ABSTRACT

THE EFFECT OF DYNAMIC STANDING ON THE BONE MINERAL DENSITY OF NON-AMBULATORY CHILDREN: A PILOT STUDY

by
Megan Diane Damcott

In recent decades, research in osteoporosis has expanded to include the effects of prolonged immobilization on the load-bearing bones of non-ambulatory children. One current therapeutic intervention for this population is a passive standing program, in which the body is fully supported and continuous, stationary loading is applied to the bones, leading to the legs being primarily inactive. This research focused upon the effect of passive standing and a new therapeutic intervention of dynamic standing, a standing therapy in which the body is supported but vertical, reciprocal displacements which mimic the walking gait are applied to the feet, causing the muscles to activate. An initial pilot study has been conducted to test the feasibility and usability of the dynamic stander in the clinical and educational settings, as well as to allow refinement of the study protocol for a 12-month study with additional subjects. Two subjects were stood, one in a passive stander and one in a dynamic stander, for 13 weeks. Pre- and post-dual energy x-ray absorptiometry (DXA) scans were completed to investigate the impact of the standing interventions on bone mineral density (BMD). The use of the dynamic stander was determined to be feasible in the clinical and educational settings with minimal modifications. The use of the supine position to obtain DXA scans was determined to be inappropriate for the population of interest and therefore the lateral, distal femoral DXA procedure must be adapted for subsequent studies as it is the current 'gold standard' for positioning non-ambulatory children.

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by

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THE EFFECT OF DYNAMIC STANDING ON THE BONE MINERAL DENSITY OF NON-AMBULATORY CHILDREN: A PILOT STUDY

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To my mother, father, brother and sister.
Without your continued love and support,
I could not have accomplished all I have.

I also dedicate my thesis to all the children with
orthopedic disabilities. Their love, innocence and hearts are a
continued motivation in my work every day.

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CHAPTER 1

INTRODUCTION

1.1 Objective

In recent decades, research in osteoporosis has expanded to include the effects of prolonged immobilization on the load-bearing bones of non-ambulatory children. One current therapeutic intervention for this population is a passive standing program, in which the body is fully supported and continuous, stationary loading is applied to the bones, leading to the legs being primarily inactive. This document further investigates the effect of passive standing, as well as focusing on a new therapeutic intervention of dynamic standing, a standing therapy in which the body is supported but vertical displacements are applied to the feet, causing the muscles to activate. The dynamic stander discussed in later pages is designed to provide reciprocal loading, mimicking the walking gait, to the limbs of non-ambulatory children. The dynamic component is adaptable to fit in current commercially available passive standers. An initial pilot study has been conducted to test the feasibility and usability of the dynamic stander in the hospital, clinical and school settings, as well as to allow refinement of the study protocol for a 12-month study with additional subjects.

1.2 Background

1.2.1 Bone Anatomy and Physiology

The human skeletal system is comprised of 206 bones, a hard, cartilaginous tissue. The skeletal system serves five main functions (Martin et al. 1998):

1. **Support:** The skeletal system creates a framework for the human body and soft tissues and provides an anchoring point for skeletal muscles.

2. **Protection:** The skeletal system provides protection for internal organs and soft tissues.

3. **Movement:** The skeletal system provides linkages to assist in movement at the site of muscle attachments.

4. **Hematopoietic:** Bones within the skeletal system are the major source for bone marrow. Red bone marrow is responsible for producing red blood cells, white blood cells and platelets. Yellow bone marrow stores lipids which serve as a chemical storage of energy for the body.

5. **Metabolic:** Bone is a reservoir of calcium, phosphorous and other essential mineral storage. These minerals can be released into the blood as needed to maintain homeostasis in the body.

Bones of the skeleton system may be classified into five types of bones (Martin et al. 1998, National Cancer Institute, 2008). They are:

1. **Long bones:** Bones characterized by a shaft and which are greater in length than in width. They are comprised primarily of cortical bone. (i.e., bones of the arm, leg, hand and foot).

2. **Short bones:** Bones characterized by their cube-like shape. They are comprised primarily of trabecular bone. (i.e., bones of the wrist and ankle).

3. **Flat bones:** Thin, curved bones in which two parallel layers of cortical bone surround trabecular bone. (i.e., ribs, shoulder blades, hip and cranium).

4. **Irregular bones:** Bones which do not fit the characteristics above. (i.e., vertebrae and facial).

5. **Sesamoid bones:** Bones which are embedded in tendons. (i.e., patella).

As this research focuses upon the impact of loading on the long bones, the anatomical structure of long bones will be further discussed. Figure 1.1 illustrates the gross anatomical structure of long bones.

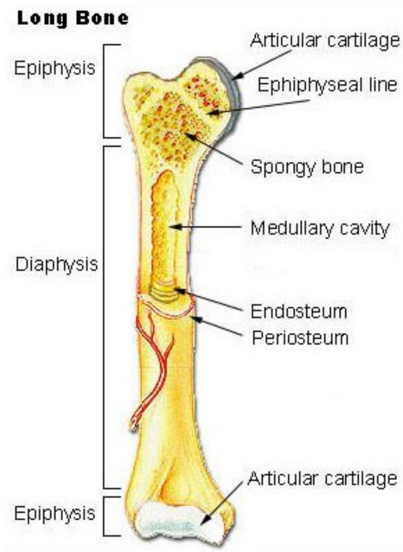

Figure 1.1. Gross anatomical structure of long bones.
Source: National Cancer Institute (2008a).

The major structural components of the long bone are:

- **Diaphysis:** The shaft of the bone. Comprised primarily of cortical bone.
- **Metaphysis:** Region of bone between the epiphysis and diaphysis where the growth plate is located. Responsible for the longitudinal growth of long bones.
- **Epiphysis:** Proximal and distal ends of the long bone. Composed primarily of trabecular bone.
- **Articular Cartilage:** Hyaline cartilage covering the epiphysis. Provides the bone with an articulation surface in the joint space.
- **Medullary Canal:** Hollow space in the diaphysis of the bone. Location of the yellow bone marrow, which is responsible for producing white blood cells, excess fat and in cases of emergency, will become red bone marrow.
- **Endosteum:** Lining of the medullary canal. Contains osteoprogenitor cells and osteoclasts.
- **Periosteum:** Outer sheathing of bone. Serves as an attachment point for ligaments and tendons. Contains blood vessels, nerves and lymphatic vessels.

Bone can be classified into two forms: cortical and trabecular. Cortical bone (also known as compact bone) is the dense bone located on the cortex of long bone and accounts for approximately 80% of the skeletal system. Trabecular bone (also known as cancellous or spongy bone) is a porous bone located in the diaphysis center and the distal and proximal ends of long bones.

The main cellular components of bone include type I collagen, hydroxyapatite, non-collagenous proteins, proteoglycans and water. Type I collagen is a triple helix backbone protein responsible for providing the high tensile strength of bone and accounting for 30% of the dry weight of bone. Hydroxyapatite accounts for 67% of the dry weight of bone and is responsible for providing the compressive strength of bone. Water comprises 60% of the wet weight of bone and is bound to the collagen.

The tensile and compressive strength of bone is fortified through its structure (Figure 1.2). Type I collagen is organized in longitudinal bundles, known as osteons. The longitudinal alignment of the type I collagen capitalizes on the tensile strength of the protein. To provide a magnitude of compressive strength, hydroxyapatite is deposited within the gaps of the collagen (Martin et al. 1998).

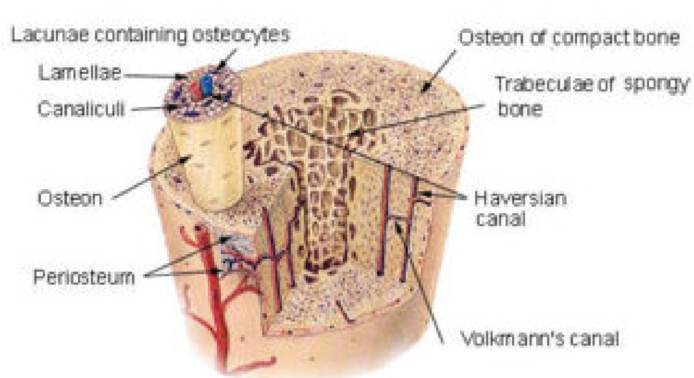

Figure 1.2. Anatomical structure of the long bone.
Source: National Cancer Institute (2008b).

