IMPROVING THE IDENTIFICATION OF OSTEOPENIA: THE RELATIONSHIP

BETWEEN MUSCLE POWER, BODY MASS INDEX AND BONE MASS DENSITY.

By

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A thesis submitted in partial fulfillment of

the requirements for the degree of

MASTERS OF NURSING

WASHINGTON STATE UNIVERSITY

College of Nursing

AUGUST 2008

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ACKNOWLEDGMENT

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Abstract

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Nurse Practitioners (NPs) play a large role in preventive healthcare, especially as it relates to low bone mass density (LBMD). With 44 million people affected by osteoporosis in the United States and two million annual hospitalizations for osteoporosis-related fractures, identifying a more cost effective way to assess and predict low bone mass density (LBMD) before fractures occur is vital for optimal health.

This study was conducted to examine the relationship between muscle power (MP) and bone mass density (BMD) and explore the use of MP according to body mass index (BMI) as a means of identifying LBMD. A prospective descriptive design was used to explore these variables among seventeen female volunteers between the ages of 30 – 65 years. Anthropometric measurements were recorded for each participant along with BMI, MP of the calf muscles, and BMD of the calcaneus.

The results demonstrate a moderately significant correlation between BMD with MP ($r = .541$) and BMI ($r = .581$) using a two-tailed Pearson's correlation coefficient test set at 0.05 level. Weight (X) MP (+) Newton's was found to be highly correlated with BMD ($r = .791$) using a two-tailed Pearson's correlation coefficient test ($p < 0.0001$).

Future research should focus on sex, age, and weight distributions to determine accurate prediction models. Using this approach, clinicians could access empirical data to assist in the identification of LBMD in the clinical setting. This approach is consistent with the preventative nature of advanced nursing practice and has the capacity to avoid unnecessary diagnostic testing and preserve millions of healthcare dollars. Study findings may help to direct future research in the use of MP as a clinical tool for identifying those at risk of LBMD and osteoporosis.

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Dedication

This thesis is dedicated with a very special thank you to my wife Kristi, and our boys, Ryan and Nathan; to my father and mother, Lloyd and Ellen Blevins, my mother in-law, Dulice Gerow, father-in-law, Roger, and his wife, Sonia Gerow; to my dear sister and her family, Mindy, Jeff, Tyler and Nya Neissl; thank you for allowing me the time needed to step out of the role as husband, dad, son, son-in-law, brother and uncle in order to focus on school as a full-time student for the last two and a half years in hopes of spending more quality time together as a family in the future.

Chapter I

Improving the Identification of Osteopenia: The Relationship between

Muscle Power, Body Mass Index and Bone Mass Density.

Using empirical data to assess the risk of low bone mass density (LBMD) before a fracture occurs may help to alleviate human suffering, and healthcare expenditures, as well as improve identification and treatment of individuals with LBMD. This approach is consistent with the focus of care that is central to advanced practice nursing. According to the National Osteoporosis Foundation [NOF] (2008), LBMD poses a great threat for many older adults. It affects approximately 44 million Americans and is responsible for two million hospitalizations annually. LBMD is considered a silent disease, as most people remain asymptomatic until they experience a sudden fracture.

Although men, women, and children of all ages are vulnerable to LBMD, it is widely accepted that women of all races have considerably lower bone mineral density (BMD) than men (NOF, 2008). When considering BMD among women of different cultures, African American women have the highest mean BMD, whereas Hispanic women have a mean BMD just slightly higher than Caucasian and Asian women. Females have been the focus of research concerning LBMD due to the strong relationship between LBMD, aging, and menopause. It is well documented that BMD decreases with age and occurs more rapidly as estrogen levels decrease during menopause (NOF, 2008). Females over the age of 50 are especially at risk, with a female to male ratio of 4:1 as having severe LBMD or osteoporosis (Connell & Seaton, 2005; South-Paul, 2001).

Risk factors for LBMD are well described, such as age, gender, height, use of walking devices, smoking status, and weight (Anders, Turner & Wallace, 2007; United States Preventative Services Task Force [USPSTF], 2002). However, these indices do not produce ideal sensitivity and specificity ratings for identifying those with LMBD or osteoporosis. Moreover, they may increase the number of patients being screened unnecessarily with dual-energy x-ray absorptiometry (DEXA) scans, the gold standard for diagnosing osteoporosis. This approach to the identification and diagnosis of LBMD and osteoporosis has added to soaring healthcare costs that are predicted to rise with the growing population of older adults (NOF, 2008).

In contrast, if empirical measures could be used to identify those at risk of LBMD and osteoporosis, then a more accurate risk assessment may lead to better identification and treatment, as well as less routine use of the expensive and time-consuming DEXA scan. Muscle power, which has shown a relationship with BMD in other studies (Iki et al., 2006; Witzke, & Snow, 1999), may be such a measure that could be used in the clinical setting to identify those at risk, as well as track treatment outcomes over time. This study will examine the relationship between MP and BMD and explore the use of MP according to body mass index (BMI) as a means of identifying LBMD.

An overview of the various factors involved in LBMD will be discussed, along with screening procedures currently used in the clinical setting. Following this, a physiologically-based theoretical framework will be presented to help identify the study variables and the proposed relationships between the variables. Finally, the review of the literature will be used to examine the results of past studies and ascertain related variables that need to be incorporated into the study measurements.

The Dynamic Element: Bone

Bone in the human skeleton is comprised of varying degrees of trabecular (cancellous) and cortical (compact) tissue, allowing for a unique BMD result in each bone of the body. The major components of bone are minerals, proteins, water, lipids, and basic multicellular units (BMUs). According to Hernandez, Beapre, and Carter (2000), BMUs are known as osteoblasts, and osteoclasts. Compact tissue forms the outer shell of the bone after calcifying while trabecular tissue forms the matrix within the encased outer layer where remodeling by resorption (breaking down) and formation (building up) take place.

Bone remodeling is a continuous life long process. The triggers that begin the process are not fully understood but osteocytes react to bone strain by stimulating resorption. Osteoclasts break the bone down, while osteoblasts monitor the osteoclasts by secreting macrophage-colony stimulating factor. This, in turn, begins a cascade of events where other factors such as parathyroid hormone, estrogen, leptin, 1-alpha-dihydroxyvitamin D, insulin like growth factor-1 and growth hormone orchestrate the activity of the BMUs (Connell & Seaton, 2005).

BMD peaks in both women and men between the ages of 18 and 30 years old before it begins to decline (NOF, 2008). In healthy individuals, after peak BMD has been reached, the bone is in a state of equilibrium. When there is an imbalance in the function of the BMUs, the BMD may decline in accordance with genetic, environmental and biochemical influences (Bubanj & Obradovic, 2002; Bamman, Shipp, Jiang, Gower, Hunter, Goodman et al., 2001; Hernandez, Beapre & Carter, 2000; Scheibl & Willnecker, n.d.).

Influences known to affect BMD can be described as primary and secondary factors (Connell & Seaton 2005; South-Paul, 2001). Primary factors include ageing, genetics and naturally occurring hormonal processes such as menopause. As age increases, BMD decreases. Due to genetic influences, each gender and race is unique in average height, body composition, and distribution of mass, including lean and fat. The natural decrease of the hormone, estrogen, during and after menopause may further contribute to LBMD.

Secondary factors include nutritional, pharmaceutical, behavioral, environmental and mechanical processes. Eating disorders affect BMD due to deficiencies in nutrients the body requires for maintaining bone strength. Glucocorticoids stimulate bone loss resulting in decreased BMD (Summey & Yosipovitch, 2006). Calcium and vitamin D promote bone formation, which can increase BMD (Anderson, 2002). Alcohol and smoking are behavioral factors known to decrease BMD, while sunlight from the environment promotes vitamin D production in the body, which is needed for calcium absorption by the gut. Physical activity is a mechanical factor associated with BMD, corresponding positively and negatively based on the intensity and regularity of activity.

