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Discordance of longitudinal changes in bone density between densitometers

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Abstract

This study examined the concordance in BMD measurement and longitudinal change in BMD between the GE Lunar Prodigy and GE Lunar DPX. Even though a high concordance between the densitometers was observed on a single measurement occasion, a significant discordance in longitudinal changes in BMD was observed.

Introduction: Measurement of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) technology plays an important role in the diagnosis and management of osteoporosis. The present study examined the concordance in BMD measurement and longitudinal change in BMD between GE Lunar Prodigy and DPX.

Methods: BMD at the lumbar spine and femoral neck was measured in 135 individuals (47 men and 88 women, mean age 73±9 years) using both GE Lunar DPX and Prodigy densitometers at baseline. In this group, 56 individuals (22 men and 34 women) had repeated BMD measurements using the DPX and Prodigy during a subsequent follow-up visit (average duration: 2.2 years).

Results: For a single BMD measurement, the coefficient of concordance between the Prodigy and DPX was greater than 0.98 at the lumbar spine and 0.96 at the femoral neck, with the slope of linear regression being approximately 1.0. During the period of follow-up, the lumbar spine BMD decreased by −0.5% (S.D. 1.8%) when measured by DPX, which was significantly different ($p=0.002$) from the change measured by Prodigy (mean change=0, S.D. 2.0%). However, there was no significant difference ($p=0.95$) in the rate of change in femoral neck BMD measured by DPX (mean=−1.6%, S.D.=2.9) and Prodigy (mean=−1%, S.D.=1.8%). The correlation in rates of BMD change between Prodigy and DPX was 0.63 at the lumbar spine and 0.52 at the femoral neck. Simulation analysis showed that the theoretical maximum correlation in rates of BMD change between Prodigy and DPX was 0.71.

Conclusions: Despite both densitometers being highly concordant in a single BMD measurement, discordance in the assessment of BMD changes between the Prodigy and DPX densitometers was observed. These findings have implications regarding the assessment of response to therapy in a multi-centre setting when different densitometers are used.

Keywords: DXA; Concordance; Bone loss; Measurement error

Introduction

Bone densitometry is an important tool to assess an individual's risk of fracture and to monitor treatment efficacy [1,2]. A standard method of skeletal assessment is the measurement of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA). In recent years, new and improved technology has been introduced into clinical practice and research settings. One of the new and widely used densitometers is the Prodigy (GE Lunar Corp, Madison, WI), which utilizes a narrow fan-beam to shorten scan times and to lower radiation dose compared to older pencil beam technology [3–6]. In-vivo comparison of the newer Prodigy technology to older DPX densitometers from the same manufacturer found small or no difference in BMD measurements between the instruments [3–6].

Various investigators have highlighted the importance of ensuring the continuity of longitudinal monitoring of changes in BMD [5,7–11]. A transition in DXA technology must be based on the concordance of measurements and more importantly, the concordance in longitudinal changes measured by the two densitometers. The concordance between BMD measurements by the DPX and Prodigy on a single occasion has been shown to be high [3,4]. However, there have been no studies on the

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concordance in the longitudinal changes in BMD between the two densitometers. The present study was designed to assess the concordance in BMD measurement and longitudinal change between the GE Lunar DPX and Prodigy densitometers.

Study design and methods

This study had two components: the first was an in-vivo comparison between the GE Lunar DPX and Prodigy systems on a single occasion; and the second component involved a comparison of longitudinal changes in BMD between the two densitometers. The St Vincent's Campus Research Ethics committee approved the study design and protocol, and written consent was obtained from all participants.

Setting and subjects

Participants in this study were drawn from the ongoing Dubbo Osteoporosis Epidemiological Study (DOES) [12]. In this study the DPX has been used since 1989, while the new Prodigy was progressively introduced in 2002. The present study involved 135 individuals (47 men and 88 women) who had measurements on both instruments at one time point; among whom, 56 (22 men and 34 women) had their BMD measured on two occasions (average interval 2.2 years) on both instruments. All subjects were aged 60+ years as at 1989 when the study was initiated. The subjects were generally healthy in the sense that they did not have any disease that is deemed to affect bone metabolism and none had sustained a low-trauma fracture.

Measurement of BMD

Bone mineral content (BMC) and BMD were measured at the lumbar spine and femoral neck by the two instruments at the same visit. Bone area was derived as BMC/BMD. A qualified technologist using a standard protocol performed the measurements.

The within-subjects coefficient of variation (CV) of measurements by the DPX was 1.5% at the femoral neck and 2.0% at the lumbar spine [7]. For the Prodigy, a study on 15 individuals found that the CV was 1.75% at the femoral neck and 2.3% at the lumbar spine. During the study period, both densitometers have undergone daily quality control, including phantom scans and monitoring of changes in precision over time (using a running scattergram). Whenever significant drift was observed, the machine would receive servicing. Metal spinal scanning phantoms (which are submerged in water) supplied by the manufacturer were used for quality control in the DPX and Prodigy. Each machine received a planned routine annual service on two occasions during the study period (follow-up approx. 2 years). No data was excluded from analysis as there were no excess drift in bone densitometry.

