The ISCD thanks the following for their review of the submitted abstracts:

Robert Downs, MD, CCD – Scientific Advisory Committee Chair
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Gerald Avery, RT, CDT – Annual Meeting Co-Chair
S. Bobo Tanner, MD, CCD – Education Committee Chair & Annual Meeting Co-Chair
**Best Abstract — Clinician**

148 Thomas N. Hangartner, PhD
IMPACT OF LONG-TERM PRECISION ON LEAST SIGNIFICANT CHANGE

**Best Abstract — Technologist**

111 Patricia Garrett, RT, CDT
PRECISION SHOULDN'T STOP WITH SCAN ACQUISITION
ISCD recommendations require the local establishment of limits for the least significant change (LSC) based on repeat patient measurements. These repeat measurements are performed over a short time period when scanner drifts or maintenance/repair related changes are unlikely to occur.

The ISCD recommendations on how to handle changes due to maintenance/repair foresee contacting the manufacturer for service/correction in the case phantom measurements result in a higher than 1% change in BMD. In practice, changes considerably higher than 1% have been observed over a 3-year period in some scanners despite the manufacturer’s corrective action.

We studied the percentage of patients classified wrongly as having a BMD change assuming various levels of LSCs combined with uncorrected scanner-induced shifts in BMD values. For instance, for an established LSC of 2.8% (1% precision), a 1% scanner shift would result in 11% of patients being misclassified although they had no actual BMD change. With lower levels of LSC, the number of misclassified patients increases. With an LSC of 2.1% (0.75% precision), the same 1% scanner shift would result in 16% of patients being misclassified.

If we assume a manufacturer service standard that attempts to calibrate the BMD values within ±1%, it would allow the possibility for changes up to 2%; a service standard of ±2% would allow changes up to 4%. Such service standards permit even larger numbers of misclassified patients.

We recommend that the recalibration limits be assessed for the various scanner models in use and that the site-specific LSCs be appropriately increased.

Title: 111 — PRECISION SHOULDN'T STOP WITH SCAN ACQUISITION
Authors: Patricia Garrett, Radology Technologist, Helen Hayes Hospital, West Haverstraw, NY New York USA; Elizabeth Vasquez, Helen Hayes Hospital; Kelly Doherty, Helen Hayes Hospital; Robert Lindsay, Helen Hayes Hospital; Jeri Nieves

The accuracy of DXA and the impact of positioning errors on DXA results have been published. However, emphasis for DXA scan analysis is placed on the auto analysis features, with little operator intervention. The aim of this study is to determine the impact on DXA results of various potential errors during analysis. Errors while using auto-analysis software can have an impact on BMD results, particularly in the osteoporosis-range. In the spine analysis (n=57 Lunar; n=86 Hologic), errors in the auto analysis include the placement and angulation of the intervertebral markers and problems in bone mapping, where large areas are sometimes automatically excluded. BMD of the spine was different when the bone mapping was adjusted to account for auto-analysis errors using Hologic (p=0.09) with no difference by Lunar. In the hip analysis (n=24 Lunar; n=34 Hologic), errors in auto analysis result from incorrect placement of the femoral neck box (e.g. soft tissue should be contained in both ends) and improper bone mapping. These errors changed Lunar DXA BMD results, where the auto analysis placed the femoral neck box to include a portion of the greater trochanter or ischium and manual adjustment led to significant differences in bone area and BMD for the femoral neck and total hip (p<0.01), whereas there was no change by Hologic. Emphasis needs to be placed on what is considered a good analysis, based on each manufacturer’s guidelines, and what potential errors commonly occur. DXA operators can then correct the automated systems when necessary.
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Thursday, February 2, 2006 ........................... 10:00 am-6:30 pm
Friday, February 3, 2006 ................................. 10:00 am-6:30 pm
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MULTISITE ULTRASOUND AND FRACTURE RISK: FINDINGS FROM THE CANADIAN MULTICENTRE OSTEOPOROSIS STUDY (CAMOS)
Antecedent administration of radionuclide has been postulated to corrupt BMD measured by DXA. Previous reports of this potential effect have yielded inconsistent results.

Ten subjects scheduled for 99mTc-MDP bone scanning and 10 scheduled for 99mTc-sestamibi cardiac scanning had BMD measured by DXA (GE/Lunar Prodigy) before and after radionuclide injection. Paired t-test and Wilcoxon-Signed rank tests were used to compare the measured differences in BMD at multiple sites.

Mean change in measured BMD following 99mTc-sestamibi (“BMD-99mTc-sestamibi”) was -0.216 ± 0.113 Gm/cm² (TB), -0.348 ± 0.300 Gm/cm² (LS), -0.040 ± 0.034 Gm/cm² (FN), -0.019 ± 0.016 Gm/cm² (Troch), -0.030 ± 0.023 Gm/cm² (TH) and was highly significant (p<0.005 at all sites); “BMD-99mTc-MDP was -0.058 ± 0.037 Gm/cm² (TB), -0.053 ± 0.049 Gm/cm² (LS), -0.013 ± 0.016 Gm/cm² (FN), -0.005 ± 0.010 Gm/cm² (Troch), -0.008 ± 0.009 Gm/cm² (TH) (p<0.05 at all sites).

Mean “BMD exceeded in vivo precision error in all cases except for “BMD-99mTc-MDP at the Troch.“BMD-99mTc-sestamibi exceeded LSC at all sites except at the Troch. “BMD-99mTc-MDP only exceeded LSC at the TB and LS. Antecedent radionuclide resulted in WHO diagnostic re-classification at the TB and LS in the majority of subjects but not at the hip. The corrupting effect was correlated with 99mTc dose but not gender, age, BMI, baseline BMD or time interval from injection to scan acquisition.

BMD measured by GE/Lunar Prodigy densitometer is corrupted by antecedent 99mTc-sestamibi and to a lesser extent by 99mTc-MDP. This effect is more frequent and substantial at the TB and LS than at the hip. Caution is warranted in scheduling and interpreting DXA studies when 99mTc has been recently administered.

Title: WHAT FACTORS IMPACT OSTEOPOROSIS MEDICATION COMPLIANCE IN CLINICAL PRACTICE?
Authors: B.A. Grimshaw, M.D., C.C.D., Lead Osteoporosis Physician, Austin Regional Clinic, Texas USA; M. Batchelor, Department of Mathematics, University Of Texas, Austin, Texas

Osteoporosis is a significant problem, which is worsening with time. As physicians, our goal is improved management thus preventing fractures and associated complications. How can we promote compliance with best treatment practices?

We wanted to identify factors that affect compliance with oral osteoporosis therapy in a multispeciality urban group practice. Factors evaluated include age, bone densitometry frequency, weight, illness severity (based on T-score), family history and concomitant illnesses. We also evaluated different medication compliance rates.

This study was a retrospective evaluation of 198 patients with a low T-score on Lunar Prodigy DXA scan between 7/01/01 and 7/01/02 at Austin Regional Clinic, in Austin, Texas. Data were evaluated using logistic regression analysis.

Compliance rates by factor varied in each of the studied medications. We hypothesized that more frequent densitometry screening would result in increased medication compliance. On bisphosphonates, patients showed 3 times higher odds of compliance if densitometry scan was repeated within 18 months, p-value=0.006. The analysis for calcium trended toward improved compliance with more frequent follow-up scanning. Calcium compliance improved with lower t-score (p=0.052) and positive family history (p=0.008). Patient numbers taking raloxifene and ERT were too small to be meaningful for separate analysis. Decreased patient weight correlated with increased compliance in bisphosphonates (p=0.002) and overall medication (p=0.015).

Statistical data confirm that follow-up bone densitometry testing is at least beneficial in encouraging patients to maintain their bisphosphonate compliance. Other factors demonstrating significance were family history and lower t-score, both showing better calcium compliance.
According to the ISCD official positions statement (2005), forearm BMD with DXA at the one-third radius site can be used for diagnostic classification of a patient. Typically the non-dominant forearm is scanned when artifact precludes satisfactory spine or femur scanning. The commonest wrist fractures are Colles’ and scaphoid fractures that do not anatomically include the one-third radius, but protocol advises us to limit the DXA exam to the dominant forearm in the case of prior non-dominant wrist fracture. To determine if there would be a change in diagnosis if both forearms were scanned in patients with prior non-dominant wrist fracture, we performed bilateral scans in 39 patients with such a clinical history. The mean one-third radius BMD T-score was -2.0 on the dominant side and -2.2 on the non-dominant side. A diagnosis of osteoporosis on the non-dominant radius was made in 17 patients, 4 of whom were osteopenic on the dominant side. The dominant radius BMD identified 13 patients as osteoporotic, 4 who were osteopenic on the non-dominant side. The number of patients diagnosed with osteoporosis increased from 13 to 20 in both forearms were scanned. There was one patient who had normal BMD of the dominant radius but osteopenia on the fractured non-dominant forearm. Overall 5 of 39 (13%) patients had a worsened diagnosis with bilateral forearm scanning. We propose that patients with a history of non-dominant wrist fracture have BMD performed on both dominant and non-dominant forearms to assure that the lowest BMD is being captured.
Centralized analysis of the DXA daily quality control (QC) has been handled by GEQAP for the phase 3 protocol of Strontium Ranelate trials, a new compound for osteoporosis treatment.

Local Hologic spine phantom (LHSP) has been measured during 6 years on each 24 QDR-1000, 19 QDR-2000 and 34 QDR-4500 of all involved centres representing 32909, 32709 and 59980 scans respectively. Central evaluation includes re-analysis of all scans, long term precision assessment (CV%) as well as the application of Shewhart rules and Cusum analysis to detect malfunctions. Daily QC warrants the stability of calibration system. Correction factors were calculated and applied to patients and phantoms data.

The uncorrected mean CVs are 0.46, 0.6 and 0.45% for the QDR 1000, 2000 and 4500 respectively, while it is 0.39, 0.5 and 0.41% respectively after correction. The number of Shewhart alarms per device over the study duration is 22.2, 31.2, 15.3 for the QDR 1000, 2000 and 4500 respectively and 32.1, 49.9 and 29.3 for the number of Cusum alarms per device. Finally averages of 5.1, 8.4 and 5.8 malfunction report have been reported per device for the whole duration of the study.

These results demonstrated the adequacy of the QC performed on the DXA devices involved in the Strontium Ranelate clinical trial, thus validating the performed patients BMD measurements. Furthermore, QDR 2000 appeared less stable and more fragile than the QDR 1000 and 4500 apparatus. Our results confirm the importance of stringent QC procedures to ensure optimal quality in long-term multicentricque clinical trials.
This study investigates the difference of the bone mineral density (BMD) at the bilateral proximal femur sites in Chinese women and men, and to determine the diagnostic value of bilateral femoral BMD measurements by dual-energy X-ray absorptiometry (DXA) densitometry.

Dual femur (femoral neck, upper neck, trochanter and total hip) measurements using GE Lunar Prodigy were performed in 587 Chinese women and 174 Chinese men. 30 subjects were enrolled for a precision trail. The precision and the least significant change (LSC) at each measurement site were calculated.

Strong correlations ($r= 0.86-0.97, P<0.01$) were found between left and right femur BMD values in both the female and male groups. There were significant ($P<0.05$) but small differences between left and right BMD at femoral neck, upper neck and total hip in the women, with the right femur values consistently higher at the neck and total hip sites. Measurement precision (RMS-CV%) with single femur was 0.7-2.2%; dual femur precision was 0.6-1.2%, depending on the site. The dual femur mean BMD (average of L/R) provides an additional 20-45% improvement in precision compared to a single femur measurement. In 85.7% of the 398 postmenopausal women there was agreement in the diagnosis when using the left and right BMD values; in 14.3% (57/398) of the group there was a discordance in diagnosis between left and right femurs. After excluding subjects in whom the BMD discordance was less than the precision error of the system, there was a diagnosis discordance in 8.3% (33/398) of patients.

In conclusion, there were significant but small differences between right and left proximal femur BMD values in Chinese women. Dual femur measurements greatly reduce precision error compared to single femur. A small group of patients may be misclassified in regard to diagnosis when only a single femur is measured.
Title: **109 — BODY COMPOSITION ANALYSIS IN SOUTHERN CHINESE WOMEN AND MEN**

Authors: Hao Xu, MD Professor of Nuclear Medicine, Guangdong, China; Qiulian Wu, Medical College of Jinan University; Zhongman Yuan, Dept. of Nuclear Medicine, The First Affiliated Hospital of Jinan University

The World Health Organization has defined obesity using Body Mass Index (BMI). However, we are concerned with abnormal fat distribution in addition to total body fat. DXA has been shown to be a rapid and accurate method for measurement of body composition. This study investigated body composition in southern Chinese women and men by DXA.

Total body (TB) bone mineral density and body composition measurements using GE Lunar Prodigy were performed in 742 southern Chinese subjects (570 women, 172 men). Results included total body bone mineral content (BMC) and % Fat, lean mass (Lean), fat mass (Fat), android %fat (A), gynoid %fat (G), and android/gynoid ratio (A/G). The android and gynoid regions correspond to the waist and hip regions respectively.

BMC and Lean mass peaked during the 5th decade, followed by a decline of 26.4% and 6.0% (females), 11.4% and 4.8% (males) for BMC and Lean, respectively by age 70-89 years. With increase of age, both in males and females, the distribution of body fat had a centripetal tendency.

In conclusion, Total body fat%, android and gynoid fat% increased with age in southern Chinese women and men.

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Title: **110 — LOW BONE MASS DUE TO HYPOESTROGENISM IN A PATIENT WITH HYPOESTROGENISM IN A PATIENT WITH CARBOHYDRATE DEFICIENT GLYCOPROTEIN SYNDROME**

Authors: Cortney V. Jones, MD, Internal Medicine Resident, Sinai-Grace Hospital, MI USA; Gary W. Edelson, MD, Endocrinology Section Chief, Sinai-Grace Hospital, Detroit, MI.; Kamal A. Nasser, MD

Background:
Carbohydrate Deficient Glycoprotein Syndrome (CDGS) is a rare autosomal recessive condition caused by incomplete glycosylation of plasma proteins. There are less than 200 documented cases of CDGS, with four described types, each caused by a specific enzyme deficiency.

Case Report:
An eighteen-year-old female with a history of CDGS was referred to an endocrinologist regarding osteoporosis. She had mental retardation, cerebellar hypoplasia, ataxia, pectus deformity, antithrombin III deficiency, and primary ovarian failure. Serum estradiol, FSH, and LH, done in February 2002, were consistent with postmenopausal values; TSH was normal. In August 2002, a bone density by DXA technique revealed a lumbar spine density of 0.465 gm/cm2 (T score 5.29, Z score -5.0). Femoral neck density was 0.498 gm/cm2 (T score 3.16, Z score 3.7). Teriparatide, and weight bearing exercises were implemented. In May 2004, repeat DXA technique revealed a lumbar spine density of 0.561 gm/cm2 (T score 4.4, Z score 4.8). Femoral neck density was 0.509 gm/cm2 (T score 3.1, Z score 3.9). An improvement of 20.6%, 2.2%, and 6.4% in spine, femoral neck, and total hip density respectively was noted with teriparatide therapy, so she was advised to continue it for 24 months and have a repeat DXA scan in 12 months.

Discussion:
Skeletal abnormalities present in CDGS include: Kyphoscoliosis, pectus carinatum, inverted nipples, ankle and hip contractures, and short stature. In our patient, primary ovarian failure led to decreased attained peak bone mass. The etiology of low bone mass was hypoestrogenism, lack of weight bearing exercise, and inadequate glycosylation of bone proteins. The only reasonable option to increase bone mass was human recombinant parathyroid hormone. Alendronate is indicated in patients with accelerated bone loss, and a hypercatabolic state is a contraindication to estrogen therapy. Literature review confirmed the use of DXA technique for bone density assessment in CDGS; however, the use of teriparatide to increase bone mass was novel.

Conclusion:
The inadequate glycosylation of plasma proteins has systemic effects. Until enzyme supplementation proves to be beneficial, the mainstay of therapy is supportive care. This entails a meticulous investigation of each organ system and should include bone density assessment.
Title: 111 — PRECISION SHOULDN’T STOP WITH SCAN ACQUISITION

Authors: Patricia Garrett, Radiology Technologist, Helen Hayes Hospital, West Haverstraw, NY New York USA; Elizabeth Vasquez, Helen Hayes Hospital; Kelly Doherty, Helen Hayes Hospital; Robert Lindsay, Helen Hayes Hospital; Jeri Nieves

The accuracy of DXA and the impact of positioning errors on DXA results have been published. However, emphasis for DXA scan analysis is placed on the auto analysis features, with little operator intervention. The aim of this study is to determine the impact on DXA results of various potential errors during analysis. Errors while using auto-analysis software can have an impact on BMD results, particularly in the osteoporosis-range. In the spine analysis (n=57 Lunar; n=86 Hologic), errors in the auto analysis include the placement and angulation of the intervertebral markers and problems in bone mapping, where large areas are sometimes automatically excluded. BMD of the spine was different when the bone mapping was adjusted to account for auto-analysis errors using Hologic (p=0.09) with no difference by Lunar. In the hip analysis (n=24 Lunar; n=34 Hologic), errors in auto analysis result from incorrect placement of the femoral neck box (e.g. soft tissue should be contained in both ends) and improper bone mapping. These errors changed Lunar DXA BMD results, where the auto analysis placed the femoral neck box to include a portion of the greater trochanter or ischium and manual adjustment led to significant differences in bone area and BMD for the femoral neck and total hip (p<0.01), whereas there was no change by Hologic. Emphasis needs to be placed on what is considered a good analysis, based on each manufacturer’s guidelines, and what potential errors commonly occur. DXA operators can then correct the automated systems when necessary.

Title: 112 — DXA-DERIVED BODY COMPOSITION BARREL INDEX INCREASES OVER THE LONG TERM WITH LIMITED CORRELATION TO EARLY CHANGES

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A barrel body composition profile (BCP) defined by the total body DXA-derived Z-%trunk_fat >0 and Z-limb_fat/h2 < 0 especially when soft (Z-limb_lean < 0) has been associated with total and specifically cardiovascular 10 - year mortality in an age (>20 years) and gender stratified study population (N = 324) from Malmö, Sweden. (Preventive Cardiology, 2004;7:109-115.) We now report results of 10-year follow-up total body scans on 128 surviving members of the original cohort all of whom were initially scanned at baseline and about 2 years later. To quantify the observed changes in BCP we defined a soft barrel index = Z-%trunk_fat - Z-limb_fat/h2 - Z-limb_lean/h2.

Correlation of the soft barrel index between scans 3, and scan 1 or 2 was nearly identical (r = 0.76, 0.70) with however, no positive correlation between change in scans 2-3 vs. 1-2 (r = -0.58). The incidence of barrel BCP in our original cohort was lowest for subjects < 40 years old, highest from 50-70 and lower again > 80. Of the 80 non-barrel subjects on scans 1,2 we found 24 (30%) were barrels by scan 3. For those initially classified barrel on at least one of the initial scans, 25% (12/47) were non-barrel on scan 3, whereas for barrels on both initial scans 93% (14/15) remained barrels. Our results support the need for periodic body scan (at least each decade) to determine BCP for clinical applications.
This study compares results of automatically and operator set L1-L4 AP lumbar spine regions of interest using Norland Illuminatus Software.

A sample of 53 AP lumbar spine scans that included the L1-L4 region from subjects between 24 and 85 years of age were included in this study. The L1-L4 regions were first analyzed using operator set L1-L4 and L1 regions to obtain regional T-scores. The same scans were then analyzed using software set regions of interest to obtain L1-L4 and L1 region T-scores. Finally, the scans were analyzed again by operator set L1-L4 and L1 region to obtain the regional T-scores.

Results show a highly significant correlation between T-scores obtained with operator and software set L1-L4 and L1 regions (L1-L4 being $y = 1.0484x + 0.0281$; $r = 0.9916$; $p<0.001$ and L1 being $y = 1.14x + 0.1023$; $r = 0.9429$; p <0.001). Difference between T-scores calculated by operator set and software set region were -0.20 (SD = ± 0.29) and -0.20 (SD = ± 0.41) for L1-L4 and L1, respectively. Similar differences [0.01 (SD = ± 0.39) and 0.03 (SD= ±0.14)] were found between T-score in the first and second operator set L1-L4 and L1 region analysis.

In conclusion, analysis by operator or software set L1-L4 and L1 regions resulted in similar T-score for both methods supporting effectiveness of the software based analysis.
Discordance of BMD results at the hip and spine exists among women when both sites are measured. It is not well known, how this discordance impacts fracture prediction. We assessed the association between BMD discordance and osteoporotic fractures within 6 years of follow-up using data from the Specialist Arm of NORA. Osteoporosis was defined by a T-score ≤ -2.5 at each site (femoral neck) and spine. Cox regression analysis assessed the association between BMD discordance and fracture prediction. The analysis included 994 women (mean age = 64.3 years): 99 (10%) were osteoporotic at both the hip and the spine; 199 (20%) were osteoporotic at one site, and 696 (70%) were non-osteoporotic at both sites. Within 6 years of follow-up, 85 women (8.6%) reported 95 osteoporosis fractures. Fracture incidence rate (95% CI) per 1,000 person-years by BMD discordance was 41.8 (23.6, 60.0) for both sites, 35.0 (23.7, 46.3) for one site, and 11.8 (8.2, 15.3) for neither site. After adjusting for age, osteoporosis treatment, and estrogen use, compared to women who were non-osteoporotic at both sites, women who were osteoporotic at both sites had a 2.9 (95% CI: 1.6, 5.3) greater risk of fracture while women osteoporotic at any one site had a 2.8 (95% CI: 1.7, 4.5) greater risk of fracture. Women who were osteoporotic at both sites or at any one site had a similar increased risk for future fracture compared to women non-osteoporotic at both sites.