Clinical Screening for Low Bone Mass Density

It is recommended that routine screening for LBMD begin in women at age sixty-five with initial testing at age sixty for those at increased risk of fracture. Practitioners rely on history taking, physical exams, surveys and questionnaires to assess risk of osteoporosis and to help the practitioner determine if further evaluation or screening is needed. Unfortunately, the history and physical exam offer limited ability to identify osteoporosis since most people are asymptomatic until a fracture has occurred.

Surveys and questionnaires, such as the Osteoporosis Risk Assessment Instrument (ORAI) and the Simple Calculated Osteoporosis Risk Estimation (SCORE), have shown sensitivity in the low 90 % and specificity in the low 40 %, both which decrease in older women. When predicting the risk for fractures, studies have shown that age, gender, height, use of walking devices, smoking status, and weight provide sensitivities in the low 70 % and specificity in the low 80 % (Anders, Turner & Wallace, 2007; United States Preventative Services Task Force [USPSTF], 2002).

Small bone density scanners are objective and are used frequently when assessing distal bones such as the elbow, wrist and calcaneus (NOF, 2008; USPSTF, 2002). If further diagnostic data is needed, a more thorough scan may be accomplished. The gold standard for measurement of BMD is a dual-energy x-ray absorptiometry (DEXA) machine, an enhanced form of x-ray with less radiation exposure than conventional x-ray machines. Alternatively, a full body DEXA scan can be used to identify osteoporosis (Brunader & Shelton, 2002). The cost for performing such tests can run from fifteen dollars for the smaller scan to four hundred dollars for the full body scan.

Although the exact cause of osteoporosis is unknown, it is associated with the amount of BMD that exists within the bones matrix. The World Health Organization (WHO) defines BMD as a T-score representing the standard deviation (SD) of BMD when compared to that of a young healthy individual. Normal BMD has a T-score greater than -1.0 SD. A T-score between -1.0 and -2.5 SD indicates osteopenia or LBMD. Osteoporosis or severe LBMD is represented by a T-score less than -2.5 SD.

Statement of the Problem

Current clinical modalities for LBMD screening may overestimate the number of individuals requiring diagnostic testing with a DEXA scan, which is expensive, time consuming, and exposes the individual to radiation. Muscle power based on the individual's BMI may provide an empirical measure that could be easily obtained in the clinical setting, and which may provide more accurate identification of those at risk for LBMD. This research project will examine the relationship between MP and BMI and explore the use of MP according to body mass index (BMI) as a means of identifying LBMD. This could potentially lead to a prediction model of LBMD using these variables.

Statement of the Purpose

The purpose of this study is to examine the relationship between MP and BMI and explore the use of MP according to body mass index (BMI) as a means of identifying LBMD among community dwelling women between the ages of 30 – 65 years. This population was chosen for testing as women are more likely to suffer the consequences of LBMD.

Definition of Terms

Body Mass Index (BMI): is a statistical measure of weight (percentage of fat and muscle mass) scaled according to height. It will be described using height and weight both continuous variables. BMI will be calculated with the National Heart, Lung and Blood Institute [NHLBI], (2000) formula: [(weight in pounds) $\div (\text{height in inches})^2$ x 703].

Muscle Power (MP): is the maximum amount of mechanical load applied to bone from the muscle or group of muscles pulling at the point of attachment.

Bone Mineral Density (BMD): is a method used to quantify the mass of bone. Normal BMD is no more than 1 standard deviation (SD) below the mean value of a healthy young population. A T-score of 0.0 would mean that the BMD is equal to that of the young adult population. A T-Score greater than -1 SD is considered normal. Osteopenia or Low Bone Mass Density (LBMD) is considered -1 to -2.5 SD. Osteoporosis is considered below a -2.5 SD (Lewiecki & Borges, 2006).

Conceptual Framework

Bone and muscle adapt to influences of the environment. BMD is determined by mechanical loading on the bone through MP. If the mechanical load does not reach a certain set point or threshold on a regular basis then resorption takes place, removing bone until the threshold is met. If the load on bone continues to exceed the threshold, then bone remodels by adding to its density, making it stronger. (Bamman et al., 2001; Bubanj & Obradovic, 2002; Hernandez, Beapre & Carter, 2000; Scheibl & Willnecker, n.d.). This tenet of the phenomenon, low bone mass density, is the fundamental relationship being explored in this research study.

However, there is an invisible threshold that exists when bone is in a state of equilibrium within its environment. At this point, very little resorption and remodeling take place and three events can be observed and measured.

1. The minimum and maximum amount of mechanical load by muscle prevents bone from remodeling (resorption and formation).

2. A person's height and weight plateau.

3. The body is at peak bone mass density at around the age of 18 in women and 20 years old in men (National Institute of Health [NIH], 2007.

After the peak BMD has been reached, it will begin to decrease, for some people much faster than others. It can be conceptualized that a healthy person based on BMI, who has a normal MP, will also have a normal BMD. If true, then the amount of mechanical load produced by the muscles can be assumed as an indirect measure of BMD. Hypothetically, if the person produces the mechanical load consistently on the muscle or groups of muscles after peak BMD has been reached, then LBMD will not occur in that area of the bone where the muscle attaches or interacts. If a person did have LBMD, then normal parameters of mechanical load would be affected with lower muscle power scores observed and a means for assessing, diagnosing, predicting and treating LBMD.

It remains unknown whether other risk factors of LBMD affect the relationship with MP, and the degree of influence. Therefore, this study will use community-dwelling women with a variety of risk factors to examine this relationship.

Review of the Literature

Many inquiries have focused on the factors associated with activity and its relationship to LBMD. Studies of space flight and the effects of gravity (weightlessness) on bone and muscle have been conducted to isolate the influence of weight-bearing activity on BMD. It has been reported that six months in space produces a 13.2 % bone loss of the calcaneus but increases the bone mass in the radius by 0.2 % - 0.5%. (Collet et al., 1997). Bone loss in young and healthy astronauts in space is equivalent to a woman going through menopause on earth, except the bone loss in space occurs at an alarming rate. The average yearly bone loss for women going through menopause is two percent yearly with as much as 20% loss seen in five to seven years.

The differences seen in astronauts with a decrease in leg BMD and increase in radial BMD are best explained due to the role reversal taking place, since the arms are used to propel the astronaut in space whereas the legs propel the astronaut on the earth. Ironically, calcium and vitamin D which are recommended for the prevention of LBMD on earth, do not prevent the development of LBMD in astronauts despite a high intake during space flight (Iwamoto, Takeda, & Sato, 2005). One reason for this is that urinary excretion and serum levels of calcium increase, while intestinal absorption decreases in space. Another explanation is due to the absence of gravity on muscle and bone, which causes the body to excrete excess calcium since it takes less to produce a contraction. This process results in decreased MP and BMD.

Head Down Bed Rest (HDBR) studies on healthy individuals showed similar results (Pavy-Le Traon, Heer, Narici, Rittweger & Vernikos, 2007). Participants placed in a Trendelenberg position, without performing work against gravity, had reduced energy requirement and a reduction of overall sensory stimulation which demonstrated an upward fluid shift, causing the central volume receptors to induce a ten to fifteen percent reduction in plasma volume. This led to cardiovascular changes identical to that seen in space. From the beginning of the study, urinary calcium excretion and plasma calcium levels increased while calcium absorption from the gut decreased. Moreover, body weight, muscle mass, muscle strength and resistance of muscle to insulin also decreased. Other changes included were decreased BMD, bone articulation in the lower legs, and spine and bone geometry. With the implementation of gravity induced exercise machines in space and weight-bearing exercises for the HDBR participants, these changes seen in the individuals reversed.

These two studies indicate that weight bearing exercise plays a key role in reversing the affects of LBMD, however the type of exercise (intensity, frequency and duration) and amount of muscle contraction needed to keep LBMD from occurring has not yet been determined. For the proposed research study, activity status will be measured and used in the final analysis.

Researchers have tried to find ways of predicting BMD or bone mineral content (BMC) using muscle strength. One such study used grip strength, arm span, and muscle length to identify correlations with BMC using a sample of 63 healthy, post-menopausal women (Sinaki et al., 1988). They found that the bone mineral content divided by its diameter did show some relation with grip strength (r=0.46, $p < 0.001$). They serendipitously found that the relationship between grip strength and arm span was significantly positive with BMD (r=0.47, $p < 0.001$). However, the researchers concluded that the tool could not be used for accurately predicting bone mineral content in a clinical setting as the study focused only on a healthy, post-menopausal sample.

