Partners in Research

Creighton University Medical Center

Spring 2008 Newsletter # 21

Biannual Newsletter

THE CREIGHTON UNIVERSITY OSTEOPOROSIS RESEARCH CENTER

Bone Mineral Density: The Gold Standard

Bone Mineral Density is often referred to as Dual-Energy X-ray Absorptiometry (DXA) scanning. The World Health Organization (WHO) has elected that Bone Mineral Density by DXA is the only test that can be utilized to determine bone health or the risk for individuals to develop a fracture. The field of bone density has made great improvements in the last 25 years; some forms of densitometry have been around for over 100 years and were first used in dentistry. When using bone density to diagnosis osteoporosis or to assess fracture risk, it is important that the measurement be accurate. When following changes in bone density over the course of time, precision becomes important. There are two important factors that can influence the results of a bone density scan, the DXA scanner and the technologist administering the test.

The Scanner

There are two main manufacturers of bone density equipment in the United States, Hologic, Inc (Bedford, Mass) and Lunar (Madison, WI). Both of these manufacturers use different techniques to measure bone density. The World Health Organization has not specified a preferred technique for measuring so, for now, the industry has two ways of obtaining bone mineral density. Whichever type of scanner is used, it is important that the machine be monitored daily by quality control procedures and that regular service be provided to detect any problems with the internal workings of the scanner that could potentially affect the results of the test. Most offices prefer one manufacturer when purchasing or upgrading equipment. For the past 18 years the Osteoporosis Research Center (ORC) has used Hologic as its scanner of choice. Recently the ORC has upgraded its scanner(s) to the latest version of software that Hologic markets. We strive to keep our equipment updated to provide the best overall accuracy and precision in bone density scanning.

It is important that repeated exams be done on the same machine if at all possible or at least repeated using the same manufacturer. At the ORC, we have had several scanners over time (all Hologic) and we are able to access records going back roughly 16 years to compare scan results.

The Technologists

In the state of Nebraska any operator of the DXA equipment must be a medical radiographer (x-ray technologist). Due to the low level of radiation produced by the DXA scanners, the state has granted permission also to limited medical radiographers to perform scans. These limited operators have been trained in specific areas of radiography and are allowed to perform DXA scans. At the ORC we have two full-time medical radiographers and a full-time limited medical radiographer.

Medical Radiographers can be certified in the field of bone densitometry like other specialty fields such as mammography, computed tomography (CT) and magnetic resonance imaging (MRI). While it is not a state or national requirement at this time, a technologist who has received this certification shows dedication to the field. At the ORC, both of our medical radiographers have received this certification through the American Registry of Radiologic Technologists. Internationally the field of bone densitometry is coming

together to provide standardization techniques for the equipment manufacturers, physicians, and technologists. This group is called the International Society of Clinical Densitometry (ISCD). The ISCD promotes specialized training for the technologists performing the scans and for the physicians who interpret the results. A technologist who receives this certification through the ISCD has expressed interest in providing accurate and precise techniques when obtaining scans. At the ORC all three of our full-time technologists have received this training.

The Client's Role

As a client receiving a bone density test there are some things you can do to make sure you are getting the best exam possible. Try to schedule your exam at the same location; ask if any repeat scans can be done on the same machine (if the clinic has more than one scanner). Ask what type of training the technologist performing the scan has.

When you are at the office make sure you tell the receptionist and the technologist that you have been in before so that they can locate your old chart and compare your new scans to your previous scans.

If you are taking a prescription medication for bone loss or have recently stopped taking a medication for bone loss, make sure you inform the technologist so, if there is a significant change in your fracture risk, he/she can pass that information along to the interpreting physician.

