Spring 5-2002

# Measurement of Bone Stiffness as a Predictor of Bone Fracture Using Mechanical Vibration Technique

Tiffany Elicia Grant
*University of Tennessee - Knoxville*

# UNIVERSITY HONORS PROGRAM

## SENIOR PROJECT - APPROVAL

Name: TIFFANY E GRANT

College: ENGINEERING          Department: MECHANICAL ENGINEERING

Faculty Mentor: DR. MEHRAN KASRA

PROJECT TITLE: MEASUREMENT OF BONE STIFFNESS AS A PREDICTOR OF BONE FRACTURE USING MECHANICAL VIBRATION TECHNIQUE

I have reviewed this completed senior honors thesis with this student and certify that it is a project commensurate with honors level undergraduate research in this field.

Signed: _Mehran Kasra_ , Faculty Mentor

Date: May 9, 2002

Comments (Optional):

# Measurement of Bone Stiffness using Mechanical Vibration

## Team D: Bone

**Tiffany E. Grant, Alissa Harmon, Kristen Loveless, and Joel Outten**
Undergraduates in the College of Engineering
University of Tennessee
Knoxville, TN 37996

Submitted to:
**Dr. Richard Jendrucko, Dr. Monica Schmidt, and Dr. Anthony English**
Mechanical, Aerospace, and Biomedical Engineering Department
College of Engineering
University of Tennessee
Knoxville, TN 37996

Submitted on:
Friday, May 3, 2002

## *Abstract*

The essence of this project was to construct a device that would allow for an inexpensive, accurate, non-invasive, and time effective method for diagnosing osteoporosis. Adjustability and mobility were also determined to be primary vital characteristics of the device. The average cross-sectional bending stiffness of a long bone is a direct indicator of osteoporotic extent and fracture risk. The ulna was determined to be the easiest and most accurate bone to analyze. By applying a perpendicular random vibration to the mid-point of the ulna, the subsequent response of the ulna can be used to evaluate the bone's stiffness (EI). A frame was constructed that would stabilize a subject's right arm while the subject horizontally reclines in a bed. A signal source then sends digital data (a random frequency: between 1 and 1200 Hz) through a D/A converter and on to a shaker, which vibrates accordingly. A parabolic steel tip, which is attached to the shaker, rests on the ulna. Both the force of this vibration and the resultant acceleration of the ulna are digitally recorded, interpreted, and analyzed to give a rough approximation of the resonance frequency of the bone. In the future, the software will be further calibrated with the constructed frame so as to give an accurate value for the stiffness of the ulna. The system has the intent to be utilized in a research, and eventually a clinical, environment.

1101 Highland Ave
Apartment 9306
Knoxville, TN 37916
865-522-1308


Dr. Jendrucko, Dr. Schmidt, and Dr. English
Mechanical, Aerospace, and Biomedical Engineering
College of Engineering
University of Tennessee
Knoxville, TN 37996


May 3, 2002


To the professors mentioned above:

Enclosed is the final report for the Biomedical Engineering 469 Senior Project entitled
*Measurement of Bone Stiffness using Mechanical Vibration.*


The purpose of Biomedical Engineering 469 was to provide the team members with a rich design
experience which builds on their previous exposure to design ideas and culminates to a "senior
capstone design". Our senior capstone design was to design a clinical testing device that utilizes
mechanical vibration to measure bone stiffness. The details involved in the construction of the
system and data acquisition are included in this report.

I hope that this report is beneficial to you. If you have any questions or comments, please feel
free to contact me at the information provided above. Thank you.

Sincerely,

Tiffany E. Grant
 Team D: Bone
University of Tennessee

# Table of Contents

## Table of Figures

## Table of Tables

E: Elastic modulus

I: Cross-sectional area moment of inertia

k: stiffness, used in context as the stiffness of a spring or of a beam

m: mass

$\omega_n$: natural, or resonant, frequency of a system

l: the length of a beam

## Summary

Every year, approximately 1.5 million bone fractures are due to osteoporosis, subsequently inducing an average annual medical cost of over $13.8 billion. In fact, this cost was approximately $17 billion in the year 2001. Determining both the extent and likelihood of osteoporosis in a patient is currently an untimely and expensive process. This project was begun with the intent of designing a more efficient and cost effective method of determining osteoporotic extent, bone strength, and fracture risk.

In this project, three different alternatives, dual energy X-Ray absortiometry (DEXA), Ultrasound Critical-angle Reflectometry (UCR), and Mechanical Vibration, were evaluated in order to isolate the design that best fit the following criteria:

- The ability to measure bone stiffness (EI), not simply bone density
- Adjustability and mobility
- Time efficiency, both for system construction and data acquisition
- Minimal patient risk
- Affordable construction
- Ability to alter testing device for future applications

These criteria were then arranged into constraints and assigned a numerical value based off of their relative importance. The three alternatives were quantitatively evaluated for each constraint and the point totals were used to narrow the project to one design. The Mechanical Vibration Testing System achieved the highest score from this evaluation, and was thus chosen as the optimal design.

After determining that the ulna would be the easiest and most accurate bone to analyze with the MVTS, designs for the device were created. These designs were founded upon the aforementioned design criteria, and were modified throughout the assembly phase of the project in response to feasibility, convenience, and in order to better fit the criteria. The designs utilized a mobile base, a stabilizing arm fixture, and a supporting arm to position the vibration applicator (an electromagnetic shaker) above the arm fixture where it could vertically vibrate without obstruction. All parts were ordered as needed, and the construction of the device took place accordingly.

Construction of the MVTS entailed four primary areas:

1. Constructing the essential frame (base and horizontal and vertical shafts)
2. Mounting the electromagnetic shaker system to the slider and then to the designated horizontal shaft of the frame
3. Assembling and attaching the forearm fixture
4. Combining the above three assemblies with signal processing hard/software to complete the Mechanical Vibration Testing System

A vertically adjustable medical table was used as the base of the frame and aluminum plates and tubing were chiefly used to attach the appropriate components to the table, construct the arm fixture, construct the vertical and horizontal shafts of the shaker-support arm, and to attach the slider, which would allow for free vertical movement of the shaker, to this support arm.

To conduct testing trials of the finished device, a subject's arm is secured into the arm fixture. A parabolic steel tip, which connects to the shaker, is placed at the midpoint of a subject's ulna. A signal generator then relays a specified random vibration to the shaker, which applies the force to the ulna. This force and the resulting acceleration are then relayed from the shaker to the A/D converter, located within the data acquisition board. The digital signal is then transferred to the signal processor, where the data is displayed by the HP Vee signal processing program. The time dependent data is converted to the frequency domain, and displayed on the interface. From these plots, a general approximation for the natural frequency of the ulna can be determined, although the accuracy has yet to be verified.

Not only did the finished system meet all of the established design criteria, but the system was able to successfully acquire data. In response to these achievements, the project was deemed a success.

With the conclusion of this project, three primary recommendations can be made for future improvements:
1) Configure and calibrate the software to reduce noise and to determine the actual bone stiffness of the ulna
2) Design a leg fixture to allow for tibial bone stiffness determination
3) Compare data with that of the DEXA system to verify validity and draw further conclusions

The MERCK Manual of Medical Information defines osteoporosis as a progressive decrease affecting the density of bones that weakens them and makes them more likely to facture[5]. Bones progressively increase in density until a maximum density is reached around age 30. If the body is unable to regulate and maintain the mineral content of bones, they become less dense and more fragile over time, resulting in osteoporosis[27]. Even though osteoporosis is principally manifested by fractures in the hip, spine and wrist, all bones are subject to the negative effects of osteoporosis.

Osteoporosis affects both trabecular and cortical bone[17]. Therefore, bone density of cortical bone structures such as ulna and mid-radius may be used as a predictor of osteoporotic fractures. Figures 1 and 2 illustrate differences between the trabecular and cortical bones with and without osteoporosis.



Figure 1: Normal Bone
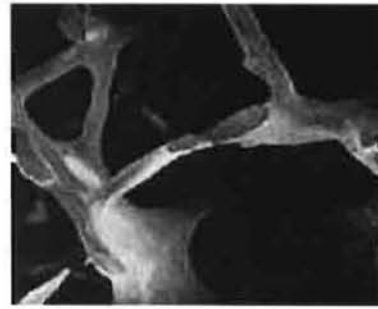


Figure 2: Osteoporotic Bone

## *The Importance of Clinical Testing*

According to the National Osteoporosis Foundation, more than 10 million people in the United States suffer from osteoporosis. 80% of those affected by osteoporosis are women. Seventy percent of non-Hispanic white and Asian men aged 50 and older are estimated to have osteoporosis, and 35 percent of non-Hispanic white and Asian men aged 50 and older are estimated to have low bone mass. One in two women and one in eight men aged 50 and over will have an osteoporosis-related fracture in their lifetime[15]. Even astronauts can benefit from clinical testing. If Mars Mission takes 30 months to complete, that's about 30% of the astronaut's bone lost. They cannot return to earth and avoid a bone fracture. Research on this problem is currently taking place at the National

Space Biomedical Institute in Houston, Texas. Research highlights include the study of the effect of weightlessness on fracture healing and evaluating the potential role of ultrasound in promoting fracture healing.

Osteoporosis causes more than 1.5 million fractures each year. Women, as well as men, are often unaware that they have osteoporosis until it is brought to their attention with an unexpected and painful fracture when they are in their fifties, sixties, or seventies. The cost of these fractures exceeded $17 billion in 2001 ($47 million each year) — more than the cost for either congestive heart failure or asthma[3]. The key to managing this debilitating disease is identification of those at risk, measuring bone density, and treating appropriately. Clinical trials are tests that are carried out to see whether or not a specific treatment is effective, safe, and can improve upon existing treatments. The results can often help save lives or ease pain.

Due to the medical applicability, the potential for extensive research exploration, and the elimination of available alternatives used to clinically test individuals at risk of developing osteoporosis, the goal for the senior capstone project was:

*To design a clinical testing device that utilizes the input of mechanical vibration onto the surface of the human bone to evaluate mechanical properties of bone including bone stiffness.*

The application of mechanical vibration onto the surface of human bone allows for the evaluation of mechanical properties, specifically bone stiffness. The obtained stiffness measurement is used as an indicator of bone density, which is applicable in making prognoses of both the likelihood and extent of osteoporosis in the target bone. Determining the likelihood of bone failure will be the equivalent conclusion inferred from the data. To execute the purpose of our project, the desired characteristics included:

- The ability to measure bone stiffness (EI), not simply bone density
- Adjustability and mobility
- Time efficiency, both for system construction and data acquisition
- Minimal patient risk
- Affordable construction
- Ability to alter testing device for future applications

Using a GANT chart, the team tentatively scheduled research and construction in order to complete the capstone project within the allotted time.

As previously mentioned, the goals of clinical testing are to establish the diagnosis of osteoporosis on the basis of assessment of bone mass, to establish the fracture risk, and to make decisions regarding the needs for instituting therapy. A history and physical examination are essential in evaluating fracture risks and should include assessment for loss of height and change in posture. The most commonly used measurement to diagnose osteoporosis and predict fracture risk is based on assessment of bone mineral density (BMD), which is principally determined by the mineral content of bone.