In a separate two-group comparison study, Demet, Feyza, & Gulseren (2004) examined the relationships between age, arm span, height, BMD, weight, and BMI among 70 young and 70 older women. The study revealed that the femur neck T-scores had a significant positive relationship with BMI (r=0.29, p= 0.01) and weight (r=0.34, p= 0.04). It further showed that height (r = -0.26, p= 0.02) and arm span (r = -0.22, p=0.05) decreased with age while an increase in age (r = 0.3, p=0.02) and loss in BMD (r = -0.36, p= 0.02) was associated with vertebral fractures. This study supports the association between BMI and BMD, variables that will be measured in the proposed study. In addition, the relationship between MP, BMI and BMD will be explored.

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Iki et al. (2006) tested the use of trunk muscle strength to predict bone loss in post-menopausal women. In this four year study, isokinetic concentric and accentric peak torques of the trunk flexor and extensor muscles were measures and compared with bone mineral density of the spine to determine annual change in 109 women. The results demonstrated an association between exercising regularly and an increasing BMD over time (p=0.05). Trunk extensors peak torque (p=0.0006) and trunk flexors peak torque (p=0.0008) had the most positive relationship with BMD. A positive correlation was found between muscle strength and bone loss when adjustments were made for age, height and weight and BMD initially (p=< 0.05). As an observation, the isokinetic machine can be used to link muscle power with BMD even though different muscles will be tested in the proposed study. Iki et al. (2006) demonstrated the utility of monitoring muscle strength over time in post-menopausal women; however, study results cannot be generalized to other populations.

Fifty-four adolescent girls were studied to predict BMD and BMC by using lean body mass, leg power and leg strength (Witzke, & Snow, 1999). Body fat, leg strength, leg power, height, weight, physical activity and menstrual status were correlated in combinations to find relationships. Results found that leg power (r=0.41 – 0.67; p=0.001) and lean mass at all sites (r=0.45 – 0.77; p= 0.001) were the most correlated with BMD, whereas the others were not. When BMC and height were compared against the variables, height had the highest correlation among the rest of the variables. The study suggests that leg power measurements and two components of BMI (height and lean muscle mass) have positive associations with BMD, further supporting the measurements needed for the proposed study.

Maeda, Oowatashi, Kiyama, Yoshida, and Sakae (2001) studied 18 women for predicting muscle strength from bone length and width. The radial, ulnar, humerus, fibula, tibia and femur were measured. Grip strength was measured with a dynamometer. Force and torque of knee extension and flexion were measured in a sitting position. Muscle strength was estimated from length, width and height of each bone. The finding showed a significant correlation for the prediction of grip strength 0.90 ($p < 0.01$) and knee strength 0.84 ($p < 0.01$) from bone length and width in the areas measured. The researchers concluded that since muscle strength measures were analyzed only in the lower extremities, the findings were inconclusive and may not be generalizable due to the study population characteristics. The proposed study will use a sample of women between the ages of 30-65 years, and will measure related variables, such as menstruation status, smoking, and activity, to increase the internal validity.

The studies to date have identified some biophysical measures, such as BMI, weight, lean muscle mass, and extremity length, that correlate with BMD. However, the generalizability of the study findings has been limited due to the sample characteristics. This study will use a community-dwelling sample of women, between the ages of 30-65, and will measure similar variables identified in the literature review. Using lower extremity MP, bone length and BMI, relationships between BMD, measured in the calcaneous with a peripheral instantaneous x-ray imaging (PIXI) scan, will be explored. The study results will provide preliminary data to assess the influence of other factors, such as age, menstrual status, smoking status, alcohol consumption and medications, on the relationship between the main study variables.

Significance to Nurse Practitioners

As advanced practical nurses, our role in patient care is to look for ways to enhance preventative health, apply safer and less-costly methods for identifying those at risk of LBMD, and use modifiable risk factors to improve health and empower the patients to take control of their own well being. This study was designed to observe and report possible ways of predicting BMD in order to find a more reliable and inexpensive means for assessing, predicting, diagnosing and treating LBMD in the clinical setting.

Improving the Identification of Osteopenia: The Relationship between

Muscle Power, Body Mass Index and Bone Mass Density

Methods

This study used a prospective, descriptive design among a convenient sample of community-dwelling females, between the ages of 30 – 65 years, to explore relationships between muscle power (MP), body mass index (BMI) and bone mass density (BMD). Variables related to BMD, such as resting energy expenditure (REE), lever measurements, co-morbidities, alcohol intake, smoking status and exercise status were also collected and included in the analyses.

Setting

Study measures were obtained at a Women's Health Care Center and a physical therapy clinic located in Spokane, Washington. The participants were asked to walk or drive to these locations. Both locations are professional business suites. Standard protocols for measurements were followed by the researcher at each setting.

Population

This study focused on Caucasian women as they are generally at higher risk for LBMD in age, gender and race. Inclusion criteria consisted of English-speaking, Caucasian women, between the ages of thirty and sixty-five years old without the diagnosis of osteoporosis. Due to the preliminary stage of the study there were no exclusion criteria.

A convenience sample of 40 volunteer, community-dwelling, non-Hispanic, Caucasian women, between the ages of 30-65 years old, participated in the study. Seventeen women completed the study measurements while the remaining participants stated that timing was a major factor in not completing the data collection process.

Procedures

After obtaining approval through the Institutional Review Board at Washington State University, women were approached by the researcher to determine their interest in study participation. After explaining the study and answering questions, interested participants were asked to read and sign the consent form (Appendix A), demographic form (Appendix B), and complete the risk assessment questionnaire (Appendix C). Together, the forms take less than 10 minutes to complete. Participants were then asked to drive to the Women's Health Care Center for measurements of height, weight, lever measurements, and to obtain a peripheral instantaneous x-ray imaging (PIXI) scan. After completion of the scan, the participant was asked to drive to a physical therapy clinic, where muscle power measures were obtained. Following these measures, the researcher thanked the participant for their time and participation. This concluded the activities of the participant in the study.

Materials

Demographics form. The Demographic form was produced to obtain possible subjective risk factors for LBMD to include date of birth, yearly income, routine medications, and known medical diagnoses.

Risk assessment survey. The LBMD risk assessment survey was borrowed and modified with permission from the New York Department of Health: Osteoporosis Prevention & Education Program (NYSOPEP). It includes specific medical diagnoses, specific medications used on a daily basis that are known to affect BMD, amount of exercise (intensity, duration and frequency), smoking, alcohol use, and menopausal status. It was designed to be read at a six to eighth grade reading level. A weakness of this form is that the data collected is subjective. This information obtained from the survey however was used to track possible risk factors, severity and influence on LBMD.

Body mass index. Height and weight were measured with light clothing on and shoes removed standing on a Detecto model 448 Beam scale made in the USA. The same scale was used for each individual by the same researcher and was calibrated daily using a five pound weight. BMI was then calculated by using the NHLBI (2000) formula: weight in pounds divided by height in inches squared x 703,

Resting energy expenditure. Resting energy expenditure was calculated from height, weight and age using the Harris-Benedict equation for women: REE = 655.1 + (9.563 X weight) + (1.850 X height) – (4.676 X age).

Lever measurements. Lever measurements from the foot (Appendix D) and fibula bone lengths were obtained using a yard stick. The foot was measured from the tip of the longest toe to the most posterior edge of the heel; from the fulcrum or ball of foot to the most posterior edge of the heel; from the load or at the center of the lateral malleolus to the effort or where the calf muscles attach at the most posterior edge of the heel and from the floor to the joint line of the knee.