Data analysis

The agreement between DPX and Prodigy measurements was assessed by the Bland–Altman method, in which individual differences between the densitometers were plotted against their means, and the 95% limits of agreement were computed [13,14].

The concordance between two densitometers was assessed by the coefficient of concordance [15]. If x_1 and x_2 denote the measurement by DPX and Prodigy, respectively, then the coefficient of concordance is defined as: $C = \frac{2\times \mathrm{Cov}(x_1,x_2)}{s_1^2+s_2^2+(\overline{x}_1-\overline{x}_2)^2}$, where $\mathrm{Cov}(x_1,x_2)$ is the covariance between two measurements, s_1^2 and s_2^2 are the variances of measurements by the DPX and Prodigy, respectively; $\overline{x}_1$ and $\overline{x}_2$ are the means of the two measurements. When the two means are similar, this correlation coefficient is equivalent to the coefficient of reliability [16].

The rate of change in BMD was estimated as the annual percentage change for individual participants and each instrument. Let D_0 and D_1 be baseline and follow-up measurements by the DPX for an individual participant. Similarly defined for the Prodigy, P_0 and P_1. The percent change was calculated as $P_{\mathrm{DPX}}=(D_1-D_0)/D_0\times 100$, and $P_{\mathrm{PRODIGY}}=(P_1-P_0)/P_0\times 100$. The difference between P_{DPX} and P_{PRODIGY} were assessed by the paired t-test. The concordance between P_{DPX} and P_{PRODIGY} was assessed by the Pearson's product–moment correlation coefficient (r). Ninety-five confidence interval of r was estimated based on the Fisher's z-transformation.

As a secondary analysis, the rate of change by DPX (P_{DPX}) and Prodigy (P_{PRODIGY}) was each categorized into three groups: decreased, unchanged, and increased. The criteria of classification were based on the least significance change [10], which is defined as $\mathrm{LSC} = 1.96\times\sqrt{2}\times CV$, where CV was the observed coefficient of variation for each densitometer as mentioned above. The agreement in the change categories between two densitometers was then assessed by the kappa statistic [17].

Simulation analysis

This analysis was intended to address the following question: given the observed correlation in a single BMD measurement between GE Lunar DPX and Prodigy, and the densitometer-specific correlation between baseline and follow-up measurements, what is the expected correlation between BMD changes measured by DPX and Prodigy (i.e., between P_{DPX} and P_{PRODIGY}). Since the longitudinal part of this study was based on a modest sample size (56 pairs of measurements), such that the estimate of correlation between P_{DPX} and P_{PRODIGY} could be unstable; a simulation study was carried out. In this simulation, baseline and follow-up measurements by DPX, baseline and follow-up measurement by Prodigy, and percent changes assessed by the two densitometers were simulated using the vector of observed means and variance–covariance matrix among the measurements as parameters. Pseudo differences for DPX (P_{DPX}) and Prodigy (P_{PRODIGY}) were calculated from individual values. The correlation coefficient between pseudo P_{DPX} and P_{PRODIGY} was assessed by the Pearson's correlation coefficient. The sample size of each simulation was 56, and the simulation was done 1000 times. The distribution of the correlation coefficients was then derived from the 1000 pseudo-studies. The simulation was conducted using the R statistical language [18].

Results

There were more women ($n=88$) than men ($n=47$) in the study. The average age for the entire sample was 73 years, with no significant difference between women and men apart from men being on average heavier and taller than women (Table 1).

Concordance of a single measurement

For a single measurement, there was a high concordance in BMD and BMC measurements between DPX and Prodigy (Figs. 1 and 2), with the coefficient of concordance being ≥ 0.95 for BMD and BMC. Consequently, all slopes of the calibration lines for BMD and BMC were virtually unity (i.e., not significantly different from 1) for both skeletal sites (Table 2). None of the intercepts of the calibration lines were significantly different from zero. The concordance in bone area, particularly at the femoral neck was lower than that in BMD (0.84 vs. 0.93). Despite the concordance, measurements of BMD, BMC and area by the DPX tended to be higher than measurements by the

Table 1
Baseline characteristics of study subjects

Characteristics	Women ($n=88$)	Men ($n=47$)
Age (years)	73.1 (9.4)	74.1 (7.7)
Height (cm)	158 (5.5)	171 (7.0)
Weight (kg)	68.4 (12.4)	80.6 (14.0)
Body mass index (kg/m^2)	27.4 (5.1)	27.4 (3.9)

Data are shown in mean (standard deviation).