Several different techniques have been developed to assess BMD at multiple skeletal sites including the peripheral skeleton, hip, and spine. The World Health Organization (WHO) has selected BMD measurements to establish criteria for the diagnosis of osteoporosis. A T-score is defined as the number of standard deviations (SD) above or below the average BMD value for young healthy white women. This should be distinguished from a Z-score, which is defined as the number of SD above or below the average BMD for age- and gender-matched controls. According to the WHO definition, osteoporosis is present when the T-score is at least minus 2.5 SD. Although T-scores were based originally on assessment of BMD at the hip obtained by Dual-energy X-ray absorptiometry (DEXA), they have been applied to define diagnostic thresholds at other skeletal sites and for other technologies. Experts have expressed concern that this approach may not produce comparable data between sites and techniques.

Newer measures of bone strength, such as ultrasound, have been introduced. Recent prospective studies using quantitative ultrasound (QUS) of the heel have predicted hip fracture and all nonvertebral fractures nearly as well as DEXA at the femoral neck. QUS and DEXA at the femoral neck provide independent information about fracture risk. In general, clinical trials of pharmacologic therapies have utilized DEXA, rather than QUS, for entry criterion for studies. There is uncertainty regarding whether the results of these trials can be generalized to patients identified by QUS to have high risk of fracture.

The University of Tennessee's Hodges Library was the primary source used for background research on osteoporosis, bone properties, and systems previously used for measuring bone density. The key words used to retrieve applicable articles used in the design project include osteoporosis, bone density, bone properties, ultrasound, and mechanical vibration. The Sci-Fi Scholar database was used to obtain journal articles based on the specified keywords. These articles are listed in the reference section of the report. In addition, pamphlets were provided by the National Osteoporosis Foundation, which provided additional background information[15].

University contacts for our research included Dr. Zemel, Head of the Department of Nutrition and Dr. Wasserman from the Department of Mechanical, Aerospace, and Biomedical Engineering at UT. Dr. Zemel provided with pertinent information regarding the DEXA system that is currently in use in the Department of Nutrition[29]. Dr. Wasserman was contacted for his expertise on the applications of electromagnetic vibrational shakers[25].

The ongoing research on mechanical vibration measurement schemes included reviewing existing patents. The search involved research through the general University of Tennessee Hodges Library Catalogs and Sci-Fi Scholar, a publication search engine accessible from the Hodges Reference Facility. The United States Patent and Trademark Office website was also utilized, which is http://www.uspto.gov [24]. The patent search was based on the specific keywords of "mechanical", "vibration", and "bone". The use of these keywords resulted in several patents that were released or filed for within the past six to seven years. Based on the search, the list was narrowed to eight patents that were relevant to the project in terms of background knowledge, alternatives, and close similarity to the team's design and purpose. Those eight patents are listed as follows:

1. Patent 5,836,876 – Method and apparatus for determining bone density and diagnosing osteoporosis
   Inventor(s): Andrew D. Dimarogonas
   Assignee: Washington University    Filed Date: March 31st, 1995
2. Patent 5,836,891 – Method and apparatus for determining the density and structural integrity of biological tissues, medical implants, and structural part
   Inventor(s): Andrew D. Dimarogonas    Filed Date: May 20th, 1997
3. Patent 5,938,610 – Bone assessment apparatus
   Inventor(s): Naoki Ohtomo Assignee: Aloka Co., Ltd. Filed Date: September 18th, 1998
4. Patent 6,264,621 – System and method for providing quantified and qualitative hand analysis

Inventor(s): William C. Paske
Assignee: William C. Paske      Filed Date: October 29th, 1999

5. Patent 6,292,535 – Digital X-ray imaging system with automatic display image greyscale enhancement and method
Inventor(s): Neil A. Williams, Gerald A. May
Assignee: Canon Kabushiki Kaisha      Filed Date: December 21st, 1999

6. Patent 6,311,562 – Human lumbar model structure capable of simulating pressure applied to nucleus pulposus in human lumbar and application equipment utilizing the structure
Inventor(s): Keiichi Hanada      Filed Date: March 3rd, 2000

7. Patent 6,308,097 – Tissue characterization based on impedance image and on impedance measurements
Inventor(s): Andrew L. Pearlman
Assignee: Transscan Medical Ltd.      Filed Date: April 28th, 2000

8. Patent 6,315,445 – Densitometry adapter for compact x-ray fluoroscopy machine
Inventor(s): Richard B. Mazess, David L. Ergun, Joseph P. Bisek
Assignee: Lunar Corporation      Filed Date: December 21st, 2000

From the above patents, the one patent that very closely related to the project was the first patent listed, Patent # 5,836,876 – *Method and apparatus for determining bone density and diagnosing osteoporosis*. This patent is for a device that was designed for the mechanical vibration application to bone. Figure 3 is a visual display of this system. This specific system involves a frequency generator, a power amplifier, a mechano-electrical vibration transducer, and a microprocessor to collect and analyze the data.
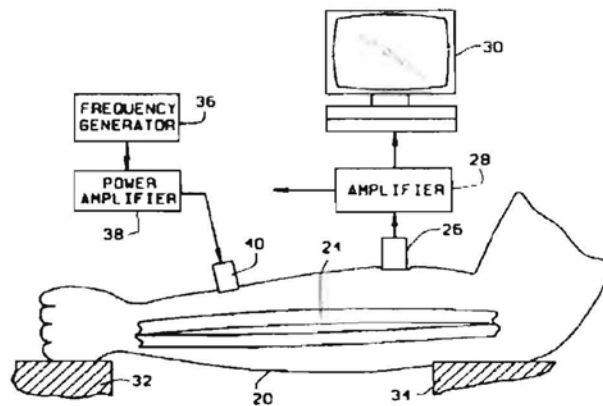


Figure 3: Patent #5,836,876 Design View

Internet websites, http://www.sti.nasa.gov/tto/spinoff1996/24.html, and www.wilcoxon.com, were used to provide non-commercial information. "A Boone for Bone Research," written by James J. Haggerty, was an article found on NASA's website which provided information on the first mechanical vibration testing system designed for the diagnosis of osteoporosis. "A Boone for Bone Research," is about a research study conducted by NASA involving the development of bone stiffness and mass measurement

device to predict fracture risks in humans and developing treatments for bone disorders. Since astronauts often work in a weightless environment in space for a long period of time, such exposure can lead to several forms of bone disorder such as bone deterioration, also known as disuse osteoporosis, and calcium deficiencies, leading to risks associated with bone fractures[9]. This article was crucial for the alternative methods research as well as establishing a baseline for the development of the project design. The second website, www.wilcoxon.com, yielded information on an electromagnetic vibrational shaker that could meet and exceed minimal requirements needed for the design project[28].

The relevance of the NASA report to our project is that our project is based on this NASA system with the objective being to use the system to measure bone stiffness to calculate bone density for prognosis of osteoporosis and other bone disorders. This article helped give background and insight into NASA's objective and purpose as well as to the company and research centers they worked with to develop the system. The NASA report also provided information regarding potential applications of this system. Our purpose was to construct and advance the NASA design for wider routine use in clinical medicine diagnosis.

Over the past year, several professional organizations have been working on establishing a standard of comparability of different devices and sites for assessing fracture risk. With this approach, measurements derived from any device or site could be standardized to predict hip fracture risk. However, the values obtained from different instruments cannot be used to predict comparable levels in bone mass. Limitations in precision and low correlation among different techniques will require appropriate validation before this approach can be applied to different skeletal sites and to different age groups.

After extensive research, an acceptable alternative to our design project must satisfy the desired characteristics of our system. These include:
- The ability to measure bone stiffness (EI), not simply bone density
- Adjustability and mobility
- Time efficiency, both for system construction and data acquisition
- Minimal patient risk
- Affordable construction

- Ability to alter testing device for future applications

Before narrowing the focus of the project, seven broad objectives were created that would serve as guidelines around which to plan the design process. The objectives were:

Objective 1: Determine which bones are most susceptible to density depletion and stiffness degradation, and then design the testing device for use on such bones.

Objective 2: Determine which specific location on the bone is preferential for maximization of acquisition of stiffness data.

Objective 3: Establish a design for applying the input signal to the desired bone(s).

Objective 4: Design a comfortable and adjustable fixture for holding the target limb or body part containing the target bone.

Objective 5: Construct the entire testing device.

Objective 6: Implement and install a software program that utilizes the raw data to output stiffness and other desired quantities.

Objective 7: Test and perform experimental trials with the device.

Prior to embarking upon the project design and assembly, the focus of the project had to be narrowed down to one specific alternative. From surveying the current methods of diagnosing bone strength, three design alternatives were generated. Each of these methods is ideal for its own specific purpose, but the research team's mission was to determine which alternative would be the most viable option for this project. The purpose, cost, design, and feasibility were the primary characteristics determined for each alternative. This information was compiled from journal articles and personal contacts. The alternatives were then quantitatively evaluated by ranking the relevance and applicability of each method in reference to established design criteria.

*Generated Design Alternatives*

*Dual Energy X-Ray Absorptiometry (DEXA)*

Dual energy X-ray absorptiometry (DEXA) is widely viewed as the preferred method to assess pediatric bone mineral content because of its speed, precision, minimal radiation exposure, and the availability of pediatric reference data[2]. The DEXA measures the body composition, bone mineral density, and bone mineral content. The system takes measurements of both calcified and soft tissue. The DEXA system, such as the one shown in Figure 4, manufactured by GE Medical (Model: Prodigy LUNAR), has an estimated cost of approximately $70,000.

The system can give a whole-body scan image in ~3-6 minutes, and two types of images are taken of the bones and soft tissue[22]. Data collected by this system includes ancillary data: bone mineral density—BMD $(g/cm^3)$, bone mineral content—BMC (g), and the estimated area of the scanned region $(cm^2)$. The load-carrying capacity of cortical bone is closely related to its geometry and to its fundamental material properties,

including BMC. In analyzing data obtained from the DEXA system, if a patient's BMC is below two and a half standard deviations from the mean value for the appropriate age group, then he/she is diagnosed with osteoporosis. The DEXA system is the most commonly used method to measure bone density. The high cost of the system, the long data collection period, and the use of harmful x-rays are disadvantages to using the DEXA system.



Figure 4: DEXA Prodigy LUNAR System

*Ultra Critical-angle Reflectometry (UCR)*

Ultrasound (US) transmission waves, or ultrasonic radiation, are mechanical vibrations that are applied to a material—in this case bone tissue—in order to study its properties, such as density, elasticity, and structure[8, 18]. Increased bone density and size are factors influencing amplitude-dependent speed of sound (AD-SoS), which is measured by the Ultrasonic Radiation system[4]. Ultrasonic Radiation has several advantages. The Ultrasound Critical-angle Reflectometry (UCR) image aids in clinical diagnoses of bone status over time by reflecting on the bone loading at a specific location[7]. The UCR is also not as costly as the DEXA. It also has the ability to predict relative risk of hip fractures. The downfall to using this device is that it mainly measures bone mass, and it does not predict bone strength. The reproducibility of data is also better in the DEXA system. Below is a picture of the Ultrasound Critical-angle Reflectometry data, a pressure wave velocity map fused with an X-ray projection of a human tibia. UCR can measure the directional dependence of the velocities in a sample at a point, from a single surface. This point of measurement can then be moved over the surface and values at specific orientations put in a pseudo-color map, as shown in Figure 5.