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Bone mass density. The calf muscles taper down to form the achilles tendon and attach at the posterior portion of the calcaneus bone in the back of the foot. Due to the prime location, this is where the BMD was measured by a peripheral instantaneous x-ray imaging (PIXI) scan machine manufactured by the Lunar Company in Madison Wisconsin (Appendix F). This machine uses x-ray technology at low doses to examine the amount of bone matrix present in bone. It uses a T-score based on normal BMD results from healthy individuals who are at their peak BMD. A standard deviation of plus or minus 1 is considered normal. A person with -1 to -2.5 would have low BMD and a person with - 2.5 or more would be considered having severe low BMD (Lewiecki & Borges, 2006). The machine is calibrated and tested daily for accuracy. Privacy and repeated experience for each subject are the most important aspect to control in this setting due to the sharing of results with the subjects, therefore each subject was tested by the same qualified researcher behind closed doors, using the same protocol for each. The subject was seated for less than five minutes in a comfortable chair while the left foot and heel were placed into the machine without a sock.

Muscle power. Measurement of MP was determined using a Biodex isokinetic machine manufactured in Shelley, New York (Appendix E). For less than ten minutes, the subjects were seated in a chair with a slight incline of the back for comfort. The left leg was raised until the lower leg was level with the ground and the foot was placed into a foot rest with a heel catch. The foot was strapped to the foot rest while the upper leg was strapped just above the knee to keep the muscle group being tested isolated from any interference from other muscle groups.

This machine measures the muscle power output in Watts made by the gastrocnemius and soleus muscles of the lower left leg during plantar flexion and dorsiflexion at two different intervals using two different resistance settings: 120 deg/sec (10 reps) and 60 deg/sec (5 reps). There was a trial run made between each setting for the subject to test the amount of resistance before the measurement. A ten-second rest period was set between the two tests. The result of the second test was recorded as the official measurement of muscle power output. To control the setting, the same operator performed the test and the same directions and settings were used for each individual tested**.**

Data Management & Analysis

Once the forms were completed, the signature page was removed, preventing any data collected from being traced back to the individual participants. The measurements were entered into the analysis program SPSS version 14 (Chicago, IL). Accuracy of data entry was instituted by the confirmation of two committee members. Means, standard deviations and t-tests were used to verify normal distribution of the data and to analyze demographic and risk assessment data. SPSS version 14 was used for database construction and analysis of results. Pearson's correlation coefficient was utilized to identify associations between BMI, MP, and BMD as well as to explore association between the demographic and risk assessment data collected. Study data was stored on a CD-R disc and stored in a locked cabinet.

Human Rights & Ethical Considerations

The researcher completed the NIH Human Participants Protection Education for Research Teams online training course (Appendix G). Information for protecting the identity, ethical issues, participant's rights, ability to refuse to participate and minimizing risks were fully evaluated to meet and exceed the requirements set out by the researcher and study committee according to IRB requirements.

Ethical considerations including risk factors, benefits, language, readability of forms and procedures were assessed and approved by the study committee consisting of four members. Risks were minimized, with a total of less than one hour out of a the participant's normal scheduled day. The highest risk anticipated and explained was a burning sensation possibly felt in the shin after isokinetic measures, however, no subjects reported this experience. Injury was not anticipated nor observed since the isokinetic machine does not allow the subject to dorsiflex or plantarflex beyond the subject's capabilities. Use of the standard protocols for study measurements by experienced staff members provided further safety and protection of participants.

Chapter III

Improving the Identification of Osteopenia: The Relationship between

Muscle Power, Body Mass Index and Bone Mass Density.

Abstract

Nurse Practitioners (NPs) play a large role in preventive healthcare especially as it relates to low bone mass density (LBMD). With 44 million people affected by osteoporosis in the United States and two million annual hospitalizations for osteoporosis-related fractures, identifying a more cost effective way to assess and predict low bone mass density (LBMD) before fractures occur is vital for optimal health.

This study was conducted to examine the relationship between muscle power (MP) and bone mass density (BMD) and explore the use of MP according to body mass index (BMI) as a means of identifying LBMD. A prospective descriptive design was used to explore these variables among seventeen female volunteers between the ages of 30 – 65 years. Anthropometric measurements were recorded for each participant along with BMI, MP of the calf muscles, and BMD of the calcaneus.

The results demonstrate a moderately significant correlation between BMD with MP ($r = .541$) and BMI ($r = .581$) using a two-tailed Pearson's correlation coefficient test set at 0.05 level. Weight (x) MP (+) Newton's however was found to be highly correlated with BMD ($r = .791$) using a two-tailed Pearson's correlation coefficient test ($p < 0.0001$).

The strong relationship between MP and BMD suggests that it may have potential clinical utility for predicting BMD. Further exploration of the predictive power of MP in various ethnic/racial populations as well as different age groups is warranted.

Future research may benefit by focusing on sex, age, and weight distributions to determine accurate prediction models. Using this approach, clinicians could access empirical data to assist in the identification of LBMD in the clinical setting. This approach is consistent with the preventative nature of advanced nursing practice and has the capacity to avoid unnecessary diagnostic testing and preserve millions of healthcare dollars. Study findings may help to direct future research in the use of MP as a clinical tool for identifying those at risk of LBMD and osteoporosis.

Introduction

Predicting low bone mass density (LBMD) is the key for preventing severe LBMD or osteoporosis from occurring. Bone and muscle adapt to influences of the environment. Bone mass density (BMD) is a dynamic phenomenon influenced by mechanical loading on the bone by muscle power. If the mechanical load does not reach a certain set point or threshold on a regular basis, resorption takes place, removing bone until the threshold is met. If the load on bone continues to exceed the threshold, then bone remodels by adding to it, making it stronger (Bubanj & Obradovic, 2002; Bamman et al., 2001; Hernandez, Beapre, & Carter, 2000; Scheibl & Willnecker, n.d.).

There is an invisible threshold that exists when bone is in a state of equilibrium or harmony with itself and its environment. At this point, very little resorption and remodeling are taking place and three events can be observed and measured.

1. The minimum and maximum amount of mechanical load by muscle prevents bone from resorption (breaking down) and prevents bone from remodeling (building up).

2. Height and weight plateau.

3. The body is at its peak bone mass density around the age of 18 years old in women and 20 in men (National Institutes of Health [NIH], 2007).

After the peak BMD has been reached, it will begin to decrease, for some people much faster than others. Theoretically, a normal BMD may be presumed if a person is reaching MP threshold and has a body mass index (BMI) in the target range. Subsequently, considering MP based on BMI may provide a more accurate measure of BMD.

Hypothetically, if a person produces the MP consistently after peak BMD has been reached, then LBMD will not occur in that area of the bone where the muscle attaches or interacts. If a person did have LBMD, then normal parameters of mechanical load would be affected with lower power scores observed.

Review of Literature

Researchers have tried to find ways of predicting BMD or bone mineral content (BMC) using muscle strength. One such study used grip strength, arm span, and muscle length to identify correlations with BMC using a sample of 63 healthy, post-menopausal women (Sinaki et al., 1988). They found that the bone mineral content divided by its diameter did show some relation with grip strength ($r=0.46$, $p < 0.001$). They serendipitously found that the relationship between grip strength and arm span was significantly positive with BMD ($r=0.47$, $p < 0.001$). However, the researchers concluded that the tool could not be used for accurately predicting bone mineral content in a clinical setting as the study focused only on a healthy, post-menopausal sample.

In a separate two-group comparison study, Demet, Feyza, & Gulseren (2004) examined the relationships between age, arm span, height, BMD, weight, and BMI among 70 young and 70 older women. The study revealed that the femur neck T-scores had a significant positive relationship with BMI ($r=0.29$, $p= 0.01$) and weight ($r=0.34$, $p= 0.04$). It further showed that height ($r = -0.26$, $p= 0.02$) and arm span ($r = -0.22$, $p=0.05$) decreased with age while an increase in age ($r = 0.3$, $p=0.02$) and loss in BMD ($r = -0.36$, $p= 0.02$) was associated with vertebral fractures. This study supports the association between BMI and BMD, variables that will be measured in the proposed study. In addition, the relationship between MP, BMI and BMD will be explored.