Located within the osteons are Haversian canals. These canals contain the capillaries and nerves which provide the necessary blood and nutrients to the bone. Transverse canals, known as Volkman canals, connect the Haversian canals and direct blood, nerves and nutrients from the periosteum to the Haversian canals. The networks of

Haversion and Volkman canals within the bone are responsible for aiding in the signaling of osteoprogenitor cells, osteoblasts, osteoclasts and osteocytes.

Osteoprogenitor cells are a class of mesenchymal stem cells located in the bone marrow, periosteum and endosteum. These cells are unspecified and have the ability to differentiate into a number of mature cells, thereby serving as the precursors of osteoblasts (bone), chondrocytes (cartilage) or adipocytes (fat). Osteoblasts are differentiated osteoprogenitor cells responsible for the formation of bone through mineralization. Osteoblasts line the endosteum surface and deposit osteoide. The osteoide is composed of type I collagen and creates a framework upon which hydroxyapatite crystals are deposited. Once the hydroxyapatite is deposited, the osteoide mineralizes into bone tissue. As additional layers of osteoide are laid down, the osteoblasts of previous layers become trapped in the matrix and become mature osteoblasts known as osteocytes. Osteocytes amplify the strains placed on bone and distribute the resulting signals to the appropriate cells in order to maintain the anatomy of the bone. Osteoclasts are responsible for bone resorption. Osteoclasts bind to the endosteum surface and secrete proteases which dissolve the hydroxyapatite and subsequently remove the organic matrix of the bone. Mechanical and electrical stimuli created by strains placed upon the long bones are responsible for the modeling and remodeling activity of the osteoblasts and osteoclasts.

1.2.2 Bone Mechanostat

The human skeletal system is a dynamic structure constantly responding to the mechanical and electrical stimuli produced, primarily by muscles, when loads are placed upon the body. In utero, “baseline conditions” are created for each individual through gene expression. These baseline conditions are responsible for determining the initial bony anatomy and the basic neuromuscular anatomy and physiology. Gene expression also aids in establishing strain threshold levels for signaling responses in bone. These threshold levels are responsible for directing the modeling and remodeling of bone (Frost, 2004).

Due to the lever arm and gravitational effects of muscles, bone modeling and remodeling is greatest in the long bones and occurs continuously to maintain the whole bone strength. Upon loading or movement, strain drifts, primarily produced by muscle forces, are generated on the long bones. (Strain is defined as the change in length divided by the original length.) While the change in length of the bone is microscopic (less than 0.3%), the deformation is sufficient to produce fluid flow within the interstitial space and cannalicular system. The oscillating fluid flow creates strain patterns within the osteocytes, which are interconnected through gap junctions to form a three-dimensional sensing system, and the resulting cellular strains are amplified by up to 30 times their initial magnitude. The strains are then transferred back and forth between the trabecular and cortical bone (Frost 2003, 2004).

In regions where the strains exceed the threshold range, bone modeling occurs to increase the whole bone strength and enable it to withstand the applied voluntary mechanical loads (VMLs or muscle forces). In response to strains below the threshold range, disuse-mode remodeling occurs, removing trabecular and endocortical bone, thereby weakening the whole bone strength. The success of reaching the threshold ranges for bone modeling is dependent upon a number of properties of physiological muscle loads. The magnitude (how large the force is), rate of increase in magnitude (whether or not the force changes over time), frequency of the load (how quickly the force is applied), accumulated number of loading events (how many times the load is applied overall) and power determine whether the signaling threshold is met. Therefore, the exposure of bone to loading is critical to maintain healthy whole bone strength and prevent nontraumatic fractures (Frost 2003, 2004).

1.2.3 Osteoporosis

Over the last decades, two widely used definitions for osteoporosis have come to be recognized: 1) "A systematic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fractures." and 2) "A skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture. Bone strength reflects the integration of two main features: bone density and bone quality." (Association of Women for the Advancement of Research and Education).

As defined in the second definition, bone health and strength is reflective of two main features: bone density and bone quality. Bone density is the grams of bone mineral content per area. Bone quality is the architecture, mineralization, turnover and damage accumulation of bone. The World Health Organization (WHO) (2008) has characterized bone density into four diagnostic categories:

1. **Normal:** Bone mineral density is within 1 standard deviation of the density for a young normal adult.

2. **Osteopenia (Low bone mass):** Bone mineral density is between 1 and 2.5 standard deviations below the density of a young normal adult.

3. **Osteoporosis:** Bone mineral density is greater than 2.5 standard deviations below the density of a young normal adult.

4. **Established or Severe Osteoporosis:** Bone mineral density is greater than 2.5 standard deviations below the density of a young normal adult and the medical history includes one or more nontraumatic fractures.

Osteoporosis is a 'silent' degenerative skeletal disorder in which the bones become increasingly brittle and susceptible to fracture. This increase in brittleness and fragility are due to an increase in bone resorption relative to bone formation. Osteoporosis is characterized as primary or secondary osteoporosis. Primary osteoporosis is largely due to changes in hormone levels and is most common in postmenopausal women. Secondary osteoporosis is the result of diseases, medications or other conditions (World Health Organization, 2008).

Research into osteoporosis has historically focused upon primary osteoporosis in postmenopausal women. This research has included both pharmacological and non-pharmacological interventions, including nutrition, calcium and vitamin D intake, hormone levels and physical activity. In recent decades however, the impact of osteoporosis in non-ambulatory children has been drawing a high degree of investigation.

Of late it has been found that the absence of loading on the long bones in non-ambulatory children leads to increased risk of osteoporosis and nontraumatic fractures in adolescence and adulthood. This increased risk is due to the fact that bone formation is dominant in childhood and adolescence with peak bone mass being obtained in early adulthood. Pre-pubescent bone formation is especially important as it creates a baseline bone density for later in life. However, due to the prolonged absence of loading, non-ambulatory children have relatively decreased bone formation and therefore a decreased bone density.

Investigation into bone loss has estimated that in strict bed rest and microgravity environments, similar to those in which non-ambulatory children reside, bone loss occurs at approximately 1-2% per month. Additional studies have determined that the longitudinal forces on the skeleton during bed rest are 83% less than those in the upright, loaded position (Flinn, 2002). Subsequent to these findings, a new therapeutic intervention known as passive standing has become a focus of study for non-ambulatory children. Passive standing and the current implications will be discussed in Section 1.3.2.

1.2.4 Devices and Techniques to Measure Bone Mineral Density (BMD)

Over the past decades, research in pediatric bone mineral density (BMD) has steadily been increasing. Motivation for this trend is based upon two contentions. First, the baseline bone density gained in prepubescent years is believed to decrease the risk of osteoporosis in later years. Secondly, identifying children with low bone density can aid in determining appropriate treatment programs.

Bone mineral density can be calculated through a number of imaging modalities. The major modalities currently used are quantitative computed tomography (QCT), quantitative ultrasound (QUS), radiographic absorbtiometry and dual energy x-ray absorptiometry (DXA). DXA was chosen to determine the BMD in the pilot study.

DXA is currently the most widely used diagnostic tool for osteoporosis and is becoming increasingly popular for use with pediatric populations due to its relatively quick scan time (less than five minutes per whole body scan) and its low radiation exposure (less than ¼ the radiation of a standard x-ray). DXA provides a two-dimensional estimate of bone mineral content (BMC) and bone area. The BMD can then be calculated by dividing the BMC by the area. Although, the two-dimensional limitation of DXA is not as advantageous as the volumetric capabilities of QCT or QUS, the resulting measurements are deemed sufficient for the pilot study (Specker & Schoneau 2005).