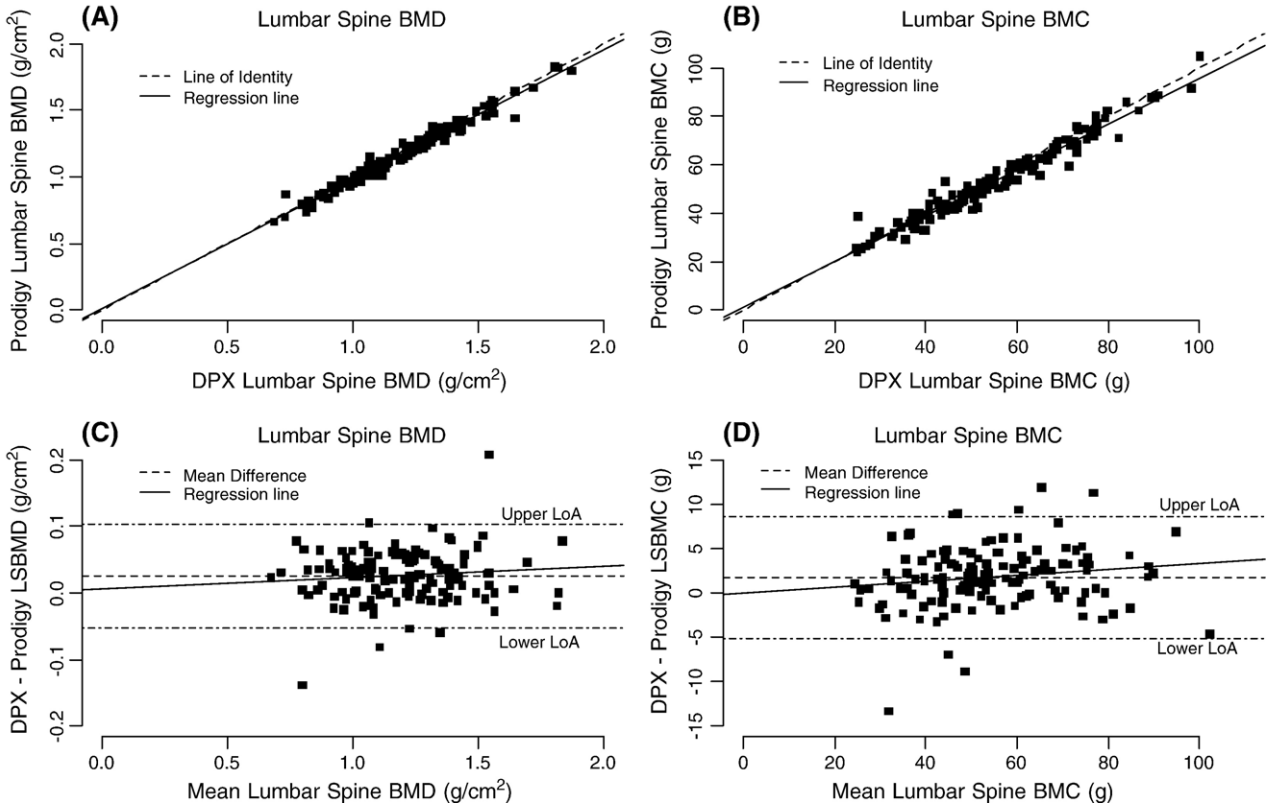

Fig. 1. Correlation between DPX and Prodigy for (A) lumbar spine BMD and (B) lumbar spine BMC. Difference in measurements between DPX and Prodigy versus mean of two instruments for (C) lumbar spine BMD and (D) lumbar spine BMC.