Iki et al. (2006) tested the use of trunk muscle strength to predict bone loss in post-menopausal women. In this four year study, isokinetic concentric and accentric peak torques of the trunk flexor and extensor muscles were measures and compared with bone mineral density of the spine to determine annual change in 109 women. The results demonstrated an association between exercising regularly and an increasing BMD over time ($p=0.05$). Trunk extensors peak torque ($p=0.0006$) and trunk flexors peak torque ($p=0.0008$) had the most positive relationship with BMD. A positive correlation was found between muscle strength and bone loss when adjustments were made for age, height and weight and BMD initially ($p=< 0.05$). As an observation, the isokinetic machine can be used to link muscle power with BMD even though different muscles will be tested in the proposed study. Iki et al. (2006) demonstrated the utility of monitoring muscle strength over time in post-menopausal women, however, study results cannot be generalized to other populations.

Fifty-four adolescent girls were studied to predict BMD and BMC by using lean body mass, leg power and leg strength (Witzke, & Snow, 1999). Body fat, leg strength, leg power, height, weight, physical activity and menstrual status were correlated in combinations to find relationships. Results found that leg power ($r=0.41 – 0.67$; $p=0.001$) and lean mass at all sites ($r=0.45 – 0.77$; $p= 0.001$) were the most correlated with BMD, whereas the others were not. When BMC and height were compared against the variables, height had the highest correlation among the rest of the variables. The study suggests that leg power measurements and two components of BMI (height and lean muscle mass) have positive associations with BMD, further supporting the measurements needed for the proposed study.

Maeda, Oowatashi, Kiyama, Yoshida, and Sakae (2001) studied 18 women to evaluate the prediction of muscle strength from bone length and width. The radial, ulnar, humerus, fibula, tibia and femur were measured. Grip strength was measured with a dynamometer. Force and torque of knee extension and flexion were measured in a sitting position. Muscle strength was estimated from length, width and height of each bone. The finding showed a significant correlation for the prediction of grip strength 0.90 ($p < 0.01$) and knee strength 0.84 ($p < 0.01$) from bone length and width in the areas measured. The researchers concluded that since muscle strength measures were analyzed only in the lower extremities, the findings were inconclusive and may not be generalizable due to the study population characteristics. The proposed study will use a sample of women between the ages of 30-65 years, and will measure related variables, such as menstruation status, smoking, and activity, to increase the internal validity.

Bone and muscles respond well to exercise, even in people with many risk factors for LBMD. After a one year study using a light exercise program in which weighted vests were used, 23 women and 1 man showed a small increase in the BMD of the femoral neck (1.0%), spine (1.0%) and hips (1.3%) (Slawta & Ross, 2004). Snow, Shaw, Winters, and Witzke, (2000) performed a five-year, randomized, controlled trial among eighteen post-menopausal women, using exercise with weighted vests. The results showed a plateau in BMD for exercise participants in the femoral neck (0.633 - 0.641), trochanter (0.583 – 0.581) and total hip (0.750 and 0.744) at five years, while controls decreased in BMD over time in the femoral neck (0.688 - 0.657), trochanter (0.645 – 0.622) and total hip (0.803 – 0.772). The exercisers were using muscle demanding exercises, three days per week with eleven pounds in the vest.

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Suominen (2006) and Veracity (2005) both found that while aerobic exercise has shown good results in overall health, muscle resistance exercises are more effective toward combating LBMD. Several studies have reported that with a decrease in activity or weightlessness, a decrease in BMD is found (Bubanj & Obradovic, 2002; Conroy et al., 1993; Slemenda et al., 1991; Snow-Harter et al., 1992; Stewart et al., 2002; Suominen, 2006). In studies that show relationships between influences such as diabetes and medications, like glucocorticoids, with LBMD, it is highly recommend that exercise be one of the interventions used to decrease bone loss (Chau & Edelman, 2002; Summey & Yosipovitch, 2006).

The studies to date have identified some biophysical measures, such as BMI, weight, lean muscle mass, and extremity length, that correlate with BMD. However, the generalizability of the study findings has been limited due to the sample characteristics. This study will use a community-dwelling sample of women, between the ages of 30-65, and will measure similar variables identified in the literature review. Using lower extremity muscle power (MP), bone length and BMI, relationships between BMD, measured in the calcaneous with a peripheral instantaneous x-ray imaging (PIXI) scan, will be explored. The study results will provide preliminary data to assess the influence of other factors, such as age, menstrual status, smoking status, alcohol consumption and medications, on the relationship between the main study variables.

As advanced practical nurses, our role in patient care is to look for ways to enhance preventative health, apply safer and less-costly methods for identifying those at risk of LBMD, and use modifiable risk factors to improve health and empower the patients to take control of their own well being. This study was designed to observe and report possible ways of predicting BMD in order to find a more reliable and inexpensive means for assessing, predicting, diagnosing and treating LBMD in the clinical setting.

Methods

The dependant variable in this study was BMD of the calcaneus. The independent variables were MP, BMI, REE, age, height, weight, lever measurements while education level, marital status, alcohol intake, exercise and menopausal status, co-morbid diseases and medications associated with osteoporosis were co-variables. This study used a prospective, descriptive design among a convenience sample of community-dwelling females, ages 30 – 65 years old.

Sample

This study focused on women as they are generally at higher risk for LBMD in age, gender and race. Inclusion criteria consisted of Caucasian female gender, between the ages of thirty and sixty-five years old without the diagnosis of osteoporosis. Due to the preliminary stage of the study there were no exclusion criteria. Factors known to affect LBMD were collected (See Table 1 for Descriptive statistics).

A convenience sample of 40 volunteer community dwelling non-Hispanic, Caucasian women, between the ages of thirty and sixty-five years old, living in Washington State were asked to participate in the study. Seventeen women completed the data gathering process. Potential participants stated that timing was a major factor in not completing the data collecting process.

Procedures

After obtaining approval through the Institutional Review Board at Washington State University, women were approached by the researcher to determine their interest in study participation. After explaining the study and answering questions, interested participants were asked to read and sign the consent form (Appendix A), demographic form (Appendix B), and complete the risk assessment questionnaire (Appendix C). Together, the forms take less than 10 minutes to complete. Participants were then asked to drive to the Women's Health Care Center for measurements of height, weight, lever measurements, and to obtain a peripheral instantaneous x-ray imaging (PIXI) scan. After completion of the scan, the participant was asked to drive to a physical therapy clinic, where muscle power measures were obtained. Following these measures, the researcher thanked the participant for their time and participation. This concluded the activities of the participant in the study.

Materials

Demographics form. The Demographic form was produced to obtain possible subjective risk factors for LBMD to include date of birth, yearly income, routine medications, and known medical diagnoses.

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Risk assessment survey. The LBMD risk assessment survey was borrowed and modified with permission from the New York Department of Health: Osteoporosis Prevention & Education Program (NYSOPEP). It includes specific medical diagnoses, specific medications used on a daily basis that are known to affect BMD, amount of exercise (intensity, duration and frequency), smoking, alcohol use, and menopausal status. It was designed to be read at a six to eighth grade reading level. A weakness of this form is that the data collected is subjective. This information obtained from the survey however was used to track possible risk factors, severity and influence on LBMD.

Body mass index. Height and weight were measured with light clothing on and shoes removed standing on a Detecto model 448 Beam scale made in the USA. The same scale was used for each individual by the same researcher and was calibrated daily using a five pound weight. BMI was then calculated by using the NHLBI (2000) formula: weight in pounds divided by height in inches squared x 703,

Resting energy expenditure. Resting energy expenditure was calculated from height, weight and age using the Harris-Benedict equation for women: REE = 655.1 + (9.563 X weight) + (1.850 X height) – (4.676 X age).

Lever measurements. Lever measurements from the foot (Appendix D) and fibula bone lengths were obtained using a yard stick. The foot was measured from the tip of the longest toe to the most posterior edge of the heel; from the fulcrum or ball of foot to the most posterior edge of the heel; from the load or at the center of the lateral malleolus to the effort or where the calf muscles attach at the most posterior edge of the heel and from the floor to the joint line of the knee.

