2.51 ± 0.83	4.43 ± 0.94					
		19.5-35.5	2.59 ± 0.35	1.83 ± 0.56	4.51 ± 1.35					
	2	3.5-6.5	2.80 ± 0.82	3.05 ± 1.41	5.48 ± 0.87					
		7.0-17.0	3.64 ± 1.78	3.58 ± 1.27	5.09 ± 1.10					
		19.5-35.5	2.79 ± 0.67	2.70 ± 1.14	5.10 ± 1.31					
	3	3.5-6.5	4.14 ± 1.78	5.49 ± 2.03	7.15 ± 1.26					
		7.0-17.0	4.76 ± 2.72	5.61 ± 3.04	7.08 ± 1.94					
		19.5-35.5	3.67 ± 1.98	5.09 ± 2.87	6.73 ± 1.71					

Table 4.10 Examination of Energy Expenditure Measured by Device and Tricep Category during Walking

Exercise (N)	Stage of Exercise	Tricep Category (mm)	KAL-X Arm kcals by tricep category	KAL-X Chest kcals by tricep category	Indirect Calorimetry kcals by tricep category	Tricep effect	Time effect	Device effect	Time x Device	Device x Time x Tricep effect
Walk (23)						0.90	p≤ 0.001	p≤ 0.001	0.007	0.77
	1	4.5-11.5	3.20 ± 1.37	2.71 ± 0.83	4.96 ± 0.83					
		12.5-26.0	2.31 ± 0.97	2.15 ± 0.61	4.11 ± 0.56					
		27.0-48.5	2.56 ± 0.37	2.05 ± 0.80	4.47 ± 1.37					
	2	4.5-11.5	3.83 ± 1.60	3.40 ± 1.40	5.78 ± 0.89					
		12.5-26.0	2.63 ± 0.92	3.08 ± 1.39	4.73 ± 0.87					
		27.0-48.5	2.77 ± 0.68	2.89 ± 1.13	5.16 ± 1.26					
	3	4.5-11.5	5.55 ± 2.48	6.49 ± 2.16	7.72 ± 1.32					
		12.5-26.0	3.27 ± 1.40	4.47 ± 2.66	6.48 ± 1.69					
		27.0-48.5	3.75 ± 1.91	5.26 ± 2.74	6.76 ± 1.67					

Table 4.11 Examination of Energy Expenditure Measured by Device and Arm Circumference Category (arm circ.) during Walking

Exercise (N)	Stage of Exercise	Arm circ. Category (cm)	KAL-X Arm kcals by arm circ. category	KAL-X Chest kcals by arm circ. category	Indirect Calorimetry kcals by arm circ. category	Arm circ. effect	Time effect	Device effect	Time x Device	Device x Time x Arm circ. effect
Walk (23)						0.13	$p \leq 0.001$	$p \leq 0.001$	0.004	0.19
	1	25.0-30.1	2.24 ± 0.56	2.05 ± 0.67	3.90 ± 0.48					
		31.4-33.3	2.28 ± 0.58	2.41 ± 1.00	4.23 ± 1.00					
		33.5-40.0	3.51 ± 1.27	2.50 ± 0.67	5.39 ± 0.76					
	2	25.0-30.1	2.48 ± 0.80	2.42 ± 0.62	4.67 ± 1.00					
		31.4-33.3	2.71 ± 0.58	3.97 ± 1.51	5.13 ± 0.86					
		33.5-40.0	4.03 ± 1.51	3.11 ± 1.24	5.86 ± 1.04					
	3	25.0-30.1	3.07 ± 1.55	4.17 ± 2.17	6.06 ± 1.64					
		31.4-33.3	3.77 ± 1.06	5.80 ± 2.59	6.97 ± 1.05					
		33.5-40.0	5.73 ± 2.62	6.32 ± 2.69	7.96 ± 1.51					

Table 4.12 Examination of Energy Expenditure Measured by Device and Bicep Category during Cycling

Exercise (N)	Stage of Exercise	Bicep Category (mm)	KAL-X Arm kcals by bicep category	KAL-X Chest kcals by bicep category	Indirect Calorimetry kcals by bicep category	Bicep effect	Time effect	Device effect	Time x Device	Device x Time x Bicep effect
Cycle (23)						0.05	p≤ 0.001	p≤ 0.001	p≤ 0.001	0.74
	1	3.5-6.5	2.15 ± 0.44	2.32 ± 0.44	3.79 ± 0.64					
		7.0-17.0	2.13 ± 0.64	2.54 ± 0.94	3.50 ± 0.53					
		19.5-35.5	2.19 ± 0.63	1.59 ± 0.79	4.04 ± 0.76					
	2	3.5-6.5	2.38 ± 0.59	3.27 ± 1.18	4.50 ± 0.68					
		7.0-17.0	2.70 ± 0.81	3.83 ± 1.75	4.24 ± 0.70					
		19.5-35.5	2.64 ± 0.91	2.28 ± 1.92	4.89 ± 0.98					
	3	3.5-6.5	3.18 ± 1.30	4.25 ± 1.10	5.51 ± 0.70					
		7.0-17.0	3.60 ± 0.80	5.36 ± 1.89	5.41 ± 0.90					
		19.5-35.5	3.16 ± 1.16	3.08 ± 2.49	6.10 ± 0.79					

Table 4.13 Examination of Energy Expenditure Measured by Device and Tricep Category during Cycling

Exercise (N)	Stage of Exercise	Tricep Category (mm)	KAL-X Arm kcals by tricep category	KAL-X Chest kcals by tricep category	Indirect Calorimetry kcals by tricep category	Tricep effect	Time effect	Device effect	Time x Device	Device x Time x Tricep effect
Cycle (23)						0.57	p≤ 0.001	p≤ 0.001	p≤ 0.001	0.79
	1	4.5-11.5	2.22 ± 0.49	2.51 ± 0.48	3.78 ± 0.64					
		12.5-26.0	2.10 ± 0.53	2.25 ± 1.01	3.65 ± 0.59					
		27.0-48.5	2.14 ± 0.70	1.70 ± 0.78	3.88 ± 0.80					
	2	4.5-11.5	2.53 ± 0.70	3.55 ± 1.28	4.42 ± 0.88					
		12.5-26.0	2.66 ± 0.67	3.40 ± 1.87	4.49 ± 0.72					
		27.0-48.5	2.50 ± 0.99	2.45 ± 1.89	4.68 ± 1.04					
	3	4.5-11.5	3.31 ± 1.10	4.67 ± 1.46	5.37 ± 0.88					
		12.5-26.0	3.59 ± 1.17	4.21 ± 1.78	5.66 ± 0.71					
		27.0-48.5	3.02 ± 1.01	3.91 ± 2.91	5.98 ± 0.87					

Table 4.14 Examination of Energy Expenditure Measured by Device and Arm Circumference Category (arm circ.) during Cycling

Exercise (N)	Stage of Exercise	Arm circ. Category (cm)	KAL-X Arm kcals by arm circ. category	KAL-X Chest kcals by arm circ. category	Indirect Calorimetry kcals by arm circ. category	Arm circ. effect	Time effect	Device effect	Time x Device	Device x Time x Arm circ. effect
Cycle (23)						0.60	$p \leq 0.001$	$p \leq 0.001$	$p \leq 0.001$	0.28
	1	25.0-30.1	1.74 ± 0.28	2.08 ± 0.88	3.51 ± 0.60					
		31.4-33.3	2.59 ± 0.57	2.53 ± 0.69	4.01 ± 0.62					
		33.5-40.0	2.19 ± 0.46	1.96 ± 0.88	3.81 ± 0.72					
	2	25.0-30.1	2.06 ± 0.29	2.83 ± 1.74	4.18 ± 0.86					
		31.4-33.3	3.11 ± 0.90	4.33 ± 1.41	4.94 ± 0.49					
		33.5-40.0	2.61 ± 0.64	2.47 ± 1.46	4.51 ± 0.87					
	3	25.0-30.1	3.05 ± 0.84	4.35 ± 2.16	5.28 ± 0.73					
		31.4-33.3	3.86 ± 1.30	5.11 ± 1.15	5.88 ± 0.69					
		33.5-40.0	3.11 ± 1.01	3.48 ± 2.38	5.83 ± 0.97					