When analyzing BMD with DXA, a comparison scale known as either the T- or the Z-score are utilized. Similar to the t- and z-values in statistics, the T- and Z-scores provide a comparison of the BMD calculated in the subjects to that of healthy young adults (T-score prediction) or healthy individuals of the same age and gender (Z-score prediction) by determining the standard deviation of their BMD from the norm. The T-score is most commonly used to determine the amount of bone loss in later years of life based upon the peak density of early adulthood. The Z-score is more suitable for the application discussed here as the pediatric population has not reached peak growth and therefore should not be expected to have the peak bone density of early adulthood. Using a prediction model calculated and analyzed by Ellis et al. in the Body Composition Laboratory of Baylor College, the BMD of the subjects found in the pilot study were compared to the Z-scores of children of similar age, gender and Tanner stage.

1.3 Literature Review

1.3.1 Current Use of Low-Magnitude, High-Frequency Vibration in Post-menopausal Women

Osteoporosis has been studied in post-menopausal women and the elderly for decades with investigation into the impact of various medications, diets, weight-bearing and exercise activities and other medical interventions. Much of the non-pharmocological intervention has focused upon physical activity and the use of low-magnitude, high-frequency vibration to increase bone density.

Physical activity is hypothesized to increase bone density by inducing bone strains of a magnitude great enough to cause microdamage and stimulate bone modeling through repair. Low-magnitude, high-frequency vibration is hypothesized to mimic the strains and loads placed on bones by muscle contractions, thereby increasing the bone strength and density through similar signaling channels produced by muscle contractions.

A twelve month study in 2006 investigating the effects of low-magnitude, high-frequency vibration on 48 healthy white females, 15-20 years of age with at least one fracture in their medical history, found a greater increase in bone density and bone quality in areas of the spine and femur when treated with vibration intervention versus no additional therapy. The vibration therapy was applied at a magnitude of 0.3g and a frequency of 30 Hz. The requested duration was 10 minutes per day for the twelve months, with an average compliance of 4.3 minutes per day. QCT and DXA were used to determine muscle and bone mass and anatomy. Muscle mass was found to initially begin increasing at 20% compliance. Average increases of 2.0% and 2.3% were found in the trabecular and cortical bone respectively in the experimental group over the control group (Gilsanz et al. 2006).

A study in 2003 with 53 healthy men and women, age 19-38 years, found no difference on the mass, structure or mechanical strength of the bones in the spine, femur or radius with the use of whole body vibration intervention. The duration of treatment was increased throughout the study beginning at two minutes and increasing to ten minutes three times a week for 8 months. The amplitude of vibration was 2 mm with the frequency increased from 30-45 Hz throughout the study (Torvinen et al. 2003).

Another study in 2003, failed to show any improvement with vibration therapy in 56 women who were 3-8 years past menopause. The study was conducted for twelve months and applied a vibration of a magnitude of 2.0 m/s^2 and a frequency of 30 Hz. The therapy intervention was given twice a day for 10 minutes during each session. As in the previously discussed studies, the compliance of the study possessed a large range from 1-95% compliance. While neither the experimental or control group showed any increase in bone density, the experimental group did possess a lesser degree of bone loss with the vibration therapy. These results show promise for future use and inclusion of vibration therapy in postmenopausal women (Rubin et al. 2004).

A number of factors could account for the conflicting results of these studies. As discussed in Section 1.2.2, several properties of physiological muscle loads are responsible for determining what strains are placed on the bones and how the cells will respond. The results of the studies above will depend upon the magnitude and frequency of the vibration chosen, whether the magnitude or frequency of the load is increased throughout the study and most importantly the compliance rate of the subjects. While two of the above studies did not discover an increase in bone density, they all showed optimistic findings for the use of vibration therapy in populations at risk of decreased bone density. Studies investigating the impact of vibration therapy on the bone density of animals have also further supported the use of vibration intervention in these populations (Flieger et al. 1998).

1.3.2 Current Use of Passive Standing with Non-ambulatory Populations

Studies investigating the impact of vibration intervention on populations at risk of low bone mass and osteoporosis have yielded promise in the ability to delay or reverse the progression of long bones weakening. However, research on vibration intervention has often focused upon an ambulant population. Therefore, recent exploration regarding the effects of applying a constant, continuous load to the limbs of non-ambulatory populations has drawn much attention. Non-ambulatory individuals are confined to their beds and wheelchairs for the duration of their lives. This confinement is estimated to decrease their bone density by 1-2% per month and lead to a prevalence of osteoporosis and nontraumatic fractures among this population. To reverse this trend, passive standing has become a highly investigated therapeutic intervention. Passive or static standing is a standing therapy in which the individual is fully supported throughout the duration of the intervention and the leg muscles are primarily believed to be inactive. The hypothesis of passive standing is that if the individual can be placed in the vertical, upright position for a short duration of time each day, the increased loading of the skeletal system will stimulate increased bone formation and decreased bone resorption, thereby increasing or maintaining the bone density of the individuals and decreasing the risk of osteoporosis and fractures. Numerous studies over the last decades have investigated this claim.

A number of studies on passive standing have focused upon individuals diagnosed with a spinal cord injury. One study determined that an early intervention therapeutic regimen including standing and treadmill walking increased trabecular bone density significantly when compared to non-ambulatory individuals over a 25 week period. However, standing only versus a combination of standing and treadmill walking did not significantly change the increase in bone density.

Another study investigating passive standing in the upright position versus sitting or exercising in the supine position demonstrated increased bone density in the upright position while the other two cases were discovered to have no impact on bone density. These results support the importance of gravitational strains along the longitudinal axis of long bones.

Numerous other studies, the number being to great to discuss each in detail, have determined that passive standing and ambulation are a critical factor for increasing bone density in individuals whom are at high risk of osteoporosis and nontraumatic fractures. Based upon these findings, passive standing is now a common intervention in the therapy programs of non-ambulatory children and individuals across the United States.

1.3.3 Physical Exercise and Previous Dynamic Stander Research

While the mechanism and required signaling for bone formation are not fully understood, research has suggested that the reciprocal loading and the increased magnitude of forces applied to the long bones during walking, running and other physical activity play an important role in increasing bone density.

Chad et al. investigated the role of physical activity in nine children with spastic cerebral palsy (CP) (1999). After 8 months, children treated with load bearing physical activities had a greater density in the femoral neck than those children who were not. While this creates optimism for decreasing the risk of osteoporosis in children with disabilities, the activities investigated in this study are physically impossible for non-ambulant populations. Therefore, a more practical solution for applying dynamic loading for non-ambulant populations, based upon the success of passive standing, has been investigated in recent years.

Dynamic standers are not a new concept in the field of standing. As discussed in Section 1.3.2, vibration platforms which provide a low-magnitude, high-frequency vibration have been one ‘dynamic’ intervention investigated. One study by Ward et al. (2004) yielded positive increases in bone density with vibration intervention. However, studies in postmenopausal women have shown that women who walk a significant amount on a daily basis in addition to the vibration intervention reveal greater bone density increases than women participating in the vibration intervention who are relatively sedentary throughout the day. These findings suggest that the magnitude of the peak reciprocal forces has a critical influence on the signaling required for bone formation. Based upon these findings, the dynamic stander designed in this study has been designed to apply reciprocal forces mimicking walking to the long bones of non-ambulant children, with the possible addition of low-magnitude, high-frequency vibration at a later stage of the research.