Immediately following spinal cord injury there is a rapid decline in bone mass of the hip and knee region which can be as high as 33% in the first 12 to 18 months following injury. Though the changes in bone mass warrant monitoring using DXA technology and subsequent treatment and/or prevention strategies to protect against future fragility fracture, acquiring scans in this patient population can be technically challenging.

The common anomalies seen in a tertiary center will be presented in a visual format and their impact on BMD acquisition and analysis will be discussed. The spine region of interest anomalies include: Spine fixation hardware, laminectomy, scoliosis, inferior vena cava filter, and ureteral stent. The common hip region of interest anomalies include: heterotopic ossification, hip subluxation, trochanteric bursitis, flexion contracture, and trochanteric shaving. Distal femur anomalies include: undetected fracture, catheter and leg bag artifact, patellar tendon repair, tibial osteotomy, and fracture callous.

A review of the relevant literature will be provided. Implications for BMD testing with this unique population at other centers will be discussed.
Internal metallic objects, like orthopedic hardware, appear white on properly exposed radiographs or in DXA scans, due to the decreased penetration of the x-ray beam. Air within the lungs is radiolucent and black on the images. We noted a recent DXA with a lead bullet within a vertebral body where the projectile scanned completely black (black hole). In addition, vascular clips that appeared radiopaque on radiographs and single energy VFA scanned as black on DXA images, making this artifact hard to recognize when overlying a vertebral body.

We stacked ½ copper squares on top of the spine phantom of a Hologic Discovery W scanner using 12.1:7 software. When the pile reached a thickness of 10 mm, the opaque/white DXA image began to turn black and when the thickness was 13 mm, the image was almost completely black. Scanning a lead bullet or vascular clips over the phantom also produced black images. The BMD of the vertebral body with the bullet was 42% greater than the BMD of the vertebral body of the phantom alone.

We conclude that when scanning a dense object by DXA, the dual energy subtraction may be zero at a certain density threshold and the object will then appear black on the DXA image. Careful attention to the BMD will reflect the increased density of the overlying metal object. Unless this phenomenon is understood, small black hole artifacts, such as vascular clips may be overlooked or misinterpreted as bowel gas on PA DXA scans.

Title: 118 — HOW OFTEN DOES NONPROGRESSION OF VERTEBRAL AREA OR BMC TRANSLATE INTO A COMPRESSION FRACTURE?
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The 2003 ISCD consensus guidelines recommended the exclusion of vertebral bodies for 1) Evidence on a focal structural abnormality; 2) Unusual discrepancy in bone mineral content or area between adjacent vertebrae. Both measures should increase from L1 to L4; and 3) Individual T-scores should be within 1 SD of adjacent vertebrae. It is unclear how often nonprogression in area, BMC and differences of 1 S.D. in T-score are predictive of abnormal vertebral morphology such as compression fractures or reflective of other causes like scoliosis.

We prospectively studied 105 individuals sent for clinical DXA scanning (22% males, 84% females, 90% Caucasian, 13% African-American, 2% Hispanic, mean age = 65.5 years, 22% were currently on steroids, 23% were taking drugs for osteoporosis). All subjects underwent the usual AP spine DXA scan and AP and lateral vertebral fracture analysis (VFA). The presence of vertebral compression fractures and/or scoliosis of the lumbar spine by VFA were correlated with nonprogression of area or BMC, and/or a difference of > 1 S.D. in T-scores (Fisher’s Exact Test). There were 16 fractures identified in L1-L4 in the population by VFA. Nonprogression of area, BMC, or difference in 1 S.D. T-score at any level was not statistically associated as a predictor of a vertebral compression fracture as assessed by VFA. Thirty percent of subjects had scoliosis by visual examination. The presence of scoliosis was significantly related to a difference in 1 S.D. T-score at L1-L4.
Title: 119 — EXCLUSION OF ANATOMICALLY ABNORMAL VERTEBRAE IN L1-L4 IN FRACTURE PATIENTS - WHAT IS THE IMPACT ON LUMBAR SPINE T-SCORES?

Authors: Low Siew Leng, Senior Laboratory Officer, Dept of Orthopaedic Surgery, Yong Loo Lin School of Medicine, National University of Singapore; Wong Pui-San, Dept of Orthopaedic Surgery, Yong Loo Lin School of Medicine, National University of Singapore; Shamal Das De, Dept of Orthopaedic Surgery, Yong Loo Lin School of Medicine, National University of Singapore

The aim of this study was to determine if the exclusion of anatomically abnormal vertebrae has an impact on the spine T-scores of patients with osteoporotic fractures. The BMD values and image of the spine L1-L4 and femoral neck were reviewed in 502 patients, consisting of 247 spine fractures and 255 hip fractures. For L1-L4 BMD, vertebrae were excluded from the analysis if there was a fracture or if it was anatomically abnormal, with more than 1.0 T-score difference compared to the adjacent vertebrae. The BMD of the remaining vertebrae were re-analyzed to derive the T-score. The mean age of patients with spine and hip fractures was 77 ± 14.1 years and 73.1 ± 11.3 years respectively. 47.8% spine fracture and 60.4% hip fracture patients had a femoral neck T-score of -2.5 and below. The lumbar spine T-scores were re-analyzed in 143 (57.9%) spine fracture patients and 22 (8.6%) hip fracture patients. The difference in T-scores between L1-L4 and the reanalyzed vertebrae ranged from 0.1 to 0.8. Re-analysis of the vertebrae changed the diagnosis of 16 (6.5%) spine fracture patients from osteopenia to osteoporosis, 9 of which already had a diagnosis of osteoporosis in the femoral neck. In the hip fracture patients, re-analysis led to another 4 (1.6%) subjects being classified as osteoporosis, all which had T-score of -2.5 and below in the femoral neck. The results showed that any anatomically abnormal vertebrae in L1-L4 should be excluded as this could lead to a misdiagnosis of lumbar spine T-score.

Title: 120 — INVESTIGATING THE EFFECT OF SOFT TISSUE ON BMD RESULTS USING DXA METHOD EMPLOYING A SPINE PHANTOM

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Background:
The effect of tissue depth on results of bone mineral content (BMC) and bone mineral density (BMD) measurements could be important for the interpretation of any study examining the effect of weight change.

The decrease in body weight has been reported to lead to an underestimation in bone mineral density. A variety of scan modes has been introduced to overcome the technical problems in scanning people having small or large tissue thickness, but an inappropriate choice of scan mode affects the validity of the DXA measurement.

Aim:
The aim of this study was to measure BMD, BMC and bone area (BA) due to influences of tissue depth for Lunar DPX-MD bone densitometer system using spine phantom.

Material and Methods:
A spine phantom was made by cooperation of Research Center for Science and Technology in Medicine (RCSTIM) and Endocrinology and Metabolism Research Center (EMRC).

This phantom consists of 1300mg, 1550mg and 2000mg K2HPO4 powder to simulate osteoporosis, osteopenia and normal status respectively. We applied 10, 15 and 20 layers of Perspex with 3 mm thickness each layer for simulation of increasing depth of soft tissue in spine phantom. 10 scans were performed phantom to obtain L2-L4 BMD, BMC and BA, without repositioning between scans and medium scan mode was applied for Lunar DPX-MD. Acquisition and analyses of scans were performed by a trained technologist.

Results:
Mean BA, BMC and BMD measured by the lunar DPX-MD system at various tissue depths. The BA results for this study were dependent on tissue depth. There was a significant decrease in BMC and BMD, for three phantoms as tissue depth decreased from 20 to 10 layers. The present study demonstrates that BA measurement depends on bone mass and is most highly underestimation when the bone mass is very low.

Conclusion:
In following up studies, the effect of body weight and changes in soft tissue depth especially in lumbar spine, are considerable and must be taken in to account. The variation of BMD in serial BMD tests must be ruled out due to the weigh and soft tissue thickness fluctuations.
**Title:** 121 — DETERMINATION OF PRECISION ERROR FOR LOW BONE MASS IN DXA BY PHANTOM STUDY

**Authors:** Ali Ghasemzadeh, Ms.c of Medical Physics Research Center of Sciences and Technology in Medicine, Tehran Iran; S.Srkar, Research Center of Sciences and Technology in Medicine (RCSTIM),Tehran University of Medical Sciences, Tehran, Iran.; B.Larijani, Endocrinology and Metabolism Research Center, Tehran University of Medical Sciences, Tehran, Iran.; A.Bajoori, Dept. of Medical Radiation, Islamic Azad University, Tehran, Iran; A.Salimzadeh , Gh.Alishiri , A.Hosein Nezhad,Z.Hamiddi ,H Heshmat

**Background**
Precision error determines the ability of DXA systems to detect small changes in patient bone mineral density (BMD).

Factors affecting precision include the scan region, consistency of scan acquisition and analysis, operator training, densitometry equipment, software, and short-and long term variation in densitometry performance. DXA systems perform best when scanning healthy young subjects of average size, when the optimal levels of x-rays reach the detectors. A variety of bone mass could be introduce to fluctuation of coefficient of variation (%CV).

**Aim:**
The aim of this study is evaluation of %CV for Hologic(QDR-4500C), Lunar(DPX-MD) and Norland (XR-46) by very low bone mass created spine phantom.

**Material and Methodes:**
A spine phantom was made by cooperation of Research Center of Science and Technology in Medicine (RCSTIM) and Endocrinology and Metabolism Research Center (EMRC). This phantom consisted of K2HPO4 powder and Perspex that simulated osteoporotic spine. 10 scan form phantom performed by each system without repositioning. Acquisition and analyses was performed by trained technologist. We used fast array mode and medium mode for Hologic and Lunar respectively, since the Norland system cannot get image in standard mode, we applied high precision mode for it.

BMD precision error was calculated as the SD*100/Mean BMD.

**Results:**
We found %CV equal 0.81, 1.46 and 0.88 for Hologic, Lunar and Norland respectively.

**Conclusion:**
We conclude that Hologic has the best %CV and SD for very low bone mass than others systems and calculation of BMD by Lunar is higher and by Norland is lower than Hologic.

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**Title:** 122 — PRECISION AND ACCURACY COMPARISON OF BONE DENSITOMETERS PRODIGY ADVANCE AND DELPHI A

**Authors:** X.P. Wu, Doctor, Professor of Endocrinology, Institute of Metabolis Hunan, China; E.Y. Liao, ; X.Z. Cao, ; S.Y. Tang, ; Z.F. Sheng, R.C. Dai

To compare short-term precision and accuracy of parameters obtained from GE-Lunar Prodigy Advance and Hologic Delphi A bone densitometers. We repeated two measurements on BA (bone area), BMC and BMD at the femur or the posterior-anterior lumbar spines L1 L4 of 66 subjects (age: 54.2±11.7 years) respectively, and compare precision (RMS-CV). In addition, we measured BA, BMC and BMD of 54 bone block models with various sizes, and incubated it for ash weight. Finally, we investigated the relationship between actual data and data obtained by densitometers. There were no significant differences of spine regions between the two densitometers (average RMS-CV of BA, BMC, BMD, Prodigy: 2.06±0.64, 2.12±0.68, 1.28±0.40, Delphi: 1.95±0.75 2.24±0.66 1.36±0.30); Partial regions of femur from Prodigy were significantly less than Delphi (Prodigy:1.66±0.58, 2.08±1.51, 1.32±0.64; Delphi: 3.08±1.56, 3.82±2.10, 1.66±1.08) BA, BMC and BMD of bone block models obtained by the two bone densitometers were highly positively correlated with actual area, ash weight and actual density of bone blocks (r=0.975 1.000, P<0.000). With the increase of actual area, ash weight and actual density, deviation of all parameters from Delphi were progressively increased and greater than that from Prodigy. We concluded that precision of BA, BMC and BMD from two densitometers is similar on spine; precision of Prodigy is significant better on femur; Accuracy of Prodigy is higher than that of Delphi.
Cardiovascular disease is the leading cause of death among women age 65 and older. Longitudinal studies have demonstrated that lateral lumbar radiographic scoring of abdominal aortic calcification (AAC) is predictive of cardiovascular disease death, which suggests the possibility of using lateral VFA images for a similar purpose. Therefore, we examined how well DXA images obtained for vertebral fracture assessment (VFA) detected AAC compared to radiography in 59 women (mean age 76.5 years, range 66 to 93). Both sets of images were blindly evaluated for AAC by a single reader using a previously validated 24-point scale. A 24-point radiographic score of $\geq 5$ was considered to be significant AAC.

The VFA and radiograph readings showed moderate agreement (intra-class correlation coefficient 0.81, 95% C.I. 0.66 to 0.90). The sensitivity and specificity of a VFA score $\geq 5$ for those with significant AAC were 65% and 90%, respectively. The area under the receiver operating characteristic curve was 0.83 using the VFA 24-point scale for the detection of those with significant AAC.

VFA imaging intended to detect vertebral deformities is a promising technology for the simultaneous assessment of a risk factor for cardiovascular disease incidence and death.

Study supported by Hologic, Inc.

Radiographic abdominal aortic calcification (AAC), assessed on a validated 24-point scale, is a risk factor for cardiovascular disease death. We devised a simpler, faster 8-point scoring scale where the total linear lengths of the posterior and anterior aortic wall calcification in front of L1-L4 were assigned a grade ranging from 0-4. Spine radiographs and lateral DXA images were each blindly evaluated by a single reader for AAC using the 24-point scale, and subsequently using the 8-point scale in 59 women (mean age 76.5 years, range 66 to 93). A 24-point score of $\geq 5$ was considered to be significant AAC on either radiography or densitometry.

On radiographs, the sensitivity and specificity of an 8-point score of $\geq 3$ for those with significant AAC ($\geq 5$ on the 24-point scale) were 69% and 100%, respectively. On lateral DXA images, the sensitivity and specificity of an 8-point score of $\geq 3$ for those with significant AAC ($\geq 5$ on the 24-point scale) were 86% and 97%, respectively. Receiver operating characteristics analyses showed areas under the curves of 0.95 using the 8-point scale to detect those with significant AAC on radiographs, and 0.98 using the 8-point scale to detect those with significant AAC on lateral DXA images.

This study shows excellent agreement between the 8-point and 24-point AAC scales, and suggests that the 8-point scale can be used with either radiography or lateral DXA to assess this cardiovascular disease risk factor. Prospective studies are needed to confirm the utility of the 8-point scale.
To explore whether BMD differs between the dominant and non-dominant forearms in children, a convenience sample of 18 healthy volunteer children (10 female, 16 caucasian) with median age of 9.5 y (5-14 y) underwent BMD assessment using Hologic Discovery A at Children’s Hospital & Research Center in Oakland bone density clinic. Seven of the subjects were involved in recreational sports using their upper extremities (2 baseball, 1 tennis and the rest were involved in sports such as basketball...). Subjects were divided in two age groups (Group A: 5-9 y and Group B: 10-14 y). Analysis was performed using non-parametric Wilcoxon signed-rank test. Data is reported as median and range; differences were considered significant when p<0.05.

When considering all subjects together as one group, median value of total BMD (g/cm2) in the dominant versus the non-dominant forearm were 0.386 (0.327-0.504) and 0.395 (0.337-0.510) respectively. For Group A, the median total BMD of the dominant arm versus the non-dominant were 0.376 (0.327-0.397) and 0.360 (0.337-0.398) respectively. In Group B, the median total BMD at dominant versus non-dominant forearm were 0.411 (0.361-0.504) and 0.410 (0.361-0.510). The median value of the total BMD was not significantly different between the two forearms in either of the groups. Similarly, median BMD was not different in sub regions (ultra distal, 1/3 distal ...). Recreational sport participation and gender did not affect the total BMD or subregional BMDs. Presented data suggest that BMD does not differ between the dominant and non-dominant forearms in children.
Densitometric vertebral fracture assessment (VFA) allows detection of clinically unappreciated vertebral fracture. However, vertebral visualization using VFA can be suboptimal. In such individuals, alternative spine positioning might enhance visualization. Consistent with this, we observed that reversal of positioning (right lateral decubitus rather than standard left lateral decubitus, subsequently referred to as reverse positioning) improved visualization. As such, when the DXA technologist observed suboptimal vertebral visualization, patient positioning was reversed and a full, or partial, repeat of the exam performed. Suboptimal vertebral visualization was defined as inability to label vertebral bodies with a high degree of confidence due to lack of clearly defined disc spaces on two or more consecutive vertebral bodies below T7. This report describes 33 such individuals (30 men, 3 women); their mean (range) age and lowest T-score (L1-4 spine, proximal femur or .3 radius) was 69.9 years (48.4-87.8) and -2.2 (-4.8 to -0.5) respectively. All images were acquired using a GE Healthcare Lunar Prodigy densitometer. Reverse VFA improved vertebral visualization in 88% (29/33) of these patients. Specifically, only 62% of vertebrae from T4-L5 were visualized using the standard left lateral position. Addition of either full or partial reverse VFA increased (p < 0.0001) the number of visualized vertebrae to 83% (384/462). This, reverse positioning allowed detection of four additional vertebral fractures, including two in patients without previously identified fractures. We conclude that in selected patients with suboptimal vertebral visualization on VFA, addition of reverse positioning improves visualization and may enhance vertebral fracture detection.

GE Healthcare has recently developed a new fan-beam densitometer, the Lunar iDXA. This study assessed comparability of BMD measurements and precision obtained on a Lunar iDXA and Lunar Prodigy densitometer.

In 245 subjects, 153 women and 91 men, age (mean [range]) 52.8 years, [20.0 - 91.5] lumbar spine and dual proximal femur measurements were obtained in the routine clinical manner. Their mean lowest BMD T-score from either the L1-4 spine, total femur or femur neck was 0.8 [3.4 to 4.3]. Additionally, in 30 postmenopausal women age 69.8 years, [61.7-78.8] from the above group, a precision assessment of the lumbar spine and proximal femur was conducted on each instrument in accordance with ISCD recommendations.

BMD at the L1-4 spine, mean total femur and mean femur neck was very highly correlated (r2 ≥ .98) between these two instruments. Bland-Altman analyses confirmed the absence of clinically significant bias. Specifically, biases at the L1-4 spine, mean total femur and mean femoral neck regions were 0.011, - 0.002 and - 0.008 grams/cm2 respectively. Moreover, the least significant change was similar when comparing Lunar iDXA to the Lunar Prodigy (0.041 and 0.044 grams/cm2 respectively at L1-4 spine and 0.013 and 0.010 grams/cm2 at the mean total femur).

In conclusion, there is excellent BMD correlation between Lunar iDXA and Lunar Prodigy densitometers. Similarly, BMD precision with these two instruments at the L1-4 spine and femur is virtually identical.
Increased rates of bone turnover are associated with loss of bone mass, trabecular architecture deterioration, mineralization decreases and increases in local stress risers caused by osteoclastic resorption. This study investigated the effects of selective bone removal from high stress regions compared to uniform surface erosion on biomechanical integrity.

Finite Element Modeling (FEM) was performed on 3D images (3.5 mm/side) of trabecular cores from 6 female vertebral samples obtained with a Scanco µCT40 scanner (16 µm). Standard mechanical properties were assigned to the models (E = 18 GPa, ν = 0.3) which underwent a simulated compression test. The resulting principal stress distribution was calculated. FEM was repeated after 5% and 10% bone volume reductions by removing: (a) highest stressed elements or (b) uniform surface erosion. An index of failure was calculated as the percentage of elements that exceeded the predefined stress threshold of 40 MPa [Weinans, 1997]. The average failure ratio of all samples was calculated for each modeling case.

For the same amount of bone loss, there was a significantly higher failure index with localized bone erosion vs. uniform surface erosion. These data suggest that directed bone loss in high stress regions can have deleterious effects on bone biomechanical properties. Preservation of trabecular architecture with anti-resorptive therapies could have a larger impact on bone strength than is suggested by BMD changes alone.

It is reasonable that the superior image quality provided by the GE Healthcare Lunar iDXA densitometer will enhance vertebral visualization. This study compared vertebral visualization and the consequent impact of scoliosis using two densitometers: Prodigy and iDXA.

Sixty-nine subjects (59 female/10 male) who met ISCD VFA indications participated in this correlation study and had AP and lateral VFA exams. Two ISCD-certified clinicians evaluated vertebral visualization and identified fractures. Prodigy images were evaluated initially, followed by iDXA scans. Severity of scoliosis was determined from the iDXA images using a semi-quantitative scale.

Subject mean (range) age was 72.3 years (47.7-91.5), and lowest T-score was 1.7 (+1.2 to 3.4). With Prodigy, 83% of the vertebral from T7-L5 were visualized; more vertebral bodies (p < 0.0001) were visualized using iDXA (94% from T7-L5). In this cohort, 8 fractures were identified with Prodigy and 14 with iDXA. Of the 8 fractures identified on the Prodigy, 7 were also identified on iDXA; 1 fracture was considered a false positive when evaluated on iDXA. In these 69 subjects, 15 were found to have scoliosis on AP iDXA scan (13 mild, 2 moderate, 1 severe). In subjects with scoliosis, visualization was 59.1% with Prodigy and 79.5% with iDXA. More vertebral bodies (p < 0.0001) were visualized in patients without scoliosis using either instrument. Specifically in subjects without scoliosis, 75.5% and 90.1% of vertebral bodies were evaluable with the Prodigy and iDXA respectively.