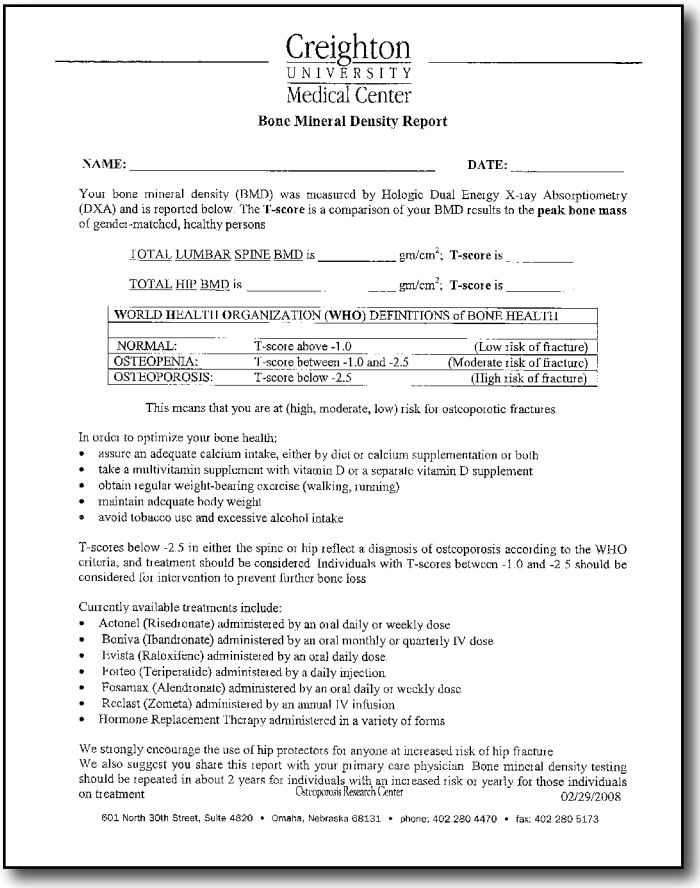
To determine bone loss/fracture risk, the lower spine and the hip should be measured; most commonly the non-dominant hip is measured. If you have had a hip replacement, inform the technologist so that the other hip can be measured. If you have had both hips replaced, then only a spine scan will be performed. If you have metal rods in your back, then only your hip will be measured.

Once you receive the scan results from your Primary Care Physician (PCP), make sure you discuss and fully understand what your fracture risk is. The World Health Organization (WHO) defines fracture risk in three categories.

- Normal Bone T-score above a -1.0
  Low risk of developing a fracture
- Osteopenic Bone T-score between -1.0 and -2.5
  Moderate risk of developing a fracture
- Osteoporotic Bone T-score below -2.5
  High risk of developing a fracture

If your results are in the bottom two categories it is important to discuss all your risk factors with your PCP so that together you can make the correct decision on prevention or treatment.

Below is a copy of the Creighton University Osteoporosis Research Center's report form; it provides you with our recommendations for keeping your bones healthy and a list of medications which our department feels are the best medications available for prevention or treatment.



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Bone Mineral Density Report

NAME: _____ **DATE:** _____

Your bone mineral density (BMD) was measured by Hologic Dual Energy X-ray Absorptiometry (DXA) and is reported below. The **T-score** is a comparison of your BMD results to the **peak bone mass** of gender-matched, healthy persons

TOTAL LUMBAR SPINE BMD is _____ gm/cm^2; **T-score** is _____

TOTAL HIP BMD is _____ gm/cm^2; **T-score** is _____

WORLD HEALTH ORGANIZATION (WHO) DEFINITIONS of BONE HEALTH		
NORMAL:	T-score above -1.0	(Low risk of fracture)
OSTEOPENIA:	T-score between -1.0 and -2.5	(Moderate risk of fracture)
OSTEOPOROSIS:	T-score below -2.5	(High risk of fracture)

This means that you are at (high, moderate, low) risk for osteoporotic fractures

In order to optimize your bone health:
- assure an adequate calcium intake, either by diet or calcium supplementation or both
- take a multivitamin supplement with vitamin D or a separate vitamin D supplement
- obtain regular weight-bearing exercise (walking, running)
- maintain adequate body weight
- avoid tobacco use and excessive alcohol intake