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Bone mass density. The calf muscles taper down to form the achilles tendon and attach at the posterior portion of the calcaneus bone in the back of the foot. Due to the prime location, this is where the BMD was measured by a peripheral instantaneous x-ray imaging (PIXI) scan machine manufactured by the Lunar Company in Madison Wisconsin (Appendix F). This machine uses x-ray technology at low doses to examine the amount of bone matrix present in bone. It uses a T-score based on normal BMD results from healthy individuals who are at their peak BMD. A standard deviation of plus or minus 1 is considered normal. A person with -1 to -2.5 would have low BMD and a person with - 2.5 or more would be considered having severe low BMD (Lewiecki & Borges, 2006). The machine is calibrated and tested daily for accuracy. Privacy and repeated experience for each subject are the most important aspect to control in this setting due to the sharing of results with the subjects, therefore each subject was tested by the same qualified researcher behind closed doors, using the same protocol for each. The subject was seated for less than five minutes in a comfortable chair while the left foot and heel were placed into the machine without a sock.

Muscle power. Measurement of MP was determined using a Biodex isokinetic machine manufactured in Shelley, New York (Appendix E). For less than ten minutes, the subjects were seated in a chair with a slight incline of the back for comfort. The left leg was raised until the lower leg was level with the ground and the foot was placed into a foot rest with a heel catch. The foot was strapped to the foot rest while the upper leg was strapped just above the knee to keep the muscle group being tested isolated from any interference from other muscle groups.

This machine measures the muscle power output in Watts made by the gastrocnemius and soleus muscles of the lower left leg during plantar flexion and dorsiflexion at two different intervals using two different resistance settings: 120 deg/sec (10 reps) and 60 deg/sec (5 reps). There was a trial run made between each setting for the subject to test the amount of resistance before the measurement. A ten-second rest period was set between the two tests. The result of the second test was recorded as the official measurement of muscle power output. To control the setting, the same operator performed the test and the same directions and settings were used for each individual tested**.**

Data Management & Analysis

Once the forms were completed, the signature page was removed, preventing any data collected from being traced back to the individual participants. The measurements were entered into the analysis program SPSS version 14 (Chicago, IL). Accuracy of data entry was instituted by the confirmation of two committee members. Means, standard deviations and t-tests were used to verify normal distribution of the data and to analyze demographic and risk assessment data. SPSS version 14 was used for database construction and analysis of results. Pearson's correlation coefficient was utilized to identify associations between BMI, MP, and BMD as well as to explore association between the demographic and risk assessment data collected. Study data was stored on a CD-R disc and stored in a locked cabinet.

Results

Mean and standard deviations are shown in Table 1. The youngest female was 31 years old; the oldest was 64, with a mean age of 46. Out of the 17 women, 29% were never married, 59% were married, and 12% divorced. For annual family income, 35% reported between $30,000 and $39,999; 18% between $40,000 and $49,999, 35% between $50,000 and $74,999 and the 12% remaining reported earnings in excess of $75,000. Regarding smoking status, 88% had never smoked before and 12% had a long history of smoking equal to or less than one pack of cigarettes per day for more than five years. Alcohol consumption was measured by asking the average amount of alcoholic drinks consumed per week. Of the sample, 52% reported drinking equal to or less than one alcoholic drink per week; 18% had more than one but less than three per week, 12% drank three to six, and 18% drank more than 6 alcoholic beverages per week. Assessment of exercise patterns revealed that 29% of the women had a long history of less than 60 minutes per week, while 53% completed between 60 – 120 minutes and 18% accomplish between 120 - 180 minutes of exercise per week.

BMD ranged from -1.2 to 2.2 with a mean of .000. Mean MP was 29.853 with a range from 16.8 to 46.0 Watts. Resting Energy Expenditure mean was 1499.82 with a range from 1192 to 1986. BMI had a range from 20.4 to 49.8 with a mean of 30.85. According to the participant's current working diagnoses (Table 2) and medication list (Table 3), the sample had numerous medical conditions.

Moderate to high significant correlations were found between BMI, MP and BMD as seen in Table 4. Other significant correlations between BMD and anthropometric measurements to report were height (r = .521, p= .039), weight (r = .717, p= .001) and REE (r= .728, p= .001) while height correlates with Tib/Fib length (r =.532, p= 0.034) and weight correlating with foot length (r =.553, p= 0.026). Formulas that were unexpectedly significant in correlating with BMD were weight (x) MP (r=.784, p=0.0001) and weight (x) MP (+) Newton's (r=.791, p= 0.0001) using a 2-tailed Pearson's correlation coefficient test set at 0.05.

Discussion & Limitations

The purpose of this study was to explore the relationship between MP based on BMI, and BMD. In this study, weight multiplied by MP plus Newton's was found to be highly correlated with BMD (Table 4). The results demonstrate a moderately significant correlation between MP and BMD (r = .541*) using a two-tailed Pearson's correlation coefficient test set at 0.05 level. Low MP scores were observed with lower BMD results and higher MP scores were observed with higher BMD results as hypothesized. Further investigations are warranted for the use of MP according to BMI as a BMD predicting tool.

A moderately significant correlation between BMI and BMD (r = .581) and a highly significant correlation between REE and BMD (r= .728) was found using a two-tailed Pearson's correlation coefficient test. This finding is consistent with past studies (Bedogni et al., (2002); van der Voort, Brandon, Dinant and van Wersch (2000) which have supported the argument that weight alone is a better indicator of BMC and BMD than those measures including body composition, height and age combined.

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The self-reported subjective data, including age, highest grade level, exercise, alcohol, smoking, menopause, psychological status, co-morbidities, and medication use, had no correlation with BMI, MP or BMD and were not included in further analyses due to insufficient relationships ($r < .50$). Married status, however, did show a significant negative correlation with MP ($r = -.661$** $p= 0.05$). The lack of significant correlations between demographic data and BMD was most likely due to the small number of participants. A larger population is required to test the identified relationships and the influence of the covariates on these relationships using a larger sample. For instance, Law and Hackshaw (1997) demonstrated the relationship between smoking and decreased BMD in a meta-analysis comprised of 29 studies.

Sport and home physical therapy have independently been associated with BMD as seen in a study where Greendale, Huang, Wang, Finkelstein, Danielson and Steernfeld (2003) found that higher sport activity was significantly correlated with BMD at the spine ($P= 0.0008$), femoral neck ($P=0.0002$) and total hip ($P < 0.0001$). Home physical activity was correlated with higher BMD of the spine and femoral neck, whereas physical activity at work or activities of daily living was not correlated to BMD. Although the authors recommend identifying the type of physical activity performed by the client, measuring MP could be a more accurate indicator regardless of type of exercise.

According to Brunader and Shelton (2002), calcaneal examination should be used as a screening source when risk for osteoporosis is low or unknown. To prevent fractures, BMD should be performed on the most reported sites known to fracture, such as the hips and spine. These areas of interest would have been ideal for use in this study but are difficult to isolate due to the numerous muscle groups and bones involved.

Conclusion

It is crucial for practitioners to accurately identify those at highest risk for LBMD among a vulnerable population. Women are known to enter menopause at different ages. Menopausal women fall between normal to severe LBMD ranges regardless of age or menstrual status. Increasing activities at any age beyond daily living shows an increase in BMD despite some risk factors, therefore identifying a measure that is not affected by age or menopausal status, such as weight (x) MP (+) Newton's, may increase reliability among these high risk groups.

As advanced practice nurses, our role in patient care is to look for ways to enhance preventative health, apply safer and less-costly methods for identifying those at risk of LBMD, and use modifiable risk factors to improve health and empower the patient/family to take control of their own well-being. This study examined the relationship between MP and BMD and explored the use of MP according to body mass index (BMI) as a means of identifying LBMD. Significant correlations between MP and BMD were found, warranting further exploration using a larger sample size with the inclusion of various ages, and ethnic/racial groups.

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Appendix A

WASHINGTON STATE UNIVERSITY
CONSENT FORM
Predicting Bone Mineral Density using Muscle Power and Bone length

Researchers:

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a copy of this form for your records.