**IN VIVO ELASTOMETRIC IMAGING BY UCR**

directional dependence of bone mechanical stiffness-human tibia
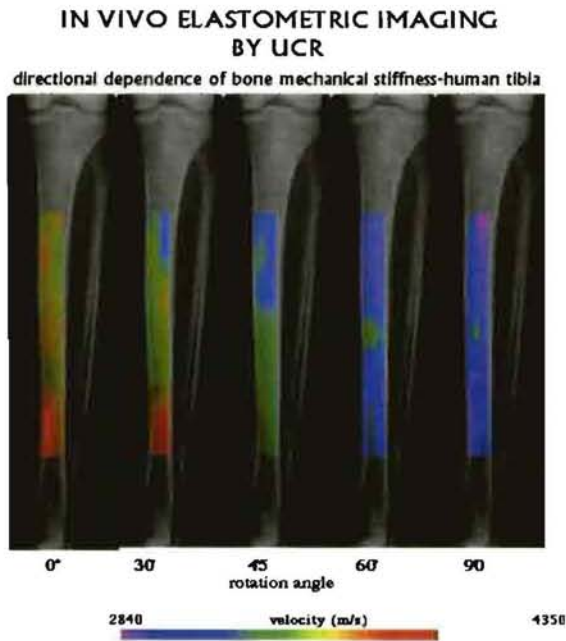
Figure 5: Ultrasound Critical-angle Reflectometry

These images can aid in clinical diagnosis of bone status over time by improving registration of data at different time-points and by creating a visual representation of local variation of properties. This local heterogeneity reflects the loading history of the bone and any changes in this image will reflect alterations in loading or bone biology at that location. It is possible to identify some parameters that are related in different ways to density and to elastic properties of bone[1]. The results of one research study showed the potentiality of the UCR technique to separate information on bone density and elasticity that X-ray-based densitometric methods do not provide[8]. The estimated cost of a UCR system is estimated at $50,000.

*Mechanical Vibration Testing System*

The MVTS applies a vibration to a bone and measures the applied force and the resultant acceleration. It determines the impedance response of low-frequency vibrations to determine the bending stiffness, EI, which is the reflection of the elastic modulus, E, and the moment of inertia, I, for the entire ulna[11, 14]. This information is useful as an

19

indicator of bone density, and this method can be used to provide an index to monitor the progress of osteoporosis[6,23].

Several advantages exist for the use of a Mechanical Vibration Testing System. The device is portable, and ionizing radiation is not used to measure the bone mineral density levels. The estimated cost is less than $5000. The use of a Mechanical vibration technique is particularly appealing for the clinic because the test is fast (several seconds), safe, and comfortable for the patient and directly measures bone stiffness, which can be a more accurate predictor of bone strength than bone mass. Unlike conventional radiological techniques, which are expensive, use bulky equipment, have a potential risk from radiation and cumbersome procedure, vibrational techniques emit no radiation, are cost effective, utilize equipment which is portable and easy to operate[10,12].

NASA developed a noninvasive measurement device known as the Mechanical Response Tissue Analyzer or MRTA. The Mechanical Response Tissue Analyzer is a portable device that does not use any ionizing radiation, and it is very inexpensive when compared to other methods of bone measurements, costing an estimated $20,000. It was a product of a team collaboration between three groups: NASA Ames Research Center, Stanford University in Palo Alto, California, and Gait Scan, Inc. a small business located in Ridgewood, New Jersey. The background lies in bending stiffness (EI), an important property of bone that reflects the bone's material quality and geometrical stability. Bone stiffness can be correlated to bone density and bone mineral content measurements. Another advantage of the MRTA is that it offers a convenient method for separating the effects of the soft tissue and bone[20].

This system identifies a bone's response to a five-second electrically induced vibration applied by a small probe on the skin surface of the limb to be tested such as the ulna (bone in the arm) and the tibia (bone in the lower leg). As a result of the stimulus produced from the vibration, the response from the resonating bone are detected and analyzed by computer software to give measurements of bone stiffness, bending stiffness, bone density, and bone mineral content. Potential applications of the MRTA range from astronaut post flight monitoring, measuring tibia strength among working women at Ames, monitoring the effects of exercise and rehabilitation on bone stiffness and in osteoporosis (Gait Scan's pursued application), and to study Osteogenesis Imperfecta

(characterized by brittle bones and increased risk of fracture), which is an ongoing research project by the Oschsner Bone Clinic in New Orleans, Louisiana. This clinic uses the MRTA to measure bone flexibility and compare the data among family members, with other data from CT scans, bone density measurements, and other test analysis, in hopes of leading to advanced treatments for osteogenesis imperfecta and other bone disorders. The team conducted research at the Ames Center and Stanford University, resulting in a device for clinical testing at the Stanford University Orthopedic Hospital. Gait Scan invested its own funds in developing this instrument to bring it to market[9].

## Design Criteria

This design project was characterized by a set of clearly defined constraints and objectives, all of which gave rise to the criteria by which the alternatives evaluated. These criteria consisted of six main points:

- Desired data output
- Adjustability and mobility
- Minimal risk to patient
- Affordable construction
- Availability of equipment
- Ability to alter testing device for future applications

### Desired data output

The primary piece of data that this design will be used to obtain is bone stiffness (EI). Therefore, it was a necessity that the design would have the capacity to obtain this information. While other items of data relating to osteoporosis and fracture risk are helpful and informative, stiffness is the only osteoporotic indicator that takes into account both the geometry and the quality of the bone material itself. Bone mineral density and bone mineral content, two commonly determined bone characteristics, are both useful for determining the quality of the bone material, but neither takes into account the geometry of the bone. It has been shown that bone stiffness is also a better indicator for bone strength than either the mineral density or mineral content.

The timely collection of data was also a focus for the desired data output of the device. A goal for this project was to develop a very efficient method for determining bone stiffness. A procedure requiring even a few minutes to acquire data was considered less than ideal.

### Adjustability and mobility

In order to make the device as convenient as possible, it would have to be able to accommodate patients of varying size and shape. This, of course, is generally a

characteristic for most biomedical devices, but it was necessary to keep this in mind during the design of the device.

It is also a necessity that the device be freely movable from one place to another. The applications of this are obvious; it will maximize the patient's comfort if the device can be transported to them, as opposed to vice-versa. Construction of the device would also be greatly facilitated by having the ability to transport the device to and from different locations.

*Risk to patient*

In order for the device to be approved, by both the patient and external standards, patient risk needed to be kept to a minimum. Since the device had the intent of determining fracture risk and possibly fracture recovery, great care would be needed with handling bones. Radiation was also a hazard that, while feasible in moderation to some patients, inevitably detracts from the appeal of a device and closes the door to some patient groups, such as pregnant women.

*Affordable construction*

The design group began the project with a limited budget of approximately $5,000. Although some designs might prove to be extremely applicable for the project, if the cost of construction was found to extend too far beyond this value, the design would have to be abandoned. The higher the cost of a design proved to be, the less feasible it would be to undertake that option, regardless of the potential product.

*Availability of equipment*

Similar to the construction cost constraint, equipment availability was not a negotiable variable. If the equipment and resources which would be needed in order to construct a particular design would prove too difficult to obtain, that design's appeal would diminish. Additionally, if one design option were to already be available for use, this would greatly enhance the appeal of that design in this regard. It was hoped that the selected design would consist of components that could be easily ordered from product catalogs in a reasonable amount of time.

*Ability to alter testing device for future applications*

The original goals for the project were both broad and relatively tentative. In the future, the final device, although meeting all of the initial requirements, might well be needed to measure bone stiffness by a different process. For example, it was presumed that designing a way to measure bone stiffness from a specific bone in the body would be the easiest and most efficient approach to the problem. In the future, it may be needed to measure the bone stiffness from another bone in the body. The best way for this to be possible would be to design an open-ended device. By constructing a device with removable and easily manipulated components, there would be a greater possibility for future alterations. If a design called for a strictly solid, "closed-box" final product, device alterations might not be an option if the situation arose.

| Ideas ➔ | Maximum Points | Alternatives | | |
|---|---|---|---|---|
| Constraints ⬇ | | DEXA | Ultrasonic Radiation | Mechanical Vibration |
| Cost | 30 | 15 | 21 | 28 |
| Risk to Patient | 20 | 5 | 12 | 19 |
| Mobility | 10 | 0 | 3 | 10 |
| Desired Data Output | 20 | 11 | 11 | 19 |
| Availability of Equipment Needed | 10 | 8 | 2 | 5 |
| Future Alterations | 10 | 2 | 2 | 9 |
| **Total Maximum Points:** | **100** | **41** | **51** | **90** |

Table 1: Alternative evaluation results

After specifying which design criteria were most important for the success of this project, the alternatives were evaluated with respect to these criteria. The constraints, as seen in Table 1, were derived from the previously discussed design criteria. Each constraint, as seen in Table 1, was assigned a maximum amount of points, as determined by the relative importance of that particular constraint. Each alternative was then assigned a point value for each constraint, determined by the extent to which the alternative met the constraint. The point values were then compiled, and the relative feasibility of each alternative was determined by comparing it to the other alternatives and to the 100 point maximum.

*Dual Energy X-Ray Absorptiometry (DEXA)*

The DEXA system, with a cost of approximately $70,000, proved to be the most expensive alternative. Hence, it was given a value of 15, which was somewhat conservative. Due to the relatively large amount of radiation that it utilizes, it was also given a patient-risk-value of 5. Radiation was one of the least attractive tools for the

team, and its avoidance was one of the reasons for the creation of this project. Due to its massive size and set-up, the DEXA system is also relatively immobile. Thus, it was given a value of zero for mobility. As previously discussed, the DEXA system does provide data for patient body composition, bone mineral density, and bone mineral content. However, it does not measure bone stiffness, and the data collection procedure requires roughly 3-6 minutes. As a result, it received a value of 11 for desired data output. The DEXA system was ranked the highest for equipment availability, due to the fact that there is already a functional system nearby. As with many purchased prefabricated systems, the DEXA system was found to be unsuitable for future adjustments and modifications, and was thus given a value of two. The DEXA system generated a total score of 41.

*Ultra Critical Angle Reflectometry (UCR)*

Compared to the DEXA system, the UCR system, estimated at $50,000, proved to be a bit more affordable, although still breaching the aforementioned financial limit of $5,000. As a result, it received a value of 21 for the cost category. As with the DEXA system, the UCR system also utilized radiation to obtain its results, although the amount of radiation was significantly less. For this reason, it was assigned a patient-risk value of 12. The UCR system is movable, but its many components and accessories do not allow for easy transportation. It was assigned a mobility value of 3, to indicate that mobility is feasible, but it is not convenient. The UCR system is designed to measure bone density and size, both which help to indicate fracture risk but, unlike bone stiffness, do not exhibit cross-sectional geometry. It is also mostly utilized to determine loading differences in single locations over a period of time, which was not relevant to this project. It was given a value of 11, equivalent to the DEXA system, in regards to the desired data. Unlike the DEXA system, there was not a UCR system nearby, and the components needed to utilize ultrasonic radiation proved too difficult to obtain and assemble. Therefore, it was given the lowest value of 2 for equipment availability. Lastly, as with the DEXA system, the UCR system, due chiefly in part to its pre-fabricated production, would offer little possibility for future modifications. It received a

score of two for this constraint. The UCR system generated a total score of 51 for the constraint evaluation.