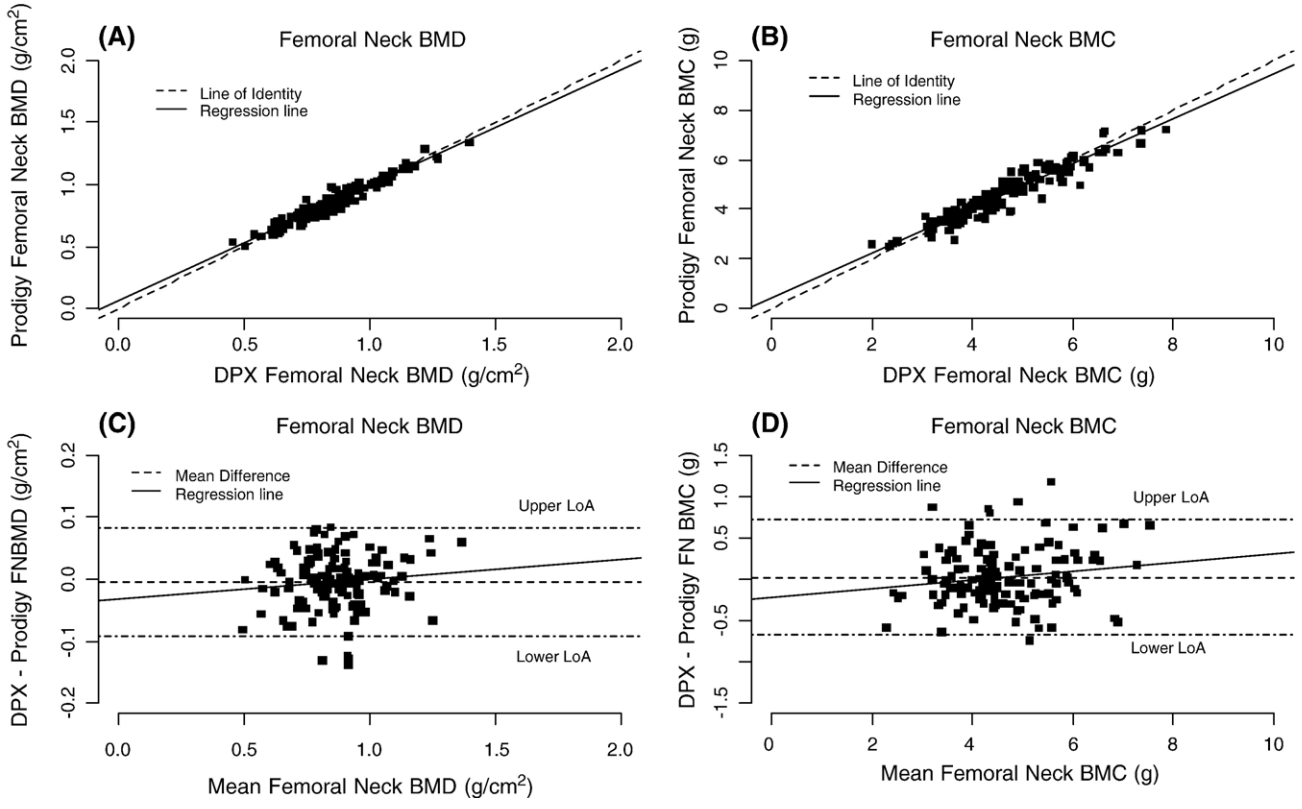

Fig. 2. Correlation between DPX and Prodigy for (A) femoral neck BMD and (B) femoral neck BMC. Difference in measurements between DPX and Prodigy versus mean of two instruments for (C) femoral neck BMD and (D) lumbar spine BMC.

Table 2
Comparison of DPX and Prodigy on a single occasion ($n=135$)

Measurement	Mean (S.D.) of measurement by		Difference between DPX and Prodigy (LoA)	Coefficient of concordance (95% CI)	Slope (and standard error)
	DPX	Prodigy			
Lumbar spine					
BMC (g)	55.29 (16.39)	53.62 (15.86)	(1.67 (−4.95, 8.48)	0.97 (0.96–0.98)	1.03 (0.005)
BMD (g/cm^2)	1.21 (0.23)	1.18 (0.23)	(0.03 (−0.05, 0.10)	0.98 (0.97–0.99)	1.02 (0.003)
Area (cm^2)	45.19 (6.89)	44.81 (6.49)	(0.38 (−4.33, 5.25)	0.93 (0.90–0.95)	1.01 (0.005)
Femoral neck					
BMC (g)	4.62 (1.07)	4.59 (1.03)	0.03 (−0.66, 0.71)	0.95 (0.93–0.96)	1.01 (0.007)
BMD (g/cm^2)	0.86 (0.15)	0.87 (0.15)	−0.01 (−0.09, 0.08)	0.96 (0.94–0.97)	0.99 (0.004)
Area (cm^2)	5.31 (0.56)	5.25 (0.51)	0.06 (−0.54, 0.65)	0.84 (0.78–0.88)	1.01 (0.005)

BMC=Bone mineral content (g); BMD=Bone mineral density (g/cm^2); Area (cm^2). LoA=Limits of agreement.

Prodigy. For example lumbar spine BMD measured by the DPX was, on average, 0.03 g/cm^2 higher than that by the Prodigy; however the difference in femoral neck BMD was around 0.01 g/cm^2.

Longitudinal analysis

The rates of BMD change measured by the DPX were generally greater than those measured by the Prodigy in both women and men. For example, in women the annual rate of BMD loss at the femoral neck measured by the DPX was 2.0% (S.D. 3.3%), versus the Prodigy (1.2% (S.D. 1.9%; $p=0.07$). Similarly, the rate of lumbar spine BMD loss in women was 0.7%/year (S.D. 1.6%) by the DPX, versus the Prodigy, 0.2% (S.D. 1.7%)($p=0.03$). In general these differences were more pronounced for BMC measurement, and less for bone area. When data for women and men were combined, there was a significant difference in the rates of changes in lumbar spine BMD and BMC between DPX and Prodigy. At the femoral neck, although a similar trend was also observed, but the differences were not statistically significant (Table 3).

The correlation coefficient between the change in BMD measured by the DPX and Prodigy ranged between 0.52 (for FN BMD) and 0.63 (LS BMD) (Figs. 3 and 4). The correlation in

Table 3
Annual rate of change in bone densitometry estimated by DPX and Prodigy ($n=22$ men and $n=34$ women)