In conclusion, vertebral visualization with iDXA is excellent. As expected, the presence of scoliosis impedes vertebral visualization with both instruments, however, this effect is reduced with iDXA.
An age stratified sample of 408 men and 400 women aged 50 years and over from Puebla, Mexico were surveyed in a face-to-face interview and invited to participate in the study to investigate the prevalence of low bone mass (Osteopenia and Osteoporosis) in accordance with the World Health Organization (WHO) Classification criteria in terms of bone mineral density (BMD) of the hip and spine measured by x-ray dual absorptiometry (DXA).

Previous consent of all participants, a questionnaire to get information on demographics and risk factors for osteoporosis was applied, and BMD of spine and hip were measured in all cases by DXA with a Lunar Prodigy densitometer. Interviews were conducted by trained personnel and DXA scans were performed at the Osteoporosis Center in Puebla.

The average age of men and women was 69.5 (11.6) and 69.9 (12.1) years. DXA data were analyzed for 408 men and 391 women; 9 scans were excluded from the final analysis due to positioning errors. The prevalence of osteoporosis was 3 fold higher in women than in men at the hip (15.6% vs. 5.8%) and two fold higher at the spine (16.8% vs. 8.5). The prevalence of osteopenia was also higher in women.

Osteoporosis and osteopenia are common in Mexican women over 50 years of age, with lower prevalence in men. Low bone mineral density is directly related to the risk of fragility fractures. These results indicate that developing countries like Mexico must take action in order to implement appropriate primary and secondary prevention against osteoporosis and fragility fractures.
Title: MEDIAL AND LATERAL TIBIAL BMD IN NORMAL AND OSTEOARTHRITIC KNEES A PRELIMINARY STUDY

Authors: Low Siew-Leng, Senior Laboratory Officer, Department of Orthopaedic Surgery, Yong Loo Lin School of Medicine, Singapore; Wong Pui-San, Department of Orthopaedic Surgery, Yong Loo Lin School of Medicine, National University of Singapore; Shamal Das De, Department of Orthopaedic Surgery, Yong Loo Lin School of Medicine, National University of Singapore

The aim of this study was to determine if there were any differences in the medial and lateral tibial BMD in normal and osteoarthritic knees. It is hypothesized that the ratio of BMD in the medial tibial plateau compared to the lateral tibial plateau reflects the loading in the knee. We measured the BMD of the hip and both knees in 24 pre-menopausal women (Group 1, mean age 45.3 ± 2.4 years), 24 post-menopausal women (Group 2, mean age 55 ± 2.6 years) and 23 postmenopausal women with osteoarthritis (OA) of the knee (Group 3, mean age 68.9 ± 4.8 years). Group 1 had significantly higher mean femoral neck BMD compared to Group 2 and 3. 69.6% of subjects with OA knees had either osteopenia (n=11) or osteoporosis (n=5) in the hip. There was no significant difference in mean medial and lateral tibial BMD among the 3 groups. The mean BMD ratio of medial tibial BMD to lateral tibial BMD (M:L) was 0.96 ± 0.11 in Group 1, 0.95 ± 0.10 in Group 2 and 1.06 ± 0.15 in Group 3. The mean M:L BMD ratio was significantly higher (p < 0.05) in OA knees compared to the groups with normal knees. The preliminary results show that the M:L ratio in the knees could be used to prospectively monitor normal subjects who may have excessive loading in the knee joints.

Title: INVESTIGATION OF THE RELATIONSHIP OF TYPE II DIABETES AND OSTEOPOROSIS USING BAYESIAN INFERENCE

Authors: Monina Sta. Romana, MSc, Auditor, Master’s Science in Public Health Major in Biotatii Philippines; Julie T. Li-Yu, MD, Asst. Prof, University of Santo Tomas Faculty of Medicine & Surgery, Espana, Manila, Philippines

The relationship between diabetes and osteoporosis appears complex. Studies of BMD in diabetes have been largely small scale or clinic based, with a likely over-representation of poorly controlled diabetes with complications. In type I diabetes, there is evidence of low bone mineral density at peripheral sites associated with several complications. However, in type II diabetes, there is normal or increased BMD. A study conducted in a community based urban setting in Australia showed that unrecognized osteoporosis is common regardless of diabetes type. Objective: This study aims to determine the prevalence of type II diabetes in women with osteoporosis and estimate the odds ratio of osteoporosis in type II diabetes using Bayesian inference. Methodology: This is a case-control study design that looked into the prevalence of diabetes among 582 females who had normal BMD and 598 females who were osteoporotic. The subjects included women at least 30 years of age who had their bone mineral density measured in the lumbar spine and/or femoral neck using dual xray absorptiometry in a tertiary center in Manila, Philippines. Results: Prevalence of type II diabetes with osteoporosis is 22.41%, while 19.07% subjects with normal BMD had diabetes. The odds of developing osteoporosis is 22.5% higher for type II diabetics. Patients with osteoporosis were older by 10 years. Forty-four percent of diabetic osteoporotics were physically active compared to 20.72% diabetics who had normal BMD. Most of the diabetics without BMD were obese while majority of diabetic osteoporotics had normal BMI. Less than 10% of diabetic osteoporotics and diabetics with normal BMD used hormonal replacement therapy. Of the 598 patients who had osteoporosis, 20.74% suffered from fragility fractures. When controlling for physical activity and BMI, the odds of developing osteoporosis was 21.73% and 53.89% higher for type II diabetes respectively. In considering all possible confounders and effect modifiers in the model which made use of diffuse normal distribution, the estimate for odds ratio is 0.67. A separate analysis excluding modifiable risk factors gave the measure f association an equal likelihood of diabetes being a protective factor or risk factor. Discussion: The crude odds ratio indicated that type II diabetes is a risk factor for osteoporosis. However, when identified confounders were included in the model, the direction of relationship changed. However, with a credible 95% CI in both models created, the study concluded that diabetes is indeed a protective factor for osteoporosis. However, with a well-known diabetes related factors, microvascular complications, visual acuity, risk for fall, one should still strongly consider assessing and screening for osteoporosis as well as fracture risk reduction in diabetes.

Table: Estimates of the Odds Ratio for Type 2 Diabetes and Osteoporosis

<table>
<thead>
<tr>
<th>Model</th>
<th>Prior for Logit Model</th>
<th>LogOR</th>
<th>OddsRatio</th>
<th>95% CI for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1</td>
<td>N(0.0,1000000)</td>
<td>-0.4006</td>
<td>0.670</td>
<td>0.464 - 0.970</td>
</tr>
</tbody>
</table>
Title: 136 — AFRICAN AMERICAN AND CAUCASIAN WOMEN HAVE DIFFERENT RISK FACTORS FOR PREVALENT VERTEBRAL FRACTURES

Authors: Tamara J. Vokes, MD, University of Chicago Illinois, USA; Ann Pham, University of Chicago

Risk factors for vertebral fractures have been studied in Caucasian (WH) and Asian populations but not in African Americans (AA). We compared the clinical risk factors and BMD associated with vertebral fracture detected on VFA in 176 AA and 345 WH female densitometry patients (age 64±13 years). Fractures were graded according to Genant scale with fractures Grade 2 and higher considered as fracture. (Patients with grade 1 fractures were excluded from the analysis). The prevalence of vertebral fractures (21%) was the same in AA and WH patients. The association of risk factors and vertebral fractures was modeled using multivariate logistic regression analysis with presence of vertebral fractures as a binary outcome and risk factors and/or BMD as predictors. In WH patients, statistically significant effects were observed for age [OR= 1.4 per decade (95%CI 1.1, 2.1), p<0.04], history of peripheral fractures as an adult [OR=3.6 (1.8, 7.5), p<0.001], and height loss [OR=4.9 (2.2, 11), p<0.001] but not for corticosteroid use [OR=2.0 (0.7, 6.0), p=0.2]. In contrast, in AA women the significant predictors were use of corticosteroids [OR=4.8 (1.7, 13.8), p=0.003], and age [1.9 per decade (1.2, 3.0), p=0.007], while the other risk factors did not show a significant association. BMD T-score had a significant effect when added to a multivariate model in WH (p=0.001) but not in AA patients. These findings indicate that the associations between risk factors, particularly corticosteroid use, and vertebral fractures differ between AA and WH women.

Title: 138 — DXA BONE MINERAL DENSITY REFERENCE DATABASE FOR THE INDONESIA POPULATION

Authors: G. Tirtarahardja, M.D.CCD Jakarta Osteoporosis Center, Medistra Hospital DKI, Indonesia; B. Setyohadi, Department of Internal Medicine, Indonesian University, Jakarta, Indonesia; Q. Zhou, GE Healthcare, Shanghai, China; LS Weynand, GE Healthcare, Madison, WI, USA

Osteoporosis is a major public health problem, particularly in women. Local reference data for bone mineral density (BMD) are necessary for the accurate diagnosis of osteoporosis. To establish reference data for Indonesia women, we recruited 910 healthy women aged 20-90 years from three centers in Indonesia. Each subject completed a health status questionnaire, and those with known factors affecting BMD were excluded from the study. Spine (L1 L4) and hip BMD were measured with Lunar DXA devices (GE Healthcare, Madison, WI USA). Precision error measured with an aluminum spine phantom on those devices was 0.27-0.56%CV. The relationship between BMD and age was assessed using various regression models, with the best-fit model used to calculate age-related reference curves. The young normal (YN) reference value to determine T-scores was defined as the mean BMD and SD from 20 to 40 years of age (n=288). YN BMD reference values in Indonesia women are similar to Filipino and Chinese values, but slightly lower than American: SDs are similar in all groups. In this study, the first Indonesia reference database for spine and hip BMD was established. With these locally derived reference values, accurate T-scores and Z-scores for the Indonesia population are now available.

Table. The young normal (YN) BMD reference value (g/cm²)

<table>
<thead>
<tr>
<th>YN BMD</th>
<th>L1-L4 (SD) (g/cm²)</th>
<th>Neck (SD) (g/cm²)</th>
<th>Trochanter (SD) (g/cm²)</th>
<th>Total Femur (SD) (g/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesian</td>
<td>1.115 (0.13)</td>
<td>0.917 (0.12)</td>
<td>0.727 (0.11)</td>
<td>0.947 (0.12)</td>
</tr>
<tr>
<td>Filipino</td>
<td>1.110 (0.12)</td>
<td>0.888 (0.12)</td>
<td>0.720 (0.11)</td>
<td>0.913 (0.12)</td>
</tr>
<tr>
<td>Chinese</td>
<td>1.114 (0.12)</td>
<td>0.930 (0.12)</td>
<td>0.759 (0.11)</td>
<td>0.975 (0.13)</td>
</tr>
<tr>
<td>American</td>
<td>1.180 (0.12)</td>
<td>0.980 (0.12)</td>
<td>0.790 (0.11)</td>
<td>1.000 (0.12)</td>
</tr>
</tbody>
</table>
**Title:** 139 — PEAK BONE MASS OF CHINESE POPULATION - A PRELIMINARY REPORT FROM CNDB


**Objective:**
To acquire the distributions of bone mineral density (BMD) for Chinese young adults of different sex and age, estimate the age-specific peak BMDs and provide important basis for setting up the reference range for diagnosis and treatment of osteoporosis in China.

**Material and Methods:**
4063 normal people aged form 20 to 39 were recruited from 10 hospitals in five cities of China, of whom the bone mineral densities of 8 parts of the body (L1, L2, L3, L4, L1-4, L2_4, femur neck and greater trochanter) were measured respectively; By statistical software SPSS11.0, the data were adjusted through regression equation, then the average peak BMDs and the corresponding age intervals were determined, and the differences between different genders and regions were examined.

**Results and Discussion:**
For males, appearing in age group 20~29, the average peak BMDs of L1_2, L2_4, femur neck and greater trochanter were 1.013±0.137, 1.070±0.150, 0.926±0.150, 0.760±0.133 (g/m2) respectively in terms of mean±standard deviation; For females, appearing in age group 30~39, those of L1_2, L2_4 were 1.018±0.129, 1.067±0.135, and appearing in age group 20~29 those of femur neck and greater trochanter were 0.809±0.115 and 0.653±0.105. The average peak BMDs for males were higher than those for females except that the average peak BMD of L2_4 has no significant difference between male and female. The age groups of peak BMDs kept the same no matter the north and south regions were separately considered or not, but the average peak BMDs of male in north were consistently higher than those in south.

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**Title:** 140 — CORRECTION IN BONE MINERAL DENSITY MEASURING IN A MULTI-CENTER STUDY

**Authors:** Jian Du, MD Public Health School of SUN YAT-SEN University Guang Dong PR. China; J.Du, J.Fang, Y. Zhao, X.Lee, H.Shi, H. Zhu W.Yu, T.Tao, X.Zhu, H.Deng , H.Cao, S. Sun, L.Wang, L. Qin, S. Zhang, S.Zhang, Ying Lu, HK.Genant, CNDB Group, Public Health school of SUN YAT-SEN University, Chinese Osteoporosis Fund

**Subject:**
The International Committee for Standards in Bone Measurement gave the correction equations for three types of DXA scanners. These three correction equations were based on white people s BMD data. The variation of BMD measures among centers is related not only to equipments but also to other aspects such as the operators, environments and so on. Therefore, the correction equations supplied by IDSC may not be appropriate in a multi-center study.

**Material and Method:**
In our study titled with The normal variation of bone mineral density and the diagnosis criterion of osteoporosis for Chinese, 10 hospitals, 10,964 male and female aged from 20-90 were recruited. In order to pool the data upon a same platform, one European standardized phantom (ESP) was itinerantly measured among the 10 hospitals.

**Result:**
Ten regression equations were developed between the measured value and the labeled true value respectively. Through these regression equations the data were standardized. We found that our equations were quite different from those supplied by IDSC.

**Conclusion:**
Based on the result we suggest that for each multi-center study, a specific correction equation should be established. The equation provided by IDSC should not be used directly.
**Title:** 141 — BONE DENSITY OF L1 IS IMPORTANT IN BMD ASSESSMENT

**Authors:** Huipeng Shi, MD Shanghai Medical Center for Orthopedic Trauma; Dep Shanghai P. R. China; H.Shi, Zhao, X.Lee, J.Du, J.Fang, H. Zhu W.Yu, T.Tao, X.Zhu, H.Deng, H.Cao, S. Sun, L.Wang, L. Qin, S. Zhang, Z.Huang, Ying Lu, HK.Genant, CNDB Group, The 6th. People Hospital of Shang Hai, Chinese Osteoporosis Fund of CDF

**Subject:**
It is common to use L2-4 to evaluate the BMD in clinical practice and research. But the L1-4 is used more and more recently in the international research. We are going to identify the difference in BMD assessment with and without L1 vertebra.

**Material and Method:**
10 hospital and 1601 people age from 20 to 39 from 5 cities of China were recruited in the study. The data came from the project <The normal variation of bone mineral density and the diagnosis criterion of osteoporosis for Chinese>. The bone mineral densities of 2 combined parts of the body (L1_4, L2_4,) were measured respectively; The variation among hospitals had been adjusted through circuit measurement by the European standardized phantom (ESP).

**Result:**
Data had been analyzed in 2 groups divided by Lunar systems and Hologic.

<table>
<thead>
<tr>
<th>Systems</th>
<th>Sites</th>
<th>Gender</th>
<th>PBM</th>
<th>SD</th>
<th>Age</th>
<th>CV X average/SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunar</td>
<td>L1-4</td>
<td>Male</td>
<td>1,151</td>
<td>0,147</td>
<td>20^29</td>
<td>0,128</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>1,134</td>
<td>0,120</td>
<td>30~39</td>
<td>0,106</td>
</tr>
<tr>
<td></td>
<td>L2-4</td>
<td>Male</td>
<td>1,174</td>
<td>0,149</td>
<td>20^29</td>
<td>0,127</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>1,171</td>
<td>0,125</td>
<td>30~39</td>
<td>0,107</td>
</tr>
<tr>
<td>Hologic</td>
<td>L1-4</td>
<td>Male</td>
<td>0,980</td>
<td>0,113</td>
<td>20~29</td>
<td>0,115</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>0,970</td>
<td>0,114</td>
<td>30~39</td>
<td>0,118</td>
</tr>
<tr>
<td></td>
<td>L2-4</td>
<td>Male</td>
<td>1,018</td>
<td>0,126</td>
<td>20~29</td>
<td>0,124</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>1,025</td>
<td>0,131</td>
<td>30~39</td>
<td>0,128</td>
</tr>
</tbody>
</table>

Both the group of Lunar and Hologic shows that the BMD of L1-4 is lower than L2-4 (1.96%~3.16%, Lunar; 3.73%~5.37%, Hologic). The difference is significantly (P<0.01), calculated by SPSS (V10.0).

**Conclusion:**
According to the data, if L1 was neglected, the individual BMD will be higher. It could cause under-diagnosis of osteoporosis or osteopenia and miss the right time to initiate the treatment. The thoracolumbar junction is a fulcrum for spine motion, where the low traumatic fracture frequently occurs. Gershon Cohen reported 26% of patients had such asymptomatic fractures usually in T11 and L1. The Official Position of ISCD stated that osteoporosis could be diagnosed if a low traumatic vertebra fracture could be diagnosed. Thus we suggest to using L1-4 to evaluate the individual BMD, which could find not only the low bone mass patients but also find vertebra fracture in time to reduce the under-diagnose rate of osteoporosis.

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**Title:** 142 — PLACEMENT OF THE LOWER MARGIN OF THE GLOBAL ROI AFFECTS TOTAL HIP BMD SIGNIFICANTLY

**Authors:** D.L. Kendler MD, Director, Clinical Research Centre, Vancouver, BC, Canada; S.T. Robertson CDT, Clinical Research Centre, Vancouver, BC

Hologic includes 10 lines of femoral shaft in the Intertrochanteric ROI. Hologic DelphiW auto analysis may place the lower margin of the global ROI box appropriately. In such cases the ROI can be manually adjusted to 10 lines below the base of the lesser trochanter. This may introduce subjectivity to the total hip result. We investigated how changing the lower border of the Total Hip ROI would change Total Hip Area, BMC and BMD in 32 postmenopausal women with low bone mass. Total hip precision in the same women was 0.88%. The lower margin of the global ROI box was optimally placed at the base of the lesser trochanter using the contrast and brightness functions. The scan was analyzed with the lower margin in optimal position, with the lower margin moved 5 lines proximal, and then 5 lines distal to the optimal position.

We observed that Area, BMC and BMD all decreased significantly when the inferior ROI margin was moved 5 lines proximal to the optimal setting. All measures increased significantly when the lower border was moved 5 lines distal to optimal due to BMC increasing more than area, leading to positive changes in BMD. Presumably, the increase in BMC, as the region is expanded distally, is due to a greater ratio of cortical to trabecular bone. The opposite is seen when the border is moved proximally. These observations reinforce the importance of checking the auto analysis placement of this ROI parameter.

<table>
<thead>
<tr>
<th>Position of lower margin of ROI box</th>
<th>∆Area (%)</th>
<th>∆BMC (%)</th>
<th>∆BMD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 lines proximal to optimal</td>
<td>-4.86*</td>
<td>-7.27*</td>
<td>-2.53*</td>
</tr>
<tr>
<td>5 lines distal to optimal</td>
<td>+4.03*</td>
<td>+6.55*</td>
<td>+2.42*</td>
</tr>
</tbody>
</table>

* p<0.001
Title: 143 — NO ETHNIC DIFFERENCE IN BONE LOSS IN PROSTATE CANCER PATIENTS RECEIVING ANDROGEN DEPRIVATION THERAPY

Authors: D.A. Nelson Ph.D., Professor of Internal Medicine, Wayne State University, Detroit, MI U.S.A.; L. Darga Ph.D., Research Associate, Wayne State University, Detroit, MI; I. Powell M.D., Professor of Urology, Wayne State University, Detroit, MI; M. Kleerekoper, Professor of Internal Medicine, Wayne State University, Detroit, MI

The purpose of this pilot study was to compare bone loss in white and African-American prostate cancer patients treated with androgen deprivation therapy (ADT). Our sample comprises 9 whites and 20 African-Americans, ages 55-82 years (mean 68.4 + 7.4 yr). We measured spine, total hip and distal forearm BMD by DXA (Hologic) at baseline and 6-8 months later, as well as serum estradiol and NTX. The mean duration of ADT use during the study period was 6.7 + 3.2 mo for whites and 6.1 + 2.6 mo for African-Americans. Rates of bone loss, adjusted to a 6-month interval, were similar in the two ethnic groups for all sites. The change was greatest in the ultra-distal radius (-1.9% for whites, -1.6% for African-Americans). In the spine, the rate was approximately 1% for both groups (-0.6% in whites, -1.2% in African-Americans). The change in the hip was 0.5% for both ethnic groups. In multivariable regression analyses, with each regional final BMD as the dependent variable, and baseline BMD, body mass index (BMI), duration of ADT use, months of observation, and ethnicity as independent variables, we found that for all three sites the 95% confidence interval for the regression coefficient for ethnicity included zero, i.e. there was no ethnic difference in BMD change. Change in hip BMD and estradiol were significantly correlated, with r = -0.52 (p=0.02), but other correlations were not statistically significant. We conclude that white and African-American men with prostate cancer have similar rates of bone loss over a 6-month period of ADT use.