*Mechanical Vibration Testing System (MVTS)*

After generating preliminary sketches of what this potential design would entail, it was determined that this system would meet the proposed budget of $5,000. The device would presumably be fabricated from aluminum tubing, with several additional components to fit the purpose. The one exception to this budget was a piece called a shaker, which would apply the vibration to a bone. Preliminary investigation placed the cost of this piece slightly below $5,000. For this reason, this system was given a rating of 28 for cost, instead of 30. In addition to cost, the MVTS scored the highest in the patient risk, mobility, desired data output, and future alterations constraints. By avoiding the use of radiation, which was the main differentiating factor amongst the alternatives, patient risk drastically decreased. Additionally, the vibrational force to be applied to a bone will not be significant enough to cause the patient any harm or discomfort. The MVTS proved to be small enough to allow for a mobile design, which the other alternatives did not allow. While the exact transportation means were not determined at this point, the mere size of the future system allowed for it perfect ten value for this constraint. As is evident in the founding theory behind the MVTS, bone stiffness can be directly determined from the data. This justified a desired data score of 19. Regarding availability, there was not already a nearby MVTS available for use, but the components were easily located in catalogs, resulting in a score of 5. Since the design of the MVTS would be created during the project, the device could be designed and constructed with the intent of allowing future needed modifications. From preliminary sketches, the pieces and components of the device were also easily designed to allow for convenient detachment. For these reasons, the system achieved a score of 9 for the future alterations constraint. The MVTS generated a total score of 90 from the evaluation.

*Justification of Selected Alternative*

Based on the previously described alternative evaluation, the use of mechanical vibration to measure bone stiffness, and thus to determine osteoporotic extent and fracture risk, was selected as the optimal design alternative. The MVTS system achieved a score of 90 out of 100 in the alternative evaluation, as compared with a 41 for the DEXA system and a 51 for UCR. It would be possible to construct the Mechanical Vibration Testing System within two semesters and retrieve post-construction data within seconds. It would be constructed with a freely movable base that provided optimal mobility for transporting the system from patient to patient or from room to room. The mechanical vibration technique would directly measure bone stiffness (EI), which is a more accurate predictor of bone strength than simply bone density. The system would be constructed, while keeping potential future modifications in mind. Mechanical vibrations do not emit radiation, unlike the DEXA or the UCR systems, maximizing patient safety, and thus, patient market.

*Theory/Design*

After narrowing the focus of the project to one alternative, vibration theory was utilized to design the device itself. The idea itself is founded upon a simple spring-mass system (Figure 6). By measuring the system's response to an applied force, the natural,



**Three Point Bending**

Accelerometer

**Applied vibration force**

$$k = \frac{48EI}{l^3}$$

k

m

$$\omega_n = \sqrt{\frac{k}{m}}$$
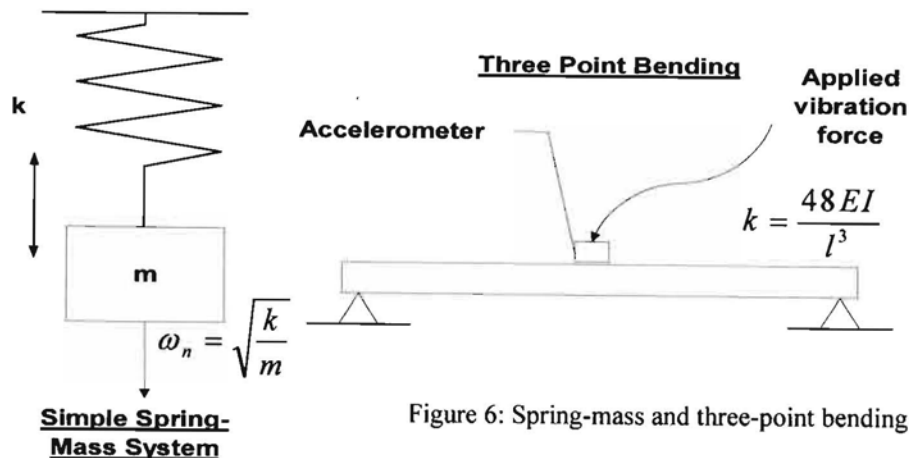
**Simple Spring-Mass System**

Figure 6: Spring-mass and three-point bending systems

or resonance, frequency of the system can be determined. The stiffness of the spring can then be found from this value. This concept can be easily extended to a beam, and by relying on three-point bending, the stiffness, k, can again be determined from the natural frequency. From Figure 6, the desired stiffness, EI, can be determined from this value. Hence, by analyzing a bone that can be approximated as a beam, this theory will be applicable.

Based off of the previous discussion, long bones were determined to be the bones of choice. Additionally, the bones would need to be near the skin surface so as to minimize interference from other tissues during vibration application. This logic led to two options: the tibia and ulna. The tibia, while having a greater fracture risk than the ulna, was initially desirable. However, because of the asymmetrical cross-sectional geometry of the tibia, the first observable mode resulting from a perpendicularly applied vibration is a combination of a bending mode and a torsional mode[19]. Since bending stiffness is measured from the bending mode, this occurrence would obscure the data, significantly decreasing data accuracy. In contrast, the symmetry of the ulna would prevent this phenomenon from happening[16]. Thus, the ulna was determined to be the ideal bone for stiffness evaluation.

Once the ulna was decided upon, the initial design of the device was created (see Figures A1, A2). This device consisted of a supporting frame, an arm fixture, and an arm to hold the vibration-applying shaker. This design was created to satisfy the design criteria of adjustability, mobility, ease of operation, and patient comfort. Throughout the semester, this design was modified to better fit these criteria and to adapt to arising situations, such as cost, availability, and feasibility (see Figures A3-A6). For example, the final design incorporated the use of a hospital table, instead of a previously proposed pneumatic chair, to allow maximum mobility and stability of the system. Also,



Figure 7: Finished device, emphasizing the arm fixture and shaker support

the arm fixture was redesigned to attach directly to the 12"x16" aluminum plate, which anchored the frame to the table, to eliminate unnecessary welding and to improve the vertical range of motion needed to meet the adjustability design criteria specified in the previous section. The finished device is displayed in Figure 7 (see additional pictures in Figures A14, A15)

*Assembly/Components*

Based on the final schematic of the design for the mechanical vibration system, the construction of the entire system entailed four specific areas:

1. Constructing the essential frame (horizontal and vertical shafts)
2. Mounting the electromagnetic shaker system to the slider and then to the designated horizontal shaft of the frame
3. Assembling and attaching the forearm fixture
4. Combining the above three assemblies with signal processing hard/software to complete the Mechanical Vibration Testing System

*Parts for the Prototype*

The parts for the frame and forearm fixture (aluminum tubing and plates, the Precision Linear Ball Bearing Slider, and the Mini Ball and Socket Universal Joint) were ordered from McMaster-Carr located in Atlanta, GA. The Model F3 electromagnetic shaker system was ordered from the Wilcoxon Research Inc., Gaithersburg, MD. The hospital table was donated from the UT Medical Center. A detailed description of all the parts used for the mechanical vibration system prototype is contained in Table B1.

*Frame and Forearm Fixture*

The frame and forearm fixture was constructed with the use three different sizes of hollow square-cross-section aluminum tubing (see Table B1). Both the 1 ¼" X 1 ¼" square aluminum tube with the thickness of 0.125" and the 1.5" X 1.5" square aluminum tube with the thickness of 0.0625" were used for the vertical shaft and horizontal shaft of the frame. The 1" X 1" tubing was only used in the forearm fixture. By inserting the smaller aluminum tubing into the larger tubing, a telescoping effect was created to meet

the adjustability design criterion allowing for varying arm lengths and widths. All inner sliding tubes are held in place by a #10-32 screw extending through the thickness of the outer tube. The vertical shaft and arm fixture were fastened to the 1" X 12" X 16" aluminum plate, which was secured to the hospital table. The 1" X 2" X 3" plate holds the slider to the horizontal shaft. The arm fixture attaches to the main plate via a #10-32 screw, which slides along a 3" groove extending through the plate (see Figures A7, A8). Two ¼" brass pins secure the arm fixture and prevent it from rotating around the fastening screw.

*Shaker Assembly*

The Model F3 electromagnetic shaker system (see Figures A9, A10) was determined to fit the specifications (lightweight, small, having an ideal frequency range, and affordable) for the design. The shaker was equipped with a force transducer and an accelerometer, which would relay the input and output, respectively, to the signal processor. The shaker, attached to the slider via circular clamps, was positioned directly above the arm fixture. In theory, the shaker would apply the vibration to the mid-point of the ulna without affecting the force due to a fixed position. Thus, the slider (see Figure A11) was utilized to allow for uninhibited vertical motion of the shaker.

Another part of the assembly is the Mini Ball and Socket Universal Joint, shown in Figure A12. This joint was attached to an adapter (see Figure A13) fabricated to connect and secure the joint to the mounting hole on the bottom of the electromagnetic shaker. A stainless steel parabolic tip, which rests upon the ulna, was attached to this joint and serves as the actuator that applies pressure and vibration.

*Patient Preparation*

Prior to data collection, several measures are conducted to standardize the location in which measurements are taken and maximize data accuracy. First, the forearm is flexed to 90 degrees and held horizontal by the arm fixture. The subject's ulna length is then measured as the distance between the olecranon process and ulnar styloid

process. The placement site for the parabolic tip is located a distance, equal to half of the length of the ulna, measured from the olecranon process.