T-scores below -2.5 in either the spine or hip reflect a diagnosis of osteoporosis according to the WHO criteria, and treatment should be considered. Individuals with T-scores between -1.0 and -2.5 should be considered for intervention to prevent further bone loss

Currently available treatments include:
- Actonel (Risedronate) administered by an oral daily or weekly dose
- Boniva (Ibandronate) administered by an oral monthly or quarterly IV dose
- Evista (Raloxifene) administered by an oral daily dose
- Forteo (Teriperatide) administered by a daily injection
- Fosamax (Alendronate) administered by an oral daily or weekly dose
- Reclast (Zometa) administered by an annual IV infusion
- Hormone Replacement Therapy administered in a variety of forms

We strongly encourage the use of hip protectors for anyone at increased risk of hip fracture
We also suggest you share this report with your primary care physician. Bone mineral density testing should be repeated in about 2 years for individuals with an increased risk or yearly for those individuals on treatment

Osteoporosis Research Center 02/29/2008

601 North 30th Street, Suite 4820 • Omaha, Nebraska 68131 • phone: 402 280 4470 • fax: 402 280 5173

In conclusion, you and your PCP should discuss how often a DXA scan is needed. Currently Medicare will pay for a scan every other year. For individuals on prescription medication for bone loss, Medicare will pay for a DXA scan every year. Private insurance usually follows the same standards; check with your individual insurance carrier prior to scheduling a scan. As always, when utilizing any form of radiation like Bone Density/DXA, you should not have a scan if you are pregnant or think you might be pregnant. The field of bone density is rapidly changing. Today there are not sufficient data on bone health in children or adolescents; however the ORC is currently participating in a national study that will provide such guidelines.

Opportunities to Participate

The Creighton University Osteoporosis Research Center is conducting the following studies. If you have any questions, please call 402-280-BONE (280-2663) or Toll-free 1-800-368-5097.

BONE QUALITY STUDY

Seeking postmenopausal women over 40 years of age
Eligible participants will receive:

- Free bone density scan (DXA) with interpretation of results
- FDA approved Micro MRI scan of wrist and spinal x-rays
- Study medication/placebo
- Calcium and Vitamin D supplements
- Physical exam and blood work
- Monetary stipend available

DO YOU (OR SOMEONE YOU LOVE) HAVE PAINFUL SPINE FRACTURES CAUSED BY OSTEOPOROSIS?

We are investigating the use of a study drug for the treatment of painful spine fractures caused by osteoporosis. The study drug is approved for osteoporosis treatment, but is being tested for reduction in pain from the related spine fractures.
You may be able to join our study if you are:

- A Woman age 45 years or older, 2 years or more post menopausal
- Suffering from a painful spine fracture caused by Osteoporosis (leading to chronic back pain)
  Qualified study participants will receive:
  - Study-related bone density scans
  - Calcium and vitamin D supplements
  - Modest compensation for your study visits

EXPERIENCED A HIP FRACTURE?

The Osteoporosis Research Center is looking for women who are age 50 or older who have had a hip fracture to participate in a genetic study. This study requires no medication.
To qualify:

- You must be a woman 50 or older
- Must have broken your hip

Qualifying individuals will receive a bone density scan. This study consists of one visit with one blood draw.

GENETIC DETERMINATIONS

The purpose of this study is to identify genes and proteins that may increase the risk of osteoporosis

- Seeking Caucasian women age 50-55
- Free bone density scan (DXA) with interpretation of results for eligible participants
- Stipend available; just 2 visits

HAVE YOU HAD A BROKEN BONE?

You may qualify for a bone density scan to evaluate your bone health. The study involves no medication.
Do you meet the following criteria?