Other dynamic standers have been investigated as well and are currently available on the market. Gudjonsdottir et al. (2002a, 2002b) designed and tested the feasibility of a dynamic stander on children with severe cerebral palsy. The dynamic stander designed in this study provides a reciprocal vertical displacement in the lower limbs and pelvis of the children. The study discovered promising results for dynamic standing interventions and the feasibility of using a dynamic stander in the therapy protocols. However, these dynamic standers are not appropriate for the non-ambulant population considered in this research study for a number of reasons. Joint contractures and hip dislocations are prevalent within the population considered in the current study. Gudjonsdottir's dynamic stander, as well as many of the other dynamic standers available on the market, does not provide enough support to prevent these contractures or dislocations. In addition, many of the current dynamic standers provide a lateral swing of the lower limbs at the hip joints. This motion increases the risk of contractures and dislocations in the pediatric population considered here.

Through their study, Gudjonsdottir et al. proved the feasibility of dynamic standing in the therapy protocols of children with disabilities. While their stander is not appropriate for the present population, many of the design suggestions made in their work are considered in the design discussed in the next chapter. For example, they concluded that an electric motor was loud and distracting in the environments in which the stander was used. This conclusion is one of the many factors that were taken into consideration during the design of the following dynamic stander.

CHAPTER 2

DESIGN OF DYNAMIC STANDER

2.1 Concept

The intent of this research is to fabricate a dynamic stander which provides reciprocal loading to the lower limbs of non-ambulatory children and conduct a pilot study in which preliminary results may be analyzed and the feasibility and usability of the device may be evaluated. It is believed that intermittent loading of the bones will create greater internal signaling at the cellular level than the current constant passive loading and thereby further increase the production and activity of osteoblasts, creating stronger, denser bones. A dynamic stander that mimics the reciprocal signaling created during a normal walking gait is presented. The pilot study is designed to not only gain preliminary insight into the advantages of dynamic standing, but to also test the feasibility and usability of the stander in a clinical, classroom or hospital setting. An evaluation of the pilot study protocol will also allow for procedural refinements for the future 12-month study.

2.2 Design and Fabrication of Dynamic Stander

Numerous design inputs were considered throughout the design and fabrication process. They were as follows:

1. Joint contractures and hip dislocations are prominent in non-ambulatory children so vertical displacement and joint rotation must be kept to a minimum.

2. Joint rotation and vertical displacement must be kept at a minimum to minimize the risk of skin abrasions and sites of excess pressure, in particular at the strap contact points.

3. The device will be used in a hospital, clinical or school setting, requiring sterility, cleanliness and minimal noise and space occupation.

4. The magnitude and frequency of the displacement and loading must be adjustable between subjects.

5. Mechanical and electrical limits must be included within the device to ensure the subject is not exposed to excessive forces or impacts.

6. The mechanical design and structure of the device must minimize procedural differences between current transfer methods and therapeutic training protocols and those required by the dynamic device.

7. The control circuit must be straightforward and user-friendly in order to allow therapists to easily control the device and accompanying parameters with little time or effort and without continuous supervision throughout the session.

8. The subject must be isolated from all electrical energy.

9. An emergency stop system must be incorporated in the programming, as well as a physical emergency stop button being present on the stander.

10. The loads applied to the subject must be recorded at all times to ensure that maximum loading never exceeds the subject’s full body weight.

11. Any and all dynamic components must be contained to prevent injury to other person(s) within the setting in which the device is being used.

The design utilized in the modification of the passive stander for the pilot study was heavily based on the design of a dynamic stander by Louis Espinosa.

2.2.1 Mechanical Design

One of the most critical mechanical design decisions was determining how to provide the reciprocal loading applied to the subject’s feet. Pneumatic actuators were chosen as they are relatively quiet compared to electrical motors, thereby alleviating one of the concerns presented in Gudjonsdottir's dynamic stander described in Section 1.3.3, and they allow the subject to be electrically isolated due to the fact that they are powered by air. The pneumatic actuators are also advantageous as they can be controlled by easily programmable valves.

The base system of the dynamic stander consists of three levels with five plates supporting the feet and body. As can be seen in Figure 2.1, the base plate is a continuous plate across both feet, providing structural support to the device and an anchoring surface for the actuators. For the pilot study, the base plate is constructed out of ¾" birch plywood. In future prototypes the plate will be constructed of ½" delrin.

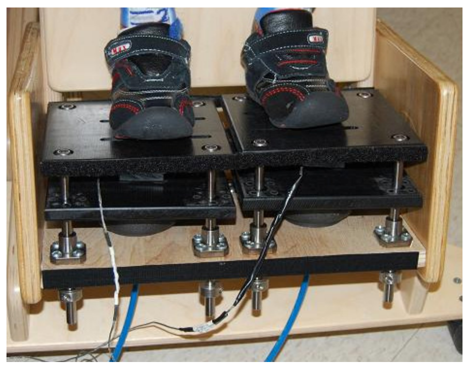

Figure 2.1. Dynamic standing component. Consists of three levels. The middle and top plates have been separated to provide independent motion for each foot. The base plate provides an anchoring point for the pneumatic actuators. The middle plates anchor to the top of the pneumatic actuators and provide a surface for the load cells to sit. The top plates contain slots identical to those of the passive stander to allow for similar placement of the foot sandals. To maintain uniform vertical displacement and minimize binding, each corner of the top plates contain shafts fed through bearings anchored to the base plate.

The middle and top plates have each been divided into two independent plates in order to allow separate control and movement of both feet. The plates are constructed of ½" delrin. The actuators are attached to the center of the middle plates in order to create uniform vertical movement and distribution of load and to decrease any binding between the shafts and the bearings. The middle plates also serve as the base attachment point for the load cell holders. (The load cell holders consist of rectangular blocks of delrin with a ¾" counterbore in which the load cell sits. The depth of the counterbore is ½" in order to allow the top of the load cell to sit flush with the top surface of the load cell holder.) The top plates rest on the load cells in order to allow the force being applied to the feet to be measured. Slots identical to those located on current standers have been machined on the top plates to allow the foot sandals to be positioned exactly as they currently are.

Located on each corner of the top plates are steel shafts (four per plate), attached perpendicular to the plate itself. These shafts are fed through bearings on the base plate and keep the three plates aligned to minimize shearing and binding during the vertical displacement. Steel collars have been placed on the lower end of the shafts to ensure that a vertical displacement of one centimeter is not exceeded. Limiting the vertical displacement to one centimeter permits the reciprocal loading to be applied to the subject's feet while minimizing the risk of joint contractures, hip displacement and pressure sores or skin abrasions at the straps.

As will be discussed in Section 2.2.3, the body of the stander remains unchanged. The heights of the top plates on the modified dynamic stander match the height of the baseplate on the current passive stander bodies.

2.2.2 Electrical Circuit Design

The circuit pictured below represents the first prototype circuit. The circuit is powered by a 12-volt power supply, which allows the circuit to be plugged into any standard 120-volt U.S. wall outlet or power strip. This is an important consideration as many of the classrooms and clinics in which the dynamic stander will be used have limited outlets available due to the number of ventilators, feeding equipment and other medical equipment requiring outlets.

Bimodal valves within the circuit are used to control the inflation and deflation of the pneumatic actuators. The valves were chosen to control the actuators as they can be controlled through relays. The relays within the circuit are controlled by MatLab programming via the parallel port. The parallel port reads the binary input from the MatLab program and turns the power on and off (1 meaning the valves are on and 0 meaning the valves are off). Diodes located prior to the relays ensure that a reverse current is not sent to the parallel port of the computer as this could damage the parallel port. Resistors within the circuit allow the desired amperage to be applied to the circuit’s components.

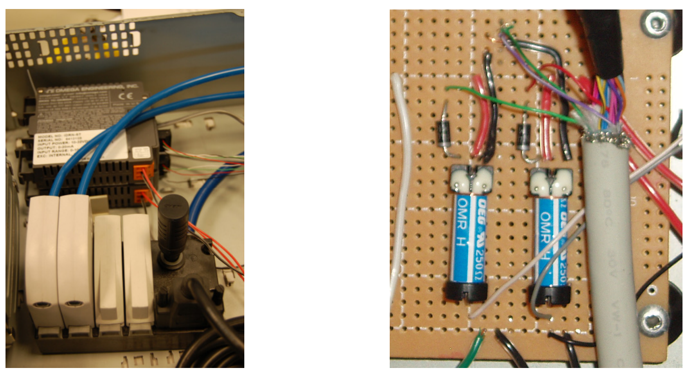

Figure 2.2. Valves and signal processors (right). Main circuit (left). Relays control the power to the valves via signal sent by the parallel port. Diodes ensure that no reverse current is sent to the parallel port. Resistors amplify the current in order to apply the necessary power.