## *Data Collection*

The signal generator relays a random vibration of a specified range to the shaker, which vibrates accordingly. Random vibration was chosen because of its speed and easy implementation and because it provides the best linear approximation to a non-linear system[26]. The force that the shaker applies to the ulna and the acceleration experienced by the shaker as a result of ulna response, are then sent to the Keithly Data Acquisition Board. This analog data is then digitized and relayed to DriverLINX Data Acquisition Driver, where it is interpreted by the HP Vee signal analyzing program. This
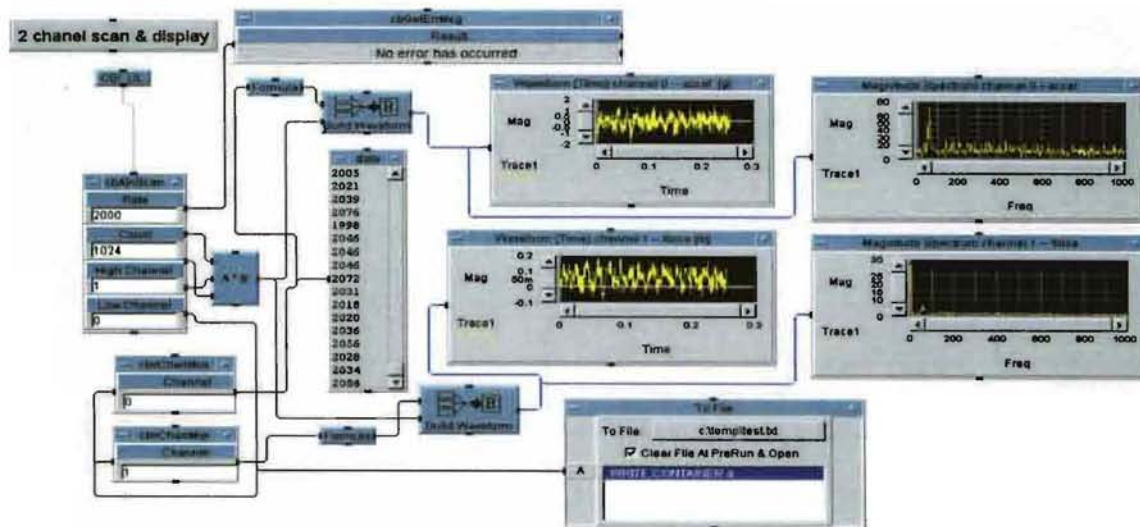


Figure 8: HP Vee signal processing program interface

program, as displayed by the graphs in Figure 8, plots both acceleration and force against time in the upper-left and lower-left graphs, respectively. A Fast Fourier Transform is then performed on this data in order to transfer it to the frequency domain. The acceleration versus frequency and force versus frequency plots correspond to the upper-right and lower-right plots, respectively. An estimate for the natural frequency of the ulna can be determined from the acceleration vs. frequency plot (upper right) at this point.

## Conclusions

As a result of the research conducted in an effort to determine the most viable method of diagnosing osteoporosis, strength, and fracture risk, four essential questions have been answered:

- What is the need for a design like the Mechanical Vibration Testing System?
- Why was this design chosen?
- Where does this device currently stand?

As discussed earlier osteoporosis is a disease that currently has no cure. Additionally, there is no guaranteed method of determining bone strength and fracture risk. In order to hinder the development of osteoporosis, minimize fracture risk and increase bone strength, early and prompt diagnoses is invaluable. The Mechanical Vibration Testing System will be utilized to collect and analyze data in an effort to advance and promote all of these goals. This clear and present need justifies this entire endeavor.

In response to the second question, alternatives were compared and contrasted to construct and assemble the system which would optimize the established design criteria. After exploring three alternatives that currently measure bone density, the following primary constraints were utilized to compare and contrast the different possibilities: cost, risk to patient, mobility, availability of equipment, desired data output, and ability of future alterations.

The Mechanical Vibration System achieved the highest score from the evaluation of the alternatives, and thus, proved to be the design most compatible with the design criteria. Specifically, the MVTS was determined to be both the safest and most inexpensive alternative. Despite its "second place" position for equipment availability, the system's components were purchased with relative ease. Overall, the conclusion was that the Mechanical Vibration System is the best alternative for evaluating bone strength, and it is the most cost and time-efficient method for diagnosing osetoporosis.

Currently, the device can be utilized to provide a rough approximation for the natural frequency of the ulna. However, this data has yet to be verified with known values or other tests. Additionally, the data cannot yet give a value for the bone stiffness, which is the long-term goal of the project.
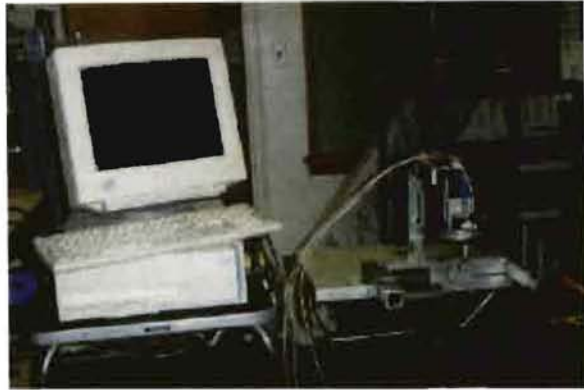


Figure 9: Completed MVTS

Nevertheless, a device has been designed and constructed which will provide a means for determining bone stiffness at some point in the future. An adjustable, mobile, easily operated frame that will firmly hold a patient's arm in position and apply a vibrational force has been assembled. The arm fixture portion of the frame has been designed to maximize patient comfort. In an effort to allow for possible future modifications, a minimal amount of welding was utilized. A data acquisition and signal processing system, which can be further calibrated and enhanced, was incorporated with the frame. Finally, tests were performed to ensure that the system was functional. This landmark was the proposed goal for this project, and thus, the project was determined to be a complete success.

## *Recommendations*

Even though we achieved all of the objectives involved with the senior capstone project and achieved the goals, improvements can be made to the overall system. The team noted three recommendations that can be performed as a senior capstone project next year.

The first recommendation is to configure and calibrate software for testing the device. With any vibrational system, there is a natural frequency involved. The system's natural frequency is presumably currently affecting our results. Due to time constraints, we did not have the opportunity to calculate the natural frequency of the system. A filtering program, possibly a low-pass filter, also needs to be included in the software to filter or minimize the noise levels and any unnecessary data.

The second recommendation deals with designing a fixture to hold the leg to allow for tibia analysis. The system currently only performs analysis on the ulna. Because the system was constructed to allow for versatility, the arm fixture can be easily removed and replaced with a leg fixture. It must be determined how the leg will be held in the fixture and which tibial location would yield the most valid and accurate results.

The last noted recommendation deals with comparing the collected data with that of the dual energy X-ray absorptiometry (DEXA) system. As mentioned in the report, the DEXA system is predominantly utilized for measuring bone mineral density as opposed to bone stiffness. Measurements taken on the DEXA system could be used to confirm the accuracy and validity of the MVTS system. Using comparative tables and charts would allow for an easy comparison between the two systems.

## *Appendix*

### *Appendix A*

Figure A1: Schematic of System on December 4, 2001
Figure A2: Schematic of Arm Fixture on December 4, 2001
Figure A3: Schematic of System on March 10, 2002
Figure A4: Schematic of Arm Fixture on March 10, 2002
Figure A5: Schematic of the Final System (front view)
Figure A6: Schematic of the Final System (side view)
Figure A7: Underside of the 1" X 12" X 16" aluminum plate, including the 3" long groove
Figure A8: Topside of the 1" X 12" X 16" aluminum plate, including the 3" long groove and securing cutout for the vertical shaft
Figure A9: The Wilcoxon F3 Electromagnetic Shaker
Figure A10: Cross-sectional schematic of the electromagnetic shaker
Figure A11: Precision Linear Ball Bearing Slide Assembly
Figure A12: Mini Ball and Socket Universal Joint
Figure A13: Universal-joint/shaker adapter
Figure A14: Full view of completed MVTS
Figure A15: Side view of completed MVTS