Title: 144 — DETERMINATION OF T-SCORE CONFIDENCE LIMITS FOR DIAGNOSING OSTEOPOROSIS

Authors: KG Faulkner, PhD, GE Healthcare WI USA; LS Weynand, GE Healthcare; WK Wacker, GE Healthcare; HS Barden, GE Healthcare;

Effective use of serial DXA measurements for monitoring BMD change requires minimization of precision error. However, even a single BMD result is subject to both offset (accuracy) errors and variability (precision) errors that influence the T-score. We determined the influence of precision error on T-score for the diagnosis of osteoporosis.

Reported Lunar Prodigy expert precision (g/cm²) in women (mean age 63±9 years) was 0.010 at L1-L4 spine, 0.013 at femoral neck, and 0.008 for total hip (1). Reported Lunar Prodigy precision at clinical centers in subjects (mean age 61±10 years) was 0.014 at L1-L4 spine, 0.025 at femoral neck, and 0.012 at total hip (2). Assuming BMD is normally distributed, the 95% confidence interval (CI) for a single T-score measurement can be estimated using the following equation:

\[ 95\% \text{ CI} = \text{T-score} \pm 1.96 \left( \frac{\text{Precision}}{\text{Population SD}} \right) \]

Using the population SD from the Lunar Prodigy reference database of 0.12 g/cm² for these skeletal sites, clinical DXA T-scores have 95% CI of ±0.2 for spine and total hip and ±0.4 for femoral neck. Therefore, T-scores variations of ±0.2 or less for spine or total hip and ±0.4 for femoral neck should not be considered significant when diagnosing osteoporosis. Minimizing precision error can increase confidence in T-scores by reducing the confidence interval to less than ±0.2 for spine and total femur and to ±0.2 for femoral neck.

1. Shepherd WCO 2004
2. Weynand ASBMR 2004

Table 1: 95% CI for T-scores based on Expert and Clinical Precision

<table>
<thead>
<tr>
<th></th>
<th>Spine</th>
<th>Neck</th>
<th>Total Hip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert</td>
<td>±0.16</td>
<td>±0.21</td>
<td>±0.13</td>
</tr>
<tr>
<td>Clinical</td>
<td>±0.23</td>
<td>±0.41</td>
<td>±0.20</td>
</tr>
</tbody>
</table>
Expanding interest in osteoporosis worldwide has furthered demand for densitometry systems that accurately and precisely measure bone mineral density (BMD) and provide improved visual assessment for analyzing scans and detecting vertebral fracture. Recently, GE Healthcare introduced the Lunar iDXA, a high-definition imaging densitometer featuring a new direct-to-digital CZT-HDTM detector with a staggered-element array to deliver precise and accurate results with near-radiographic image quality.

We compared the precision and accuracy of the Lunar iDXA to Lunar Prodigy. Forty subjects, 30 females and 10 males (mean age 56.7 yrs, SD 13.7), were measured 3 times on both densitometers at the spine, femur and total body with repositioning between scans.

BMD measurements for Prodigy and iDXA were highly correlated at the L1-L4 spine ($r^2>0.98$), femur neck, trochanter, and total femur ($r^2=0.99$), and total body ($r^2=0.96$). Linear regression analysis comparing iDXA with Prodigy showed a unity slope at the L1-L4 spine, the trochanter and total femur, and a small, clinically insignificant, bias at the femur neck (-0.003 g/cm²). There were no significant differences in precision (CV) at the L1-L4 spine (1.1% vs 1.2%), femur neck (1.3% vs 1.4%), trochanter (1.4% vs 1.2%), and total femur (0.8% vs 0.7%) for iDXA and Prodigy, respectively. Total body precision was significantly better with iDXA (CV = 0.6% vs 0.9%).

In conclusion, BMD measurements of the spine and hip on the Lunar iDXA and Prodigy are equivalent. Precision at the spine and femur was nearly identical between instruments and total body precision was significantly better with Lunar iDXA.
Title: 147 — EFFECT OF ABDOMINAL THICKNESS ON THE ACCURACY OF BONE DENSITOMETRY MEASUREMENTS USING THE LUNAR IDXA SCANNER
Authors: Michael K. O’Connor, Ph.D., Professor of Radiologic Physics, Mayo Clinic, Rochester, MN USA

This study examined the effect of increased abdominal thickness on the accuracy of bone mineral density (BMD) measurements on the iDXA (GE Lunar, Madison, WI) bone densitometer. This system incorporates a fan-beam DXA device and a high resolution CZT detector. The iDXA unit was evaluated using Hologic and RSD spine phantoms with BMD values ranging from ~0.6 gm/cm^3 to 1.3 gm/cm^3. Simulated abdominal thicknesses ranged from ~10 cm to ~37 cm. Scans of the spine were acquired at 3 different x-ray fluxes (thin, normal and thick mode for patient studies). Five scans were acquired in each mode at each depth. Mean and standard deviation of BMD and effective abdominal thickness were recorded. At high and medium BMD values, results for all 3 scan modes were identical for abdominal thicknesses of 25 cm or less. At the low BMD value, thin mode was required for thicknesses below ~17 cm to prevent detector saturation. Thin mode yielded precise results up to ~25 cm thickness. Normal mode gave consistent results up to ~30 cm, while thick mode could image ~35 cm of tissue. At thickness beyond the limit of each mode, apparent BMD values increased dramatically. In conclusion, the iDXA bone densitometer should be capable of image patients with a supine abdominal thickness of up to 35 cm. Coupled with an imaging table capable of supporting up to 200 kg, this should enable accurate measurement of bone mineral density in patients with severe ascites and in patients who are morbidly obese.

Title: 148 — IMPACT OF LONG-TERM PRECISION ON LEAST SIGNIFICANT CHANGE
Author: Thomas N. Hangartner, Ph.D., Professor of Biomedical Engineering, Medicine OH USA

ISCD recommendations require the local establishment of limits for the least significant change (LSC) based on repeat patient measurements. These repeat measurements are performed over a short time period when scanner drifts or maintenance/repair related changes are unlikely to occur.

The ISCD recommendations on how to handle changes due to maintenance/repair foresee contacting the manufacturer for service/correction in the case phantom measurements result in a higher than 1% change in BMD. In practice, changes considerably higher than 1% have been observed over a 3-year period in some scanners despite the manufacturer’s corrective action.

We studied the percentage of patients classified wrongly as having a BMD change assuming various levels of LSCs combined with uncorrected scanner-induced shifts in BMD values. For instance, for an established LSC of 2.8% (1% precision), a 1% scanner shift would result in 11% of patients being misclassified although they had no actual BMD change. With lower levels of LSC, the number of misclassified patients increases. With an LSC of 2.1% (0.75% precision), the same 1% scanner shift would result in 16% of patients being misclassified.

If we assume a manufacturer service standard that attempts to calibrate the BMD values within ±1%, it would allow the possibility for changes up to 2%; a service standard of ±2% would allow changes up to 4%. Such service standards permit even larger numbers of misclassified patients.

We recommend that the recalibration limits be assessed for the various scanner models in use and that the site-specific LSCs be appropriately increased.
Title: 149 — CROSS CALIBRATION OF GE-LUNAR IDXA AND PRODIGY BONE DENSITOMETERS

Authors: Lorna Cole, CDT, Oregon Osteoporosis Center, Portland, OR USA; Edward Mossman, Oregon Osteoporosis Center, Portland, OR USA; Michael McClung, Oregon Osteoporosis Center, Portland, OR USA

Bone mineral density (BMD) measurement at the lumbar spine and proximal femur with dual-energy X-ray absorptiometry (DXA) is the acknowledged gold standard for diagnosing and monitoring patients with osteoporosis and assessing fracture risk. The recently introduced Lunar iDXA (GE Healthcare, Madison, WI) fan-beam densitometer uses a new CZT detector that provides markedly improved image quality. We evaluated the BMD performance of the iDXA compared to the Lunar Prodigy at the spine and proximal femur.

Thirty postmenopausal women (mean age 61.3 years) were measured once at the spine on both devices, and 29 postmenopausal women (mean age 61.8 years) were measured once at the femur on each of the 2 DXA systems.

BMD measurements for Prodigy and iDXA were highly correlated ($r^2 = 0.99$) at the L1-L4 spine, femur neck, trochanter, and total femur. Neither slope nor intercept differed significantly from the identity values of 1 and 0 respectively (alpha=0.05). There was a small bias of +0.004 g/cm² for total femur by paired t-test.

We conclude that BMD agreement between iDXA and Prodigy densitometers was excellent at the spine, femur neck, trochanter, and total femur measurement sites.

This study was funded by a grant from GE Healthcare.

Title: 150 — BONE MINERAL DENSITY AND BODY COMPOSITION IN POSTMENOPAUSAL WOMEN

Authors: Catalina Poiana, MD, PhD, FACE, CCD, Assistant Professor of Endocrinology, Carol Davil Romania; Luminita Stoian, MD, C.I.Parhon Institute of Endocrinology, Bucharest, Romania

Osteoporosis is the most frequent metabolic bone disease, a systemic, skeletal disease, characterised by low bone mass and microarchitectural deterioration of bone tissue with a consequent increase in bone fragility and decrease in bone strength. One of the major determinants of the bone mass is the total fat body mass.

The aim of our study was to evaluate the impact of body composition on bone mineral density (BMD) in postmenopausal women with osteoporosis.

We studied a group of 254 postmenopausal white women, with a mean age of 59.18±9.3 years, with osteoporosis (T score: -2.4±1.3 SD) and in addition a group of 42 premenopausal healthy white women, mean age: 36.38±7.2 years. BMD was evaluated by Dual-Energy X-ray Absorptiometry - DXA at lumbar spine, using a Lunar DPX-L scan. Body composition was performed by a Body Composition Analyzer TBF 310 GS (Tanita Corporation) measuring Body Mass Index (kg/sqm)-BMI, Fat%, Fat Mass (kg)-FM, and Fat Free Mass (kg)-FFM.

BMI and fat mass were not different between groups (premenopause vs. postmenopause: 26.62 ±6.0 vs. 27.11±5.4 kg/sqm, respectively 25.98±11.1 vs. 25.83±10.8 kg). BMD correlates positive, statistically significant with BMI and especially with fat mass only in postmenopausal women, and not also in the premenopausal group.

We conclude that low BMI and particularly, low fat mass, are good predictors for the risk of osteoporosis in postmenopausal white women.
Title: 152 — EFFECT OF FEMALE DATABASE USE FOR T-SCORE Derivation in Men
Authors: L. Wiemann, Student UW Osteoporosis Clinical Research Program WI, USA; D. Krueger, University of Wisconsin; N. Vallarta-Ast, University of Wisconsin; N. Binkley, University of Wisconsin

Whether to use a male or female database to derive T-scores in men remains controversial. This study evaluated the impact of deriving male T-scores using female databases in 350 men age 22.8-93.5 (mean 67.5) years who were referred for clinically-indicated DXA scans. Spine, femur and non-dominant radius scans were obtained in routine clinical manner using a GE Healthcare Lunar Prodigy densitometer. Analyses were performed using software version 9.30. Initially the manufacturer’s male normative database was utilized. Subsequently, scans were reanalyzed using female databases, GE for spine and radius, NHANES III for the femur. Using the male database, T-scores (mean [range]) of the L1-4 spine, femur neck, total femur and .3 radius were 0.0 [-4.6 - 8.5], -1.6 [-4.3 - 2.3], -1.1 [-4.0 - 3.3] and -0.7 [-5.3 - 2.9] respectively. Upon reanalyzing with female databases, T-scores improved (p < 0.0001) with a positive bias of 0.34, 0.33, 0.58 and 1.20 respectively at the above four sites. Using female databases, the proportion of men classified as having normal bone mass increased from 22% to 33% and those identified as osteoporotic decreased from 29% to 17%. If pharmacologic treatment were prescribed at a T-score < -2.0, female database use reduced those treated for low bone mass from 46% to 32%. In conclusion, using a female database to derive male T-scores results in improvement of diagnostic classification for some men. Additionally, fewer men will be diagnosed with, and potentially treated for, low bone mass.

Title: 153 — DOES SPINAL DEGENERATIVE DISEASE DECREASE HIP DXA PRECISION?
Authors: Robert D. Blank, Endocrinology & Osteoporosis Research and Clinical University WI USA; Diane C. Krueger, Osteoporosis Research and Clinical Center, U. of Wisconsin; Nellie L. Vallarta-Ast, William S. Middleton VAMC; Brenda J. McCarney, Osteoporosis Research and Clinical Center, U. of Wisconsin; Karen M. Elver, Marc K. Drezner, Neil C. Binkley, Karen E. Hansen

We previously reported that spinal degenerative changes, manifested as focal structural defects (FSD), adversely affect dual energy X ray absorptiometry (DXA) precision at the lumbar spine. Since osteoarthritis is often a generalized condition, we hypothesized that spinal FSD would be associated with poorer DXA precision at the hip. Three radiology technologists from a University Hospital and a Veterans Affairs Medical Center each obtained hip and spine precision scans on 30 patients. Three International Society for Clinical Densitometry-certified physicians reviewed all lumbar spinal scans to note the presence of focal structural defects. We calculated precision for the total left hip for each technologist, and for “virtual samples” of patients with and without physician-identified vertebral FSD. The least significant changes (LSC) at the total left hip for the 3 samples are 0.020, 0.023, and 0.028 g/cm2. The ranking of the LSCs corresponds to the prevalence of FSDs in the samples. The LSCs of the virtual samples composed of patients without FSD and with FSD in 3 or more vertebrae are 0.026 and 0.035 g/cm2, respectively. While lower hip BMD precision is noted in the sample with spinal FSD, differences do not reach statistical significance. However, a power calculation reveals that samples of about 600 individuals with and without spinal FSD would be needed to test the hypothesis that hip precision worsens in the presence of spinal FSD. These data support the validity and feasibility of conducting such a study, perhaps assembling the sample from precision assessments performed in ISCD members practices.
Primary hyperparathyroidism (PHPT) is often associated with reduced bone mineral density (BMD). We conducted a double-blind, randomized, cross-over trial of alendronate (ALN), 10mg daily for one year, in patients with PHPT and reported that ALN significantly increases BMD at 12 and from baseline values. That sample included both men and women (28/9) and pre- and postmenopausal women (4/24). This analysis focused on the skeletal effects of ALN in men and premenopausal women. Paired t-tests on the baseline and 12 month data were completed for the men. Total hip BMD was significantly improved among the men (mean diff. 0.021; SE 0.009, p=0.045) as it was for the whole group. Lumbar spine BMD was also improved (mean diff. 0.033, SE 0.010, p=0.050). Femoral neck BMD was significantly improved in the whole group but not significantly different in the subgroup of men. Two markers of bone turnover, BSAP and urinary NTX excretion, were significantly decreased among the men (BSAP mean diff. -10.428, SE 3.579, p<.027; NTX mean diff. -58.289, SE 20.99, p=0.032), as the whole group.

The analysis of premenopausal women showed similar results to the total group however the analysis was limited to four premenopausal women.

ALN has similar efficacy in increasing BMD among men as seen in postmenopausal women.
Title: 156 — MONITORING TIME INTERVAL FOR BMD AT DIFFERENT SKELETAL SITES IN CHILDREN
Authors: Li Wang, MD, MQIR Group, Department of Radiology, University of California, CA, USA; Ying Lu, Ph.D. MQIR Group, Department of Radiology, University of California, San Francisco, CA; Bo Fan, MD, MQIR Group, Department of Radiology, University of California, San Francisco, CA; Karen Winer, Ph.D. National Institute Child Health and Human Development, John A. Shepherd, Ph.D. MQIR Group, Department of Radiology, University of California, San Francisco, CA

Introduction: Children between 6-16 years of age are experiencing rapid changes in bone mineral density (BMD). Monitoring time interval (MTI) estimates the duration (years) between two BMD measurements during which 50% of the population changes more than the least significant change (LSC). It is important in planning longitudinal follow-up measures in clinical BMD exams for children. Material and Methods: We studied 1554 healthy children (863 in girls and 691 boys) between 6 and 16 years of age. Aerial BMD (g/cm2) at the posterior-anterior lumbar spine (L1-L4), the left femur (femoral neck and total hip), the non-dominant 1/3 radius and whole body were measured by a dual-energy X-ray absorptiometry (DXA) (Hologic Inc, Bedford, Ma). Each child was measured at 0, 1, 2 years. A subset of 150 children were scanned twice at baseline to estimate the precision and LSC as a function of age and region of interest. Results: The shortest MTIs were found during the highest annual rates of change. The MTIs for total spine was better than any other site at all ages for both sexes with MTIs from 0.2 to 1.1 years, while the neck and 1/3 distal regions had similar and long MTIs (0.6 to 4.3 years). Boys, in general, had smaller MTIs than girls of the same age for all sites. Conclusion: Children's MTIs vary by region of interest, by age, and by sex from 0.2 to 4.3 years. The shortest monitoring time intervals were for the AP spine at any age and for both sexes.

Title: 157 — THE VALUE OF CROSS-CALIBRATION IN NATIONAL QUALITY ASSURANCE PROGRAMS
Authors: Laura R. Fairbanks, M.S. Associate Director, Quality Assurance, UCSF, Dept. CA US; Mary E. Sherman, RT, UCSF Dept. of Radiology; B. Fan, MD, UCSF Dept. of Radiology; John A. Shepherd, Ph.D. UCSF Dept of Radiology

Several nation wide Quality Assurance programs have been established in recent years, including a new ISCD Site Accreditation program. However, few of these programs include a cross-calibration component. Cross-calibration is a tool that is most frequently associated with research involving multiple centers to allow for comparison of data. However, cross-calibration is also necessary at individual centers to ensure consistent machine performance, even for different manufacturers, throughout a country or region. Such programs ensure that centers work under the most recent and recognized standards of quality. Each approved center would be validated as to their %CV, CVs and LSC. Errors in diagnosis due to faulty Bone Mineral Density readings should decrease dramatically.

We present several examples of sites that were found to be measuring BMD up to 15% above the level considered accurate. The error was not revealed by their longitudinal quality control scanning. Individuals measured at each site could have clinically significant difference in their T-scores and it is conceivable that treatment should have been initiated in at least some of those individuals, but was not due to faulty measurement.

Stringently regulated and monitored standards would ultimately lead to increased credibility to referral physicians as well as the public in general. We will summarize existing cross-calibration programs across the world and make a case for the importance for such programs.
Title: 158 — A NEW METHOD OF QUALITY MANAGEMENT FOR DXA
Authors: Bo Fan, MD, University of California San Francisco California, USA; Laura Fairbanks, University California San Francisco; Mary Sherman, University of California San Francisco; John Shepherd, University of California San Francisco

Quality assurance is inversely correlated with errors that degrade data. Quality procedures can increase the efficiency of data processing and help ensure data integrity. QA procedures for analyzing DXA images generally involve assigning image quality codes. We have observed that the degree of agreement of scan quality can vary between scan analysts, as well as over time with the same analyst. Expert review to assess the images and coding reduces this variability. These procedures are usually done on prints of the analyzed scans and then entered into a database. The procedure is tedious and error prone.

We have developed an ACCESS based electronic quality assurance program for scoring DXA scan quality using expert review of analyzed scans for the NHANES study. The system uploads subject biographical information and results from Hologic databases. Coding is entered directly into the system. Multiple reviewers can independently review the scans. Discrepancies are automatically identified allowing for adjudication until agreement is achieved. The tool interfaces with SAS to access analyzed scan results and calculate T and Z scores.

Because the original coding and the expert review coding are stored separately, the tool can serve as a means of evaluating individual performance during the QA process, as well as to monitor agreement between reviewers. This system can be used as a training system or as a method to track the quality of scans.

In summary, we postulate that this tool will reduce error associated with scan analysis and increase the efficiency of quality data generation.

Title: 159 — QUANTIFYING IMAGE QUALITY OF DXA SCANNERS PERFORMING VERTEBRAL FRACTURE ASSESSMENT USING RADIOGRAPHIC PHANTOMS
Authors: L.G. Jankowski, CDT, Chief DXA technologist, Illinois Bone and Joint Institute, IL USA; M. Costello, RTR, CDT, Senior DXA technologist, Division of Endocrinology, University of Chicago Hospitals, Chicago, IL USA; S.B. Broy, MD, FACP, Illinois Bone and Joint Institute, Morton Grove, IL USA

We imaged commercial radiographic phantoms on a digital X-ray (DXR) system and DXA scanners performing vertebral fracture assessment (VFA) and report the results.

A contrast-detail (CD) phantom, a line-pair resolution phantom and aluminum step-wedge were scanned on a GE-Prodigy and GE-iDXA, Hologic Discovery-A, and a digital x-ray system in identical configurations. Images were acquired using manufacturer specific VFA protocols, and thoracic spine technique for DXR. DICOM files of the images were evaluated under identical viewing conditions by two independent observers. The inverse Image Quality Figure (invIQF) and Correct Observation Ratio (COR) from the CD phantom, and horizontal and vertical line-pair resolutions were recorded. Step wedge phantoms were graded pass/fail.

The inviQF values were 0.94, 0.83, 0.82, 0.43, and 0.24, and COR values were 63, 62, 60, 43, and 29 percent, for DXR, Hologic IVA-HD, Hologic IVA, GE-iDXA, and GE-Prodigy respectively. Vertical line resolution was 2.7, 0.6, 0.6, 0.7, and <0.5, and horizontal line resolution was 2.7, 1.4, 0.8, 0.6, and <0.5 lp/mm, for DXR, Hologic IVA-HD, Hologic IVA, GE-iDXA, and GE-Prodigy respectively. All systems resolved all the steps in the aluminum wedge phantom.