PURPOSE AND BENEFITS

You have been asked to participate in this research study because you are already scheduled for a Bone Mineral Density scan of your hips, spine, wrists and/or heels. The results of the bone mineral density scan will be compared to the muscle strength and bone length for comparisons and similarities for predicting bone mineral density. Participants must be female, between 30-60 years of age and cannot be taking medications for or having conditions that affect bone density. The study is being performed on a total of 40 individuals in the Spokane area. You will likely receive no direct benefit from taking part in this research study. The findings however may be used for development of a less-expensive, convenient and easily administered tool for assessing the risk of low bone mineral density.

PROCEDURES

You will be asked to complete a demographics form and undergo your pre-scheduled DEXA scan. The researcher will obtain a copy of your DEXA scan results (without your name, medical record number or any other identification

information). After completion of your DEXA scan, you will be asked to go to Star Physical Therapy office at 601 W. 5th Avenue, Spokane WA, 99223. The total amount of time that will be asked of you is no more than 1 hour, from start to finish.

1. A measurement from the ball of your foot to the end of your heel will be taken by a measuring stick. This will give the length of the lever or bone (s) which make up the distance from the fulcrum (ball of foot) to the attachment of the effort (Achilles tendon). This procedure takes approximately 5 minutes.

2. A test of the calf muscle strength and power output will be obtained by an isokinetic measurement machine where the participant will sit up in a comfortable chair and one leg at a time will be tested. One leg will be raised into a stirrup and the operator will ask you to push the toes forward and then pull them back towards you as fast and as hard as you can with some resistance from the machine. There will be a 15 rep, 10 rep and 5 rep exercise with 3 different intensities. The procedure takes approximately 20 – 30 minutes.

After completion of these tests you may leave the facility and have fulfilled your participation in the study.

RISKS, STRESS, OR DISCOMFORT

The possible risks of this research study may include a burning sensation in the shin directly after the exercises but quickly dissipates over the next several minutes. The muscles may feel slightly tired from the exercise and this as well dissipates within minutes. There is a minimal risk of muscle/ligament strain of the calf, however, if you do experience ongoing symptoms, you will be evaluated by Dr. Starkweather.

OTHER INFORMATION

Participants may refuse to participate or may withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. "If you are injured as a direct result of study procedures, you will be cared for by a member of the investigating team.

_Shayne Blevins_____

Printed name of researcher   Signature of researcher   Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have general questions about the research, I can ask one of the researchers listed above. If I have questions regarding my rights as a participant, I can call the WSU Institutional Review Board at (509)335-9661. This project has been reviewed and approved for human participation by the WSU IRB. I will receive a copy of this consent form.

_____

Printed name of subject   Signature of subject   Date

Appendix A Consent Form was developed by the author with the sample, requirements and checklist obtained from the WSU / IRB taken from the internet at: http://www.spokane.wsu.edu/research&service/HREC/IRB/#Investigator's%20Packets for development of this document.

Appendix B

DEMOGRAPHIC QUESTIONNAIRE

The following questions will provide us with information about you and your background. Please answer each question by filling in the blanks or by circling the correct answer. If you so wish, you may refrain from answering any questions.

Thank you.

1.   **Birth date_____**

2.   **Marital status (check one)**

                        _____Single   _____Married
                        _____Separated   _____Divorced
                        _____Widowed

3.   **Ethnicity**
                   _____White (non-Hispanic)   _____Black (non-Hispanic)
                   _____Hispanic/Latino   _____Asian/Pacific Islander
                   _____American Indian or Alaskan Native

4.   **What is the highest grade that you completed in school?**
                   _____years

5.   **Total yearly income in you household from all sources before taxes.**
                   ____Less than $10,000
                   ____$10,000-19,999
                   ____$20,000-29,999
                   ____$30,000-39,000
                   ____$40,000-49,999
                   ____$50,000-74,999
                   ____More than $75,000

6.   **Do you use tobacco?**
                        yes____ no_____

          If yes, for how long? _____years

7.   **Describe any illnesses you have had in the past month? _____**

        _____

        _____

8.   Please list any chronic health problems that you have been diagnosed

        with (hypertension, diabetes, congestive heart failure,

        etc.)._____

        _____

        _____

9.   What medications do you take on a regular

        basis?_____

        _____

        _____

        _____

        _____

        _____

10.   We will measure your height and weight next.

        Height_____   Weight_____   BMI_____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE.

Appendix C

Check if you...   Case Number_____

How old are you today?_____

What is your Birth Date? _____ (ex: 09/08/1971)

☐ ☐	• **are less than 30 years old or greater than 60** • **are currently or could be pregnant**
☐	• **weigh less than 127 lbs (low weight)**
☐ ☐ ☐	• **have any relatives who have/had osteoporosis (broken bone of the wrist, hip, leg or spine occurring without major trauma** • **a height loss of more than 1-1/2 inches** • **a stooped back**
☐	• **have a personal history of fractures (broken bones) during adulthood (without trauma, such as a car accident or severe sports injury)**
☐	• **have previous fractures of the spine or x-ray evidence of bone loss**
☐ ☐ ☐	• **have a temporary loss of monthly periods for more than 12 consecutive months or infrequent periods for several years (excluding pregnancy).** • **Are post menopausal** • **have had early or surgically induced menopause**
	have any of the following chronic diseases/conditions often associated with osteoporosis:
	☐ **AIDS** ☐ **Cancer**
	☐ **Chronic lung disease** ☐ **Chronic Renal Failure**
	☐ **Diabetes, Type I** ☐ **Diabetes, Type II**
	☐ **Eating disorders (anorexia, bulimia)**
	☐ **Hyperparathyroidism (excessive parathyroid hormone)**
	☐ **Hyperthyroidism (excessive thyroid hormone)**
	☐ **Inflammatory bowel disease**
	☐ **Kidney disease**
	☐ **Liver disease**
	☐ **Lupus**

	☐	Malabsorption (from celiac sprue or other gastrointestinal disorders)
	☐	Neurological diseases (such as stroke and multiple sclerosis)
	☐	Rheumatoid arthritis
☐		have a history of bed rest or immobility for more than 6 months
☐ ☐ ☐ ☐ ☐ ☐		are taking or have taken any of the following medications:* • Vitamin D • Biphosphonates: Fosamax (alendronate), Actonel (risedronate sodium) • Evista (raloxifene) • Miacalcin (calcitonin) • Hormone Replacement Therapy: Estradiol, Estrogen, Testosterone
	☐	Blood thinning agents when necessary for chronic use (such as long-term use of Coumadin or Heparin)
	☐	Chemotherapy
	☐	Dilantin (Phenytoin), and some other drugs used to treat seizure disorder or depression
	☐	Gonadotropin-releasing hormone analogues (Lupron and Zoladex) used to treat endometriosis
	☐	Immunosuppressants (such as methotrexate or cyclosporin)
	☐	Steroids (such as prednisone or cortisone) used for more than 3-6 months to treat asthma, arthritis or other diseases
	☐	Thyroid medications, taken in high dosages, or lack of routine blood tests for TSH-level monitoring
☐		have had a lifelong history of low calcium intake (few, if any, dairy products with no calcium supplements)
☐ ☐ ☐		• (1) have a lifelong history of little exercise (less than 60 minutes per week) Circle the one that applies to you (walking, aerobic exercise or weight training) • (2) Walking, (3) aerobic exercise or (4)weight training more than 60 minutes per week but less than 120 minutes per week • (5) Walking, (6) aerobic exercise or (7) weight training more than 120 minutes per week but less than 180 minutes per week

☐	• (8) Walking, (9) aerobic exercise or (10)weight training more than 180 minutes per week
☐ ☐	(11) do not smoke (12) have a history of long-term smoking (more than 1 pack a day for more than 5 years) (13) smoke 2 or more packs a day for more than 5 years
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	(14) consume less than 1 alcoholic beverage per week (15) Consume more than 1 and less than 3 alcoholic beverages per week (16) Consume more than 3 and less than 6 alcoholic beverages per week (17) Consume more than 6 alcoholic beverages per week (18) have a history of alcohol abuse (19) are you Caucasian (20) Hispanic (21) Asian (22) African American

(Appendix C) was taken and modified with permission from the New York Department of Health: Osteoporosis Prevention & Education Program (NYSOPEP). Taken from http://www.nysopep.org/page.lfm/40. For purposes of this study, exclusion would be indicated by agreement of consuming any of the medications and having any of the diseases or conditions listed above that affect BMD. Other factors with numbers 1 – 22 will be monitored and used in analysis for comparison and relationships.