Measurement	Percent change (mean, S.D.)		Mean difference between Prodigy and DPX (95% CI of means)	*P*-value[a]	Coefficient of correlation (and 95% CI)[b]
	DPX	Prodigy			
LSBMC					
Women	−1.5 (2.6)	−0.3 (3.1)	1.3 (0.25, 2.35)	0.016	0.36 (0.02–0.61)
Men	−0.4 (2.9)	0.3 (2.6)	0.7 (−0.54, 1.94)	0.267	0.50 (0.10–0.76)
Combined	−1.1 (2.7)	0.0 (2.9)	1.1 (0.32, 1.88)	0.005	0.44 (0.20–0.63)
LSBMD					
Women	−0.7 (1.6)	−0.2 (1.7)	0.5 (−0.02, 1.02)	0.061	0.62 (0.36–0.79)
Men	−0.2 (2.6)	0.6 (1.9)	0.8 (0.0, 1.60)	0.055	0.62 (0.27–0.82)
Combined	−0.5 (1.8)	0.0 (2.0)	0.5 (0.07, 0.92)	0.002	0.63 (0.44–0.77)
LS Area					
Women	−0.8 (1.8)	0.0 (1.7)	0.8 (−0.03, 1.64)	0.081	0.09 (−0.25–0.42)
Men	−0.2 (2.7)	−0.3 (2.2)	0.1 (−1.18, 1.38)	0.884	0.29 (−0.15–0.63)
Combined	−0.6 (2.2)	−0.1 (1.9)	−0.5 (−1.22, 0.22)	0.212	0.15 (−0.12–0.40)
FNBMC					
Women	−0.4 (5.1)	0.3 (2.6)	0.7 (−0.94, 2.34)	0.402	0.44 (0.12–0.68)
Men	0.2 (2.6)	−0.3 (2.0)	0.5 (−0.83, 1.83)	0.461	0.20 (−0.24–0.57)
Combined	−0.2 (4.4)	0.1 (2.4)	−0.3 (−1.47, 0.87)	0.071	0.38 (0.13–0.58)
FNBMD					
Women	−2.0 (3.3)	−1.2 (1.9)	0.8 (−0.04, 1.64)	0.071	0.70 (0.47–0.84)
Men	−1.0 (2.6)	−0.8 (1.4)	0.2 (−1.00, 1.40)	0.688	−0.16 (−0.54–0.28)
Combined	−1.6 (2.9)	−1.0 (1.8)	−0.6 (−1.27, 0.07)	0.955	0.52 (0.30–0.69)
FN Area					
Women	1.5 (2.1)	1.5 (2.1)	0.0 (−1.30, 1.30)	0.955	0.27 (−0.07–0.56)
Men	1.3 (2.0)	0.5 (2.1)	0.8 (−0.09, 1.69)	0.099	0.52 (0.13–0.77)
Combined	1.5 (3.1)	1.2 (2.2)	0.3 (−0.56, 1.16)	0.476	0.52 (0.30–0.69)

[a]Paired *t*-test. [b]Pearson's correlation coefficient. LS=lumbar spine; FN=femoral neck.

changes in BMC were lower: $r=0.38$ for lumbar spine BMC and $r=0.44$ for femoral neck BMC (Figs. 3 and 4).

When BMD changes were categorized into 3 groups using the LSC criteria, there was a poor agreement between the two densitometers. For example at the lumbar spine, out of 7 individuals classified by the DPX as "decreased", 4 (57%) were classified by the Prodigy as "unchanged". At the femoral neck, out of 21 individuals classified by the DPX as "decreased", 12 were classified by the Prodigy as "unchanged" or "increased". The Kappa statistic of agreement was 0.42 for LSBMD and 0.32 for FNBMD (Table 4).

Simulation

With regard to the correlation in BMD changes measured by DPX and Prodigy, an important question is: given the concordance in a single measurement by two densitometers, what is the expected correlation in the rate of changes measured by the two densitometers. In 1000 simulations as described in the Study design and methods section, the average correlation coefficient between percent change in femoral neck BMD measured by DPX and Prodigy was 0.37 with the 95% confidence interval ranging between 0.13 and 0.56; minimum and maximum correlations observed were −0.05 and 0.71, respectively (Fig. 5).

In a further simulation analysis, it was "pretended" that the baseline and follow-up Prodigy measurements represented duplicated baseline and follow-up DPX measurements, respectively. A simulation analysis was conducted to heuristically determine the expected correlation in the "duplicated" rates of BMD change. It was found that the correlation was virtually zero. In other words, if the duplicated measurements represented measurement error, then there should not be any correlation between the rates of change.

Discussion

The importance of BMD measurements to monitor treatment effect and assess fracture risk is widely accepted [1]. Therefore, the concordance in measurement of BMD on a single occasion and monitoring longitudinal changes in BMD among densitometers is important, both in research and clinical settings. Results of this study have shown a very high concordance between the DPX and Prodigy on a single measurement, but