4.8 Additional Analyses

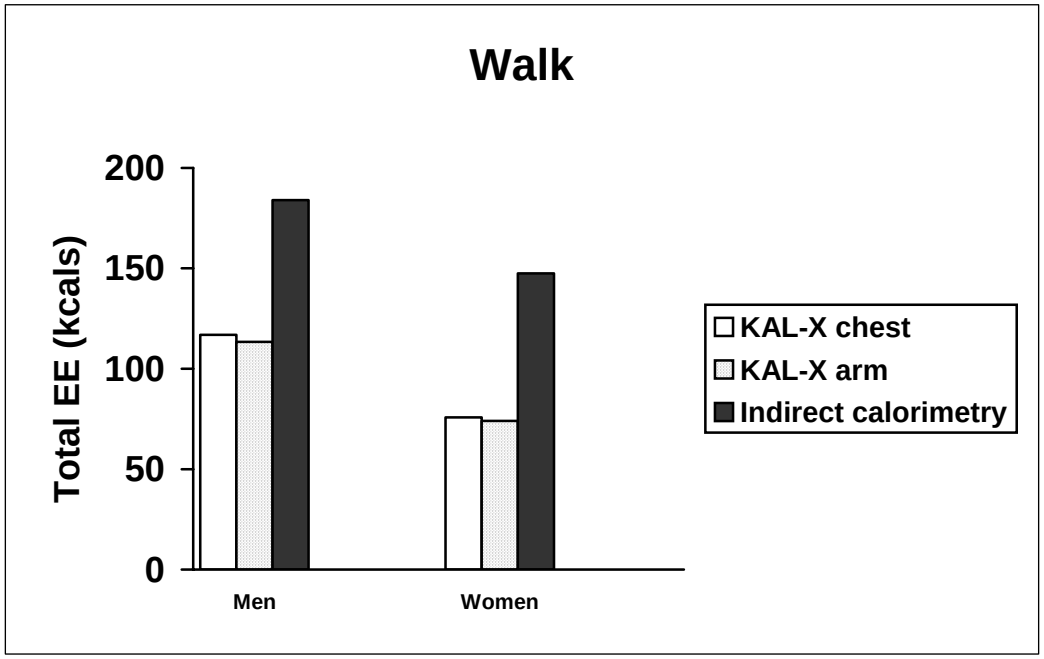
4.8.1 Comparison of Percent Heart Rate Tertiles and Energy Expenditure

An additional analysis was performed to examine if there was an interaction between relative heart rate and energy expenditure by device (Indirect Calorimetry vs KAL-X Sensor^{TM}). Subjects were divided into tertiles for percent heart rate for walking (41.05-56.04%, 56.05-63.79%, and 63.80-87.31%) and cycling exercises (38.65-50.72%, 50.73-60.35%, and 64.36-81.27%) during the last 10 minutes (21-30 minutes) of each exercise. A repeated measures ANOVA design was utilized with device as the within subject variable and heart rate group as the between subject variable. For walking, there was no significant interaction (exercise stage x device x percent heart rate tertile) effect when heart rate was included in the model ($p= 0.60$). A similar pattern was revealed for cycling, with no exercise stage x device x percent heart rate effect ($p= 0.68$).

4.8.2 Comparison of Total Energy Expenditure (kcals) by Gender

An additional analysis was performed to examine if there was an effect of gender on total energy expenditure (kcals) results. A repeated measures ANOVA design was utilized with device as the within subject variable and gender as the between subject variable. For walking, there was a significant device ($p\leq 0.001$) and gender effect ($p\leq 0.001$) however, there was no significant device x gender effect ($p= 0.96$) (Figure 4.4). For cycling, there was a significant device effect ($p\leq 0.001$) however, there was a non-significant device x gender effect ($p= 0.61$) and a non-significant gender effect ($p= 0.08$) (Figure 4.5).

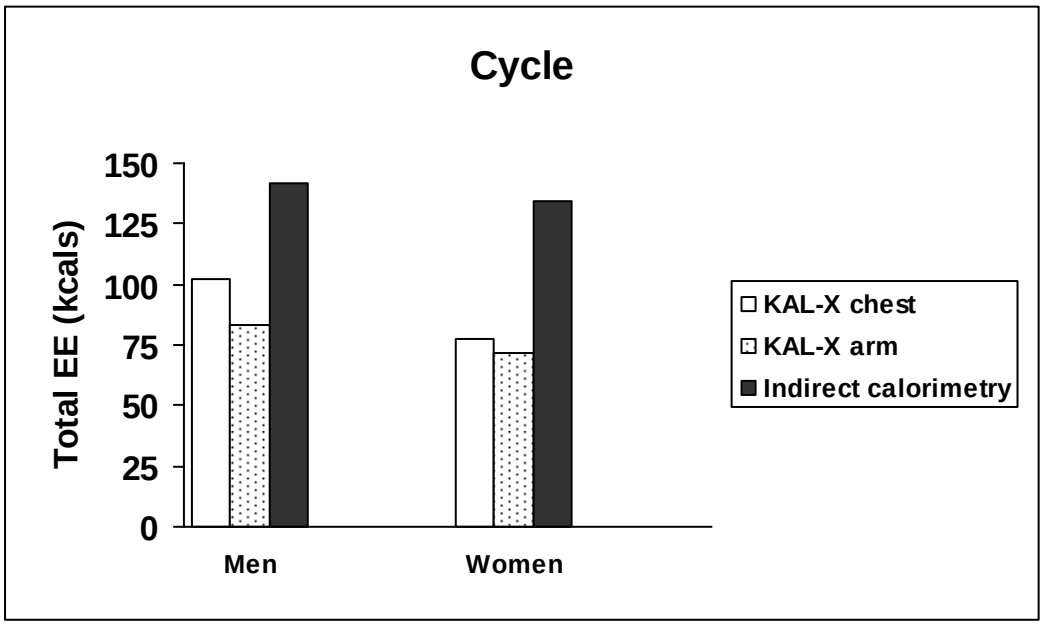
Figure 4.4 Total Energy Expenditure (kcals) by Gender during Walking Exercise



p-values:

device effect: p≤ 0.001
gender effect: p≤ 0.001
device x gender interaction: p≤ 0.96

Figure 4.5 Total Energy Expenditure (kcals) by Gender during Cycle Exercise



p-values:

device effect: $p \leq 0.001$
gender effect: $p \leq 0.08$
device x gender interaction: $p \leq 0.61$

4.8.3 Applying Correction Factor to KAL-X Sensor™ Data for Energy Expenditure

Linear regression analysis was used to compute a regression coefficient that could be applied to the KAL-X data to improve the estimation of energy expenditure when compared to indirect calorimetry. For the regression analyses, total energy expenditure using indirect calorimetry was the dependent variable with the independent variable being energy expenditure for the KAL-X Sensor™. Separate regression analyses were computed for the walking and cycling exercise for both the arm and chest KAL-X Sensors™, and these data are presented in Table 4.15.