Radiographic phantoms can be evaluated in VFA mode on DXA devices, and may be useful to detect image degradation of DXA systems over time. Image resolution testing should be part of routine DXA quality control. Further research is needed to determine whether phantom results infer relative ability of VFA devices to detect vertebral deformities or differentiate fracture from other etiologies.
An observational registry was established to explore temporal changes in spine and hip BMD in postmenopausal women by using QCT. Radiology records were retrospectively reviewed to identify patients with e2 QCT spine and hip analyses performed from 2001-2004. Postmenopausal, ambulatory women aged 40-90 years with osteopenia or osteoporosis, were eligible.

Of 365 identified patients, 67 received no osteoporosis therapy throughout the study period. Data from these women represent the untreated natural history of bone loss as assessed by QCT. Mean±SE age (62.5±1.2 years), baseline lumbar spine T-score (2.07±0.17), and time between QCT assessments (1.8±0.1 years) were similar to the means for the entire cohort. QCT measurements were used to estimate trabecular spine BMD based on volumetric density and to characterize hip total, cortical, and trabecular BMD using both areal and volumetric density.

In the untreated patients, mean lumbar spine BMD decreased by 5±1 mg/cm³ (P<0.001), and mean lumbar spine T-score decreased by 2.0±0.0 (P<0.001). BMD of the total bone compartment decreased at the total hip, femoral neck, trochanter, and intertrochanter; while T-score decreased significantly only at the total hip and intertrochanter. Analysis of the hip cortical bone compartment showed significant decreases in both areal and volumetric BMD at the intertrochanter; and femoral neck BMD decreased significantly in areal BMD. No significant changes were observed for the trabecular compartment of any hip regions.

These data suggest that QCT is useful for monitoring subtle temporal BMD changes, and that trabecular bone loss at the hip and spine occur at different rates.
Ibandronate and alendronate are nitrogen-containing bisphosphonates indicated for the prevention and treatment of postmenopausal osteoporosis. Both have proven efficacy in reducing fractures, increasing bone mineral density (BMD), and suppressing biochemical markers of bone turnover. Until now, there have been no head-to-head studies comparing their efficacy and safety.

MOTION (Monthly Oral Therapy with Ibandronate for Osteoporosis intervention) is a 1-year randomized, multinational, double-dummy, Phase IIIb trial designed to demonstrate the non-inferiority of once-monthly oral ibandronate (150 mg) versus once-weekly oral alendronate (70 mg). The study population comprises approximately 1,800 postmenopausal women aged 55-84 years with lumbar spine BMD T-scores between -2.5 and -5.0. Co-primary efficacy endpoints are relative change from baseline in mean lumbar spine (L2-L4) and total hip BMD at 12 months. The margin of clinical equivalence is set at 1.41% for lumbar spine and 0.87% for total hip BMD, respectively. Secondary efficacy endpoints include absolute changes at 12 months from baseline in mean lumbar spine BMD and total hip BMD, relative and absolute changes from baseline in trochanter BMD. Approximately 30% of patients are being assessed for absolute and relative changes from baseline in bone-resorption marker C-telopeptide crosslinks of type I collagen and bone-formation marker procollagen type I N-terminal propeptide. Clinical vertebral and non-vertebral fractures are being assessed as adverse events, and safety laboratory parameters are being monitored.

Comparative data for monthly ibandronate and weekly alendronate should enable better-informed decisions for the choice of treatment of women with postmenopausal osteoporosis.
Title: AUTOMATED HIGH-SPEED FILM DIGITIZATION METHOD WITH QUALITY ASSURANCE
Authors: Eric Lee, EE, Staff Research Associate, University of California, CA USA; Chyi Huang, Staff Research Associate, University of California, San Francisco; Serghei Malkov, Associate Specialist, Ph.D, University of California, San Francisco; Jeff Wang, Staff Research Associate, University of California, San Francisco; Li Wang, Staff Research Associate, University of California, San Francisco; John Shepherd, Assistant Professor in Residence, Ph.D, University of California, San Francisco

With emerging digital imaging technologies, many clinics are beginning to take advantage of digital images in their studies. However, there are a large numbers of existing x-ray films, such as lateral spine films collected for fracture studies that are enormously useful for retrospective analysis with modern digital analysis tools. This can be efficiently done with high quality radiographic film digitizers. The UCSF Breast and Bone Density Group has developed a digitizing system for completely automated high-speed digitization with complementary quality assurance reports. Our purpose here is to present the description of a novel method and its quality control results for 6 months of use. Our Matlab-controlled algorithm has features of automated barcode recognition and film tag blinding, and can digitize films up to 14 x 17 at pixel resolutions of 50 to 170 microns with a clinical optical density range of 0 to 3.85 in 16 bit depth gray scale. The throughput is up to 800 films/day. The automatic quality assurance system is augmented with a manual QC interface for additional code entry if needed. An automatic QA report for each digitized image is generated including various film parameters and information obtained by optical character recognition. Recently we implemented our automatic digitization method in the M-Os (Osteoporosis in Men Study) and SOF (The Study of Fractures) studies and have successfully digitized various sizes of conventional spine, hip, and hand x-rays into DICOM format. We conclude that our automatic digitization method with its automatic QA technique is a useful mechanism for radiologists to utilize digital image processing tools, and for secure archival.

Title: THE INCIDENCE OF UNDIAGNOSED OSTEOPOROSIS AND OSTEOPENIA IN A COMMUNITY GENERAL ORTHOPEDIC REFERRAL PRACTICE
Authors: Margaret M. Baker, MD, Orthopedic Surgeon, Center for Bone & Joint Surgery, WA USA; Kathleen O’Neill, PA-C, Physician Assistant, Center for Bone & Joint Surgery

Introduction:
Osteoporosis and related fractures are epidemic today in the U.S. and other developed countries. Unfortunately, despite current accurate diagnostic methods and effective preventative treatments many American’s bone health issues are not optimally addressed.

Methods:
Patients meeting NOF or ISCD guidelines for DXA screening were selected from a general orthopedic referral practice over a year period. Four hundred and seventy five patients met inclusion criteria, and were scanned on our Hologic Delphi DXA. The two technologists and clinical densitometrist are ISCD certified, and precision of 98.54% was established. Testing included spine, hip and forearm BMDs plus lateral vertebral assessment, which we consider our gold standard scan.

Results:
The incidence of previously undiagnosed osteopenia / osteoporosis in males meeting screening criteria was 70%. A comparison was made between our gold standard scan, and the usual central (hip and spine only) DXA routinely accomplished at other local scanners. Without scanning the forearm and lateral spine, the false negative rate was 34%.

Discussion and Conclusion: Even in a specialty referral only setting, patients sent to us most frequently have not had adequate bone health screening. Males and Native Americans were particularly underserved...
Title: 166 — HYPOVITAMINOSIS D IS COMMON IN PHYSICIANS BUT MEASUREMENT DOES NOT AFFECT PATIENT CARE
Authors: H.L. Kramm, M.D., Rheumatology Fellow, University of Wisconsin, Madison, WI USA; K.E. Hansen, Professor of Rheumatology, University of Wisconsin, Madison, WI

While osteoporosis specialists acknowledge the skeletal impact of vitamin D and the high prevalence of vitamin D insufficiency, other physicians may not recognize hypovitaminosis D as a common health problem. We designed a study to evaluate 1) the prevalence of hypovitaminosis D in primary care physicians and 2) whether measurement of serum 25(OH)D in physicians increases the frequency of testing patients for the condition.

We recruited primary care providers by email letter of invitation. Following the consent of 26 physicians, serum 25(OH)D was measured using a reverse phase HPLC assay. Serum 25(OH)D results were mailed to each physician's home along with an explanation of the result. Subsequently, the Information Technologies Department provided the number of serum 25(OH)D tests ordered by each physician and the number of patient encounters for the twelve weeks preceding and following receipt of test results.

Five among 26 physicians (19%) had hypovitaminosis D (<24 ng/ml by HPLC). At the time of abstract submission, sixteen doctors had adequate follow up data to assess the frequency of 25(OH)D testing among their patients. Only 3 of 16 physicians increased the frequency by which they ordered 25(OH)D levels among their patients following study participation (P>0.05, Wilcoxon rank sum test). Moreover, physicians with hypovitaminosis D were no more likely to increase vitamin D testing among their patients than physicians with normal vitamin D stores.

We conclude that although hypovitaminosis D is common among physicians, measurement of serum 25(OH)D does not alter the frequency by which they order 25(OH)D in patients.

Title: 167 — SOMATOTYPE AND BONE MINERAL DENSITY IN POSTMENOPAUSAL WOMEN: A PILOT STUDY
Authors: Alvaro L. Ronco, MD, Epidemiologist, Centroseo Diagnostic Clinic, Montevideo, Uruguay; Carlos Miranda, Gynecologist, Centroseo Diagnostic Clinic; Diana Wiluzanski, Director, Centroseo Diagnostic Clinic

In order to explore possible associations between bone mineral density (BMD) and fat and muscular distribution in postmenopausal women, we conducted a study based on bone densitometry by Dual X-ray Absorptiometry (DXA) and somatotype. Somatotype is an internationally known technique, frequently applied in medical research apart from sports medicine. It combines numeric values for endomorph, mesomorph and ectomorph components in each subject, expressed through a specific graphic, the somatocart. Forty-seven women 27 osteopenic and 20 normal ones according to W.H.O.- who were examined at a densitometry center, were administered a brief questionnaire about sociodemographics, menstrual, reproductive, family and medical history. They were measured a series of skinfolds, girths and diameters, specifically to estimate somatotype in each patient. According to this analysis, study population showed a high meso-endomorphic pattern. Osteopenic patients were less endo- (p=0.04) and mesomorphic (p=0.04) and more ectomorphic (p=0.15) than controls, especially within the subgroup of menopause at ages <=44 years. Endo- and mesomorphic component correlated positively with total BMD of lower limbs (r = 0.43), trunk (r=0.34) and total (r=0.37), whereas the ectomorphic component displayed negative correlations (r= -0.35, -0.23 and 0.23 respectively). According to our knowledge, this report on quantification of body shape in the study of bone density is the first one communicated in the specialized literature. Since somatotype is modifiable through nutrition and physical exercise, it raises the possibility to broaden primary prevention of osteoporosis within a theoretical high-risk subgroup like menopausal women are.
Title: 168 — BODY COMPOSITION AND BONE MINERAL DENSITY: INITIAL RESULTS OF A CASE-CONTROL STUDY IN EARLY POSTMENOPAUSAL WOMEN

Authors: Diana Wiluzanski, MD, Director, Centroseo Diagnostic Clinic, Montevideo, Uruguay; Alvaro L. Ronco, Epidemiologist, Centroseo Diagnostic Clinic, Montevideo, Uruguay; Carlos Miranda, Gynecologist, Centroseo Diagnostic Clinic, Montevideo, Uruguay

Although a slender and light bone structure is mostly recognized as more prone to bone demineralization in women, and at the same time, a high body mass index is raised as a possible protection, findings are not conclusive. We conducted a research, currently ongoing, in order to analyze possible associations between body composition and the risk of osteopenia in Uruguayan postmenopausal women, in particular within a subgroup having had an early menopause. With that aim, 37 patients proceeding from the pre-paid healthcare system in Montevideo, capital city of Uruguay, were included in the study. Patients had their menopause between ages 40-46. 23 of them recent cases of osteopenia and 14 healthy controls with normal densitometry. They were diagnosed with the same Dual X-ray Absorptiometry equipment, and interviewed on menstrual, reproductive, family and medical history. All were measured on 18 skinfolds, girths and anatomic diameters, together with weight and height. Densitometry enabled us to get account of 25 anthropometric variables at upper limbs, lower limbs, trunk and total body. We found negative associations between several body measurements and the risk of osteopenia. Women with higher absolute adipose and muscular weight were found as low-risk ones, albeit their proportionality was similar to osteopenic ones. Broader girths and diameters in limbs, as well as a higher adipose loading in the upper body were also positively associated with bone mineralization. Results would confirm a protective role for a high body mass index, if further studies replicate these findings.

Title: 169 — ASSOCIATION BETWEEN ADHERENCE TO BISPHOSPHONATE THERAPY AND REDUCED NONVERTEBRAL FRACTURE RISK

Authors: Stuart L. Silverman, MD, Medical Director, Osteoporosis Medical Center, Beverly Hills, CA, USA; Steven T. Harris, Clinical Professor of Medicine, University of California, San Francisco, CA; Charles E. Barr, Director, Data Analytics, Roche Laboratories Inc., Nutley, NJ; Ethel S. Siris, Columbia Univ. College of Physician Surgeons

The effect of adherence to bisphosphonates on the risk of nonvertebral fracture, a major cause of morbidity and mortality in postmenopausal women with osteoporosis, was investigated.

Data were analyzed from 2 Medstat MarketScan medical and pharmaceutical claims databases covering 6 million individuals for the period 1999-2003. Subjects were women 45 years of age with an index prescription for a bisphosphonate (Alendronate or Risedronate) and continuous data from the 6-month baseline and 24-month follow-up periods. Two adherence measures were evaluated: compliance, as measured by the Medication Possession Ratio (drug available ≥80% of the time), and persistence (no gaps in refills >30 days).

During the 24-month follow-up period, 2856 of the 35,537 women analyzed had nonvertebral fractures, including 702 hip fractures. The risk of nonvertebral fracture was 7.1% in compliant women and 8.8% in noncompliant women (p<.0001). The Adjusted Odds Ratio was 0.80 (p<.0001) and the relative risk was 0.81 for compliant vs noncompliant subjects. The risk of hip fracture was 1.6% in compliant versus 2.3% in noncompliant women (p<.0001). The risk of nonvertebral fracture was 6.3% in persistent women and 8.5% in nonpersistent women. The Adjusted Odds Ratio was 0.71 (p<.0001) and the relative risk was 0.75 for persistent vs nonpersistent subjects. The risk of hip fracture was 1.3% in persistent women and 2.1% in nonpersistent women (p<.0001).

Adherence to bisphosphonate therapy, as assessed in medical and pharmaceutical databases, was associated with significant reductions in nonvertebral fracture risk, in particular the risk of hip fracture.
Title: 170 — DISTRIBUTION OF BONE MINERAL DENSITY WITHIN THE HIP SCAN REGION

Authors: J M Wang, Technologist, Norland—a CooperSurgical Company Beijing, People’s Republic of China; J C Lin, Dept of Nuclear Medicine, PLA 304th Hospital, Beijing, PR China; TV Sanchez, Norland—a CooperSurgical Company

Mineral distribution within the hip has been implicated as a factor in fracture. While the Ward’s region is usually located somewhere near the intersection of the lower femur neck boundary and neck bisecting line; occasionally the Norland system—which seeks area of minimal content to set a Ward’s region locates high on the femur neck or deep in the trochanteric region. This study examines density distribution in hip scans with a Ward’s in typical distribution (NOR), high femur neck distribution (FN) or a deep trochanteric distribution (TR).

Bone density in eleven operator set regions were evaluated in fifty-one Norland hip scans with a Ward’s in NOR distribution (n = 17), FN distribution (n = 17) or TR distribution (n = 17). Regions in FN distribution studies showed densities 70-90% of the NOR studies. Regions in the TR distribution samples showed densities between 56-92% that of the NOR. When compared to the NOR studies, scans with a FN distribution showed the greatest reduced density in region 2 (70%) while those with a TR distribution showed the greatest reduced relative densities in regions 7 (57%) and 10 (66%). Significantly, both FN and TR distribution samples included regions that were similar to regions in the NOR distribution samples.

In conclusion, Norland hip scan studies placing the Ward’s region high in the femur neck or deep in the trochanter represent studies with significant specific regional bone loss this may place the subject at an increased risk of a specific fracture.

Title: 171 — VERTEBRAL FRACTURE RISK IN PATIENTS WITH LOW LUMBAR SPINE BMD: EFFECT OF IBANDRONATE BY AGE GROUP

Authors: C. Simonelli, MD, Director, Osteoporosis Service, HealthEast Clinics MN USA; R.E. Cole, Director, Osteoporosis Testing Center of Michigan, Brooklyn, MI; C.E. Barr, Director, Data Analytics, Roche Laboratories Inc., Nutley, NJ; S.B. Tanner, Assistant Professor, Vanderbilt University, Nashville, TN

The purpose of this study was to examine the relationship between age and the antifracture efficacy of ibandronate treatment.

A post-hoc analysis of data from the BONE trial was performed. BONE was a 3-year, double-blind, placebo-controlled, parallel-group trial of daily and intermittent ibandronate in 2946 randomized women. Women enrolled in the study had a bone mineral density (BMD) T-score of -2.0 to -5.0 in at least one vertebra (L1-L4) and 1-4 prevalent vertebral fractures (T4-L4). Subjects were grouped by age and a proportional hazards regression model was used to estimate hazard rates and compare relative risks for treated (2.5 mg daily) versus placebo arms; where the relative risk reduction is 100%, the log-rank test was used. Fracture incidence rates were estimated by the Kaplan-Meier method.

Subjects <60 years (n=167), <65 years (n=507), and <70 years (n=1011) had vertebral fracture rates of 9.3% vs 0%, 11.5% vs 0.96% and 11.0% vs 3.9% for placebo versus treated groups, respectively. The corresponding absolute risk reductions were 93%, 10.53% and 7.1%, respectively. Relative risks for vertebral fracture were significantly reduced for the <60, <65, and <70 years subgroups by 100% (P=0.0069), 92% (P=0.0007), and 72% (P<0.0001), respectively.

Ibandronate significantly reduced vertebral fracture risk versus placebo in all age subgroups studied, being particularly effective in the <60 years subgroup where no fractures were seen in the treated cohort. These data suggest that early menopausal women may gain particular benefit from ibandronate treatment.
Title: 172 — A COMPARISON OF BMD AND DEMOGRAPHIC DATA FOR PREDICTING CLINICAL FRACTURES OVER 5 YEARS

Authors: Richard Prince, Associate Professor University of Western Australia; Amanda Devine, Doctor; Ian Dick, Doctor

It has been suggested that BMD is not required to predict fracture risk if demographic data for the individual is known. We have compared the relative power of hip BMD and demographic data in determining incident fracture risk in elderly postmenopausal women.

Demographic variables, total hip BMD (Hologic 4500A), and 5-y incident fracture data were collected on 1125 women (75±3y). Two models were developed for fracture prediction Model 1 - using BMD SD (Z) score and Model 2 using demographics - Age, BMI, timed up and go (TUAG), smoking and prevalent fracture. Beta coefficients were used to calculate 5-y fracture hazards for each person and plotted as ROC's compared to actual incident fractures.

185 individuals (16.4%) sustained 1 fractures over 5 years. Areas under the curves for each ROC were identical for each model (0.62±0.02). In both models fewer fractures occurred in the lower compared to the upper quartiles (Model 1: 9.5% vs. 23.8%; Model 2: 9.4% vs. 23.6%). However, only 39% of patients in the lowest risk quartile using demographics had high BMD in Model 1, only 42% in the highest risk quartile using demographics had low BMD in Model 1.

Thus BMD and demographic data have similar predictive power to determine fracture risk but in many patients predicted to be at high or low risk of fracture using demographic data the risk is not related to bone structure and therefore may not respond to therapies designed to improve bone structure.

Title: 173 — PREVALENCE OF VERTEBRAL COMPRESSION DEFORMITIES IN HEALTHY POSTMENOPAUSAL WOMEN WITH OSTEOPENIA

Authors: Angela M. Cheung, MD, PhD, CCD, Director, Osteoporosis Program; University Health Ontario Canada; Hazel Sinclair, Osteoporosis Program, University Health Network, Toronto, Ontario, Canada; Judite Scher, Christina Djokoto, Gillian Hawker

This study’s aim was to describe the prevalence of vertebral compression deformities (VCDs) among postmenopausal women with osteopenia.

We recruited 441 postmenopausal women through community advertisements, posters and health fairs for an osteoporosis prevention trial. Women were excluded if they were on osteoporosis medications, had a clinical fragility fracture or had a T-score<−2.0 at the lumbar spine, total hip or femoral neck. All underwent baseline BMD and VFA using Hologic Delphi 4500A. VFA scans were then analysed by two trained reviewers. VCDs were scored based on the Genant semi-quantitative method and by quantitative morphometric assessments.

Mean age at baseline was 59.2 years (range 40-82 years), mean height 161.7cm, mean weight 68.4kg and mean BMI 26.1kg/m2. Mean L1-L4 BMD was 0.923g/cm2 (T-score=-1.2), total hip 0.869g/cm2 (T-score=-0.6) and femoral neck 0.712g/cm2 (T-score=-1.2). Participants were 88.6% Caucasian, 2.3% African-Caribbean, 6.2% Asian and 2.8% other. 35.0% had a family history of osteoporosis. 65.8% used some alcohol. 6.2% were current smokers, 46% ex-smokers, and 47% never smoked. 45% of women had previously used HRT. 93.0-99.5% of vertebrae between T4 and L4 were analyzable on VFA. Of those analysed, approximately one in eleven women had one or more VCDs. 7.7% had a single deformity and 1.1% had two deformities at baseline. Most VCDs (41/44) were Grade 1 deformities.