### *Appendix B*

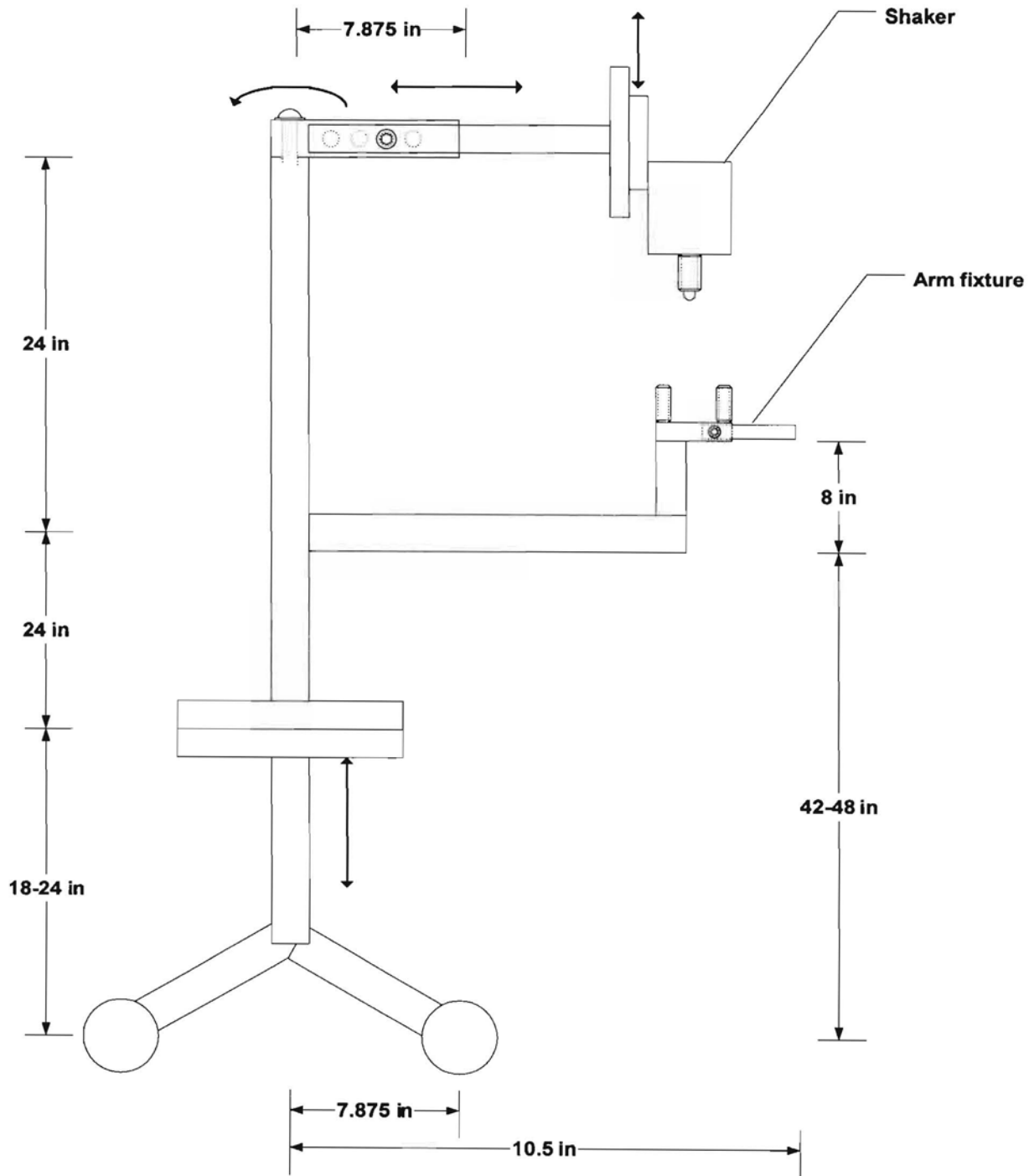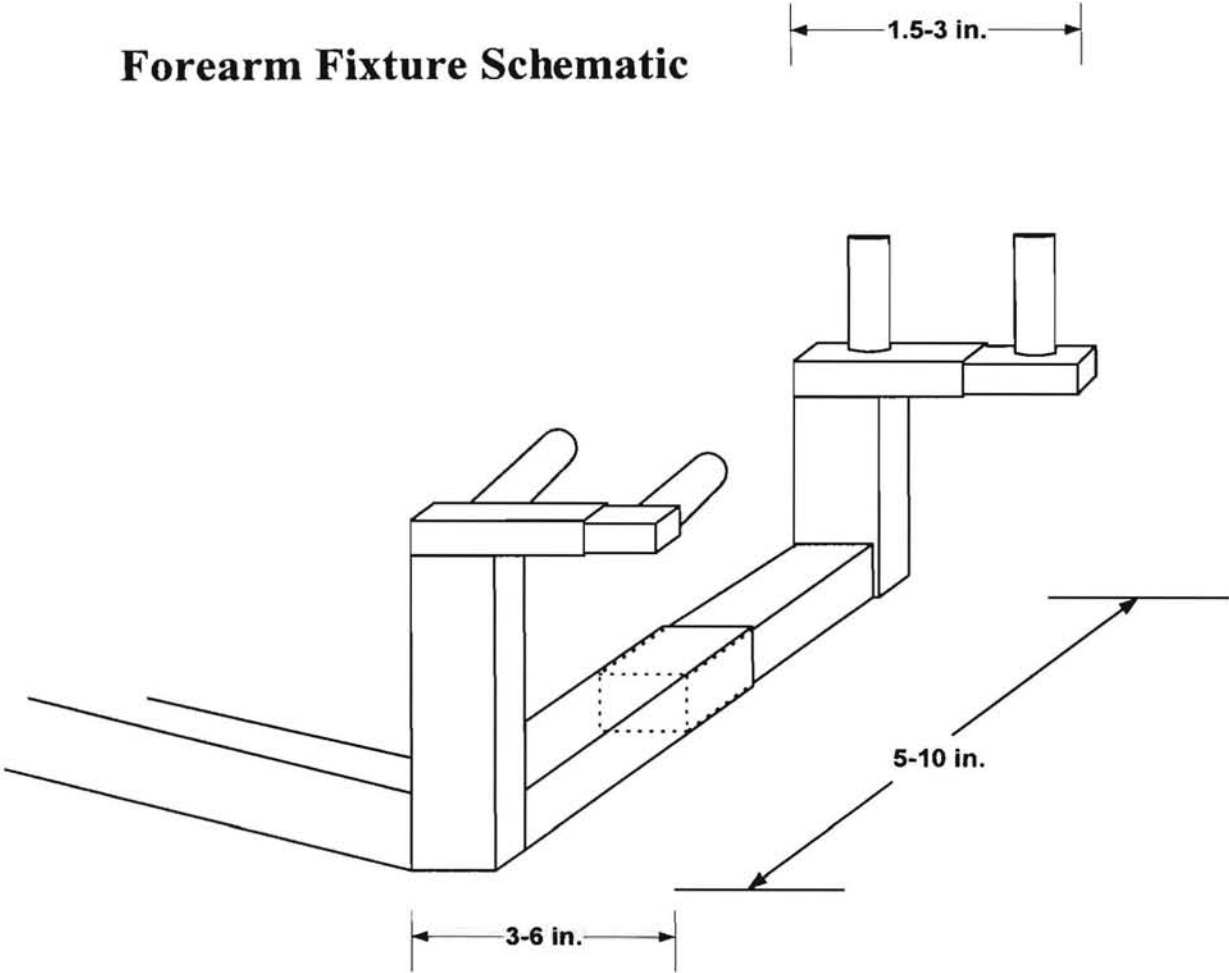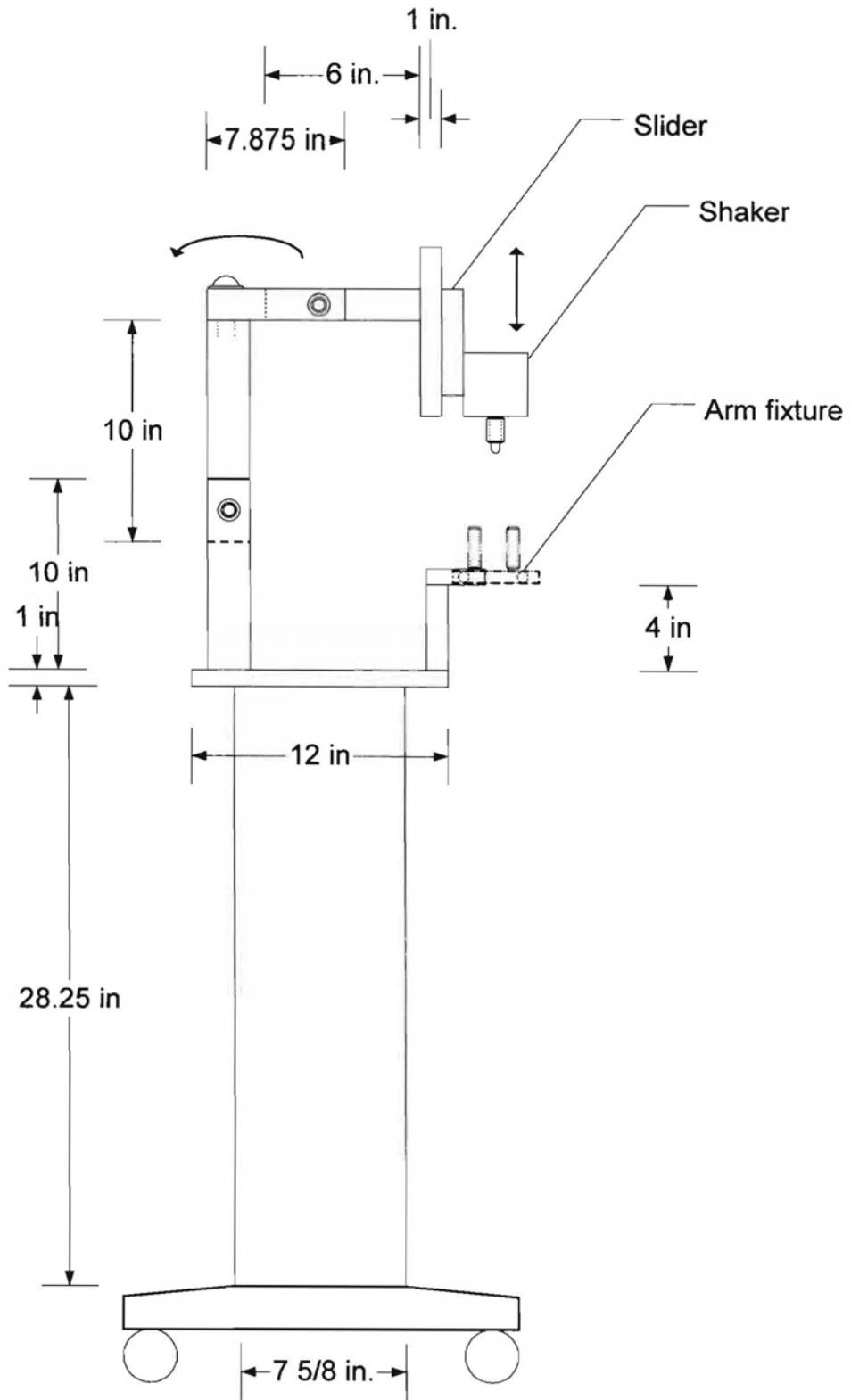Table B1: Design parts list

*Appendix A*

# Frame Assembly Schematic



**Figure A1: Schematic of system on December 4, 2001**

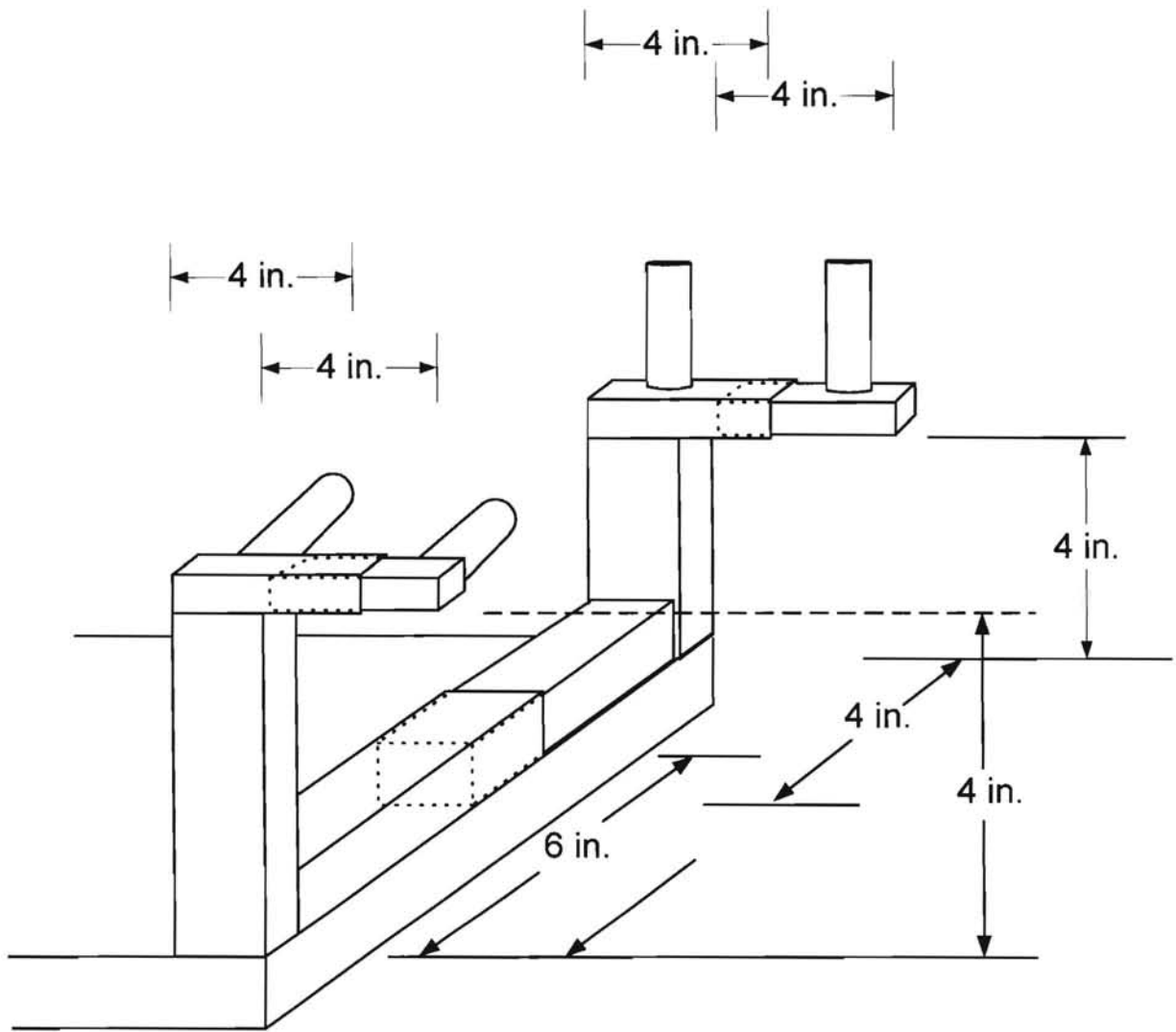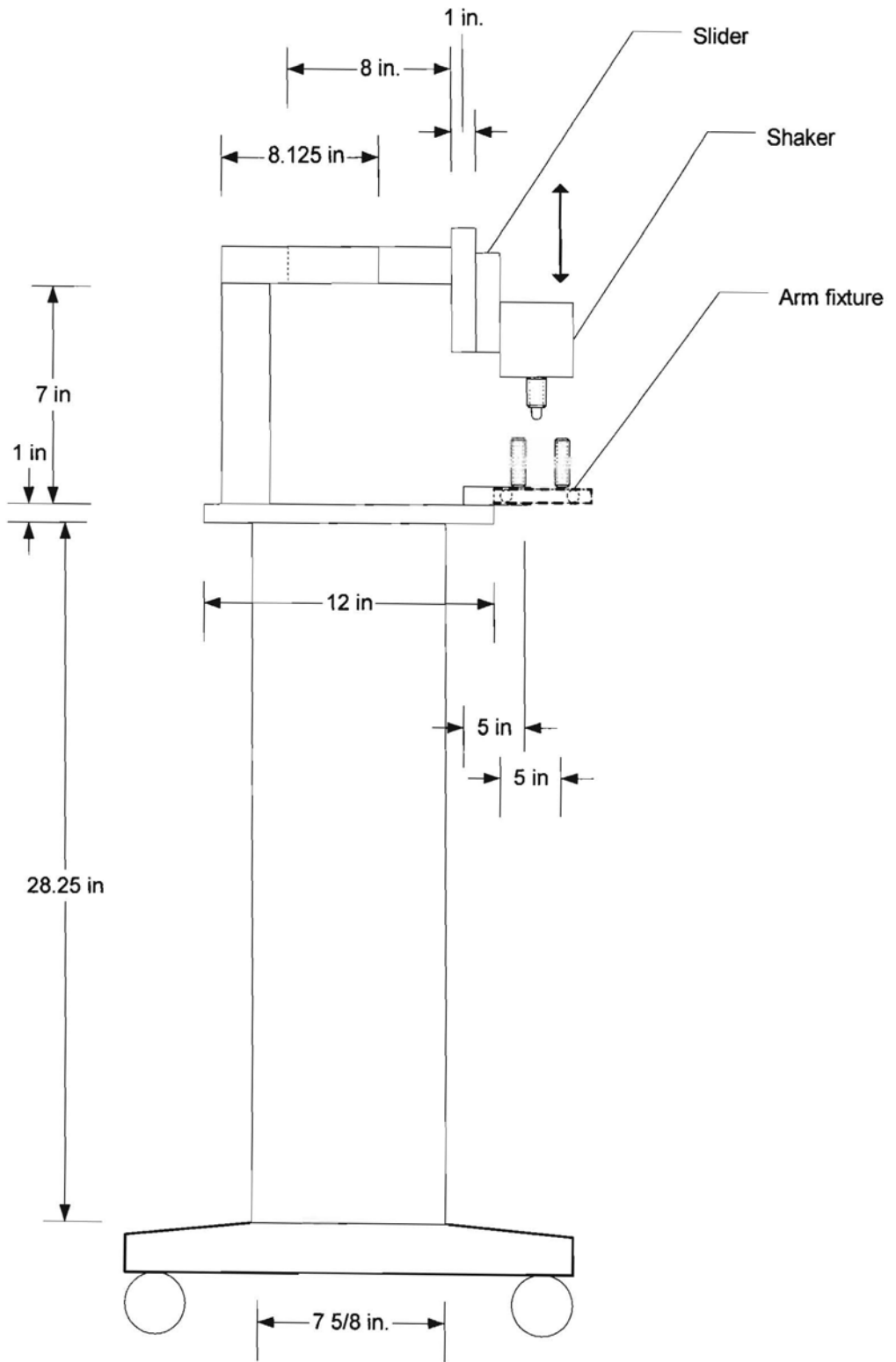# Forearm Fixture Schematic