- Women ages 20 to 48 who are having regular menstrual cycles.
- Not currently on treatment for osteoporosis

** The broken bone occurred after age 18.*

OSTEOPOROSIS MEDICATION STUDY

Seeking postmenopausal women 65 years of age and older who have been diagnosed with osteoporosis or low bone density to participate in a clinical research study comparing the osteoporosis medications Boniva and Fosamax

- Eligible participants will receive study related care and medication and may be compensated for their time.

RESEARCH STUDY FOR 13 AND 14 YEAR OLD GIRLS

This is a one year research study at the Osteoporosis Research Center evaluating the role of dairy consumption on weight management.
Requirements:

- 5 visits
- Painless evaluations
- Monetary stipend

GENETICS AND YOU

Seeking volunteers age 20 and older to participate in a genetic study of bone health. It is a one-time visit and eligible participants will receive a Free Bone Density Measurements with interpretation of results. Monetary Stipend available.

- Women age 20 and older

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May 01, 2008

To our Patients, Research Participants and Donors:

This note is to thank you for giving us the privilege of caring for you, and for volunteering to participate in research studies that we have conducted at the Osteoporosis Research Center. Without the help of our research participants and their generous contributions of time and effort, we could not advance the cause of osteoporosis prevention and treatment. We regard you as our partners in this scientific endeavor and have the greatest respect and admiration for your enthusiastic support. I also wish to thank those donors who have contributed memorials to the Osteoporosis Research Center, and have supported its endowment. This is a great help to us in sustaining our efforts to conquer osteoporosis and its resulting fractures.

Sincerely,

Robert R. Recker

Robert R. Recker, M.D., M.A.C.P., F.A.C.E.
Professor of Medicine
Director
Osteoporosis Research Center

THE GIFT OF GIVING

Consider a donation in honor of a loved one to the Osteoporosis Research Center

Just mail this form to: Osteoporosis Research Center
601 North 30th Suite 5766
Omaha NE 68131

A Contribution is enclosed to the Recker/Pappajohn Osteoporosis Research Center Endowment

____In memory of ____In honor of ____To Celebrate

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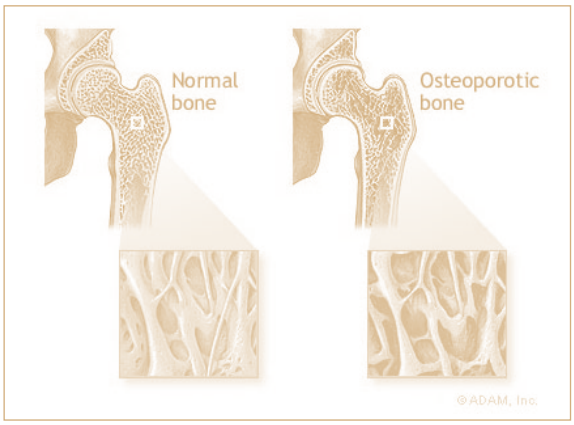
I give permission to print donor & recipient name in a future newsletter _____Yes _____No

Basic Concepts about Bone Mineral Density

Dual Energy X-ray Absorptiometry (DXA) is now widely used by physicians and clients concerned about bone loss. It has become a very useful tool to measure bone density in humans and to predict an individual's risk of developing a fracture. The machine itself consists of an x-ray tube and a wide range of detectors and a computer to monitor all the data. The machine uses an x-ray tube with a defined x-ray beam that passes through the client's body. As the beam emerges on the other side it is picked up by the detectors. Calculations made from the emerged beam allow a very accurate measurement of bone mass, i.e. the weight of the bone. This measurement is converted into two main groups: 1) the bone mineral content (BMC), the weight of the bone and 2) area (the size of the overall bone). These two measurements are used to determine bone mineral density (BMD).



Early in the development of DXA many prospective human studies were performed in which large numbers of people had measurements by DXA and then were followed for a decade or more to determine fractures in relation to what their DXA measurement was before they fractured. These studies helped to determine what should be considered normal density and also loss of density as people age. These large studies thus provide the background against which an individual who is scanned today is compared. In other words, these studies give us solid data on which to base our estimation/prediction of future fracture risk in people today. The basic measurements are performed on lumbar spine (lower back) and the proximal femur (hip).