Our study showed that moderate to severe VCDs are uncommon among osteopenic postmenopausal women without a clinical history of fragility fracture; however approximately one in eleven postmenopausal women with osteopenia have Grade 1 or more VCDs. Further studies are needed to assess the risk of future fractures associated with Grade 1 VCDs.
**Title:** 174 — DENOSUMAB (AMG 162) INHIBITION OF RANK LIGAND INCREASES BONE MINERAL DENSITY AFTER TWO YEARS OF TREATMENT IN POSTMENOPAUSAL WOMEN WITH LOW BONE MINERAL DENSITY

**Authors:** E.M. Lewiecki, MD, New Mexico Clinical Research & Osteoporosis Ctr, NM, USA; P.D. Miller, Colorado Center for Bone Research; M.R. McClung, Oregon Osteoporosis Center, Portland, OR; S.B. Cohen, Radiant Research, Dallas, TX; Y. Liu, Amgen Inc., Thousand Oaks, CA; A. Wang, Amgen Inc., Thousand Oaks, CA; L.A. Fitzpatrick, Amgen Inc., Thousand Oaks, CA

Denosumab (AMG 162), a fully human, monoclonal antibody, inhibits RANKL, a primary mediator of osteoclast activity. Previous reports from this placebo-controlled, dose-ranging study in 412 postmenopausal women with low BMD (T-score <= -1.8) showed that denosumab significantly increased BMD and decreased bone turnover markers compared with placebo after 1 year. Here we report a prespecified, exploratory analysis of denosumab efficacy and safety after 2 years.

Subjects were randomly assigned to treatment with subcutaneous injections of placebo, denosumab (3-monthly [6, 14, or 30 mg] or 6 monthly [14, 60, 100, or 210 mg]), or open-label oral alendronate (ALN; 70 mg once weekly).

A total of 337 (82%) subjects completed 2 years of study (38 placebo, 259 denosumab, 40 ALN). At 2 years the mean increases in BMD for the denosumab dose groups ranged from 4.25%-8.95% for lumbar spine, 2.76%-6.11% for total hip, 0.59%-2.47% for distal 1/3 radius, and 0.90%-4.46% for total body. Changes were significantly greater (P<0.001) than for placebo (-1.04%, -1.75%, -2.82%, and -1.62%, respectively). ALN caused the following BMD changes at 2 years: 0.22% (lumbar spine), 3.40% (total hip), -0.81% (distal 1/3 radius), and 1.51% (total body). Occurrence of adverse events was similar among the treatment groups; no new pattern of events was seen in year 2. No neutralizing antibodies to denosumab were observed throughout 2 years.

Denosumab treatment for 2 years led to sustained, significant increases in BMD. These data suggest denosumab, when administered twice yearly, may offer a promising alternative for the prevention and treatment of osteoporosis.

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**Title:** 175 — THE ASSESSEMENT BY DIGITAL X-RAY RADIOGRAMMETRY IN BONE MASS CHANGE IN POSTMENOPAUSAL WOMEN TREATED WITH ALENDRONATE

**Authors:** Corina Galesanu, Professor of Endocrinology, University of Medicine, Romania; Roxana Gabriela Galesanu, Centre Of Imaging And Radiologic Diagnosis, Iasi, Romania; Ciprian Ciubotariu, Centre Of Imaging And Radiologic Diagnosis, Iasi, Romania; Gabriel Melnic, Centre Of Imaging And Radiologic Diagnosis, Iasi, Romania

Digital X-ray Radiogrammetry (DXR) is an efficient clinical method of estimating bone mineral density (BMD). The system has shown to have a good correlation (>0.90) to DXA, and a good in vivo reproducibility.

Four thousand and five hundred healthy women addressed (spontaneously or at doctor's recommendation) to our bone densitometry service using DXR-BMD (Pronosco X-posure system TM). Among them 3,212 were in postmenopause. Using the WHO criteria for osteoporosis diagnosis, 535 from them presented osteoporosis and 987 osteopenia.

At 72 postmenopausal osteoporotic women the treatment was Alendronate (ALN) 10 mg daily for 12-24 months and then ALN 70 mg once weekly for 24 months. The witness group was represented by 30 postmenopausal osteoporotic women who received 1 mcg Alfacalcidol (TEVA) daily.

The mean age of osteoporotic patient was 69.4 years. The BMD by DXR was measured at each 12 months for 4 years.

The change of BMD after the treatment with ALN was +3.1% after 1 year, +4.2% after 2 years, +5.0% after 3 years and +5.3% after 4 years.

The change of SD was from -2.97±0.8 to -2.12±0.8 after 4 years of treatment. At the treatment with Alfacalcidol in witness group the change of BMD was from +1.8% to +2.8% after 4 years.

Conclusion: Alendronate induced increase BMD in women with postmenopausal osteoporosis. This increase was significantly higher after Alendronate compared with patients treated with Alfacalcidol only. DXR-BMD, largely used by us in the diagnosis and follow up of therapy in osteoporosis is a reliable method.
Title: 176 — PROFOUNDED INCREASE BONE DENSITY OF 45% AT THE SPINE AND 87% AT THE HIP AFTER 16 MONTHS WITHOUT PHARMACOLOGICAL THERAPY: CAN YOU BELIEVE THIS?

Authors: Jan M. Bruder, MD CCD, University of Texas Health Science Center, Associate Professor of Medicine, Endocrinology Texas USA; Beatrice Talayero, Medicine Resident UTHSCSA; Sarah Lapey, Assistant Professor of Medicine, UTHSCSA

A 39 year-old man was admitted to the hospital with generalized pain and weakness. He traced his symptoms 3 years back prior to presentation, when he began experiencing diffuse arthralgias, involving legs, ribs, and shoulders. His pain progressed, associated with generalized weakness, eventually necessitating a wheelchair for ambulation. Physical examination was notable for symmetrical proximal muscle weakness and localized areas of tenderness overlying the greater trochanter, spine, and sacroiliac joints. He also exhibited right sided enophthalmos. Initial laboratory studies were significant for a low serum phosphorus level and an elevated serum alkaline phosphatase. X rays revealed diffuse osteopenia, T11 compression fracture and other healing fractures. Bone mineral density T-scores of the L1-L4 spine (0.769g/cm2) and Total Hip (0.513g/cm2) were -2.9 and -3.4 respectively. Further laboratory testing evidenced an inappropriately low 1,25 dihydroxyvitamin D level and hyperphosphaturia. CT of the orbit and sinus revealed a right sino-nasal mass. Biopsy demonstrated a hemangiopericytoma. Removal of the tumor normalized serum phosphorus with dramatic improvement of symptoms. He was treated post-op with vitamin D and calcium for 16 months. Repeat BMD revealed a significant increase of 45% in the spine (L1-L4 = 1.117g/cm2; T-score 0.2) and increase of 87% at the hip (Total Hip 0.961 g/cm2; T-score -0.5). This rare condition known as oncogenic osteomalacia is characterized by the presence of benign tumors of mesenchymal origin whose hormonal products, phosphatins, reduce proximal renal tubular phosphate reabsorption resulting in urinary phosphorus wasting and overall depletion of body phosphate stores. Removal of the tumor with restoration of phosphate and calcium homeostasis resulted in a marked and unprecedented increase in BMD.

Title: 177 — UNUSUAL CASE OF HYPOCALCIURIA IN PRIMARY HYPERPARATHYROIDISM

Authors: Christiane Zoghbi, PGY1pgy1,East Tennesse State University TN USA; Richard Jordan, Professor of Medicine, Chief Division of Endocrinology and metabolism, Residency Program Director East TN State University College of Medicine, Chief Medical Services at James Quillen VA medical center; Alan Peiris, Professor of medicine at East TN State University

The case report discusses a possible confounding effect of hypocalciuria in the workup of primary hyperparathyroidism. The patient is a 76 year old man referred for work up of hypercalcemia. He denied a previous history of kidney stones, pancreatitis. His past medical history was significant for multiple myeloma, osteoporosis, osteoarthritis, perforated gastric ulcer, hyperlipidemia, coronary artery disease and benign prostatic hypertrophy. His medications consisted of Alendronate 10mg one tablet per day, Pamidronate 90mg one dose every month, Atenolol, Clopidogrel, Furosemide, Simvastatin, Terazosin, Finasteride.

The physical exam was unremarkable except a previously noted mild systolic murmur 2/6 best heard at the left lower sternal border. His laboratory findings were significant for a serum calcium level of 10.5mg/dl(normal range 8.4-10.2mg/dl), with a 24 hours urine calcium collection of 57 mg(normal range 100-300mg/24h). Ionized calcium was 6.3mg/dl(normal range 4.5-5.6mg/dl), Intact PTH 211pg/ml(normal range 12-65pg/ml), serum albumin 25-hydroxyvitamin D, magnesium, creatinine, phosphorus and the rest of the basic metabolic panel was within normal limits. A Technetium Sestamibi scan revealed a parathyroid adenoma located in the lower pole of the right lobe of the thyroid gland.

Familial hypocalciuric hypercalcemia was unlikely since the patient had prior normal serum calcium levels and lack of family history. We hypothesize that the decrease in urine calcium is due to the exposure to Bisphosphonates which can produce a significant decrease in urinary calcium even one week after treatment(1,2,3).

In conclusion, Clinicians need to be aware that urine calcium measurements may be significantly altered by the concomitant use of Bisphosphonates and may impact the workup of patients with suspected hyperparathyroidism.
Title: 178 — ADDITIVE VALUE OF BONE DENSITY, CLINICAL RISK FACTORS (AGE) AND RADIOGRAPHIC TEXTURE ANALYSIS (RTA) PERFORMED ON DENSITOMETRIC HEEL IMAGES IN ASSESSING BONE FRAGILITY

Authors: Tamara Yokes, Dr. Associated Professor of Medicine Illinois USA; Ann Pham, University of Chicago Dept. of Medicine; Maryellen Giger, University of Chicago, Dept. of Radiology

Bone fragility is determined by bone mass, measured as bone mineral density (BMD), and by trabecular structure, which cannot be easily measured using currently available non-invasive methods. RTA applied to radiographs is an investigational, non-invasive way of assessing bone structure. This cross-sectional study was undertaken to determine whether RTA performed on high resolution heel images obtained on a peripheral densitometer (PIXI) can differentiate subjects with and without osteoporotic fractures. We assessed clinical risk factors, measured BMD of the hip, spine and heel, and performed RTA on densitometric heel images in 170 postmenopausal women (42 with prevalent vertebral fractures and 128 without any osteoporotic fractures) who had no secondary causes of osteoporosis and were not receiving treatment for osteoporosis. Vertebral fractures were diagnosed using VFA. The fracture and non-fracture groups differed in age, T-score of all sites and RTA results. The only clinical risk factor that was independently associated with presence of vertebral fractures was age. In univariate logistic regression analysis with presence of vertebral fractures as binary outcome there was a significant (p<0.001) effect and area under ROC curve for age (0.74), hip T-score (0.70) and RTA (0.70). In multivariate logistic regression analysis which included all 3 variables, there was a significant effect of age (p<0.001), hip T-score (p=0.03) and os calcis RTA (p=0.002), with the area under the ROC curve for the multivariate model of 0.80. This study suggests that RTA of densitometer-generated calcaneus images, BMD, and age provide independent and complementary estimates of bone fragility.

Title: 179 — DISTAL FOREARM BONE MINERAL DENSITY IN TAIWAN ADOLESCENTS

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This study aimed at establishing normative data for BMD in healthy Taiwan adolescents and to evaluate the relationship between calcium intake and bone mineral status. Two hundred eighty-five healthy adolescents (149 females and 136 males) aged from 17 to 21 years were studied. Areal bone mineral density (BMD) and bone mineral content (BMC) of the nondominant distal forearm were measured by dual-energy X-ray absorptiometry (DXA), utilizing an osteometer DXT-200 device. Food and nutrient intakes were estimated by means of a 24-hour dietary recall and a simple semiquantitative food frequency questionnaire. In males, mean height was 171.82 ± 5.44 cm and body mass was 64.69 ± 10.98 kg, and the body mass index (BMI) (body mass/height2) was 21.86 ± 3.51. Mean BMD values in the young males groups was 0.53 ± 0.06 g/cm2(mean ± S.D.), with mean Z scores ranging was -1.16 ± 0.88 SD. BMC maximum mean value (mean ± S.D.: 3.62 ± 0.56 g) for boys was found to be in the 21-year-old group with difference between gender becoming significant in the 17-21-year-old groups (p < 0.05). Males showing a greater BMD and BMC values than females (p < 0.05). In females, mean height was 159.65 ± 5.46 cm and body mass was 51.32 ± 7.06 kg, and the body mass index was 20.13 ± 2.48. The distal forearm BMD values in young females was 0.45 ± 0.04 g/cm2 (Z scores = -0.57 ± 0.70 SD) and BMC maximum mean value (2.67 ± 0.35 g) were increased until 20 years of age, with no significant difference between age groups older than 20. The distal forearm BMD showed mild increment through adolescence in boys and girls. Mean calcium intake was 644.05 ± 537.10 mg/day among the boys and 589.15 ± 489.02 mg/day among the girls, and of which primary 48 %–55 % was provided by milk and milk products. The average calcium intakes among this study groups are low at 1000–1200 mg/capita per day (about 49.1%–53.7 % of the Taiwan RDA). Higher consumption of meat and soy beans products in boys than in girls groups (p < 0.05). These results suggest that bone mass of distal forearm in healthy Taiwan adolescents may accrue in certain groups of young males beyond age 21. Promotion of milk consumption should be considered for achieving optimal bone mass in these population groups.
A pilot study evaluating osteoporosis risk assessed by calcaneal ultrasound and vitamin D status in 49 nursing home residents in the Midwest was performed. We hypothesize that osteoporosis by calcaneal ultrasound is under-diagnosed and vitamin D deficiency is common, under-diagnosed and under-treated and may be associated with falls. A descriptive analysis, Chi-square test, general linear model and logistic regression model were applied to this population data. Thirty-eight female and 11 male Caucasian residents aged 65-102 (mean=85, sd=8.7) underwent medical record review, calcaneal ultrasound testing with GE-Lunar Achilles® instrument and serum 25-OH vitamin D assessment (DiaSorin, Mayo Clinic, Rochester, MN). 25(OH) vitamin D total levels ranged from 6-74ng/mL (mean=22.4, sd=13.1) and 35 (81%) had levels <30ng/mL. Use of a multivitamin was associated with higher total vitamin D level (mean 29), p=0.001. Mean calcaneal T-score was -2.5 (range=-4.3 to 1.5, sd=1.5) and 45 (92%) were <-1 with 26 (53%) <-2.5. Nine residents had a diagnosis of osteoporosis in their medical record and six of these were on a bisphosphonate. Eleven (22%) had a recorded fall in the past 30 days and 35 (71%) had a fall in the prior 180 days. After adjusting for age and sex, Vitamin D level did not have a significant effect on T-score category (OR=0.98, p=0.44) or fall rate. Small sample size was a limitation of this study. In this nursing home population there is significant undiagnosed and untreated osteoporosis and vitamin D deficiency. Further study is needed to assess future intervention models.

It has been shown that quantitative ultrasound (QUS) parameters of the calcaneus and bone resorption markers predict osteoporotic fractures. Maintaining physical activity reduces the risk of fractures. Walking steps measured by pedometers have been used for physical activity assessment in The National Nutrition Survey in Japan. The purpose of this cross-sectional study was to investigate the effects of daily walking steps on QUS parameters of the calcaneus and urinary deoxypyridinoline (DPD) in elderly Japanese women.

The subjects were 114 postmenopausal women aged 60-85 years. They were members of a senior citizen’s club. Subjects with a history of disease known to affect bone metabolism and with a history of oophorectomy were excluded. Stiffness in the right calcaneus was measured with A-1000 (Lunar, USA). Spot urine samples were collected between 09:00 and 10:00. The value of DPD was adjusted for creatinine concentration. A pedometer (HJ-002, Omron, Japan) was given to each subject. The subjects were instructed to wear the pedometer during waking hours for 7 consecutive days.

Stiffness showed a positive correlation with walking steps. DPD showed a negative correlation with walking steps. These relationships remained significant after adjustment for age and/or body weight. These results indicate that subjects with a high number of walking steps have higher QUS parameters of the calcaneus and lower levels in marker of bone resorption. It is suggested that maintaining daily walking activity could help in the prevention of osteoporotic fractures in elderly women.
Title: 191 — EARLY OSTEOPOROSIS TREATMENT AND SUBSEQUENT FRACTURE PREVENTION AMONG WOMEN WITH CLINICAL VERTEBRAL FRACTURE
Authors: Lindsay R., M.B.Ch.B., Ph.D., F.R.C.P. Chief of Internal Medicine, Helen Hayes Hospital NY, USA; Borisov N.N., Senior Economist, Procter & Gamble Pharmaceuticals, Inc., Mason, OH; Sheer R.L., Analyst, Procter & Gamble Pharmaceuticals, Inc., Mason, OH; Steinbuch M., Procter & Gamble Pharmaceuticals, Inc., Mason, OH

This study evaluated osteoporosis treatment use and its effect on prevention of subsequent fractures among women with clinical vertebral fracture, utilizing integrated administrative, medical and pharmacy claims database.

A retrospective cohort study was conducted among 7,233 women (aged 45+) with new vertebral fracture verified with diagnostic code and record of radiologic exam, between July 1, 2000 and June 30, 2003. The cohort was followed for 12 months after vertebral fracture to identify subsequent fracture and osteoporosis treatment use.

The majority of population (80%) did not receive any osteoporosis treatment (bisphosphonates or nasal calcitonin) after vertebral fracture; 1,056 women (15%) received treatment within 90 days, mean 21 days (early-treatment cohort); 358 women (5%) received treatment after 90 days, mean 193 days (late-treatment cohort). Subsequent fractures were observed among: 1,039 (18%) untreated women, 85 (8%) women in the early-treatment cohort (RR=0.51, p<0.01), and 76 (21%) women in the late-treatment cohort (RR=1.05, p=0.73). Osteoporosis treatments were effective in their subsequent vertebral fracture prevention compared to no treatment as follows: risedronate (RR=0.26, p=0.02), alendronate (RR=0.46, p<0.01), and nasal calcitonin (RR=0.63, p=0.05); and for non-vertebral fractures: risedronate (RR=0.34, p=0.04), alendronate (RR=0.53, p<0.01), and nasal calcitonin (RR=0.75, p=0.19).

The majority of women with clinical vertebral fracture remained untreated after their fracture. The early treatment significantly reduced risk of subsequent fracture during the 1-year follow-up. The late treatment appeared not to prevent second fracture within that year that may be due to insufficient exposure to the treatment in the observation period. Further evaluation of fracture protection beyond one year would be warranted.

Title: 192 — OSTEOPOROSIS RISK FACTORS AND PREVENTION AMONG FEMALE PHYSICIANS IN NORTHERN CALIFORNIA
Author: R.B. Mims, M.D., M.D. Director, Endocrine Metabolic Center, Santa Rosa CA USA

On Doctor’s Health Day, we encountered one female physician (F-MD) with an unexplained low BMD. We wondered if F-MD had unique risk factors, or were not practicing common Osteoporosis prevention. We studied 36 F-MDs between the ages of 36-56, mean (M) age of 46 years, whose M Ht was 66 in (62-72), M Wt of 137.5 lbs (118-175), and 32 were White, 4 were Asian, and one Hispanic. Our risk factor assessment showed no one who smoked, 28/38 had 1-6 children (M=2), and 20/20 breastfed. Five were menopausal, one PMP. 2 had declining menses, one took thyroid hormone and 5 claimed Depression. There was minimum use of alcohol, wine, coffee, colas and 3/36 took bone depleting meds. For Osteoporosis prevention 24/36 (67%) were practicing preventive measures for five years. 56% took 1000-1200 mg of elemental calcium/d and did adequate weight bearing exercise. Another 28% were very busy. Three were immobile for up to six months, and one consumed increased protein. The back BMDs for 3/36 F-MDs were below, and 9/36 BMDs were above population norms. No specific cause was found for the 3 low BMDs. Likewise, no hip BMDs were below population norms, and 5/36 were above norms. We conclude that no unique Osteoporosis risk factors were identified in this group of Northern California F-MDs, and that most practiced common Osteoporosis prevention.
Peripheral QCT (pQCT) allows for the measurement of three dimensional bone strength and calculates an index of bone strength, the Stress Strain Index (SSI), thus producing more data than DXA scans for bone structure.

In women 25 years post-menopause we examined the association of endogenous estrogen status on incident fracture risk and peripheral quantitative computerized tomography (pQCT) 3D measured cortical structure.

Study design: In 1150 women mean (SD) age 75(2.6) baseline serum estradiol and SHBG were measured and the free estradiol index (FEI) calculated; radiologically verified fractures were recorded over five years; pQCT was measured at the radius 4% site (Stratec XCT 2000) to evaluate bone structure in 3D and bone strength (Stress Strain Index SSI) in the three directions. Analyses were adjusted for BMI, age and calcium supplementation; hazard ratios (HR) for time to fracture were calculated by Cox regression.

16% of patients fractured over five years. Fracture risk was related additively to baseline FEI (HR per SD 0.75, 0.58-0.97) and the total pQCT bone density (HR per SD 0.67, 0.55-0.82), fracture rates in the bottom and top quartile of FEI and pQCT bone density were 21.7% and 11.8% and 26.3% and 10.5% respectively.

FEI was positively associated with cortical bone volume and density (beta coefficients 0.16, p<0.001 and 0.21, p<0.001) and strength (SSI) in the x, y and polar directions (0.16, p<0.001; 0.19, p>0.001 and 0.19, p<0.001 respectively).