1.5-3 in.

5-10 in.

3-6 in.

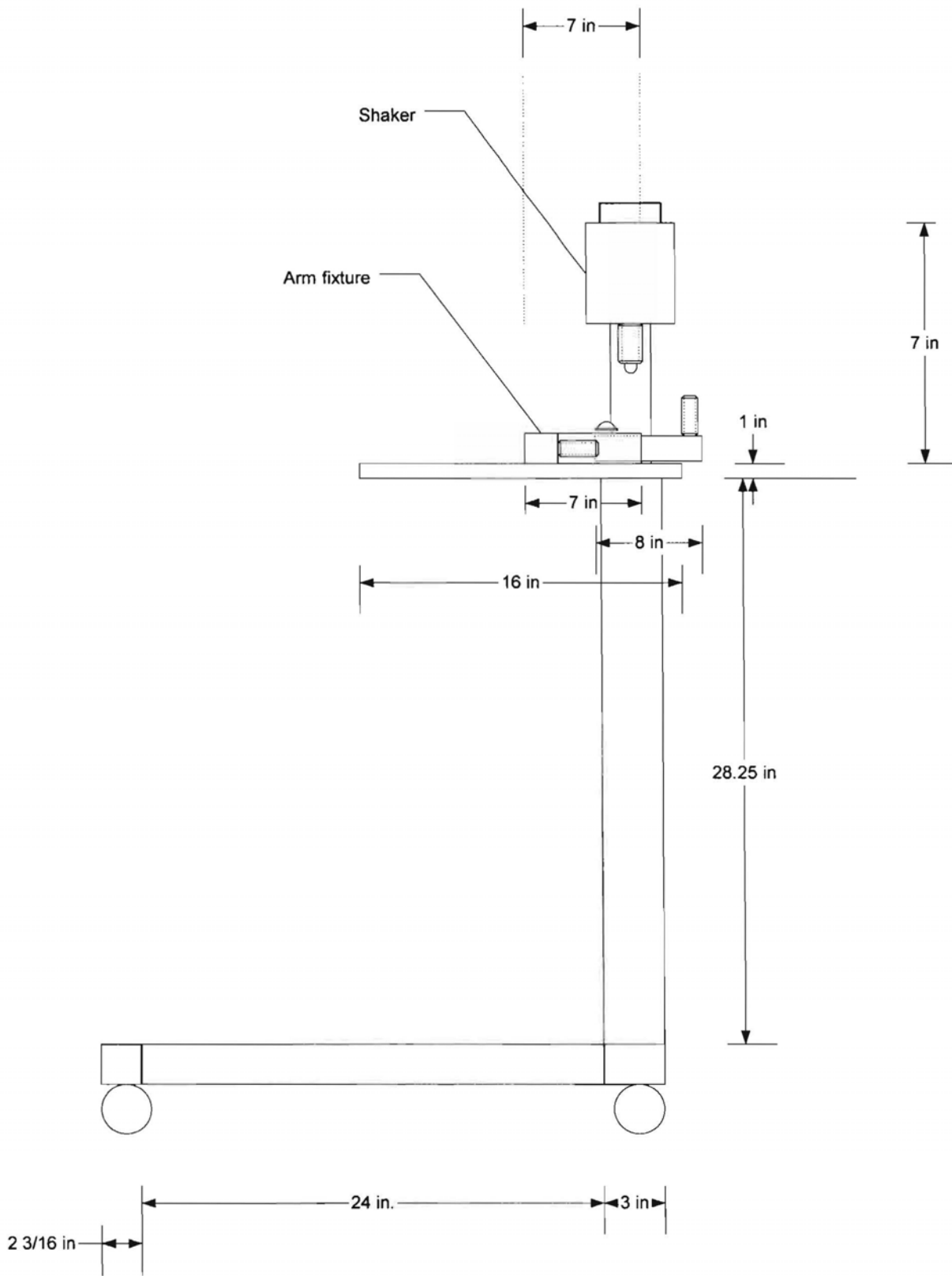Figure A2: Schematic of arm fixture on December 4, 2001

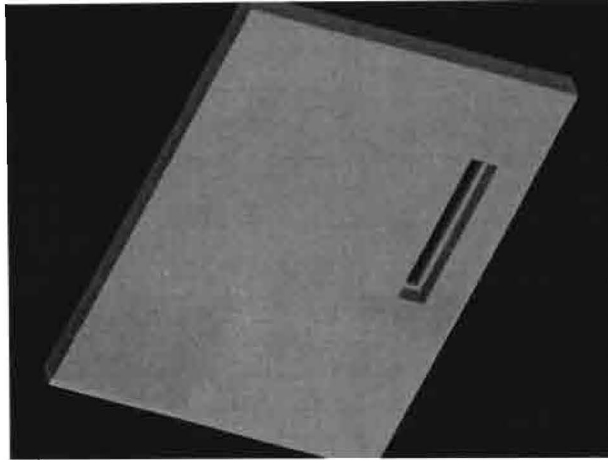**Figure A3: Schematic of system on March 10, 2002**

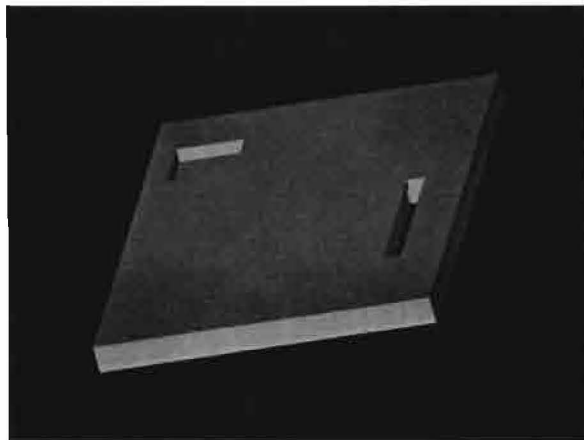**Figure A4: Schematic of arm fixture on March 10, 2002**

**Figure A5: Schematic of the final system (front view)**

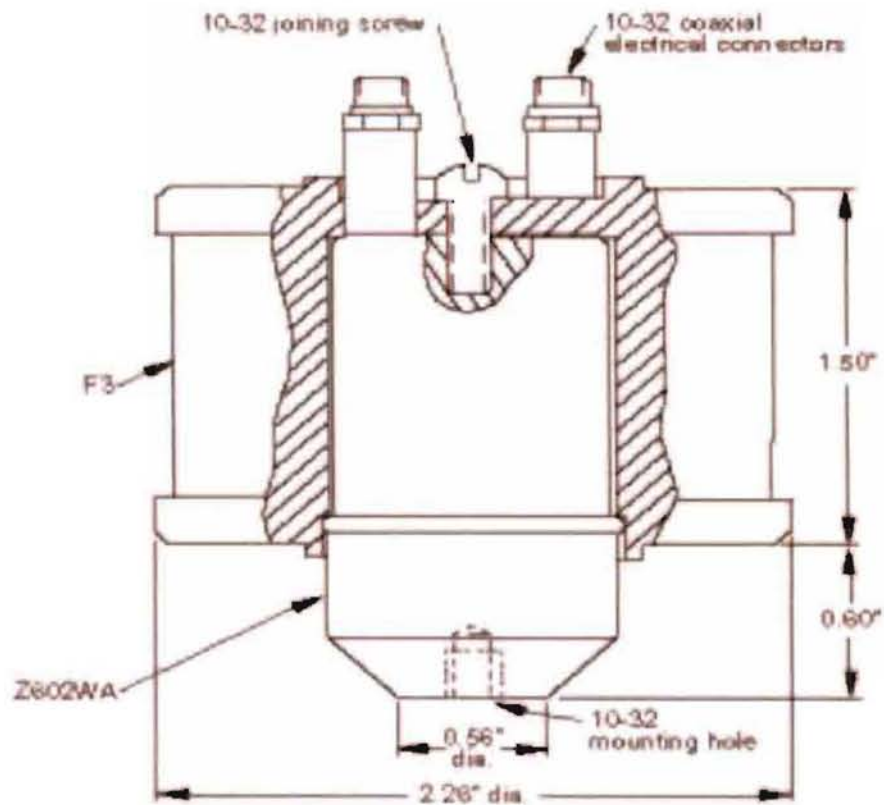**Figure A6: Schematic of the final system (side view)**