One condition for the pilot study is to continuously monitor the forces being applied to the subject’s feet. Load cells and signal processors are utilized for this task. The load cells are strain gauges which measure a change in voltage, corresponding to the change in force applied to the feet. The signal processors are capable of outputting data at 8 Hz. The signal processors are powered through the 12-V external power source and in turn power the load cells. The load cells are placed between the top and middle plates of the dynamic stander as described in Section 2.2.1 and the signal processors are connected to the computer via RS232/Serial or RS232/USB connections.

The complete circuit is housed in a former computer circuit housing. The circuit is completely enclosed to maximize electrical isolation and minimize the risk of electrical shock or danger to others in the setting in which the stander is being used, specifically other children.

A hospital grade 25 liter compressor has been chosen to provide the required air pressure for the pneumatic actuators as it is designed to maintain the sterility of the hospital or clinical environment and its air capacity minimizes the running hours of the compressor, thereby minimizing the noise and distraction.

2.2.3 Fabrication

Presently, passive standers are readily available and used in therapy programs of many non-ambulatory children. Therefore, the decision was made to fabricate the dynamic component of the stander in such a way that it can easily be incorporated into existing passive standers. Due to the wide use of Prospect Design standers at Children's Specialized Hospital (CSH), collaborators in this study, a Prospect Design supine stander was modified for the pilot study.

Modifying an existing passive stander allows many of the design goals to easily be met. The dynamic component has been adapted to the passive stander in such a way that the foot plates for the dynamic stander sit at the same height on the body of the stander as the previous foot plate. This allows the main body of the stander to remain unchanged and continue to provide the necessary head and trunk support, as well as minimize the hip and knee rotation. The placement of the straps and pads remains unaltered to continue to allow the same transfer procedures to be utilized by the therapists and staff. The base of the stander itself also remains unchanged, maintaining the original stability of the overall stander and adjustability of the height and trunk angle.

The design of the dynamic component of the stander requires minimal tools (ie. table saw, band saw, drill press, router and hand tools), thereby allowing all machining to be done through the New Jersey Institute of Technology's (NJIT) Biomedical Engineering Department's and CSH's machine shops.

The figure below illustrates the complete finished set-up of the dynamic standing system. The compressor is connected to the valves through 3/8" nylon tubing. The computer system and circuit housing sit upon a printer stand. The load cells and ¼" nylon tubing run from the circuit housing to the dynamic component of the stander.

Figure 2.3. Finished set-up of the dynamic standing system. (Not pictured is the hospital grade compressor used to control the pneumatic actuators.)

2.2.4 Computer Programming

MatLab 7.0 was used for all computer programming. A complete copy of the script is included in Appendix A. A graphical user interface (Figure 2.4) is used for the dynamic stander and allows the user to enter the desired session time and the weight of the subject. This allows for the dynamic stander to be universal between subjects while still being able to be customizable to fit each individual's therapeutic requirements. The start button at the bottom begins the session, while the stop button terminates the session in case of emergency.

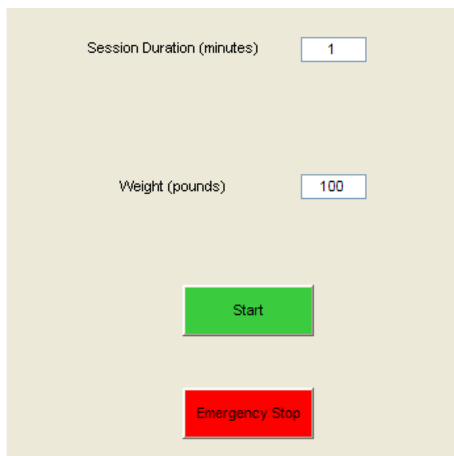

Figure 2.4. Graphical user interface (GUI) created in MatLab 7.0 to allow user input in the program.

MatLab's 'digitalio' function is utilized to control the valves through the parallel port of the computer. This built-in function converts a binary digital code to an analog code which either turns on (when the numeral '1' is sent) or off (when the numeral '2' is sent) the power to the parallel port pin.

Human locomotion, otherwise known as walking, has been greatly researched for decades. Human locomotion is split into gait cycles, the time between when the heel of one foot strikes the ground to the time at which it strikes the ground once again. The gait cycle is further divided into phases known as single stance, double stance and swing. Single stance for a leg refers to the phases in which only one foot is in contact with the ground; double stance refers to the phases in which both feet are in contact with the ground; and swing refers to the phases in which the foot is not in contact with the ground.

Each individual person's gait cycle varies slightly, but the average duration of a complete gait cycle ranges between 1 to 1.5 seconds. The gait cycle time in the dynamic standing program created for the pilot study is approximately 1.5 seconds and can be modified within the program. The timing of the reciprocal loading is based upon a percentage of the inputted gait cycle and is divided to account for periods of single stance, double stance and swing. The following illustrates the timing of the program based upon the inputted gait cycle time, T:

1. double stance for 10% of T (0-10% of T)
2. single stance (leg 1) and swing (leg 2) for 40% of T (10-50% of T)
3. double stance for 10% of T (50-60% of T)
4. swing (leg 1) and single stance (leg 2) for 40% of T (60-100% of T)

2.2.5 Design Verification and Validation via Two Trials with Healthy Subjects

Prior to the commencement of the pilot study, two separate sessions were held to test the dynamic stander with two healthy subjects. The subjects were 7 years of age and were able to communicate with the researchers throughout the sessions to provide feedback. Subject assent and parental consent were obtained prior to the sessions.

The first session was held in August 2007. The primary design was determined to be successful, but a few minor adjustments were required. Binding occurred during the sessions. This was improved by re-machining the base plate and getting rid of the bearings anchored to the middle plate. The timing of the applied forces also had to be modified in the program as the timing did not produce smooth motion of the plates (jarring of one foot plate occurred between the gait cycles). The session was able to verify that no chaffing or excess pressure occurred at the straps. Both individuals provided positive feedback and reported that the displacement and movement was not uncomfortable.

A second session verified that the modifications from the first session were successful.

CHAPTER 3

PILOT STUDY

3.1 Subjects and Study Design

Medical clearance and prescriptions for the DXA scans were obtained from each subject's doctor prior to their inclusion into the study. The study protocol, design and assent and consent forms were approved by Children's Specialized Hospital (CSH) and the New Jersey Institute of Technology (NJIT) Institutional Review Board (application F85-07). Assent and consent were obtained from the subjects and their parents prior to the commencement of the study. Due to the limited cognitive ability of the subjects, reaffirmation of consent was obtained for each subject from the parents as clear assent could not be obtained from the subjects themselves. Staff in the Long Term Care (LTC) unit of CSH and Fanwood Pre-school and Primary School was briefed on the purpose and objectives of study beforehand.

Two children from the LTC unit at CSH in Mountainside, New Jersey participated in the pilot study. Both subjects were male (age 2 and 7 years) with a passive standing protocol included in their current therapy programs. Members of the research team met with the parents and subjects to describe the purpose and intent of the study. Neither subject had suffered previous fractures. A complete chart review was done prior to the start of the study to ensure the subjects were appropriate for the study and all guidelines were met.

Pre- and post-study height and weight were recorded. Both subjects are in the Tanner I stage of puberty. Both subjects are tube fed with a strict daily dietary allowance.

This diet was recorded throughout the duration of the study. The 2-year old subject was placed in the dynamic stander while the 7-year old subject maintained his daily passive standing regimen.