Table 4.15 Regression analysis to compute energy expenditure using KAL-X Sensor™

Regression Model	Dependent Variable	Independent Variable	Regression Beta Coefficient	p-value for Beta Coefficient
Walking Exercise	Indirect Calorimetry	KAL-X Arm Sensor™	1.580	<0.001
Walking Exercise	Indirect Calorimetry	KAL-X Chest Sensor™	1.478	<0.001
Cycling Exercise	Indirect Calorimetry	KAL-X Arm Sensor™	1.696	<0.001
Cycling Exercise	Indirect Calorimetry	KAL-X Chest Sensor™	1.323	<0.001

These regression coefficients were applied to the energy estimated using the KAL-X Sensor™ to provide a corrected estimate of total energy expenditure during both walking and cycling exercise. These data are presented in Table 4.l6. Dependent t-test indicated that the corrected total energy expenditure for the KAL-X Sensors™ (arm and chest sensors) were not significantly different than total energy expenditure measured using indirect calorimetry for both the walking and cycling exercises. However, only the corrected total energy expenditure for the KAL-X arm Sensor™ was significantly correlated with total energy expenditure measured using indirect calorimetry for walking exercise ($r = 0.46$, $p \leq 0.05$). The other correlations between corrected total energy expenditure for the KAL-X Sensor™ and indirect calorimetry were not statistically significant (Table 4.16).

Table 4.16 Comparison of corrected energy expenditure (KAL-X) with measured energy expenditure

Exercise (N)	Energy Expenditure (kcal)**			Correlation Coefficients	
	Indirect Calorimetry	KAL-X Arm***	KAL-X Chest***	Indirect Calorimetry vs. KAL-X Arm	Indirect Calorimetry vs. KAL-X Chest
Walk (23)	166.5 ± 35.2	149.4 ± 60.4	143.8 ± 53.5	0.46*	0.30
Cycle (23)	138.0 ± 20.7	131.4 ± 33.3	119.2 ± 50.5	0.30	0.19

*indicates correlation coefficient significant at $p < 0.05$.
**energy expenditure representing 30 minutes of exercise for either walking or cycling.
***corrected energy expenditure based on the application of regression coefficient shown in Table 4.13.

Linear regression analysis was also used to compute a regression coefficient that could be applied to the combination of both the KAL-X and heart rate data to improve the estimation of energy expenditure when compared to indirect calorimetry. For the regression analyses, total energy expenditure using indirect calorimetry was the dependent variable with the independent variables being energy expenditure for the KAL-X Sensor™ and heart rate summed over the last 10 minutes of the exercise protocol. Separate regression analyses were computed for the walking and cycling exercise for both the arm and chest KAL-X Sensors™, and these data are presented in Table 4.17.

Table 4.17 Regression analysis to compute energy expenditure using KAL-X Sensor™

Regression Model	Dependent Variable	Independent Variables	Regression Beta Coefficient	p-value for Beta Coefficient
Walking Exercise	Indirect Calorimetry	1. KAL-X Arm Sensor™ 2. Heart rate	0.521 0.980	<0.019 <0.001
Walking Exercise	Indirect Calorimetry	1. KAL-X Chest Sensor™ 2. Heart rate	0.431 1.031	<0.025 <0.001
Cycling Exercise	Indirect Calorimetry	1. KAL-X Arm Sensor™ 2. Heart rate	0.926 0.567	<0.001 <0.002
Cycling Exercise	Indirect Calorimetry	1. KAL-X Chest Sensor™ 2. Heart rate	0.373 0.933	<0.007 <0.001

These regression coefficients were applied to the energy estimated using the KAL-X Sensor™ and the exercise heart rate data to provide a corrected estimate of total energy expenditure during both walking and cycling exercise. These data are presented in Table 4.l8. Dependent t-test indicated that the corrected total energy expenditure for the KAL-X Sensors™ (arm and chest sensors) were not significantly different than total energy expenditure measured using indirect calorimetry for both the walking and cycling exercises. A significant relation was found between the corrected total energy expenditure for the KAL-X arm Sensor™ and total energy expenditure measured using indirect calorimetry for walking exercise ($r = 0.42$, $p \leq 0.05$). However, no other significant relations between corrected total energy expenditure for the KAL-X Sensor™ and indirect calorimetry were found for walking or cycling exercises (Table 4.18).

Table 4.18 Comparison of corrected energy expenditure (KAL-X) with measured energy expenditure

Exercise (N)	Energy Expenditure (kcal)**			Correlation Coefficients	
	Indirect Calorimetry	KAL-X Arm***	KAL-X Chest***	Indirect Calorimetry vs. KAL-X Arm	Indirect Calorimetry vs. KAL-X Chest
Walk (23)	166.5 ± 35.2	163.4 ± 31.5	162.0 ± 25.6	0.42*	0.36
Cycle (23)	138.0 ± 20.7	133.8 ± 22.1	135.7 ± 20.8	0.31	0.24

*indicates correlation coefficient significant at $p < 0.05$.
**energy expenditure representing 30 minutes of exercise for either walking or cycling.
***corrected energy expenditure based on the application of regression coefficient shown in Table 4.15.

5 DISCUSSION

5.1 Introduction

There is evidence that there is an increasing prevalence of overweight and obesity in the United States (Hedley et al., 2004, Flegal et al., 1998), and this has significant public health implications. Weight gain is primarily influenced by an energy imbalance, which results from energy expenditure being less than energy intake. Thus, to better understand the causes of obesity and to develop effective interventions to control body weight, it is important to understand the contribution of each of the components of energy balance (e.g., energy expenditure and energy intake). The primary aim of this study was to examine the validity of a portable to device (KAL-X Sensor^{TM}) to measure energy expenditure across a range of body weights. If this device proves to provide a valid estimate of energy expenditure, this may provide a valuable intervention tool that can be incorporated into research and intervention initiatives related to weight control.

There are numerous techniques available to quantify energy expenditure and physical activity. However, there are limitations to each of these technologies which prohibit use in free-living settings or affect the validity/reliability of the estimate of energy expenditure (Jakicic et al., 1999, Crouter et al., 2004, Crouter et al., 2003, Welk et al., 2000, King et al., 2004, Jakicic et al., 2004, Fruin et al., 2004, Schneider et al., 2004, Tudor-Locke et al., 2001, Janz 2002, Mcfarlane 2001, Montoye et al., 1983, Pambianco et al., 1990, Montoye et al., 1996). The KAL-

X Sensor™ has been developed to provide an estimate of energy expenditure using technology to measure heat flux. However, there are limited published data available on the validity of the KAL-X Sensor™. Studies by Jakicic et al. (1993) and Winters et al. (1998) have compared the energy expenditure measured using the KAL-X Sensor™ to energy expenditure measured from indirect calorimetry while individuals were performing a variety of exercises (e.g., for activities such as walking, cycling, stepping, and a slide board). Although these initial studies reported that the KAL-X Sensor™ may provide an accurate estimate of energy expenditure under specific activity conditions, the limited sample size and somewhat homogeneous characteristics of the participants in these studies may limit the generalizability of these findings (Jakicic et al., 1993, Winters et al., 1998). Therefore, the current study was designed to examine the validity of the KAL-X Sensor™ to measure energy expenditure across different modes and intensities of activity, and across different categories of body mass index.

5.2 Conclusions

5.2.1 Validity of the KAL-X Sensor™ to Measure Energy Expenditure

A primary aim of this study was to examine the validity of the KAL-X Sensor™ to estimate energy expenditure during motorized treadmill walking. Results of this study revealed significant differences in energy expenditure measured by indirect calorimetry and estimated by the KAL-X Sensor™ at 0 and 5 percent walking grade and 2.5 and 3.0 mph (see Table 4.3). The finding of a significant difference between indirect calorimetry and KAL-X Sensor™ in energy expenditure at 0 percent walking grade at 3.0 mph confirms the results reported by Winters et al. (1998), which also showed a significant difference in energy expenditure measured by the KAL-X Sensor™ and indirect calorimetry. However, the results of this current study conflict with the

results by Jakicic et al. (1993), which found no significant differences between the KAL-X Sensor™ and indirect calorimetry during level treadmill walking. In addition, the results from the current study are opposed to the results reported by Winters et al. (1998) when examining walking on a treadmill at 5 and 10 percent grade. Winters et al. (1998) reported no difference in energy expenditure between the KAL-X Sensor™ and indirect calorimetry at 5% and 10% walking grades (difference scores were 0.1 ± 1.2 and -0.7 ± 2.1 kcal/min), while the current study showed a significant difference in energy expenditure by device at 5% grade (difference score was 2.79 ± 1.93 kcal/min between indirect calorimetry the KAL-X arm Sensor™, see Table 4.3).