Other methods have been developed to measure bone mass such as x-ray scans of the forearm or lower limb or computed tomography scans. These scans can measure bone density of areas such as the tibia or the spine. They can also measure hip density. One of the problems in interpreting them in terms of fracture risk is that the long-term risk data are not available for any of them. In fact, only DXA has risk prediction data coming from the studies mentioned above.

We use the DXA extensively to determine when to prescribe drugs for prevention or treatment of osteoporosis. It is always a problem to decide when treatment or intervention is warranted. In somebody who is fracturing the answer is easy – treatment is needed. However, in someone who has not fractured but has low bone mass, the question is a little more difficult. One of the treatment areas in question is women who are in late pre-menopausal years. Data from our department show that if a women passes through menopause without any bone-sparing medication, approximately one degree (or one T-score) of bone will be lost. Therefore, if she starts menopause with a T-score of -1, she will exit the menopausal period about four or five years later with an overall 12% loss of bone. The loss is about equal to one degree (or one T-score). Therefore, when a women has completed the menopause transition, she ends up with 2 ½ fold increase in the risk of fracture due to the bone-losing effect of menopause. This effect of menopause is not completely prevented by calcium, vitamin D and exercise and usually requires prescription medication. Thus, an important time to measure bone mass is just prior to the onset of menopause.

The most recent innovation regarding bone density measurement is the ability to estimate ten-year risk of fracture. The World Health Organization has a mathematical formula available that calculates the 10-year risk of fracture (combining the DXA measurement with age, gender, bone mineral density, and a number of risk factors). This will permit a much more refined decision on whether to intervene with treatment. One can find this formula on the internet by doing a search on FRAX.

Finally, there are many new treatments in the process of development for osteoporosis. Some of them are very interesting because they do not depend on administration of bone-sparing medications and others may actually build bone. One needs to stay tuned to the health literature because some developments look very exciting. As always, at the Creighton University Osteoporosis Research Center, we strive to be alert to all of the new advances in the prevention and treatment of osteoporosis and fractures.

Osteoporosis Research Center

Creighton University Medical Center
Suite 4820
2500 California Plaza
Omaha, Nebraska 68178

Address Service Requested

Phone: 402-280-4470 Fax: 402-280-5173 Website: **osteoporosis.creighton.edu** e-mail address: **orc@creighton.edu**

The Dairy Council of Nebraska

Nebraska's Dairy Nutrition Headquarters

The American Dairy Association and Dairy Council (ADA/DC) of Nebraska staff strives to ensure that Nebraskans understand the importance of including dairy foods (such as milk, cheese, and yogurt) as part of a healthy diet. Affiliated with the National Dairy Council, which has been a leader in nutrition education since 1915, the ADA/DC is funded by Nebraska's dairy producers. It serves as a resource for consumers, parents, schools, health professionals and others looking for science and research-based nutrition information.

With the countless beverage options (many of which lack important nutrients such as calcium) available in today's marketplace, many people fall short on consuming the recommended 3 daily servings of dairy foods needed for bone health. Beyond bone health, research indicates that milk-group foods may have a beneficial effect on obesity, hypertension, dental problems, some forms of cancer, and diabetes.

To find out more about the many health benefits of dairy foods, delicious recipes, and other resources available through ADA/DC, contact one of the staff registered dietitians at 888-NEB-MILK or visit us at www.nebmilk.org.

~ TESTIMONIAL ~

"I am writing to tell you how grateful and touched I am that Creighton University has a research center for osteoporosis. Having had the disease for twenty years, I didn't think it could be possible that there was a university that cared enough to have an entire center devoted to research on this painful disease that most associate with useless, bent-over, old women."

Auburn, Alabama