3.2 Dynamic Standing Intervention

The dynamic standing sessions were completed in the LTC unit of CSH in Mountainside, New Jersey. The subject stood five days a week for thirteen weeks, following the frequency described in Section 2.2.4.1. During the first two weeks, the daily duration of the stimulus was increased from 30 minutes to one hour. These weeks were not included in the analysis. During week 3 through 13, the daily duration was approximately one hour each day, following the subject's normal standing protocol.

3.3 Passive Standing Intervention

The passive standing sessions were completed at CSH's Fanwood Preschool and Primary Program facility in Fanwood, New Jersey. The subject stood five days a week for thirteen weeks. Due to the logistical constraints of the classroom schedule, the daily duration of the passive sessions was 30 minutes while the subject was in school, following his normal therapy regimen. During a two-week break from school (weeks 4 and 5), the subject was passively stood in the LTC unit of CSH in Mountainside, New Jersey for daily sessions of one hour.

The difference between the session durations of the dynamic and passive standing therapies will be accounted for during the analysis of the results. While the duration of the daily session is believed to have an impact on the success of the intervention, a study investigating the impact of passive standing on 26 non-ambulant children (age 2-19 years old) with cerebral palsy concluded that a 50% increase in the duration of standing (30 minutes to 60 minutes) increased the volumetric density in the spine, but had no impact on the density in the proximal tibia. This finding suggests that a more significant increase in duration of therapy, for instance 1 hour to 6 hours, is necessary to increase the bone density in non-ambulatory populations and thus despite the differences in session duration it is appropriate to compare the results of the subjects in the pilot study.

3.4 Dual Energy X-ray Absorbtiometry (DXA) Procedure

The bone density of each subject was assessed by DXA using the same pediatric DXA scanner (Pediatric Lunar Prodigy; General Electric, Waukesha, Wisconsin, USA) and the same spinal phantom for calibration (General Electric). The same technician performed all scans. A distal femoral scan was obtained for the right and left leg of each subject at 0- and 13-weeks, using the AP Spine setting of the scanner in order to allow multiple regions of interest to be analyzed in the future.

Figure 3.1. Lunar Prodigy Dual Energy X-ray Absorbtiometry Scanner.
Source: General Electric, Waukesha, Wisconsin, USA.

The subjects were laid in the supine position with the leg to be scanned placed on the midline of the scanning area. The area to be scanned was determined through visual estimations. During the scan, the subject was held at the proximal tibia and proximal femur to minimize any motion of the femur. The subjects were calmed by personalized music throughout the procedure. The time of the scans themselves took less than 3 minutes each.

Once the scans were complete, three regions of interest were chosen for the analysis. Encore Software (General Electric) was used to analyze the results. These regions were determined based upon the previous work done in DXA imaging with children with disabilities by Henderson et al. (2002). The width of the proximal diaphysis of the femur, y, was measured in each scan. The first region began on the proximal edge of the growth plate and extended vertically upwards 2y. This region is dominantly trabecular bone. The second region began at the proximal edge of region 1 and again extended upwards 2y. This region encompasses the transition from metaphyseal bone to diaphyseal bone and therefore includes trabecular and cortical bone. Region 3 extends upwards 2y from the proximal edge of region 2 and contains primarily cortical bone. Due to the difficulty of determining the clear growth plate in a number of the images, the distance from the joint space to the distal edge of region 1 was measured to verify that the regions between images coincided. The full width of the bone in all regions was used in the analyses. Figure 3.2 illustrates the regions used in the analyses.

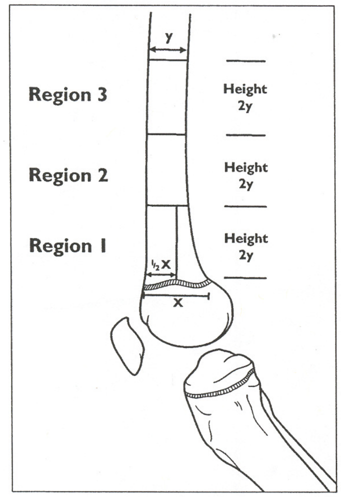

Figure 3.2. Regions of interest in the DXA images. y represents the proximal width of the femur's diaphysis. Region 1 begins at the proximal edge of the growth plate. Region 2 begins at the proximal edge of region 1. Region 3 begins at the proximal edge of region 2. All regions possess a height of 2y.
Source: Henderson et al. (2002).

CHAPTER 4

RESULTS AND DISCUSSION

4.1 Design Evaluation

While the current dynamic stander prototype proved to be feasible, certain aspects of the design must be altered before the device can be utilized without supervision in the hospital and classroom setting for the 12-month study.

4.1.1 Design and Fabrication Modifications

The current mechanical design of the stander proved to be feasible in the clinical setting. The transfer procedure does remain unchanged from that of transferring the patient to the passive stander. The dynamic stander also maintains stability similar to that of the passive stander. The only modification in the mechanical design will be the addition of a gate to enclose the plates and prevent other children from injuring themselves in the moving components. This gate was not included during the pilot study as the stander was constantly supervised by a researcher and continuous access and viewing was required to evaluate the operation of the dynamic component.

The electrical design of the stander has been found infeasible in the clinical setting. With the electrical circuit and valves located on a separate cart, two wires for the load cells and two air lines ran between the cart and the device thereby hindering the transfer process and creating an additional danger. During Week 1 of the pilot study, a nurse tripped on one of the wires while transferring the subject and broke one load cell wire, demonstrating the risk involved when running wires and air lines between components. To alleviate this problem, the load cells and tubing were disconnected after each session before the subject was transferred to the wheelchair and reconnected at the next session after the subject had been transferred to the stander. While this was sufficient for the pilot study, the additional time and procedure this requires will not be sufficient on a daily basis in the clinical and classroom setting. Therefore, a new circuit enclosure is being investigated which will allow the circuit to be located on the base of the stander itself in order to allow all additional wires and tubing to run under the stander and alleviate the risks associated with the connection of two separate devices. Placing the circuit on the stander and using a laptop instead of a desktop will also negate the additional cart, thereby saving space, which is a critical issue in the clinical and school settings. This will also require transportation of one less piece of equipment as the standers and related equipment are not often kept in the same room in which they are utilized. An emergency push button will also be located on the stander to kill the circuit in case of emergency.

4.1.2 Computer Programming and User Interface Modifications

While the programming was generally successful and accomplished the objectives sought in the pilot study, it is not sufficient for use by therapists, teachers or other supervisory individuals unfamiliar with the MatLab program and language. As mentioned in Section 4.1.1, a laptop will be utilized in the future for all programming control. The synchronization of the timing with the desktop used in the pilot study and MatLab differs slightly from that of the laptop and MatLab. Therefore, before the laptop can be used, the synchronization algorithm for the laptop and MatLab must be determined.

In the pilot study, an asynchronization of MatLab and the serial ports in which the load cells were connected occurred in a majority of the sessions. This asynchronization caused the pneumatic actuators to pause for 4 to 5 minutes while the program tried to synchronize MatLab and the ports. This asynchronization must be resolved before the 12-month study.

In the 12-month study the program will be used with multiple subjects simultaneously, therefore the graphical user interface (GUI) must be modified. Each subject will be assigned a number for the 12-month study. The GUI will need an additional text box in which the subject's number may be entered in order to differentiate recordings between subjects. Ideally, a recording of the 'time in' and 'time out' will also be included. This will allow the researchers to determine if the subject is left standing passively for a significant amount of time before being removed from the stander each day.

4.2 Pilot Study Results

4.2.1 Dynamic Standing Results

Due to logistical complications, a few sessions were missed throughout the 13 weeks, so the total number of days stood dynamically during the pilot was 58 with an average of 60 minutes per day after the first two weeks. The subject stood passively an additional 4 days throughout the study for 60 minutes per session.