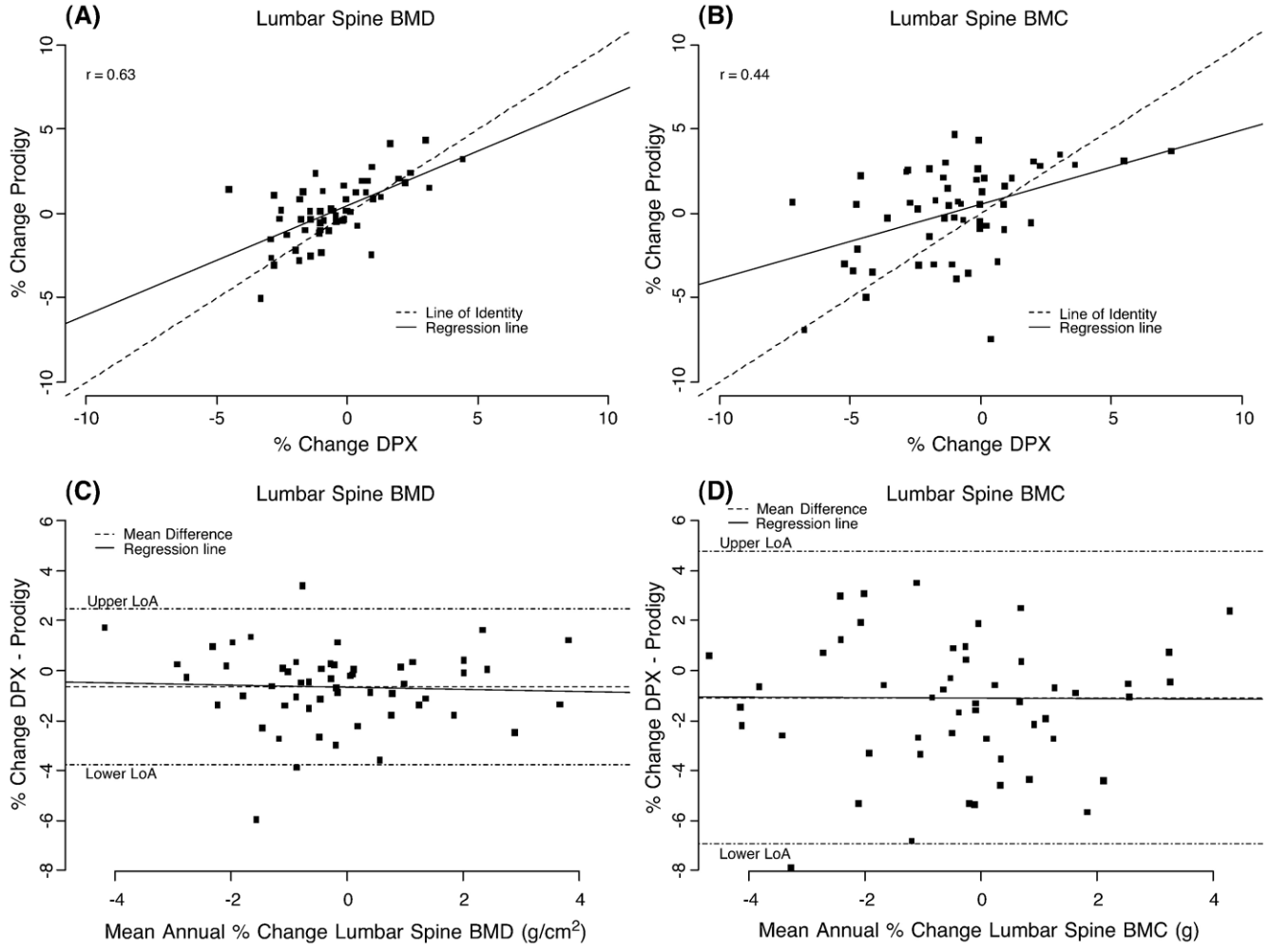

Fig. 3. Correlation between DPX and Prodigy in the annual rate of change in (A) lumbar spine BMD and (B) lumbar spine BMC. Difference between DPX and Prodigy versus mean of two instruments for change in (C) lumbar spine BMD and (D) lumbar spine BMC.