**Figure A7: Underside of the 1" X 12" X 16" aluminum plate, including the 3" long groove**



**Figure A8: Topside of the 1" X 12" X 16" aluminum plate, including the 3" long groove and securing cutout for the vertical shaft**

**Figure A9: The Wilcoxon F3 Electromagnetic Shaker**



**Figure A10: Cross-sectional schematic of the electromagnetic shaker**
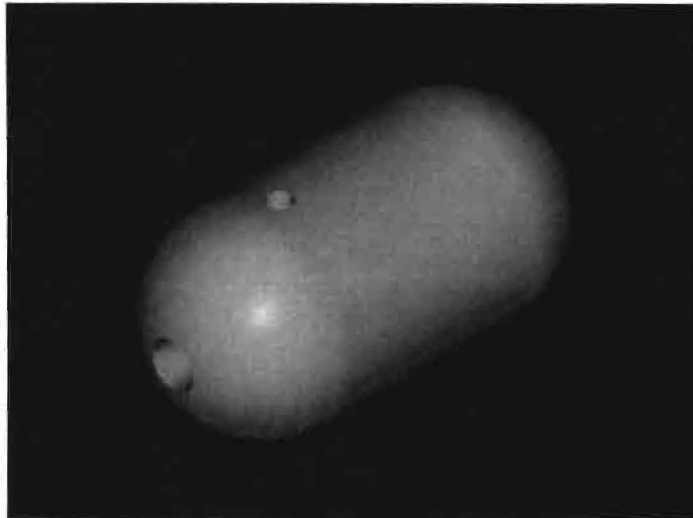
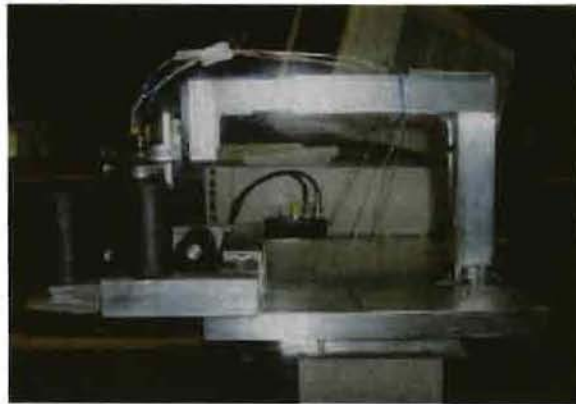**Figure A11: Precision Linear Ball Bearing Slide Assembly**



**Figure A12: Mini Ball and Socket Universal Joint**



**Figure A13: Universal-joint/shaker adapter**

**Figure A14: Full view of completed MVTS**



**Figure A15: Side view of completed MVTS**

*Appendix B*

| Parts | Description | Purchased from |
|---|---|---|
| Aluminum Tubing | Hollow square-cross section tubing; three different sizes used: 1" * 1", 1 1/4" * 1 1/4", and 1.5" * 1.5". | McMaster-Carr |
| Aluminum Plate | 1" * 12" * 16" plate served as the platform for the device. | MABE Machine Shop |
| Model F3 Electromagnetic Shaker | Model F3 Electromagnetic shaker is a cylindrical permanent magnetic shaker. Low center of gravity minimizes rotational excitation by the shaker. Designed for operation over a very wide range of audio frequencies. | Wilcoxon Research Inc. |
| Model Z602WA Impedance Head | A cylindrical structure containing a piezoelectric accelerometer and a piezoelectric force gage; provided with the Model F3 Electromagnetic Shaker. | Wilcoxon Research Inc. |
| #10-32 screws | Screw Size = #10, Approximate threads per inch = 32; Used to secure adjustable, telescoping tube pieces | Home Depot, MABE Machine Shop |
| Precision Linear Ball Bearing Slide Assembly | Designed for smooth, precise, low-friction linear motion without side play, backlash, or wobble, the top carriage of these slides rides on a row of balls that run along a preloaded raceway on each side of the stationary base. | McMaster-Carr |
| Mini Ball and Socket Universal Joint | Made up of Type 303 Stainless Steel; Attached to the adapter fabricated to connect and secure the joint to the mounting hole on the bottom of the electromagnetic shaker. | McMaster-Carr |
| Hospital Table | Vertically adjustable, mobile, lightweight. | UT Medical Center |

| | | |
|---|---|---|
| Keithley DAS 800 Data Acquisition Board | Contains the A/D converter, which converts the analog data from the shaker into digital data to be interepreted by the processor. | Keithley Instruments, Inc. |
| DriverLINX Data Acquisition Device Driver | Initially receives digital data from the data acquisition board. | Keithley Instruments, Inc. |
| HP Vee Software Program | Interprets data from the DiverLinx sofware and presents the data on a usable interface for the operator. Allows operator to choose sampling rate and sampling size. | Dennis Higdon, MABE Faculty Support |
| Signal generator, amplifier, 486 PC | Produce, amplify, and receive the signal, respectively. The generator has a minimum output of 125 kHz, but was used within a range of 1-1200 Hz for this device. | Dennis Higdon, MABE Faculty Support |

**Table B1: Design parts list**

References

1. Arici, M., et al. "Bone mineral density in hemodialysis patients: A comparative study of dual-energy X-ray absorptiometry and quantitative ultrasound," Nephrol Dial Transplant, 15 (11): 1847-1851; 2000.

2. Bachrach, L. K. "Dual energy X-ray absorptiometry (DEXA) measurements of bone density and body composition: promise and pitfalls," Journal of Pediatric Endocrinology & Metabolism, 13 (2): 983-988; 2000.

3. Barefield, Eric. "Osetoporosis-Related Hip Fractures Cost $13 Billion to $18 Billion Yearly http://www.ers.usda.gov/publication/foodreview/jan1996/frjan96e.pdf. 1996.

4. Baroncelli, G. I., et al. "Bone quality assessment by quantitative ultrasound of proximal phalanxes of the hand in healthy subjects aged 3—21 years," Pediatric Research, 49 (5): 713-718; 2001.

5. Berkow, Robert, et al. The Merck Manual of Medical Information. Home Edition. Whitehouse Station, N.J.: Merck Research Laboratories, 1997: 218-220.

6. Cheng, S., et al. "In vivo vibrational wave propagation in human tibiae at different ages," European Journal of Applied Physiology and Occupational Physiology, 59 (1-2): 128-130; 1989.

7. Cummings, S. R., et al., "Bone Density at Various Sites for Prediction of Hip Fractures," The Lancet, 341: 72-75; 1993.

8. De Terlizzi, F., et al. "Influence of bone tissue density and elasticity on ultrasound propagation: an in vitro study," Journal of Bone and Mineral Research: the Official Journal of the American Society for Bone and Mineral Research, 15 (12): 2458-2466; 2000.

9. Haggerty, James J. National Aeronautics and Space Administration Spinoff 1996: Office of Space Access and Technology, Commercial Development and Technology Transfer Division. "A Boon for Bone Research." https://www.sti.nasa.gov/tto/spinoff1996/24.html. 1996.

10. Kasra, Mehran, et al. "A clinical evaluation of vibration testing in the assessment of osteoporosis," American Society of Mechanical Engineers: Advances in Bioengineering, 48: 213-214; 2000.

11. Keller, Tony S. "Predicting the compressive mechanical behavior of bone," Journal of Biomechanics, 27 (9): 1159-1168; 1994.

12. McCabe, F., et al. "Noninvasive assessment of ulnar bending stiffness in women," Journal of Bone and Mineral Research: the Official Journal of the American Society for Bone and Mineral Research, 6 (1): 53-59; 1991

13. McMaster-Carr, Atlanta, GA. No. 96: 1990.

14. Myburgh, K., et al. "In vivo assessment of forearm bone mass and ulnar bending stiffness in healthy men," Journal of Bone Mineral Research: the Official Journal of the American Society for Bone Mineral Research, 7 (11): 1345-1350; 1992.

15. National Osteoporosis Foundation. "Men and Osteoporosis http://www.nof.org/men/index.html. November 25th, 2001.

16. Nordin, Margareta and Nihat Ozkaya. Fundamentals of Biomechanics: Equilibrium, Motion, and Deformation. 2nd Edition. New York: Springer, 2000: 210.

17. Ott, Susan, M. D. University of Washington. "Bone Physiology http://courses.washington.edu/bonephys/opbmd.html. 1999.

18. Panteliou, S. D., et al. "Low-frequency acoustic sweep monitoring of bone integrity and osteoporosis," Journal of Biomechanical Engineering, 121 (4): 423-431; 1999.

19. Quig, R.L., Kasra, M., and Grynpas, M. "Finite Element Dynamic Response of the Human Tibia," Senior Thesis Project, Dept. of Mechanical Engineering, Univeristy of Toronto: 1997.

20. Roberts, S. G., et al. "Noninvasive determination of bone mechanical properties using vibration response: a refined model and validation in vivo," Journal of Biomechanics, 29 (1): 91-98; 1996.

21. Roberts, S. G., and C. R. Steele. "Efficacy of monitoring long-bone fracture healing by measurement of either bone stiffness or resonant frequency: numerical simulation," Journal of Orthopaedic Research, 18 (5): 691-697; 2000.

22. Roubenoff, Ronenn, et al. "Use of Dual-Energy X-Ray Absorptiometry in Body-Composition Studies: Not yet a "Gold Standard," The American Journal of Clinical Nutrition, 58: 589-591; 1993.

23. Steele, C. R., et al. "Noninvasive Determination of Ulnar Stiffness from Mechanical Response—In Vivo Comparison of Stiffness and Bone Mineral Content in Humans," Journal of Biomechanical Engineering, 110: 87-96; 1988.

24. The United States Patent and Trademark Office. http://www.upto.gov.

25. Dr. Wasserman, Professor of Biomedical Engineering Department of Mechanical and Aerospace Engineering and Engineering Science, University of Tennessee, Knoxville. November 1st, 2001.

26. Wasserman, J. Modern Methods in Experimental Vibrations. Knoxville, TN, University of Tennessee, 1984: 123.

27. Werner, H. J., et al. "The loss of stiffness as osteoporosis progresses," Medical Engineering and Physics, 18 (7): 601-606; 1996.

28. Wilcoxon Research Inc. F3 / Z602WA Electromagnetic Shaker System. http://www.wilcoxon.com. November 15th, 2001.

29. Dr. Zemel, Head of the Department of Nutrition and Director of the Nutrition Institute, and Professor of Nutrition and Medicine, University of Tennessee, Knoxville.
October 25th, 2001.