Another primary aim of this study was to examine the validity of the KAL-X Sensor™ to estimate energy expenditure during stationary cycling. Results indicate significant differences in energy expenditure ranging from -1.38 to -2.34 kcal/min between indirect calorimetry and the KAL-X Sensor™ (see Table 4.3), resulting in the rejection of the second primary aim of this study. These findings are inconsistent with the results reported by Winters et al. (1998), which showed non-significant differences between the KAL-X Sensor™ and indirect calorimetry ranging from 0.3 to 0.9 kcal/min during stationary cycling.

The current study reports different findings compared to previous studies that have also compared the KAL-X Sensor™ and indirect calorimetry (Winter et al., 1998, Jakicic et al., 1993). The differences in energy expenditure results could have been a result of a few influences. For example, the speed of the treadmill was 3.5 mph in the aforementioned study by Winters et al. (1998) with the treadmill speed set at 2.5 and 3.0 mph in the current study, and this difference in intensity could have impacted the results. In addition, participants in previous studies (Winters et al., 1998, Jakicic et al., 1993) were leaner than the participants in the current

study, (23.3 ± 3.5 kg/m^2 and 22.3 ± 1.9 kg/m^2 vs. 27.5 ± 3.9 kg/m^2), and this may have influenced the results of these studies. Assuming that a higher BMI representative of a higher level of body fatness, this may explain these findings (see section 5.2.3. for further details). Thus, differences in walking speed or subject characteristics may partially explain the differences between studies of the KAL-X Sensor^{TM} and these factors should be considered when interpreting the findings.

5.2.2 Correlation Between the KAL-X Sensor^{TM} and Indirect Calorimetry

Despite finding significant differences in energy expenditure between the KAL-X Sensor^{TM} and indirect calorimetry in the current study, analysis of the data showed significant, yet modest correlations between energy expenditure estimated from the KAL-X Sensor^{TM} placed on the arm. These significant correlation coefficients were observed for walking at 3.0 mph at both 0% grade (r = 0.42) and 5% grade (r = 0.50), and across a 30 minute period of treadmill walking (r = 0.46), with these results shown in Table 4.3. Unfortunately, the relation between the KAL-X Sensor^{TM} located on the chest and indirect calorimetry were not statistically significant. These correlation coefficients between energy expenditure measured using indirect calorimetry and the KAL-X Sensor^{TM} appear to be weaker than what has been reported when indirect calorimetry has been compared with other portable devices. For example, the correlation coefficient between energy expenditure measured using indirect calorimetry during treadmill walking and energy expenditure estimated using accelerometry has ranged from r = 0.66 to r = 0.72 (Jakicic et al., 1999). Moreover, the correlations between energy expenditure measured using indirect calorimetry during treadmill walking and the SenseWear Pro Armband^{TM} have ranged from r = 0.78 to r = 0.86, respectively (Jakicic et al., 2004).

In the current study, correlations between the KAL-X Sensors^{TM} (arm or chest) and indirect calorimetry during stationary cycling were not statistically significant and ranged from r = 0.15 to r = 0.38 for the arm sensor and from r = -0.03 to r = 0.37 for the chest sensor (Table 4.3). These results are similar to correlations between energy expenditure estimated from other portable devices and indirect calorimetry during stationary cycling. For example, correlations during stationary cycling between energy expenditure measured using indirect calorimetry and estimated from the Tritrac accelerometer ranged from r = 0.04 to r = 0.43 (Jakicic et al., 1999), whereas correlations with energy expenditure estimated using the SenseWear Pro Armband^{TM} ranged from r = 0.23 to r = 0.34 (Jakicic et al., 2004).

In summary, the correlations in this current study are lower than correlations found by other energy expenditure devices during walking and are comparable to other devices while cycling (Jakicic et al., 1999, Jakicic et al., 2004). No significant correlations were found for cycling in this present investigation, which is similar to previous findings (Jakicic et al., 1999). Although the correlations for walking in this study were lower than correlations between accelerometry and indirect calorimetry (Jakicic et al., 1999), significant correlations were found between the KAL-X Sensor^{TM} and indirect calorimetry ranging from r = 0.42 to r = 0.50 (Table 4.3). Therefore, while it appears there may be no relationship between the KAL-X Sensor^{TM} and indirect calorimetry for cycling, a significant yet modest relationship exists when examining treadmill walking.

5.2.3 Effect of Body Mass Index on the Validity of the KAL-X Sensor™

Although there were significant differences in energy expenditure measured from the KAL-X Sensor™ during both walking and cycling exercises (See Table 4.3), this investigation showed no significant differences in the accuracy of the KAL-X Sensor™ to measure energy expenditure for different BMI classifications (normal 20-24.9 kg/m^2, overweight 25-29.9 kg/m^2, and obese 30-35 kg/m^2) (see Table 4.5 and 4.6). It is expected that BMI could impact the accuracy of measured energy expenditure since a higher BMI may equate to more adipose tissue. Greater body fat could impact the KAL-X Sensor™ since the sensor relys on heat flux to estimate energy expenditure and more insulation may affect the flow of heat to core and peripheral tissues (Sessler 2000). In the current study the inaccuracy of the KAL-X Sensor™ to measure energy expenditure was consistent across all BMI classifications. These findings may be important because they suggest differences in estimated energy expenditure are not related to an individuals level of body mass index but might be because of other characteristics of the KAL-X Sensor™ that may affect accuracy of this device.

5.2.4 Effect of Sensor Location on the Validity of the KAL-X Sensor™

An additional aim of this study was to examine the accuracy of the KAL-X Sensor™ according to anatomical placement site of the sensor (chest vs. arm). Results of this study revealed no significant differences in the accuracy of energy expenditure from the KAL-X Sensor™ according to anatomical placement of the sensor during treadmill walking (see Table 4.4). These findings are consistent with studies of other portable devices. Results reported by Jakicic et al. (1999) showed that placing a Tritrac accelerometer on the back posterior waist versus the anterior waist did not result in a difference in estimates of energy expenditure during

treadmill walking. When examining cycling, the current study found no significant differences in the accuracy of energy expenditure from the KAL-X Sensor™ according to anatomical placement of the sensor (see Table 4.4). Based on this current study it appears that sensor location may not contribute to differences in estimated energy expenditure using the KAL-X Sensor™.

Even though no significant differences were found in energy expenditure based on sensor location, few significant correlations were found between the KAL-X Sensors™ for walking and cycling exercises (Table 4.4). One potential explanation for the lack of significant correlations between the two sensor locations may be a result of the bodies core heat being at the center of the body, which is close to the placement of the chest sensor rather than the arm sensor. For example, temperature in the peripheral compartment is usually 2-4°C less than the core temperature in moderate environments, however this difference can become large during extreme thermal or physiologic circumstances (Sessler, 2000). Additionally, heat flows rapidly to the core and slowly to peripheral tissues (Sessler, 2000). While, this explains a potential reason the estimated energy expenditure from KAL-X chest and arm Sensors™ were not related, this may also show that the KAL-X Sensor™ may not have been impacted by these factors since no significant differences were found between the sensors and indirect calorimetry (Table 4.4). This warrants further investigation in future studies of the KAL-X Sensor™.