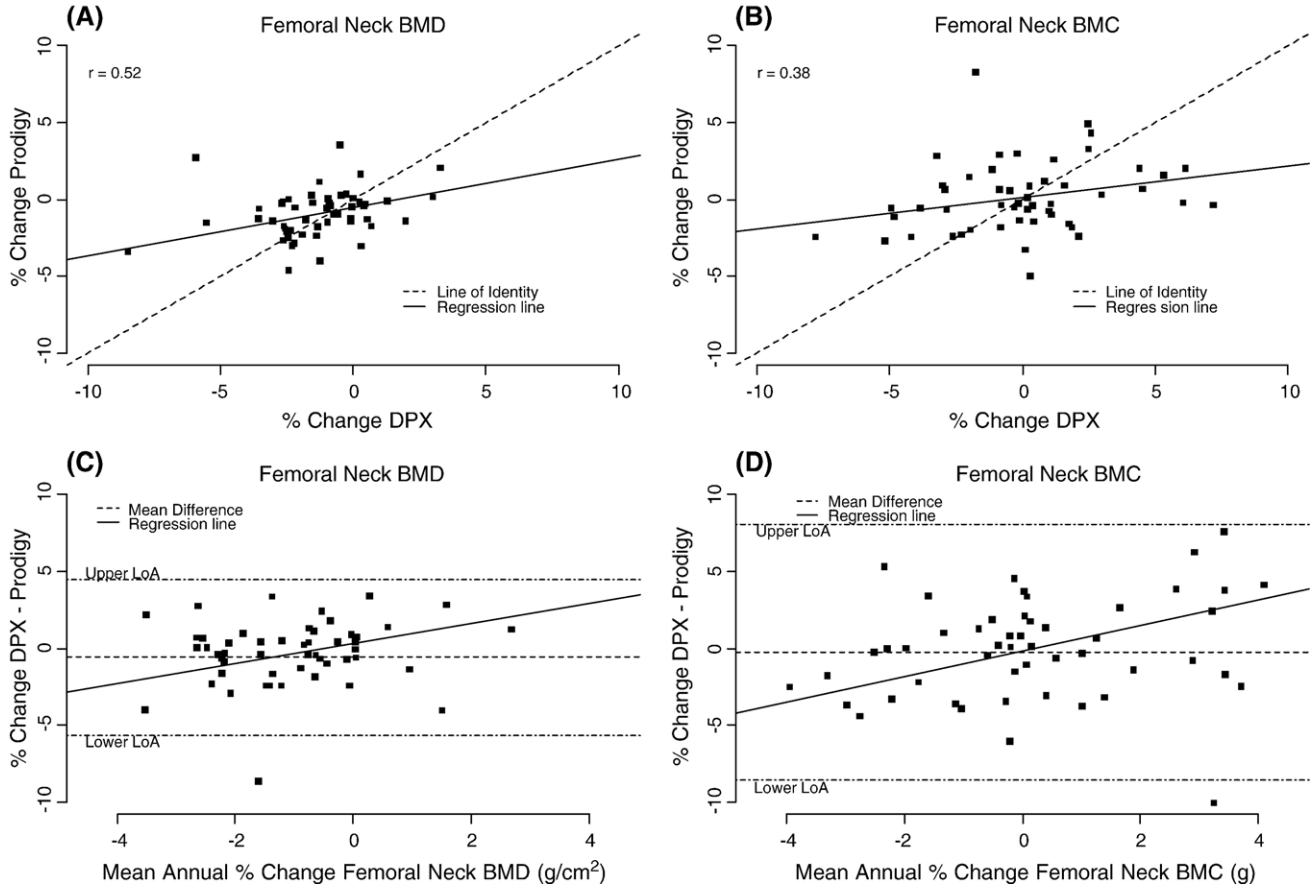

Fig. 4. Correlation between DPX and Prodigy in the annual rate of change in (A) femoral neck BMD and (B) femoral neck BMC. Difference between DPX and Prodigy versus mean of two instruments for change in (C) femoral neck BMD and (D) femoral neck BMC.

more importantly, however, a significant discordance in the assessment of BMD changes for a group of individuals as well as for an individual. Even with a correlation of 0.97 between DPX and Prodigy for a single measurement, the highest correlation in the rate of change in BMD between two instruments is expected to be 0.71.

The high agreement in BMD measurements by the DPX and Prodigy on a single occasion in this study is consistent with previous studies [3,4]. This is expected, because the manufacturer has calibrated Prodigy measurements, by design, against the DPX. Discordance in BMD changes between different densitometers has been recognized previously [19,20]. In a comparative study on the GE Lunar DPX and Hologic QDR-1000/W (Hologic Inc., Waltham, MA) in a group of 17 postmenopausal women at baseline and after 2 years, the estimated longitudinal change at the lumbar spine was higher in the DPX compared to the QRD-1000 [19]. Another study, found the mean rate of loss in BMD over an average interval of 4.8 years not to be statistically different between the GE Lunar DPX and Hologic QDR-1000 at the lumbar spine and femoral neck; however a statistically significance difference was found at the proximal femur (DPX − 0.6% (S.D. 6.7) versus Hologic −3.3% (S.D. 8.9)) [20].

The magnitude of correlation in the rate of BMD change at the femoral neck between the DPX and Prodigy found in this study (0.52) is similar to that reported previously (0.55) between the DPX and Hologic QDR-1000 [20]. The correlation between the rates of change in BMD at the lumbar spine measured by the DPX and Prodigy reported in this study (0.63) is within the range that has been observed in previous studies (0.47 and 0.82) that compared DPX measurements from different manufacturers [19,20]. The similarity and discrepancies between our results and previous research may indicate a true random error component to longitudinal change in BMD measurements that is independent of DPX technology. Results of our simulation

Table 4
Classification of the annual rate of change in lumbar spine and femoral neck BMD measured by the DPX and Prodigy ($n=56$)

Measurement	Change category (DPX)	Change category (Prodigy)		
		Decreased	Unchanged	Increased
Lumbar spine BMD	Decreased	3 (42.8%)	4 (57.2)	0
	Unchanged	3 (6.5%)	41 (89.1%)	2 (4.3%)
	Increased	0	1 (33.3%)	2 (66.7%)
Femoral neck BMD	Decreased	9 (42.9%)	11 (52.3%)	1 (4.8%)
	Unchanged	4 (12.5%)	27 (84.4%)	1 (3.1%)
	Increased	0	2 (66.7%)	1 (33.3%)

The numbers outside brackets refer to the number of individuals; the numbers inside brackets refer to the percent of each row's total. The "change category" was classified based on the least significant change (LSC) rule. The Kappa statistic for lumbar spine BMD: 0.42 (95% CI 0.21, 0.63), femoral neck BMD: 0.32 (95% CI 0.11, 0.54). Percent of agreement for lumbar spine BMD was 82%, femoral neck BMD 66%.