In elderly women bioactive oestrogen is an important determinant of both cortical bone structure and strength and fracture risk.
Title: 195 — NORMATIVE REFERENCE DATABASE FOR DIGITAL RADIOGRAMMETRY FOR KOREAN MEN

Authors: Seoung-Oh Yang, M.D., Professor of Diagnostic Imaging, Eulji University Korea; Shi-Kyung Lee, Kangnam General Hospital Public Corporation1, Seoul, Korea

This study was an open cross-sectional study providing normative reference data for DXR-BMD and DXR-MCI in Korean men.

Demographic data (age, height, weight) and a short medical history was obtained. The man consulted a study physician and gave his written informed consent prior to any study related procedures. A radiograph was acquired of each subject's non-dominant hand and forearm. The radiographs were scanned and analyzed using the Pronosco X-posure System V.2 and the DXR-BMD, bone width and cortical thickness were calculated.

The number of subjects included for the study was 140 men. A total of 167 normal Korean men between 20 and 79 years of age were enrolled. Among them 27 men were excluded due to underexposed radiographs, and the remaining 140 men were included and their radiographs were analyzed. Korean males between the age of 20 and 79 who were generally healthy and free from diseases which would impact on bone density and were able to understand and wanted to sign the Ethics Committee approved informed consent.

The reference curve was based on a regression of DXR-BMD versus age and age2 (second order polynomial). The reference level for estimating T-score and the corresponding standard deviation were found to be 0.579 g/cm² and 0.045 g/cm² respectively based on young adult men (20-39 years of age).

A polynomial of the second degree of age was the best model to illustrate the relationship between DXR-MCI and age. In adult men over age 50, a decline in mean DXR-BMD with age was demonstrated.

Title: 196 — RADIOGRAPHIC ABSORPTIOMETRY AS A PRE-SCREENING APPROACH FOR THE OSTEOPOROTIC PATIENT’S EVALUATION

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DXA and case-history assessment are widely used for the diagnosis of osteoporosis, but the huge number of patients can represent a limiting factor. To improve procedures and reduce the operational costs, we recently introduced a pre-screening process based on a short risk factors questionnaire and a middle phalangeal radiographic absorptiometry (RA) of the non-dominant hand using a monoenergetic X-rays (60 kV) equipment. RA has an extremely short performing time (<1 second), reduced exposure (<0.012 μSv) and an in vivo precision of 1.5-2.0%. 186 consecutive unselected patients (63.3+-7.8 yrs) were evaluated with both RA (Alara Metriscan) and DXA (Hologic QDR 4500A). Mean T-scores were -1.50+-1.3 for RA, -1.92+-1.2, -1.65+-0.9 and -1.21+-0.9 for lumbar spine (LS), femoral neck (FN) and total femur (FT) DXA respectively. The T-score correlations between RA and DXA BMDs were 0.645 at the LS, 0.493 at the FN and 0.491 at the FT.A RA T-score lower than -0.7 identified 98% of osteoporotic (OP) and 91% of osteopenic patients (OS) diagnosed at the LS by DXA (90% of OP and 87% of OS for the FN). With a RA T-score cutoff <1.0, 30.3% of the subjects would have avoided the DXA scanning with a substantial reduction of the waiting list without impairing the diagnostic process and the patients approval rate.
Patient-reported preference and convenience for once-monthly ibandronate and once-weekly alendronate was evaluated.

Postmenopausal women (N=342) were enrolled in a 6-month, prospective, randomized, open-label, 2-sequence, 2-period, crossover study (BALTO I). Patients received once-monthly ibandronate (150 mg) followed by once-weekly alendronate (70 mg) for a total of 6 months (Sequence A; N=170) or weekly alendronate followed by monthly ibandronate for a total of 6 months (Sequence B; N=172); patients took each regimen for 3 months. Preference and convenience were assessed via a self-administered questionnaire.

Of the 276 patients that expressed a preference, 71.4% preferred once-monthly ibandronate while 28.6% preferred once-weekly alendronate. The preference rate for ibandronate was statistically significant (p<0.0001). The sequence in which medications were taken did not affect results (Gart-order-effect P=0.1855). The most common reasons cited for patient preference were (1) ease of following treatment for a long time (ibandronate, 169/276; alendronate, 70/276) and (2) dosing schedule better fitting their lifestyle (ibandronate, 152/276; alendronate, 59/276). Of the 264 women who expressed an opinion on convenience, 74.6% found once-monthly ibandronate to be more convenient compared with 25.4% patients who found once-weekly alendronate to be more convenient. The convenience rate for ibandronate was statistically significant (p<0.0001). The incidences of upper GI adverse events were 7.5% (N=24) and 9.4% (N=30) during ibandronate and alendronate treatment, respectively.

The majority of women preferred the once-monthly ibandronate and found it more convenient than the once-weekly alendronate. Monthly ibandronate provides a convenient dosing option for the treatment of postmenopausal osteoporosis and may enhance long-term adherence.
A primary objective of the DIVA study was to compare the safety of intravenous ibandronate injections with the oral regimen.

DIVA was a 2-year, randomized, double-blind, double-dummy, Phase III, non-inferiority study. Subjects (n=1395) were aged 55-80 years, menopausal for >5 years, and had lumbar spine bone mineral density (BMD) T-scores between -2.5 and -5. Patients received intravenous ibandronate (2 mg every 2 months [q2mo] or 3 mg every 3 months [q3mo]) together with oral placebo or oral ibandronate (2.5 mg daily) with intravenous placebo. Adverse events were continuously monitored and classified by body system. Serum creatinine concentration was monitored to evaluate kidney function.

Safety populations were 465, 448, and 469 patients in the daily, q2mo, and q3mo dosing groups, respectively. After 2 years, the incidence of adverse events was similar across treatment groups. Influenza-like illnesses and gastro-intestinal intolerance were seen primarily in year 1 with slight increases during year 2 for all groups. Fracture incidence (reported as adverse events) was low and similar in the treatment groups. Treatment-related adverse events leading to withdrawal occurred in 6.0% (daily), 6.5% (q2mo), and 7.7% (q3mo) of patients. Changes in serum creatinine and reported renal events were considered unlikely to be treatment-related. Osteonecrosis of the jaw was not reported.

The safety profile observed in women receiving intermittently administered intravenous injections of ibandronate was acceptable. No new imbalances were identified between years 1 and 2. Safety with intravenous ibandronate was comparable to the daily oral regimen, which has a similar safety profile to placebo.

DIVA compared the 2-year efficacy and safety of intermittent intravenous ibandronate with that of daily oral ibandronate in women with postmenopausal osteoporosis.

DIVA was a randomized, double-blind, double-dummy, Phase III study designed to demonstrate the non-inferiority of intermittent intravenous ibandronate compared to approved daily oral ibandronate. The study enrolled 1395 postmenopausal women, aged 55-80 years and <5 years since menopause, with osteoporosis as defined by lumbar spine BMD T-score between -2.5 and -5.0. Patients received intravenous ibandronate (2 mg every 2 months [q2mo] or 3 mg every 3 months [q3mo]) or oral ibandronate (2.5 mg daily), and intravenous or oral placebo. Efficacy endpoints included changes in lumbar spine and hip BMD and bone-turnover marker serum C-telopeptide crosslinks of type I collagen (sCTX).

After 2 years, lumbar spine BMD increased over baseline by 6.4%, 6.3%, and 4.8% for patients receiving the q2mo (n=320), q3mo (n=334), and daily (n=334) regimens, respectively (per protocol population). Both intravenous regimens were non-inferior (margin: 1.3%) and proved superior (p<0.001) to the oral regimen. Total hip, femoral neck, and trochanter BMD increased by 2.2-5.0% across regimens, with consistently greater gains in the intravenous groups. sCTX levels were significantly reduced (median reduction: 53.4-59.9%) for all regimens at 2 years. The results support 1-year observations.

The efficacy of intermittent intravenous ibandronate noted at 1 year persisted at 2 years. Intravenous ibandronate could provide an alternative to oral bisphosphonate treatment. Intravenous ibandronate regimens provide superior BMD increases compared to the daily oral regimen.
Title: 201 — BMD IMPROVEMENTS IN POSTMENOPAUSAL OSTEOPOOROSIS: MOBILE SHOWS CONTINUED SUPERIORITY OF ONCE-MONTHLY IBANDRONATE AT 2 YEARS

Authors: R.R. Recker, MD Professor of Medicine and Director, Osteoporosis R NE USA; E.M. Lewiecki, Osteoporosis Director, New Mexico Clinical Research & Osteoporosis Center, Albuquerque, NM; P.D. Miller, Clinical Professor, Department of Medicine, Colorado Center for Bone Research, Lakewood, CO; R.D. Emkey, Medical Director, Emkey Arthritis & Osteoporosis Clinic, Wyomissing, PA

Bone mineral density (BMD) was measured in women with postmenopausal osteoporosis receiving approved daily and once-monthly oral ibandronate in the MOBILE study. MOBILE was a multinational, randomized, Phase III, non-inferiority study in 1609 women aged 55-80 years (mean, 66 years) with lumbar spine BMD T-score between 2.5 and 5.0 (mean, 3.28). Approximately half the patients in each treatment arm had a history of fracture. Women who received 2.5 mg oral ibandronate daily (n=402) or 150 mg once monthly (n=401) were analyzed here. Lumbar spine and proximal femur (total hip, femoral neck, trochanter) BMD were monitored by DXA and compared with baseline values using a non-inferiority test (margin at 1 year, 1.3%). For the 2-year per protocol population, mean lumbar spine BMD increased relative to baseline by 3.7% in the 2.5 mg daily group and 4.8% in the 150 mg monthly group after 1 year; while the respective groups had increases of 5.0% and 6.6% after 2 years. Ibandronate 150 mg monthly was non-inferior and superior to the daily dose (p<0.001). After 2 years, superior mean BMD increases were seen with 150 mg ibandronate versus 2.5 mg (total hip, 4.2% vs 2.5%; femoral neck, 3.1% vs 1.9%; trochanter, 6.2% vs 4.0%). The BMD efficacy of oral ibandronate in treating postmenopausal osteoporosis found in the 1-year analyses of MOBILE was maintained at 2 years. After 1 year on once-monthly ibandronate, BMD improvements were at least as great as those seen at 2 years with daily ibandronate.

Title: 202 — MEDICATION BURDEN IN WOMEN WITH OSTEOPOOROSIS

Authors: S.L. Bonnick, MD, Medical Director, Clinical Research Center of North TX USA; D.T. Gold, Associate Professor, Medical Sociology, Duke University Medical Center, Durham, NC; M.M. Amonkar, Manager, Global Health Outcomes, GlaxoSmithKline North America; H.K. Kamel, Director, Geriatrics and Extended Care, St. Joseph’s Mercy Health Center, Hot Springs, AR

Oral bisphosphonates are an efficacious treatment for postmenopausal osteoporosis, but adherence with therapy is suboptimal. It has been hypothesized that polypharmacy may contribute to non-adherence, and this analysis was undertaken to determine whether bisphosphonate users have a large burden of concomitant medication. Prescription information, over 56 months, from 14,000 retail pharmacies across the USA was used to identify women, ≥50 years old receiving alendronate or risedronate, the bisphosphonates approved for osteoporosis treatment at the time of this study. Concomitant medications were defined as ≤14 days of prescription supply in the same month as ≤14 days supply of a bisphosphonate. From November 1999 to June 2004, the number of bisphosphonate users in the database increased from 78,909 to 250,286. On average, of the patients prescribed concomitant medications, 74% had ≤2, 52% had ≤3 and 15.4% had ≤6 concomitant medications. The proportion of women filling ≤6 additional prescriptions rose from 11.9% to 19.1% during the course of the study. Most common concomitant drug classes were cholesterol reducers, synthetic thyroid hormones, calcium channel blockers, beta blockers, ACE inhibitors, and systemic anti-arthritis. Women prescribed daily bisphosphonates received a higher mean number of concomitant medications than those receiving weekly bisphosphonates (4.16 versus 3.77 as of June 2004) as did older women (3.97 for those ≥75 years versus 3.09 for those 50-64 years; June 2004 data). In conclusion, patients receiving bisphosphonate therapy for postmenopausal osteoporosis have a substantial pill burden. Adherence to therapy may be improved if physicians consider prescribing less frequently dosed medications.
Title: 203 — COMPLIANCE CONTINUUM AND FRACTURE RISK REDUCTION WITH BISPHOSPHONATE TREATMENT FOR OSTEOPOROSIS

Authors: Steven T. Harris, MD, Clinical Professor of Medicine, University of California, CA USA; Ethel S. Siris, Columbia Univ. College of Physician Surgeons, New York, NY; Stuart L. Silverman, Medical Director, Osteoporosis Medical Center, Beverly Hills, CA; Charles E. Barr, Director, Data Analytics, Roche Laboratories Inc., Nutley, NJ

The purpose of this analysis was to examine the relationship between the full range of patient compliance levels based on Medication Possession Ratio (MPR) and fracture risk. Two medical databases (Medstat MarketScan Commercial and Medicare) were retrospectively analyzed to determine patient compliance with bisphosphonate therapy and fracture risk. The databases included medical and pharmaceutical claims data (1999 to 2003) from 6 million individuals. This study examined claims from women 45 years of age with an index prescription for a bisphosphonate (Alendronate or Risedronate) and continuous data for the 6-month baseline and 24-month follow-up periods. Compliance was determined by the Medication Possession Ratio, which was calculated as the number of days of medication supply divided by follow-up time in days. In addition to analyses using an MPR cut-off point of 80% (based on historical precedent) the effect of compliance on fracture risk across the full range of MPR values from 0% to 100% was analyzed. The occurrence of osteoporotic fractures was defined by specific diagnostic codes.

The probability of fracture remained essentially unchanged until refill compliance reached approximately 50%. Above 50% refill compliance, fracture rates declined progressively as compliance increased. Between 50% to 75%, and then more sharply from 75% to 100%, there were progressive decreases in fracture risk.

The observed continuous positive correlation between refill compliance and fracture risk reduction suggests that strategies to improve the adherence to bisphosphonate therapy will improve the fracture risk reduction achievable in clinical practice.

Title: 204 — INCREASES IN BONE MINERAL DENSITY WITH ONCE-MONTHLY IBANDRONATE: A POST HOC RESPONDER RATE ANALYSIS OF THE MOBILE STUDY

Authors: M.C. Hochberg, MD, Professor of Medicine, University of Maryland, School of Medicine, MD USA; S.L. Silverman, Medical Director, Osteoporosis Medical Center, Beverly Hills, CA; C.E. Barr, Director, Data Analytics, Roche Laboratories Inc., Nutley, NJ; S.A. Weinerman, Director of the Metabolic Bone Disease Program, North Shore University Hospital, Lake Success, NY

The proportion of women achieving BMD gains e3%, e5% (responders) or decreases e-3% (nonresponders) at various sites following 1 year of treatment with once-monthly ibandronate 150 mg in the MOBILE study was determined. Responder cut-points have previously been established(1) on the premise that changes of this magnitude can be determined accurately by dual-energy X-ray absorptiometry (DXA) and can predict the antifracture efficacy of bisphosphonates.

MOBILE (Monthly Oral iBandronate In LadiEs) was a multinational, randomized, Phase III, non-inferiority trial of 1609 women aged 55-80 years with lumbar spine BMD T-score between -2.5 and -5.0. The approved 2.5 mg daily ibandronate dose was compared with 3 monthly regimens.

After 1 year, 67.1% and 41.8% of women randomized to 150 mg ibandronate once-monthly had lumbar spine BMD increases e3% and e5%, respectively. At the total hip, 45.3% and 19.0% of women had BMD increases e3% and e5%, respectively. At the femoral neck, 33.3% and 16.5% had BMD increases e3% and e5%, respectively, and at the trochanter corresponding responder rates were 64.0% and 38.5%. Only 2.7% (lumbar spine), 5.7% (femoral neck), 2.4% (total hip), and 2.7% (trochanter) of women had declines in BMD of e-3%.

At the e3% cut-point, the majority of postmenopausal women were responders to 150 mg ibandronate treatment at the lumbar spine and trochanter, and large numbers responded at the other sites. Few patients were classified as non-responders.

### Title: 205 — SAFETY OF ONCE-MONTHLY IBANDRONATE IN POSTMENOPAUSAL OSTEOPOROSIS: MOBILE 2-YEAR DATA

**Authors:** E.M. Lewiecki, MD, Osteoporosis Director, New Mexico Clinical Research, NM, USA; M.R. McClung, Director, Oregon Osteoporosis Center, Portland, OR; R. Civitelli, Sydney M. and Stella H. Schoenberg Professor of Medicine, Washington University School of Medicine, St Louis, MO

Second-year safety data for ibandronate 2.5 mg daily and 150 mg once-monthly from the MOBILE study in women with postmenopausal osteoporosis were analyzed.

MOBILE was a randomized, Phase III, non-inferiority study comparing daily and monthly ibandronate doses. Women (n=1609) aged 55–80 years with lumbar spine BMD T-score between 2.5 and 5.0 were included. Adverse events (AEs) were continuously monitored, and laboratory safety parameters were determined every 6 months.

In the safety population, 395 patients received ibandronate 2.5 mg daily and 396 received 150 mg once-monthly; approximately 81% completed 2 years of treatment. The occurrence of AEs was evenly balanced across treatment arms. There were similar and low numbers of gastrointestinal events in the daily versus monthly groups after 2 years (dyspepsia, 7.8% vs 7.8%; nausea, 5.3% vs 6.6%; diarrhea, 5.3% vs 5.6%) and influenza-like illness (0.5% vs 3.5%). The majority of AEs were mild or moderate; serious AEs considered related to treatment occurred in 2 patients (0.5%) in the daily group and 1 patient (0.3%) in the monthly group. The incidence of clinical fractures was comparable across treatment arms (6.6% with 2.5 mg vs 7.3% with 150 mg). Osteonecrosis of the jaw was not reported.

Safety outcomes reported for oral ibandronate in the treatment of postmenopausal osteoporosis found in the 1-year analyses of MOBILE were sustained at 2 years. The 150 mg monthly dose appears to be as safe and well tolerated as the approved daily dose, which has been demonstrated to have a similar safety profile to placebo.

### Title: 206 — SUSTAINED REDUCTION OF BONE TURNOVER MARKERS THROUGHOUT THE TIME-INTERVAL BETWEEN WEEKLY DOSES OF ALENDRONATE OR RISEDRONATE

**Authors:** Henry Bone, MD Michigan Bone & Mineral Clinic Michigan United States; Paul Miller, Colorado Center for Bone Research; Elizabeth Rosenberg, Merck & Co., Inc.; Erluo Chen, Merck & Co., Inc.; Anne de Papp, Merck & Co., Inc.

For bisphosphonates, the duration of the time-interval between doses has become longer. This post-hoc analysis of the randomized, double-blind FACT trial determined whether reductions in bone turnover markers (BTMs) that occur in response to treatment with once-weekly (OW) alendronate or risedronate are consistently maintained between doses. OW alendronate 70 mg or OW risedronate 35 mg was taken on any chosen day of the week by postmenopausal women with low bone density. BTMs (urine N-telopeptide of type I collagen [NTX] and serum C-telopeptide of type I collagen [CTX], bone-specific alkaline phosphatase [BSAP], and N-terminal propeptide of type I procollagen [PINP]) were measured at baseline and 3 months. Mean percent reduction from baseline in BTMs was compared among 878 per protocol patients, who were grouped according to how many days prior to their 3-month BTM measurement they had taken their last bisphosphonate dose. Increasing time (measured in days) since last alendronate dose did not significantly influence the reduction from baseline in NTX (P=0.122). Increasing time since last risedronate dose resulted in a trend toward decreased NTX response (P=0.041). However, no significant changes in response over time since the last dose of either drug were detected for CTX, BSAP, or PINP. Thus, both OW bisphosphonates (OW alendronate 70 mg and OW risedronate 35 mg) provided a sustained reduction of bone resorption and bone formation markers throughout the dosing interval, similar to the effect achieved with daily dosing.
Title: 207 — SUPPRESSION OF BONE-TURNOVER MARKERS AT 3 MONTHS IS MAINTAINED AT 2 YEARS WITH ONCE-MONTHLY IBANDRONATE: MOBILE 2-YEAR DATA

Authors: E.M. Lewiecki, MD Osteoporosis Director, New Mexico Clinical Research NM USA; P.D. Miller, Clinical Professor, Department of Medicine, Colorado Center for Bone Research, Lakewood, CO; R. Civitelli, Sydney M. and Stella H. Schoenberg Professor of Medicine, Washington University School of Medicine, St Louis, MO; S.L. Silverman, Medical Director, Osteoporosis Medical Center, Beverly Hills, CA

The effect of oral ibandronate on bone-turnover markers, surrogates for bisphosphonate efficacy, was analyzed in women with postmenopausal osteoporosis who participated in the MOBILE study.

MOBILE was a multinational, randomized, Phase III, non-inferiority study comparing oral ibandronate 2.5 mg daily with 150 mg once-monthly. The study enrolled 1609 women aged 55-80 years (mean, 66 years) with lumbar spine BMD T-scores between -2.5 and -5.0. Serum C-telopeptide crosslinks of type I collagen (sCTX) and bone-specific alkaline phosphatase (BSAP) were measured at 3, 6, 12, and 24 months. The proportion of patients with sCTX reductions ≥50% from baseline was also prospectively identified.