Appendix D

Class 1 Lever   Class 2 Lever   Class 3 Lever
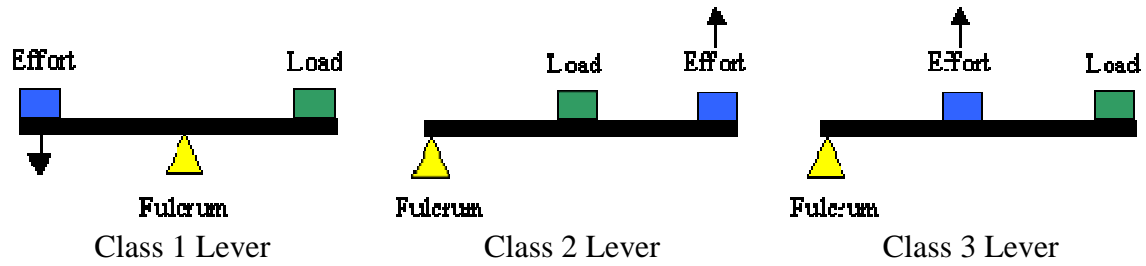
(Appendix D) Is an example of the lever system as it relates to the human body for movement and lifting. In the second class lever, the fulcrum would represent the ball of the foot, the load would be the weight of the body pushing down through the tibia and fibula onto the mid bones of the foot, and the effort would be the calf muscles contracting lifting the heel up off the floor.

Appendix E

(Appendix E) A picture of the Biodex isokinetic machine used for muscle power measurements, and example of foot and leg placement during procedure..

Appendix F
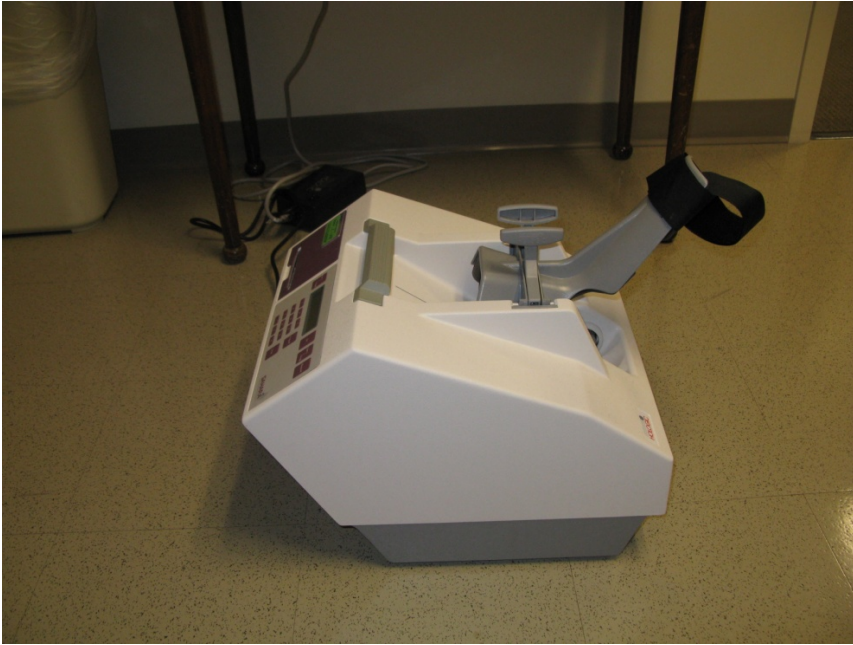
(Appendix F) is a picture of the PIXI scanner used for the calcaneus BMD measurements

Appendix G

Completion Certificate

This is to certify that

Shayne Blevins

has completed the **Human Participants Protection Education for Research Teams** online course, sponsored by the National Institutes of Health (NIH), on 01/17/2007.

This course included the following:

- key historical events and current issues that impact guidelines and legislation on human participant protection in research.
- ethical principles and guidelines that should assist in resolving the ethical issues inherent in the conduct of research with human participants.
- the use of key ethical principles and federal regulations to protect human participants at various stages in the research process.
- a description of guidelines for the protection of special populations in research.
- a definition of informed consent and components necessary for a valid consent.
- a description of the role of the IRB in the research process.
- the roles, responsibilities, and interactions of federal agencies, institutions, and researchers in conducting research with human participants.

National Institutes of Health
http://www.nih.gov

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Table 1

Table 1: Descriptive Statistics (N=16)

(N=17)	Minimum	Maximum	Mean	Standard Deviation
Age	31	64	46.18	9.174
Body Mass Index	20.4	49.8	30.859	8.8886
Muscle Power	16.8	46.0	29.853	9.4166
Bone Mass Density	-1.2	2.2	.000	.9663
Weight	110	295	177.9706	49.03585
Height	59.5	68.5	63.4559	2.64757
Foot Length	8	10.25	9.2647	.52642
Fib/Tib length	16.50	21	17.9706	1.14183
Highest Grade Level	11.50	16	13.0294	1.23073
Resting Energy Expenditure	1192	1986	1499.82	225.937

Table 2

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Table 2: Current working diagnoses

Insomnia	1
Depression	3
Bipolar	2
Hypertension	5
Hypercholesterolemia	3
Post menopausal	5
Surgical induced menopause	3
Diabetes Type II	3
Celiac Disease	1
GERD	1
Hyperthyroidism	2
Myocardial Infarction	1
Chronic Back Pain	1

Table 2 represents the number of participants in the study who have voluntarily acknowledged having been diagnosed with the corresponding illnesses.

Table 3

Table 3: Current Medication List

Abilify	1	Lisinipril	1
Ambien	2	Lovastatin	1
Asprin	1	Lexapro	1
Atenolol	1	Metformin	1
Bio Identical Estrogen	1	Multi Vitamin	2
Calcium	3	Norvasc	1
Cymbalta	1	Oxycontin	1
Depakote ES	1	Percocet	1
Effexor	1	Prilosec	1
Fish Oil	1	Soma	1
Geodon	1	Synthroid	2
Glyburide	1	Tramadol	1
Herbal Diuretic	1	Tums	1
Hormone Replacement Therapy	7	Vitamin D	1
HCTZ	1	Vytorin	1
Hyzaar	1	Zocor	1
Insulin	3		

Table 3 represents the number of people who have voluntarily listed medications currently taking at the time of the study.

Table 4

Table 4: Pearson's Correlation (N=17)

	BMI	MP	BMD	REE	W*MP	W*M+N
BMI PC	1	.144	.581*	.926**	.673**	.706***
Sig. (2-tailed)		.582	.014	.000	.003	.000
MP PC	.144	1	.541*	.295	.791***	.761***
Sig. (2-tailed)	.582		.025	.250	.000	.000
BMD PC	.581*	.541*	1	.728	.784***	.791***
Sig. (2-tailed)	.014	.025		.001	.000	.000
REE PC	.926**	.295	.728**	1	.632**	.829***
Sig (2-tailed)	.000	.250	.001		.006	.000
W*MP PC	.673**	.791**	.784**	.632**	1	.999***
Sig (2-tailed)	.003	.000	.000	.006		.000
W*M+N PC	.706***	.761***	.791***	.829***	.999***	1
Sig (2-tailed)	.000	.000	.000	.000	.000	

***. Correlation is significant at the 0.0001 level (2-tailed) test

**. Correlation is significant at the 0.001 level (2-tailed) test

 *. Correlation is significant at the 0.05 level (2-tailed) test

BMI= Body Mass Index   W*MP= Weight * Muscle Power

MP= Muscle Power   W*MP+N= Weight * MP + Newton's

BMD= Bone Mass Density   PC= Pearson's Correlation

REE= Resting Energy Expenditure