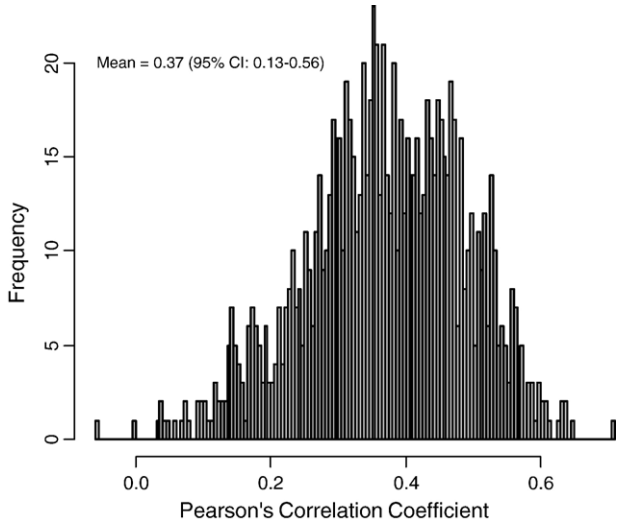

Fig. 5. Distribution of the coefficients of correlation between changes in femoral neck BMD measured by DPX and changes measured by Prodigy. The distribution was obtained from a simulation of 1000 pseudo-studies, each study with 56 individuals. The parameters of simulation were based on observed means and variance–covariance matrix of individual DPX and Prodigy measurements.

experiment which generated pseudo BMD measurements at the femoral neck, suggest at best the true correlation between changes estimated on the same population by the DPX and Prodigy would most likely be below 0.65 (this being the 99th percentile of the result from the simulated data).

Is the discordance in longitudinal changes due to random error measurement or real difference between two instruments? In the simulation analysis, it was shown that if the Prodigy measurements were treated as duplicated DPX measurements (so that the correlation is now an indicator of measurement error), then the expected correlation in BMD changes is zero. However, the observed correlation in BMD changes was 0.52 (at the femoral neck), which suggests that the discordance was due partly to systematic difference between densitometers rather than due to random measurement error. Nevertheless, it is not possible to estimate the extent of discordance that is attributable DPX or Prodigy. Since the two densitometers have comparable reproducibility, it is likely that the random error component present in the longitudinal data is a synergistic result of two sources of measurement error.

Differences in edge detection algorithms used by different densitometers have been suggested to be a potential source of the error in DPX measurements of BMD [3,6,20]. Results of this study support the benefit that manufacturers offer when updating DPX technology to a newer model from the same company. To this end, it appears that the concordance in BMD measurements on a single occasion between the DPX and Prodigy has been ensured. However, analysis of longitudinal data provides a different situation in which poor agreement between the two densitometers was observed.

The discordance between densitometers found by this study indicates that combining or comparing rates of change in BMD between research centres or clinical settings using different DPX technologies should be approached with caution. This also has implications for both monitoring response to treatment aimed at reducing bone loss and the observation of long term bone loss within a population or study group; the quantification of an individual's fracture risk related to bone loss; classification of individuals into diagnostic groups in relation to changes in BMD, such as that deemed eligible for inclusion in a study or for interventions to treat osteoporosis and/or prevent fracture.

The discordance in longitudinal changes between the DPX and Prodigy was particularly apparent when an individual was classified into one of 3 groups (decreased, unchanged or increased). It has been suggested that discordance between DPX technologies can be avoided by comparison of individuals within the same research or clinical setting using the same DPX technology. The present study's results indicate that even though agreement between DPX machines may be assured on a single occasion, when longitudinal change is assessed by different densitometers, residual discordance is a potential problem.

A strength of this study is the longitudinal nature of the comparison of the DPX and Prodigy to monitor the rate of change in BMD. Previous studies have undertaken similar analysis that compared densitometers from different manufacturers [19,20], but this study has undertaken this task on two densitometers from the same manufacturer. A weakness of this study may be the small sample size, especially in relation to the number of male participants, to have the power to find a difference between the rate of change in BMD estimated by the DPX and Prodigy. The sample of women ($n=34$) included in the study was able to detect a difference in the rate of change in lumbar spine BMC between the two densitometers as low as 1%; whereas, in the smaller sample of men in this study ($n=22$) no differences between the two densitometers rates of change reached statistical significance.

In summary, this study found an in-vivo concordance between the DPX and Prodigy in the measurement of BMD on a single occasion. However a significant discordance between the DPX and Prodigy in monitoring the rate of longitudinal change in BMD at both the lumbar spine and femoral neck was observed. The discordance presents difficulty in the assessment of BMD change in an individual, particularly when different densitometers are used.

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