5.2.5 Effect of Anthropometric Characteristics on the Validity of the KAL-X Sensor™

An additional analysis was performed to examine potential effects of anthropometric measurements on measured energy expenditure. When anthropometric variables such as bicep skinfold were added to the model non-significant interactions were observed for both walking and cycling exercise (Table 4.7 and Table 4.10). Similarly, when tricep skinfold or arm circumference were added to the model non-significant interactions were also observed for both walking and cycling exercises (Table 4.8, 4.9, 4.11, 4.12). However, it may have been expected that anthropometric measurements such as skinfolds would impact the accuracy of measured energy expenditure. For example, studies have shown fat free mass and fat mass have contributed to the variation in energy expenditure and the variation would be dependent on the activity performed (Plasqui et al., 2005). In addition, since the KAL-X arm Sensor™ is placed over the midpoint of the upper arm close to the bicep skinfold measurement it may potentially explain some of the differences in the arm and chest sensors energy expenditure results. Flow of heat to peripheral tissues is mediated by conduction of heat into tissues. It has been reported that conduction heat transfer depends mostly on tissue characteristics and not only does fat insulate three times as well as muscle but it also provides substantial insulation (Sessler 2000). While fat as an insulation layer may impact heat transfer, this current study did not find that all anthropometric measures impacted the accuracy of energy expenditure of the KAL-X Sensor™. Therefore, the inaccuracy of the KAL-X Sensor™ remained regardless of an individuals fat insulation, and may account for the weak correlations and significant findings in this study.

5.3 Limitations and Recommendations for Future Research

This study is not without limitations and these may affect the application of these findings. Future studies should address these factors when examining the validity of the KAL-X Sensor™ to estimate energy expenditure and when applying this technology to interventions.

1. This study examined the ability of the KAL-X Sensor™ to estimate energy expenditure during specific exercise modes, which included treadmill walking and stationary cycling. It is not known if the KAL-X Sensor™ will accurately measure energy expenditure during other modes of activity such as other forms of structured exercise (e.g., other exercise equipment, resistance exercise, etc.), sports (e.g., tennis, basketball, etc.), or free-living lifestyle activity. Previous literature suggests devices such as accelerometers do not accurately assess lifestyle activities and provide poor estimates of energy expenditure for free-living activity (Welk et al., 2000, Welk 2002). Future studies should be performed to assess the ability of the KAL-X Sensor™ to measure energy expenditure for other form of activities which may include sports and free-living lifestyle activities.
2. The present investigation examined the effects of BMI classification on energy expenditure and included individuals with body mass indices ranging from 20-34.9 kg/m^2, which is a larger BMI range than previous research examining the KAL-X Sensor™ (Winters et al., 1998, Jakicic et al., 1993). This study appears to be the first to examine potential effects of BMI classification on energy expenditure and does not confine its sample to lean adults. More studies are needed to examine the validity of the KAL-X Sensor™ in different populations such as children, elderly, athletes, etc.
3. The present investigation examined the accuracy of the KAL-X Sensor™ to measure energy expenditure during specific exercise intensities (see Table 4.2). This is potentially

problematic because this study had specific intensity levels and it is not known how accurate the KAL-X Sensor™ would be across a wider range of exercise intensities. In addition, it is difficult to make comparisons of energy expenditure results from the KAL-X Sensor™ based on intensity since the protocols used in two pilot studies on the KAL-X Sensor™ were slightly different than what was used in this study (Jakicic et al., 1993, Winters et al., 1998). Differences in absolute intensity, such as speed and grade, may explain some of the inconsistency in KAL-X Sensor™ energy expenditure results across studies. Future studies should incorporate broader exercise intensities to assess the validity of KAL-X Sensor™ to measure energy expenditure during lighter and more vigorous exercise applications.

4. The design of this study examined exercise that was thirty minutes in duration. It is not known if the KAL-X Sensor™ would overestimate, underestimate, or accurately measure energy expenditure for exercise of shorter and longer durations compared to indirect calorimetry. Previous protocols for the KAL-X Sensor™ have been shorter in length for cycling exercise with 5 to 20 minute protocols (Jakicic et al., 1993, Winters et al., 1998), which makes a comparison to the current study difficult. Although one study of the KAL-X Sensor™ by Winters et al. (1998) included a 30 minute treadmill walking protocol, this protocol had a different walking speed and grade compared to the present investigation. It is not known if the KAL-X Sensor™ is better suited to measure energy expenditure during long durations lasting greater than thirty minutes or during short durations, such as in the study conducted by Jakicic et al. (1993). Future studies should include alternative exercise durations other the one provided by this current study to allow for further exploration of the validity of the KAL-X Sensor™.

5. The current study has the largest sample size tested for the KAL-X Sensor™, with 24 adults versus studies with sample sizes of 7 and 20, respectively (Jakicic et al., 1993, Winters et al., 1998). However, the sample size for this study did not permit the secondary analysis of the data to determine if there was a differential response in estimated energy expenditure based on gender, ethnicity, or other demographic characteristics. Gender effects have been observed for various accelerometers (BioTrainer-Pro, TriTrac R3D, and the RT3) and the SenseWear Pro Armband™, with lower energy expenditure values for women than men (King et al., 2004). There is limited KAL-X Sensor™ research directed equally to men and women, with one of two known studies other than this investigation directed at males only (Jakicic et al., 1993). Future studies with the KAL-X Sensor™ should examine potential effects of gender on energy expenditure outcomes.
6. The current study included a broad age range for both male and female subjects. When comparing age, the pilot studies by Winters et al. (1998) and Jakicic et al. (1993) included much younger subjects (21.5 ± 3.38 yrs, 21.57 ± 5.06 yrs) than the current study (33.8 ± 8.5 yrs). Demographics such as age can factor into energy expenditure results. For example, previous studies have shown differences in accelerometer counts in men and boys and age has accounted for some of the variance in energy expenditure results (Rowlands et al., 2004, Plasqui et al., 2005). It is not known if age affects the accuracy of energy expenditure devices such as accelerometers and the KAL-X Sensor™. Future studies should examine whether a demographic characteristic such as age affects the accuracy of the KAL-X Sensor™ to measure energy expenditure.

7. The current investigation did not consider if ethnicity had an effect on energy expenditure or anthropometric measurements. It is expected that ethnicity would impact energy expenditure and anthropometric results. For example, African Americans have greater bone mineral density and greater fat-free body density than whites as well as differences in the distribution of subcutaneous fat (Wagner and Heyward, 2000), both of which can impact energy expenditure. Future studies should examine the effectiveness of the KAL-X Sensor^{TM} to estimate energy expenditure across diverse samples of subjects to improve the generalizability across different population groups. Futhermore, future studies should attempt to include a sample that would allow enough power to test for significance for factors such as age, gender, ethnicity, etc.
8. The findings of this study showed estimates of energy expenditure by the KAL-X Sensor^{TM} were significantly different than energy expenditure measured by indirect calorimetry. The use of a regression equation resulted in non-significant differences in energy expenditure estimated from the KAL-X Sensor^{TM} compared to energy expenditure measured from indirect calorimetry. Based on this current study it appears that the conversion of heat flux to energy expenditure, which is the basis of the KAL-X Sensor^{TM}, can be improved or may need to be adjusted for measured factors which can not be accounted for at this time. Future studies should be performed to examine if a correction factor would be accurate in an independent sample.

5.4 Summary

The results of this study did not support the hypotheses that the energy expenditure measured by the KAL-X Sensor™ would not be significantly different than energy expenditure measured by indirect calorimetry for walking or cycling. These findings are inconsistent with previous pilot studies in this area where energy expenditure from the KAL-X Sensor™ was not significantly different than energy expenditure from indirect calorimetry (Jakicic et al., 1993; Winters et al., 1998). In addition, the KAL-X Sensor™ appeared to be impacted by location of the sensor (arm vs. chest), with few significant correlations found between the two locations (Table 4.3). An important finding of this study is the non-significant differences in the accuracy of the KAL-X Sensor™ to measure energy expenditure for different BMI classifications for walking or cycling exercises. While there are limited studies related to the validity of the KAL-X Sensor™ to measure energy expenditure, one strength of the current study is that it appears to be one of the first to examine the accuracy of the KAL-X Sensor™ to measure energy expenditure for overweight and obese adults. The replication of this current study may help to further investigate the validity of the KAL-X Sensor™ to measure energy expenditure.