The peak-to-peak amplitude of the reciprocal vertical displacement in the dynamic stander was a maximum of 1 centimeter. Using data retrieved from the load cells placed under the subject's feet, the average range of the peak-to-peak force applied to the subject's lower limbs was found to be 25-75% of body weight. Recordings retrieved during additional passive standing sessions, revealed that in passive standing the average range of peak-to-peak forces applied through the body's natural postural shifting was 45-55% of body weight.

4.2.2 Passive Standing Results

Due to logistical complications, a few sessions throughout the 13 weeks were missed in the passive standing therapy as well, so the total number of days stood in school during the pilot was 41 with a total of 1216 minutes stood (an average of 28 minutes per session while standing in school). Throughout the two weeks in which the subject stood in LTC, the subject stood a total of 785 minutes in 13 days for an average of 60 minutes per session. Altogether, the subject stood a grand total of 2001 minutes during the 13-week period.

The static loading and postural shifts of the passive standing subject were not recorded during the pilot study due to the complications with the load cell wire breaking during the first week of the pilot study. It is anticipated that this subject will participate in the 12-month study and the postural shifts will be recorded during that study.

4.2.3 DXA Results

The right and left distal femurs of each subject were scanned at 0- and 13-weeks, giving a total of eight DXA scans. A Quality Assurance (QA) scan was completed prior to each session to provide calibration data. The following images and tables illustrate the results found from the 0- and 13-week DXA scans:

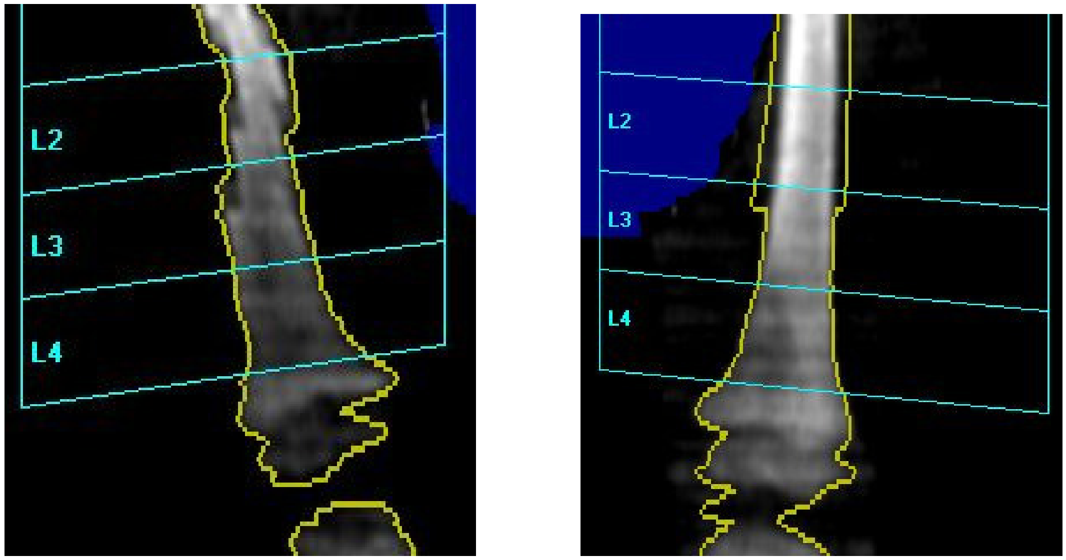

Figure 4.1: Dynamic standing 0-week images. 0-week right and left images for the subject placed in the dynamic stander.

The densities (g/cm^2) for the 0-week dynamic standing subject were found to be:

Table 4.1 Bone Mineral Densities for Dynamic Standing at 0-weeks

Densities in g/cm^2		**Region L4**	**Region L3**	**Region L2**
Right Leg		0.257	0.314	0.378
Left Leg		0.257	0.327	0.302

These results match expectations in a two regards. First, it is expected that the density of each region will increase from Region L4 to L2 due to the fact that L4 primarily contains the less dense trabecular bone, while L2 is primarily dense cortical bone. This pattern does exist in the findings. The other expectation is that the density in both legs will be relatively similar as the majority of daily ‘loading’ and activity experienced by both limbs is equal. The one outlier to these expectations is the density in the left leg region L2. However, upon closer examination of the yellow outline for the area in the image, it can be seen that the area of the left leg in L2 is overestimated by the Encore software. As the bone density is determined by the bone content divided by the area, the inclusion of the empty space in the L2 region will increase the area and thereby decrease the calculated density. If a correction for an overestimation of 25% is considered and accounted for, this increases the bone density of L2 in the left leg to 0.378 g/cm^2, which meets expectations. In the future, additional software may be used to correct the edge detection of the Encore Software. In addition, the image of the right leg has gross movement of the bone during the scan. In future studies, multiple scans will be done when necessary to obtain a satisfactory scan with no movement artifact.

Similar expectations were met with the 0-week right and left leg densities (g/cm^2) for the subject assigned to passive standing.

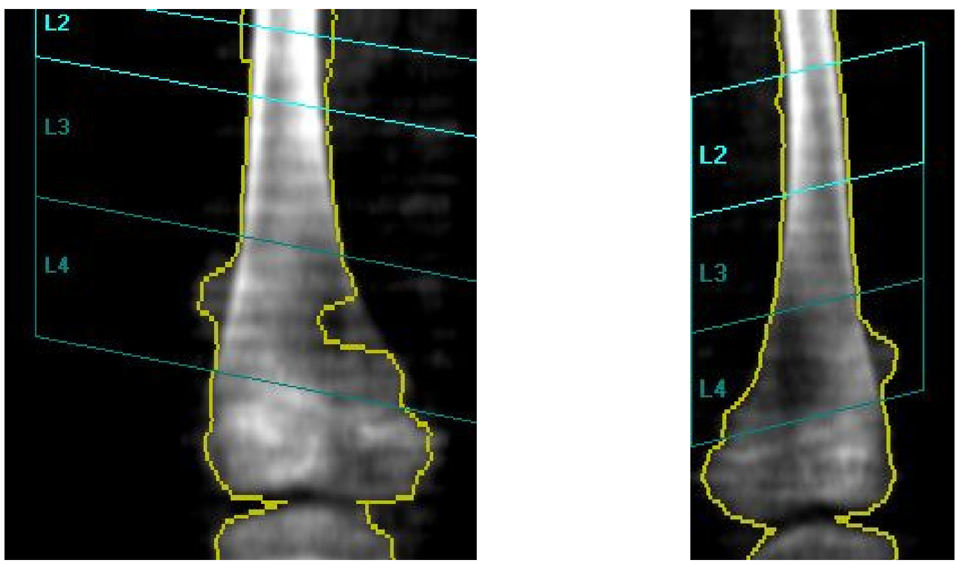

Figure 4.2. Passive standing 0-week images. 0-week right and left images for the subject placed in the passive stander.

Table 4.2 Bone Mineral Densities for Passive Standing at 0-weeks

Densities in g/cm^2		**Region L4**	**Region L3**	**Region L2**
Right Leg		0.209	0.389	0.465
Left Leg		0.209	0.392	0.565

Once again the densities increase between Regions L4 to L2. The densities of coinciding regions of each leg are also similar with the exception of L2. The difference of densities in L2 could be accounted for in the regions measured. Due to the right leg scan being cut short on the proximal femur, the area that was obtained was half the height of that obtained on the left leg. If the full height of region L2 could be considered, it would be expected to increase the density as the diaphysis is primarily dense cortical bone and therefore it is hypothesized that the two regions would be very similar in density and follow the pattern seen in the other regions.