For both doses of ibandronate, median sCTX levels were significantly suppressed at 3 months, falling by 53.6% with 2.5 mg daily treatment and 66.4% with 150 mg once-monthly. Between 6 and 12 months, sCTX levels approached steady state, and remained similar through to the 2 year assessment (median reductions at 2 years vs baseline, 61.5% for 2.5 mg and 67.7% for 150 mg). BSAP followed a similar pattern, with median reductions of 23.2% and 36.6% at 2 years for daily and monthly, respectively. The percentage of patients with a ≥50% decrease in sCTX relative to baseline was significantly greater in the 150 mg once-monthly treatment group (78.7%), than in the 2.5 mg daily group (65.6%). Both doses of ibandronate brought sCTX values within the normal premenopausal range at all timepoints measured.

Oral ibandronate caused a rapid suppression of the bone turnover marker sCTX, which was maintained over 2 years.

Title: 208 — GREATER GAINS IN BMD WITH ONCE-WEEKLY ALENDRONATE COMPARED TO ONCE-WEEKLY RISEDRONATE: 2-YEAR RESULTS FROM THE FOSAMAX® ACTONEL® COMPARISON TRIAL (FACT)

Authors: Sydney Bonnick, MD, FACP Clinical Research Center of North Texas Texas United States; Kenneth Saag, University of Alabama; Sherri-Ann Burnett, Massachusetts General Hospital; Marc Hochberg, University of Maryland School of Medicine; Anthony Sebba, Arthritis Associates, asebbata@tampabay.rr.com; Risa Kagan, Foundation for Osteoporosis Research and Education, risa@fore.org; Elizabeth Rosenberg, Merck & Co., Inc., elizabeth_roseberg@merck.com; Erluo Chen, Merck & Co., Inc., erluo_chen@merck.com

Changes in bone mineral density (BMD), percent responders at prespecified BMD cut-points, and changes in bone turnover markers (BTMs) with once weekly (OW) alendronate (ALN) or OW risedronate (RIS) were compared in a 12-month extension of the original 1-year, randomized, double-blind FACT study. 833 postmenopausal women with low BMD entered the extension, continuing their same blinded treatments (OW ALN 70mg or OW RIS 35mg). ALN produced greater mean increases from baseline in BMD at 24 months than RIS: hip trochanter (ALN: 4.6%; RIS: 2.5%), lumbar spine (ALN: 5.2%; RIS: 3.4%), femoral neck (ALN: 2.8%; RIS: 1.0%), and total hip (ALN: 3.0%; RIS: 1.3%) (P<0.001 for all). More ALN than RIS patients had measured BMD increases of ≥0% (P<0.001) at hip trochanter (ALN: 96%; RIS: 75%), lumbar spine (ALN: 92%; RIS: 75%), femoral neck (ALN: 76%; RIS: 59%), and total hip (ALN: 86%; RIS: 67%). More ALN than RIS patients had measured BMD increases of ≥3% (P<0.001), and fewer ALN than RIS patients had declines of ≥3% (P<0.001), at each site. Significantly greater mean percent reductions in BTMs (NTX, CTX, BSAP, and PINP) were seen with OW ALN compared to OW RIS. No differences between treatment groups were seen in upper gastrointestinal adverse events (UGI-AEs) or discontinuations due to UGI-AEs. In conclusion, patients receiving OW ALN 70mg had greater gains in BMD, were more likely to maintain or gain BMD, and had greater reductions in BTMs than patients receiving OW RIS 35mg after 24 months, without differences in UGI tolerability.
Title: 209 — OSTEOPOROSIS MEDICATION PROFILE PREFERENCE: RESULTS FROM THE PREFER-US STUDY

Authors: Thomas W. Weiss, DrPH, Manager, Merck & Co., Inc., West Point, PA; Shuvayu S. Sen, PhD, Merck & Co., Inc.; Colleen A. McHorney, Merck & Co., Inc.

Objective:
Assess patient preferences for osteoporosis medication profiles.

Methods:
3,368 women age 50+ diagnosed or at risk for osteoporosis based on 2003/2004 internet-based National Health and Wellness Survey responses received the PREFER survey via internet. Preferences assessed by comparing Drug A vs. Drug B with the same out-of-pocket costs, side effects, potential for drug interaction, and spine fracture efficacy. The two drugs differed by the following attributes: time on market (recently vs. 10 years); dosing frequency (monthly vs. weekly); drug effectiveness (not proven vs. proven to reduce non-spine or hip fracture after three years); and dosing procedure (60 vs. 30 minute wait). Patients (1) force-rank ordered, from 1-4, the four attributes according to their preference and (2) separately rated the importance of each attribute from 1 (extremely unimportant) to 7 (extremely important).

Results:
We collected 999 responses after three days and stopped compiling responses after achieving sample size targets. Mean age was 65. Drug B was chosen by 96% of respondents. Drug effectiveness was ranked as the most important determinant of their preference (80% ranked as #1 reason for their choice). Effectiveness had the highest mean importance rating (6.1, S.D. 1.8), followed by time on market (4.7, S.D. 1.7), dosing procedure (4.6, S.D. 1.4), and dosing frequency (4.5, S.D. 1.4).

Conclusion:
The drug profile with proven data on fracture risk reduction was chosen by almost all respondents. Drug effectiveness was the most important determinant of preference for 80% of the respondents, while dosing frequency was a weaker determinant of preference.

Title: 210 — THE PREFER-US STUDY: AN EVALUATION OF PATIENT PREFERENCES FOR OSTEOPOROSIS MEDICATIONS AND THEIR ATTRIBUTES

Authors: Stuart L Silverman, MD, Cedars-Sinai/UCL, CA; Thomas W. Weiss, DrPH, Merck & Co., Inc.; Deborah T. Gold, PhD, Duke University Medical Center; Colleen A. McHorney, PhD, Merck & Co., Inc.

Objective:
To assess patient preferences for eight medication attributes that patients may consider when evaluating prescription osteoporosis medications.

Methods:
The eligible sample was 3,368 women age 50+ who responded to the 2003 or 2004 internet-based National Health and Wellness Survey as being diagnosed with osteoporosis, considered themselves at-risk, or had a family history of osteoporosis. In this internet survey, respondents were asked to: (1) force-rank order, from one to eight, the eight attributes according to their preference and (2) separately rate the importance of each attribute on a Likert scale from 1 (extremely unimportant) to 7 (extremely important).

Results:
We collected 999 responses on three days and stopped compiling responses after achieving sample size targets. Mean age was 65. Drug effectiveness (e.g., ability to reduce the risk of fractures) was force ranked as the most important attribute (37% ranked as #1). The other seven attributes were force ranked #1 as follows: side effects (36%), out-of-pocket costs (10%), drug interactions (10%), time on market (3%), dosing frequency (2%), formulation (1%), and dosing procedure (1%). Drug effectiveness had the highest mean importance rating (6.1, S.D. 1.6); dosing frequency had the lowest (4.7, S.D. 1.8).

Conclusion:
Drug effectiveness was both the highest ranked and highest rated osteoporosis medication attribute that patients seek in an osteoporosis therapy. The side effects attribute was also of high importance, while dosing frequency was of lower importance. These findings may be useful for clinicians initiating discussions with women about osteoporosis medications.
**Title:** 211 — ALENDRONATE IMPROVES THE STRUCTURAL GEOMETRY OF THE PROXIMAL FEMUR IN POSTMENOPAUSAL OSTEOPOROTIC WOMEN

**Authors:** T. J. Beck, ScD, Department of Radiology, Johns Hopkins Medical Institute, MD USA; J. R. Cauley, Dr.PH, University of Pittsburgh Graduate School of Public Health; A. de Papp, M.D., Director of Clinical Development, Merck & Company, Inc.; L. E. Wehren, M.D., Medical Communications Department, Merck Research Laboratories; D. T. Baran, M.D.; National Scientific Director, Merck & Company, Inc.

We sought to determine if alendronate treatment produced positive changes in the structural geometry of the proximal femur in postmenopausal women with either prevalent vertebral fractures (VF) or femoral neck BMD T-Scores less than -2.5. A subset of 319 women from the University of Pittsburgh clinic enrolled in the Fracture Intervention Trial (FIT) were evaluated after 3 (VF) or 4 (BMD T-score <2.5; no VF) years of treatment with placebo (PBO, N=155) or alendronate (ALN 5 mg/2 yrs; 10 mg/3-4 yrs) N=164). Hips were scanned using Hologic QDR2000 DXA scanners and images were compared to baseline using the Hip Structure Analysis (HSA) software. Conventional BMD and cross-sectional geometries were evaluated at the narrowest point on the femur neck (NN), across the intertrochanteric (IT) region along the bisector of the neck and shaft axes and across the shaft at 1.5 x minimum neck width distal to the axes intersection. Follow-up parameters were adjusted for prevalent VF and the baseline value by ANCOVA. Compared to PBO, at all three cross-sectional regions, ALN-treated women showed significantly (p <0.05) increased BMD (4-6%), cortical thickness (4-7%), bone cross-sectional areas (4-7%), and section moduli (4-8%) and reduced buckling ratios (-4% -7%). Changes in the latter 3 parameters indicate improvement in resistance to axial and bending loads, as well as increased cortical stability. Treatment increased periosteal apposition at the IT region, but not at the NN or shaft regions. We conclude that alendronate has favorable effects on hip structural geometry.

**Title:** 212 — BASELINE CHARACTERISTICS OF NON-RESPONDERS TO BISPHOSPHONATE THERAPY IN THE FACT STUDY

**Authors:** Kenneth Saag, MD, MSC, University of Alabama AL United States; Anthony Sebba, MD, Arthritis Associates; Sydney Bonnick, MD, Clinical Research Center of North Texas; Elizabeth Rosenberg, PhD, Merck & Co., Inc.; Erluo Chen, MD, Merck & Co., Inc., Anne E. de Papp, MD, Merck & Co., Inc.

Bone mineral density (BMD) non-response to therapy is of potential concern to clinicians. The objective of this analysis was to compare apparent BMD non-responders between treatment groups, in a 12-month extension of the randomized, double-blind FACT study, and to identify the baseline characteristics of BMD non-responders compared to responders. 833 postmenopausal women with low BMD entered the extension and continued their same double-blind treatment (OW ALN 70 mg or OW RIS 35 mg). For purposes of this analysis, “non-responders” were defined as those individuals with measured BMD losses of >0% in at least 2 of the 4 BMD sites (lumbar spine, femoral neck, hip trochanter, or total hip) after 24 months. Non-responders were more frequent among RIS patients (37.6%) than ALN patients (14.5%), P<0.001. Non-responders were younger at the onset of menopause (non-responders 45.3 years, responders 47 years, P=0.013) and more likely to have a family history of osteoporosis (non-responders 50%, responders 38.4%, P=0.002). Non-responders had numerically higher baseline BMD at all sites and numerically lower baseline levels of all bone turnover markers examined (NTX, CTX, BSAP, and PINP). Non-responders and responders did not differ in baseline fracture history or baseline use of tobacco, alcohol, or caffeine. In conclusion, more patients receiving OW RIS than OW ALN for 24 months were apparent BMD non-responders to therapy. Although small differences were seen in baseline characteristics between non-responders and responders, identifying non-responders prior to initiation of bisphosphonate therapy is likely to be difficult in the clinic.
**Title:** 213 — PATIENTS PREFERENCE FOR OSTEOPOROSIS MEDICATIONS: PREFER-INTERNATIONAL

**Authors:** Jesus A Walliser, M.D., Medical Director of the Clinical de Metabolismo Mexico City Mexico; Susan C. Bolge, Senior Research Director, Consumer Health Sciences, Princeton, NJ; Shuvayu S. Sen, Director, Outcomes Research, Merck & Co., Inc., Whitehouse Station

**Objective:**
To evaluate patients preferences for two different osteoporosis medication profiles and the reasons for their preferences.

**Methods:**
Physicians were randomly selected in France, Germany, Mexico, Spain and UK, and asked to consecutively refer 4 osteoporotic women aged 50 years or older seen in their practices. These patients were asked over telephone or face-to-face (Mexico) to indicate their preference between two hypothetical osteoporosis medication profiles, A and B, for treatment of osteoporosis which differ in efficacy (proven to reduce risk of spine and hip fracture vs. proven to reduce only spine fracture), time on market (10 year vs. recently introduced), dosing frequency (weekly vs. monthly) and dosing procedure (30 vs. 60 minute wait). Patients were also asked to rate and rank the importance of each of these 4 attributes as reason for their preferences.

**Results:**
A total of 3000 patients were interviewed of whom 1500 were on prescription treatment for osteoporosis while rest were not. A majority of these patients (78%) preferred drug A over drug B. Effectiveness in reducing risk of fracture was most frequently (72%) ranked as the most important reason for their preference followed by time on market (13%), dosing frequency (9%) and dosing procedure (6%).

**Conclusion:**
The drug profile A with proven hip fracture reduction was chosen by majority of the patients over drug B. Effectiveness in reducing risk of fracture was the most important reason for selection of a drug profile.

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**Title:** 214 — MODELLING OF SERUM CTX LEVELS WITH DAILY AND MONTHLY ORAL IBANDRONATE

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In the MOBILE study, we graphed serum C-telopeptide crosslinks of type I collagen (sCTX) concentrations obtained prior to dosing at 3, 6, 12, and 24 months for the two approved ibandronate doses, 2.5 mg daily and 150 mg monthly.[1] These values represent pre-dosing residual turnover inhibition. We utilized a model derived from data from 720 patients [2,3] to elucidate the between-dose sCTX profile.

Excellent correlation was found between modeled values and empirical data available from the MOBILE study. In the modeled sCTX profiles, both the daily and monthly regimens deliver rapid CTX reduction. The monthly dose consistently reduces sCTX more than the daily dose. Both regimens continuously maintain a level of reduction known to provide fracture protection, with sCTX concentrations within the premenopausal normal range.

At steady state, a minimal variation in sCTX peak-trough fluctuation is predicted with the monthly dose. This pharmacokinetic profile is associated with significant increases in BMD of a magnitude superior to that produced by daily 2.5 mg. Thus, the temporary recovery of sCTX between monthly doses does not negatively affect efficacy, but rather suggests that bone mass can be increased without irreversibly or excessively depressing bone remodelling. Interestingly, a cyclical CTX variation has been described in normal, menstruating women.[4]

The extended life expectancy with its resultant increase in frailty and disability has led to the demand for a variety of long term care services and the rapid growth in assisted living (AL) facilities. Little has been done to assess osteoporosis (OP) risk in AL. 47 individuals (30 community-dwelling controls [C], 17 AL) have provided information on fracture history, OP evaluation, qualitative heel ultrasound (QUS), 25-hydroxyvitamin D (25OHD), intact parathyroid hormone (PTH) and physical function measures including walking speed, 6 minute walk, balance measures, Get Up and Go, and strength. The mean age was 81±6 years. Seven (23%) of C and 9 (53%) AL reported fracture (p=.04). 7 (23%) C and 4 (24%) AL had been diagnosed with OP (p=1.00). Twenty-three (77%) C and 6 (35%) AL reported bone density assessment (p=.005). Twelve (40%) C and 3 (18%) AL reported taking medications for OP (p=.11). QUS stiffness index was 85.6±24.3 C and 64.5±21.0 AL (p=.004). 25OHD levels were 48.8±14.8 ng/ml C and 26.0±14.0 ng/ml AL (p<.001) and PTH levels were 54±24 pg/ml C and 65±35 pg/ml AL (p=.278). Physical performance was more impaired in AL (p<.05), except for hand grip strength (p=.450).

Residents of AL are less likely to be diagnosed with or receive treatment for OP despite higher fracture rates, lower QUS and 25OHD levels. AL residents are more impaired in physical performance. OP risk assessment needs to be improved in AL residents.

Lead exposure continues to be a serious environmental issue. Virtually all of the lead in humans resides in the mineral compartment of the skeleton and thus bone cells are exposed to sustained high levels. Laboratory and animal studies evaluating cell function and trabecular bone volume have clearly demonstrated the adverse effects of this toxic heavy metal. However, the few reports evaluating it on human BMD measurements indicate little or no effect.

We have generated data to demonstrate that the early generation DXA scanners display an artifactual overestimate of bone density that is not observable in ultrasound (US) bone densitometers. Using specimens of bovine bone we were able to show that adding lead (from 4 to 40 micrograms/gram of bone) increased the apparent density when measured on a Lunar DPX-L scanner but had no effect when measured on the Lunar Achilles ultrasound densitometer. Moreover, we were able to show a statistically significant inverse relationship (r = 0.58; p = 0.013) between areal DXA density and ultrasound stiffness in lead exposed human subjects. That is, the ratio of DXA BMD/US stiffness decreased as a function of increasing blood lead levels. The study was performed in 19 subjects with blood lead levels ranging from 1 to 45 micrograms/dl.

These results suggest that early generation DXA scanners substantially overestimated BMD. Since most human studies examining the effects of lead on BMD were performed with these scanners, lead exposure may have been overlooked as a risk factor for osteoporosis.
Title: 217 — COMPARISON OF TWO QUS BONE SCANNERS IN THE COMMUNITY RESEARCH SETTING

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One aim of the CLOE study (California Lesbian Osteoporosis Evaluation, n=411) was to compare BMD screening rates using two different peripheral QUS scanners in community-based field research. Recruitment occurred at community events/social organizations throughout Southern California. Calcaneal BMD was measured using the Lunar Achilles and the Quidel QUS-2.

Mean age was 47.2 years and mean body mass index (BMI) was 28.7 kg/m2 with 30.4% classified as obese (BMI>=30.0 kg/m2). Quidel QUS-2 classified 13.6% as osteopenic and 7.0% as osteoporotic (T-score>=2.0), whereas the Lunar Achilles rates were 18.1% and 2.1%, respectively. Although these rates were generally similar, overlapping (same) subjects classified as normal were 69.8%, 63.3% as osteopenic, and 3.9% as osteoporotic. The Kappa coefficient was 0.44, indicating only moderate agreement. The Pearson correlation for the T-scores was 0.53 (p < 0.001). Ambient sound levels at community venues varied considerably by site (mostly loud 82.2%) vs. quiet which may have affected machine performance. When stratified by a crude measure of ambient venue sound level, the Pearson correlation was higher in the quiet (r=0.63) vs. the mostly loud (r=0.53) sites.

These results suggest using QUS bone scanners for community-based field research may be dependent on the manufacturer and the sound level of the venue. Although screening rates using two different peripheral QUS scanners were similar regardless of manufacturer, actual subjects in each of these categories were considerably different. We recommend field collection of BMD levels by QUS technology be conducted in a quiet, clinic-like setting for the most accurate and reliable results.

Title: 218 — SCREENING FOR LOW DENSITY WITH HEEL ULTRASOUND IN THE DEVELOPMENTALLY DISABLED

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Commercial Relationship: V. Varma, None; C. Culig, Allegheny Valley School; H. Smolensky, None; K. D. Krohn, None; K. Hunter, Allegheny Valley School

Introduction:
A study was conducted to determine the prevalence of low bone mass in the institutionalized population of developmentally disabled individuals utilizing heel ultrasound densitometry.

Methods:
Men and women, twenty years of age and older, residing at an intermediate care facility with both institutionalized and group community settings were included in this study. The facility houses a mixture of individuals with varying degrees of both mental retardation and physical limitation. The participant’s non-dominant foot was evaluated using Sahara heel ultrasound densitometer. Age, race and weight bearing status were also noted. Bone mineral density (BMD) and T-score were recorded. We chose a T-score of 1.0 or lower as an indicator of low bone mass.

Results:
A total of 141 participants were screened. The women ranged in age from 20 to 85 (mean 50 years). The men ranged in age from 21 to 74 (mean 45 years). Of that group, satisfactory heel ultrasound results were obtained in 112 individuals. Eighty five percent (47 out of 55) of the women and seventy-nine percent (45 out of 57) of the men had evidence of low bone density by predetermined T-score value. Results of the patient’s T-score and BMD were forwarded to the facility’s physician. In those patients who were non weight bearing (n = 51), 96% had low bone mass compared with 72% in those who were weight bearing (n = 61).

Conclusions:
The results of this study suggest that low bone mass is common in this group. Heel ultrasound screening may be a valuable tool by which to initially identify low bone density in this population. When possible, low bone density values on the heel ultrasound screening should be verified by DXA at the discretion of the treating physician. Our study shows that individuals who are non-weight bearing are at very high risk for low bone mass.
This investigation used a subset of the Canadian Multicentre Osteoporosis Study (CaMOS) dataset to cross-sectionally assess the association between ultrasound (speed of sound) at the distal radius, phalanx or tibia and vertebral deformity (>3 SD lower than population mean in anterior, middle, or posterior vertebral height) in women aged 50 years or greater. A Sunlight OmniSense Multisite Ultrasound was used for all ultrasound assessments and all ultrasound data was collected at year 5 of CaMOS. A general linear model analysis was used to assess the association between ultrasound measures at all sites and vertebral deformity risk with correction for height, weight, age, and CaMOS centre. Following a radiograph of the spine at year 5 of CaMOS, 744 women (74.4%) were found to have no vertebral deformity, whereas 256 women had a vertebral deformity (25.6%). Women without a vertebral deformity had higher ultrasound measurements at the distal radius by 30.2 m/s (95% CI: 5.5, 55.1), at the tibia by 32.3 m/s (95% CI: 9.6, 55.0), and at the phalanx by 10.6 m/s (95% CI: -20.8, 42.0; NS). This analysis has shown that the Sunlight OmniSense Multisite Ultrasound has the ability to discriminate between women with or without vertebral deformity whether used at the distal radius or tibia site. Since analyses are ongoing, updated results regarding the use of Sunlight OmniSense Multisite Ultrasound for discriminating between those with a risk for both vertebral deformity and non-vertebral fracture will be reported at the meeting.