APPENDICES

APPENDIX A- Informed Consent

University of Pittsburgh

School of Education
Physical Activity and Weight Management Research Center

Suite 600 Birmingham Towers
2100 Wharton Street
Pittsburgh, PA 15203
412-488-4184
Fax: 412-488-4174

Approval Date: February 8, 2005
Renewal Date: February 7, 2006
University of Pittsburgh
Institutional Review Board
IRB #0402062

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: New Portable Technology to Improve the Assessment of Physical Activity

PRINCIPAL INVESTIGATOR: John M. Jakicic, Ph.D.
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CO-INVESTIGATORS: Amy D. Otto, Ph.D., RD
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SOURCE OF SUPPORT: National Institutes of Health

DESCRIPTION:

Energy expenditure (the number of calories your burn) is important for weight management. However, it is difficult to accurately measure energy expenditure in individuals while they are active in non-laboratory situations. Because of the need to better understand the energy expenditure of individuals in non-laboratory situations, a number of portable devices have been developed that can be worn by individuals under free-living situations. However, it is unclear whether these devices can accurately and reliably measure energy expenditure. In this research study, we will compare the LifeChek KAL-X Sensor to energy expenditure measured using a metabolic cart (a metabolic cart is a device that measures the air that you are breathing in and out).

Participant's Initials: _____

Approval Date: February 8, 2005
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The LifeChek KAL-X Sensor is classified as a non-significant risk device by the University of Pittsburgh Institutional Review Board. This means that it has been determined that using this device will not put you at medical or physical risk. The metabolic cart has been approved by the FDA to measure metabolic parameters similar to what is being measured in this study.

You are being invited to take part in this research study because you are within the body weight range for this study, and do not have any medical conditions that would prohibit you from participating in vigorous activity. People invited into this study have to be either males or females between 18-50 years of age and, if female, cannot be pregnant. You will be required to accurately report whether you are pregnant to the investigators prior to beginning this study and during the study if your status should change. The study is being performed on a total of **60** individuals at the University of Pittsburgh.

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical care:

Screening Procedures:

Procedures to determine if you are eligible to take part in a research study are called "screening procedures", and this will occur prior to you participating in any exercise sessions related to this study. Completion of all of the screening procedures occur at the Physical Activity and Weight Management Research Center at the University of Pittsburgh. It will take approximately 60 to 90 minutes to complete all of these screening procedures. For this research study, the screening procedures include:

1. You will complete a physical activity readiness questionnaire (PAR-Q), and this will take approximately 5 minutes to complete. You will also complete a detailed medical history, and this will take approximately 20 minutes to complete. These questionnaires will allow the investigators to determine if you have any significant medical condition that would indicate that exercise is unsafe for you.
2. If it is determined that you have risk factors that may make it unsafe for you to participate in vigorous intensity exercise (examples include high blood pressure, high cholesterol, and others), you may be required to provide written clearance from your personal physician prior to participating in this study. If medical clearance is required, you will be responsible for the cost of obtaining the medical clearance from your personal physician. If you take medication that will affect your heart rate or your blood pressure you will not be eligible to participate in this study.
3. If you have a history of known heart disease, diabetes (high sugar levels), are currently pregnant, or have other medical conditions that can become worse if you exercise, you will not be eligible to participate in this study.
4. Your height and weight will be measured using standard procedures which are similar to how your height and weight are measured during a medical visit. The measurement of your height and weight will take approximately 5 minutes.

Participant's Initials: _____

5. Your blood pressure will be measured using a standard blood pressure cuff and will follow standard measurement procedures. If your resting blood pressure is elevated, or if you take medication to control your blood pressure, you will not be eligible to participate in this study. The measurement of your resting blood pressure typically takes approximately 10 minutes.
6. You will have your fitness measured, which will provide information about how fit your heart and lungs are to perform exercise. Your fitness will be estimated by having you walking on a treadmill. The speed of the treadmill will be kept at 3.0 miles per hour, which is considered to be a brisk walking pace, however the grade of the treadmill will increase 2.5 percent every 3 minutes so that it feels like you are walking up a hill. As you are walking, your heart rate, blood pressure, and perception of physical exertion will be measured. Your heart rate will be measured using an electrocardiogram, which is also known as an ECG. The ECG will require that electrodes be placed on the chest and abdomen areas of your body. You will continue to walk on this treadmill until you reach a heart rate that is 85 percent of your maximal capacity, and then the test will be stopped. This test will be reviewed by a physician associated with this study, and if this review indicates that exercise may put you at increased health risk, you will be ineligible to participate in this study. The measurement of your fitness typically takes approximately 30 minutes.

Experimental Procedures:

If you qualify to take part in this research study, you will undergo the following experimental procedures:

1. You will perform six exercise sessions in a laboratory: 1) walking on a treadmill wearing a short sleeved t-shirt, 2) walking on a treadmill wearing a long sleeved t-shirt, 3) pedaling a stationary bike, 4) moving your arms in a circular motion, 5) resistance exercise, 6) a combination of walking, pedaling a stationary bike, and sitting. You will come to the exercise laboratory in Birmingham Towers on six separate days. On each of these days you will perform one of these six exercises. The order of which exercise you will do on each day will be random (like the flip of a coin) and will be determined by a computer program. During each activity, the number of calories that you are burning will be measured using a metabolic cart (a metabolic cart is a device that measures the air that you are breathing in and out) and the LifeChek KAL-X Sensor (see descriptions of these on Pages 4 and 5 of this consent form). During each of these activity sessions, your heart rate and blood pressure will be monitored. Your blood pressure will be measured using a blood pressure cuff and stethoscope which is similar to the method of measuring your blood pressure during a routine medical visit. Measurement of your heart rate will require that you wear a heart rate monitor that is attached around your chest with an elastic strap. If your heart rate or your blood pressure reaches an unsafe level while

Participant's Initials: _____

participating any of the exercise sessions, the exercise session will be stopped. Each of the exercises that you will perform are described in detail below:

a. You will walk on a motor-driven treadmill at a speed of 2.5 miles per hour and the elevation set at 0 percent, 3.0 miles per hour at 0 percent elevation, and 3.0 miles per hour at 5 percent elevation. You will walk at each speed and elevation for a period of ten minutes (30 minutes total). For this session you will wear a short sleeved t-shirt.
b. You will walk on a motor-driven treadmill at 2.5 miles per hour at 0 percent elevation, 3.0 miles per hour at 0 percent elevation, and 3.0 miles per hour at 5 percent elevation. You will walk at each speed and elevation for a period of ten minutes (30 minutes total). For this session you will wear a long sleeved t-shirt.
c. You will pedal a stationary exercise bicycle. You will pedal at 50 revolutions per minute and at a resistance of 0 kilograms, 60 revolutions per minute and at a resistance of 0 kilograms, and 60 revolutions per minute and at a resistance of 1 kilogram. You will pedal for 10 minutes at each speed and resistance (30 minutes total).
d. You will move your arms in a circular motion (similar to pedaling a bicycle) using an arm crank device. The resistance will be set at 0 kilograms at 50 revolutions per minute for 10 minutes, 0 kilograms at 75 revolutions per minute for 10 minutes, and 0.5 kilograms at 75 revolutions per minute for 10 minutes (30 minutes total).
e. You will perform a series of seven different resistance exercises that will exercise the muscles in your chest, arms, back, and legs. You will first participate in a session that will determine the maximal amount of weight that you can lift for each exercise. This will involve you selecting a weight that you can comfortably lift, and this weight will be increased for each lift until the maximal weight that you can lift is determined. Determining the maximal weight that you can lift will take approximately 30 minutes. You will then participate in an exercise session that will require you to lift 60 percent of your maximal weight for each exercise 12 times consecutively. You will be permitted to rest for one minute between each exercise. It is anticipated that this exercise session will take 30 minutes to complete.
f. You will perform a combination of exercises that will include sitting, walking, and pedaling a bike. This session will last 60 minutes and will involve the following:
   1) 10 minutes of sitting with no exercise.
   2) 10 minutes of walking on a treadmill at 3.0 miles per hour and 0 percent elevation.
   3) 5 minutes of sitting with no exercise.
   4) 2 minutes of walking on a treadmill at 2.5 miles per hour at 0 percent elevation.