For the DXA scans at 13-weeks, the following images were obtained for the dynamic standing subject and passive standing subject, respectively:

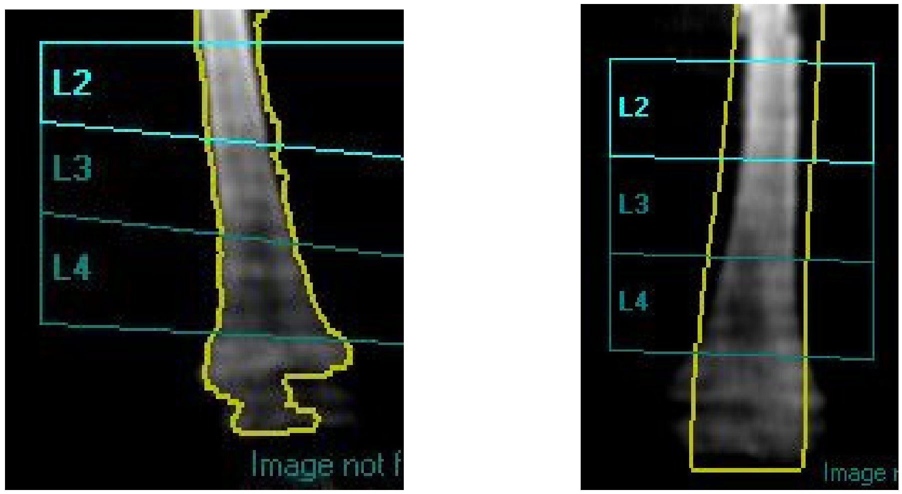

Figure 4.3. Bone mineral densities for dynamic standing at 13-weeks.13-week right and left images for the subject placed in the dynamic stander.

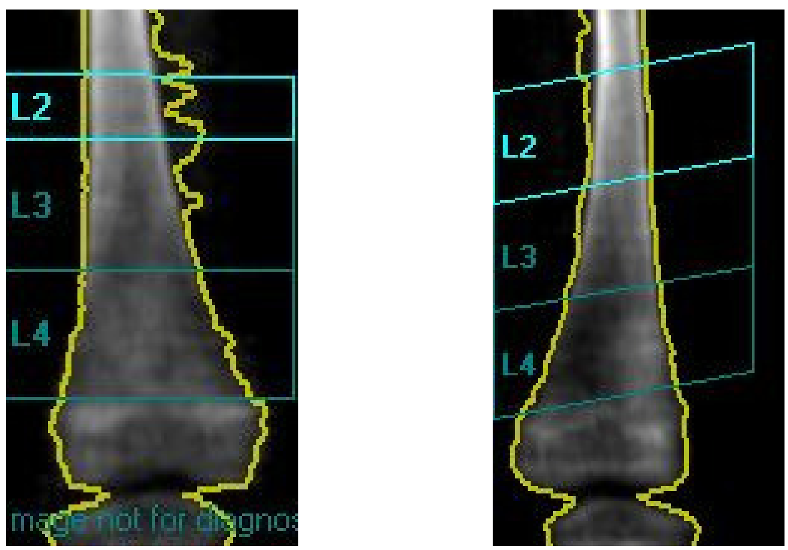

Figure 4.4. Bone mineral densities for passive standing at 13-weeks. 13-week right and left images for the subject placed in the passive stander.

A comparison analysis of the normalized densities for each subject at 0- and 13-weeks is as follows (dynamic and passive, respectively):

Table 4.3 Bone Mineral Densities for Dynamic Standing

Densities in g/cm^2		**Region L4**	**Region L3**	**Region L2**
Right Leg				
0-weeks		0.257	0.314	0.378
13-weeks		0.366	0.477	0.621
Left Leg				
0-weeks		0.257	0.327	0.302
13-weeks		0.216	0.215	0.237

Table 4.3 Bone Mineral Densities for Passive Standing

Densities in g/cm^2		**Region L4**	**Region L3**	**Region L2**
Right Leg				
0-weeks		0.209	0.389	0.465
13-weeks		0.197	0.273	0.367
Left Leg				
0-weeks		0.209	0.392	0.565
13-weeks		0.215	0.370	0.594

Analyzing the dynamic standing densities, the right leg shows an increase in density of 42%, 52% and 64% in regions L4, L3 and L2 respectively. This trend agrees with the expected results, as it was hypothesized that the reciprocal loading created by the dynamic stander would increase the bone density of the subject. An analysis of the left leg illustrates a reversal of the expected trend. Considering the left leg, a decrease of density in regions L4, L3 and L2 of 19%, 52% and 27% respectively occurred. However, upon further investigation of the 13-week image, it can be seen that the area once again is dramatically overestimated by the Encore software. Due to the error in the edge detection and area calculation of the 13-week DXA for the left leg, the results for the left leg will not be discussed further.

For the passive standing analysis, it is expected that the bone density will either remain the same or increase slightly. With previous research suggesting that 1-2% of bone density is lost for each month of immobilization, a 3-6% bone density loss would be expected during the 3-month duration of the study if no intervention was provided. For the right leg, the bone density loss was determined to be 6%, 42% and 27%. However, a visual inspection of the image once again illustrates an overestimation of area in the L3 and L2 regions. This overestimation most likely explains why L4 yields relatively expected results, while regions L3 and L2 do not. In the left leg the density was determined to increase 3% and 5% in regions L4 and L2 respectively. In region L3, the density decreased 6%. These results more closely illustrate the expected trends and visual inspection of the image reveals a practical estimation of the area lending credence to the results found.

Overestimation of the area of the bone was a significant problem with the Encore software throughout the images obtained. In the future, the selected area will be analyzed at the time of the scan in order to determine the credibility of the measurement. If necessary, other software, such as MatLab, will be used to correct the edge detection and any resulting overestimation of the area during analysis.

In addition to analysis modifications in future DXA scans, numerous procedural modifications will be made. The reliability of the DXA scanner will be verified by scanning an animal specimen multiple times on subsequent days before the initial scans of the 12-month study are completed.

In the pilot study, the subjects were laid on the scanner in the supine position. However, with the prevalence of joint contractures in the population being considered, this position is not the most suitable as there is no guarantee that the leg is completely flush against the bed of the scanner. If an incline of the femur exists, the reliability of the scans could be questionable. Therefore in the 12-month study, the subjects will be positioned similar to the position used by Henderson et al. (2002). Each subject will be laid on their side with the leg being scanned flat upon the bed of the scanner and positioned on the midline. The opposite leg will be positioned to remain out of the scanning field. The necessary supports will be used to maintain the comfort of the subject.

Four scans will also be procured during the 12-month study versus two. Each leg will be positioned and scanned. After the first scan the leg will be repositioned and scanned a second time. This will allow the reproducibility of the research team's positioning of subjects to be investigated. A scan of the spine will be conducted as well to investigate the impact of the dynamic standing vertebrae.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

5.1 Pilot Study Conclusions

While a number of modifications must be done to the stander and the programming of the stander, the current design has proven to be feasible in the clinical setting. Preliminary results with the two subjects, while not conclusive, yield positive findings to support the use of passive and dynamic standing interventions in the therapy protocols of non-ambulatory children. The results for dynamic standing show significant increases in bone mineral density while the results of passive standing demonstrate that passive standing aids in maintaining and increasing the bone mineral density. Overall, the pilot study was able to provide the necessary information to make the required refinements to the study protocol for the 12-month study.

5.2 Future Work

While the pilot study has revealed that dynamic standing in the clinical setting is feasible, much work remains before the dynamic stander discussed above can be implemented in the clinic. Numerous modifications in the design and fabrication of the stander, the study protocol and the DXA procedures have been discussed in Chapter 4. These concerns and issues will continue to be addressed and resolved prior to the commencement of the 12-month study with 20 subjects from CSH's Fanwood Pre-school.

In the future, it is also desired to investigate the impact of passive and dynamic standing on not only bone density, but other aspects of health in which non-ambulation has a significant impact. Immobilization has a dramatic impact on the musculoskeletal system, renal and urinary tract, skin and underlying tissue, respiratory system, cardiovascular system and digestive system. Determining the additional benefits of standing on these pathological systems would aid in understanding the human body and its systems, as well as further substantiating the use of standing in therapeutic protocols for non-ambulatory populations.

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