Participant's Initials: _____

5) 5 minutes of sitting with no exercise.
6) 2 minutes of arm exercise at 75 revolutions per minute with the resistance set at 0.5 kilograms.
7) 5 minutes of sitting with no exercise.
8) 2 minutes of walking on a treadmill at 3.0 miles per hour at 0 percent elevation.
9) 5 minutes of sitting with no exercise.
10) 2 minutes of arm exercise at 75 revolutions per minute with the resistance set at 0.5 kilograms.
11) 5 minutes of sitting with no exercise.
12) 2 minutes of walking on a treadmill at 2.5 miles per hour at 0 percent grade.
13) 5 minutes of sitting with no exercise.

2. You will perform one exercise session outdoors that will last 40 minutes. This outdoor session will only occur when the outdoor temperature is between 50-70 degrees and the relative humidity is less than 70 percent. This session will require you to be seated with no exercise for 5 minutes, walk for 30 minutes, and be seated again with no exercise for 5 minutes. During this exercise session the number of calories that you burn will also be measured using a portable metabolic cart that will measure the air that you breathe in and out. You will also wear the LifeChek KAL-X Sensor.

3. You will wear the LifeChek KAL-X Sensor during your waking hours for a period of 7 days in a row. You will also be required to log all of your activity in a diary each day. Upon return of the KAL-X Sensor you will also complete a physical activity questionnaire reflecting your activity patterns over the previous 7 day period, and it will take approximately 15 minutes to complete this questionnaire.

During the exercise session performed in the laboratory (walking on a treadmill wearing a short sleeved t-shirt, walking on a treadmill wearing a long sleeved t-shirt, pedaling a stationary bike, moving your arms in a circular motion, resistance exercise, a combination of walking, pedaling a stationary bike, and sitting) and the 40 minute walking session that you will perform outdoors, your energy expenditure will be measured using a metabolic cart and the LifeChek KAL-X Sensor. During the 7-day free-living period you will have your energy expenditure measured using the LifeChek KAL-X Sensor. The metabolic cart and the LifeChek KAL-X Sensor methods are described below:

1. Metabolic Cart: The metabolic cart is a device that will measure the air that you breathe in and out. The air that you breathe in and out is used to calculate the number of calories that you are burning. To do this, you will breathe through a sterilized mouthpiece and wear a set of noseclips so that no air flows through your nose.

Participant's Initials: _____

2. LifeChek KAL-X Sensor: You will wear an armband at the midpoint of your upper arm. This armband has a heat flow sensor built into it that will measure the number of calories that you are burning. The armband will be cleaned before you will wear it.

Each exercise session will be separated by at least 48 hours apart, and you will complete all the exercise sessions within a 2 month period. If you are unable to complete all of the exercise sessions within a 2 month period, you will need to complete a new physical activity readiness questionnaire (PAR-Q) detailed medical history, and may be required to complete additional procedures as outlined in the Screening Procedures.

RISKS and BENEFITS:

As with any research study, there may be adverse events or side effects that are currently unknown, and it is possible that certain of these unknown risks could be permanent, serious or life-threatening. The possible risks of this research study may be due to the exercises that you will be performing or the techniques used to measure energy expenditure.

Risks

A. Risks of the Exercise Sessions: There are risks associated with participating in an exercise test or exercise session. You may experience general fatigue or you may become short of breath during your participation in these activities. It is likely that you will experience these feelings because greater than 25% of people report these feelings during this type of exercise. In addition, during exercise, your heart rate and blood pressure will increase, and under extreme conditions, this can lead to a serious cardiac event (i.e., heart attack). The risk of experiencing a serious cardiac events (e.g., heart attack) is rare (occurs in less than 1% or 1 out of 100 people). The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20, 000 in exercising adults. In the event that you experience a serious medical condition during your exercise session, the session will be stopped and appropriate emergency medical care will be provided. This may include providing CPR until Paramedics or other appropriate medical personnel arrive.

There is also the risk that you may experience other injuries related to your participation in this study. This may include injuries resulting from falling while exercising, muscles strains, sprains, or sore muscles. Within this study the risk of this happening to you is infrequent because it occurs in 1-10% of people (1 to 10 out of 100 people). In the event that this should occur your will be instructed to consult with your personal physician for treatment. In the event that this is a serious injury that requires immediate medical attention, appropriate medical personnel such as the Paramedics will be contacted to provide this treatment to you.

There is also risk with exercising outdoors. Risk of participating in exercise outside in cold weather may include hypothermia (low body temperature) if sufficient

Participant's Initials: _____

clothing is not worn. The risk of experiencing hypothermia is rare (less than 1% of 1 out of 100 people) when the temperature is above 50 degrees Fahrenheit, which is the minimal temperature for the outdoor exercise session in this study. Risk of participating in exercise outside in warm weather may include an increase in body temperature and sweating, which may result in heat stroke or dehydration. The risk of experiencing heat stroke or dehydration is rare (less than 1% of 1 out of 100 people) when the temperature is below 75 degrees Fahrenheit and the relative humidity is less than 70 percent, which is the maximal temperature and relative humidity for the outdoor exercise session in this study. In the event that this should occur your will be instructed to consult with your personal physician for treatment. In the event that this is a serious condition that requires immediate medical attention, appropriate medical personnel such as the Paramedics will be contacted to provide this treatment to you.

To avoid risk to the fetus, it is important that women not become pregnant while participating in this research study. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if you are a woman and choose to be sexually active, you should use the appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or contraceptive sponge, in addition to male use of a condom), or the female should be using prescribed "birth control" pills, injections, or implants. Such birth control methods should be used for 30 days prior to beginning your participation in this study and continue throughout the study period. If you choose to be sexually active during this study, you understand that even with the use of these birth control measures pregnancy could still result. The risks of participating in the exercise sessions for this study while pregnant include potential loss of pregnancy or possible birth defects.

B. Risks of Assessing Energy Expenditure: When measuring the calories that you burn using a metabolic cart, you may experience a dry mouth. This happens to most individuals, and it is likely that you will experience a dry mouth.

C. LifeChek KAL-X Sensor: Some people may experience mild skin irritation at the site where the armband is worn. One cause of skin irritation has already been identified in people who wear the armband for extensive periods of time (i.e., more than 24 hours). Specifically, the build-up of sweat that can be trapped between the skin and the armband can cause pink pustules or pimples to appear. This condition is named miliaria, or prickly heat. This condition occurs in less than 1% of people that wear the sensor, which means that the chance of this happening to you is rare. To help to prevent this condition we will clean your arm using rubbing alcohol before we put the sensor on you. Also, we will clean the sensor before we put it on your arm. We also will clean the elastic strap of the sensor by using a soap and water solution. We will also wipe off the equipment using rubbing alcohol and allow this to dry before putting it on your arm.

Participant's Initials: _____

If we should find out about a medical condition you were unaware of, with your written permission, this information will be shared with the doctor of your choice.

Benefits

You will likely receive no direct benefit from taking part in this research study. However, there may be indirect benefits to you for your participation that may include generalized knowledge about exercise and the measurement of the calories that you burn.

NEW INFORMATION

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

COSTS and PAYMENTS

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). However, if you are required to provide medical clearance from your primary care physician prior to beginning this study, you will be required to pay the cost of obtaining this medical clearance.

You will be paid $25 for each of the indoor exercise sessions that you perform in the laboratory (6 possible session at $25 per session = $150). This will be paid to you once you complete all 6 of these exercises. You will be paid an additional $25 for completing the outdoor exercise session, which will be paid once you complete this session. You will be paid $25 for wearing the sensor for 7 additional days and answering the activity questionnaire, which will be paid to you once you complete this 7-day period. If you are unable to complete the entire study, you will be compensated for each of the exercises that you complete. You will be paid at the point when you terminate your participation in this study. You will not be compensated for exercise sessions that you voluntarily do not complete. However, you will be compensated for exercise sessions that are stopped before completion by the investigators to protect your safety in this study.

At the completion of your participation in this study a request for payment will be made to the appropriate University of Pittsburgh department. It is anticipated that it will take approximately 2-4 weeks for this request to be processed and for a check to be sent to you at the address which you specify to the investigators.

Participant's Initials: _____

COMPENSATION FOR INJURY

University of Pittsburgh researchers and their associates who provide services at the UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or a co-investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of the UPMC. It is possible that the UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. You will not receive any monetary payment for, or associated with, any injury that you suffer in relation to this research.

This policy applies also to injuries that you may experience during your unsupervised exercise that you will participate in as part of your involvement in this study. In the event that you are injured during your unsupervised exercise, please inform the Principal Investigator or co-investigator listed on the first page of this form.

CONFIDENTIALITY

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. In addition, all research databases will have password controlled access, and this will be controlled by the researchers. Only the researchers listed on the first page of this form and their staff will have access to your research records. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release). University of Pittsburgh policy requires that research records be kept for a period of not less than five years after the study ends.

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (e.g., physician office) records. The information that will be recorded will be limited to information concerning medical clearance from your physician to participate in this research study. This may include information related to coronary heart disease risk factors such as blood pressure, blood cholesterol, or other medical conditions that may increase the risk of heart disease and/or indicate that exercise participation may be unsafe for you. This information will be used to

Participant's Initials: _____

determine whether it is safe for you to participate in this research study. This research study will result in identifiable information that may be placed into your medical records held at the office of your primary care physician based on your request or consent. The nature of the identifiable information resulting from your participation in this research study that may be recorded in your medical record includes your medical history or results from the exercise test completed at the screening visit.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, your research records may be required to release identifiable information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the researchers learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical record information related to your participation in the study.

Authorized representatives of the sponsor of this research study, the National Institutes of Health, will review and/or obtain identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical record information, the UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research

 Participant's Initials: _____

study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e., quality assurance).

RIGHT TO PARTICIPATE or WITHDRAW FROM PARTICIPATION

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. However, if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.

Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with the University of Pittsburgh.

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. However, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study. Any identifiable research or medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no affect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Under certain circumstances the investigators may need to withdraw you from further participation in this study. These circumstances may include an adverse event that does not

Participant's Initials: _____

allow you to safely participate in this research study, if you are a woman and become pregnant, or your failure to comply with any aspect of the study protocol.

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your participation in this research study for 5 years following the completion of this study, as per University policy, or when such is approved by the sponsor of this study, whichever should occur last.

****

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature _____ Date _____

CERTIFICATION OF INFORMED CONSENT

I certify that I explained the nature and purpose of this research to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent _____ Role in Research Study _____

Signature of Person Obtaining Consent _____ Date _____

APPENDIX B- PAR-Q

Physical Activity Readiness Questionnaire (PAR-Q)

Subject ID: _____

Please read the questions carefully and answer each one honestly: check YES or NO

1. Has your doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?

   ❑yes ❑no

2. Do you feel pain in you chest when you do physical activity?

   ❑yes ❑no

3. In the past month, have you had chest pain when you were not doing physical activity?

   ❑yes ❑no

4. Do you lose your balance because of dizziness or do you ever lose consciousness?

   ❑yes ❑no

5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?

   ❑yes ❑no

6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

   ❑yes ❑no

7. Do you know of any other reason why you should not do physical activity?

   ❑yes ❑no

Reference: American Medical Association: Guides to the Evaluation of Permanent Impairment. AMA, Chicago, 1990.

APPENDIX C- Medical History

GENERAL HEALTH HISTORY

Subject ID:_____

1. Do you have or have you ever had any of the following medical conditions?

				Approximate Date of Diagnosis	Describe the Problem
a.	Heart Attack	❑yes	❑no	_____	_____
b.	Angina (chest pain on exertion)	❑yes	❑no	_____	_____
c.	Irregular Heart Problems	❑yes	❑no	_____	_____
d.	Other Heart Problems	❑yes	❑no	_____	_____
e.	Stroke	❑yes	❑no	_____	_____
f.	Fainting Spells	❑yes	❑no	_____	_____
g.	High Blood Pressure	❑yes	❑no	_____	_____
h.	High Cholesterol	❑yes	❑no	_____	_____
i.	Thyroid Problems	❑yes	❑no	_____	_____
j.	Cancer	❑yes	❑no	_____	_____
k.	Kidney Problems	❑yes	❑no	_____	_____
l.	Liver Problems	❑yes	❑no	_____	_____
m.	Gout	❑yes	❑no	_____	_____
n.	Diabetes	❑yes	❑no	_____	_____
o.	Emotional/Psychiatric Problems	❑yes	❑no	_____	_____
p.	Drug/Alcohol Problems	❑yes	❑no	_____	_____

2. Do you have any medical problems that would prevent you from participating in a regular walking program? ❑yes ❑no

If yes, please describe the problem:_____

_____

3. Have you participated in a regular exercise program over the past 6 months which consists of at least 20 minutes of activity, 3 days per week? ❑yes ❑no
Please describe:_____
_____

4. Do you have to sleep with extra pillows or have to sit up in the middle of the night because of shortness of breath? ❑yes ❑no

5. Please list all medications that you are currently taking on a regular basis (make sure to indicate if you are taking medication for high blood pressure or cholesterol):

MEDICATION	REASON FOR TAKING
_____	_____
_____	_____
_____	_____
_____	_____

6. Over the last 6 months, on how many weekdays (Monday through Friday) do you usually drink wine, beer, or liquor on average?

(0) ❑ Never
(1) ❑ Less than once/month
(2) ❑ 1-2 times/month
(3) ❑ 1 day/week
(4) ❑ 2 days/week
(5) ❑ 3 days/week
(6) ❑ 4 days/week
(7) ❑ 5 days/week

7. On those weekdays that you drink wine, beer, or liquor how many drinks do you have? ❑❑

8. Over the last 6 months, on how many weekend days (Saturday and Sunday) do you usually drink wine, beer, or liquor?

(0) ❑ Never
(1) ❑ Less than once/month
(2) ❑ 1-2 times/month
(4) ❑ 1 weekend day/week
(5) ❑ 2 weekend days/week

9. On those weekend days that you drink wine, beer, or liquor how many drinks do you have? ❑❑

10. In the past year, have you regularly smoked cigarettes, pipes, cigars, or used chewing tobacco?

		Please describe daily habit
Cigarettes	❑yes ❑no	_____
Pipe	❑yes ❑no	_____
Cigars	❑yes ❑no	_____
Chewing Tobacco	❑yes ❑no	_____

11. Do you plan to spend frequent time out of town on business or vacation during the next 18 months? ❑yes ❑no Please describe:_____
_____

12. Is it possible that you will relocate in the next 18 months? ❑yes ❑no
Please describe: _____

WOMEN ONLY ANSWER THE FOLLOWING QUESTIONS

13. Are you currently pregnant? ❑yes ❑no

14. Were you pregnant within the past 6 months? ❑yes ❑no

15. Do you plan to become pregnant in the next 18 months? ❑yes ❑no

16. Have you gone through menopause or the change of life? ❑yes ❑no

17. Have you had a hysterectomy? ❑yes ❑no

18. When was your last menstrual period? DATE:❑❑/❑❑/❑❑

19. Do you take :

Birth Control Pills?	❑yes ❑no
Estrogens (ie. Premarin)?	❑yes ❑no
Progesterone (ie. Provera)?	❑yes ❑no

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