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Cross-calibration of the GE-Lunar iDXA and Prodigy for the assessment of lumbar spine and total hip bone parameters using three statistical methods

Hind K, Cooper W, Oldroyd B, Davies A, Rhodes L.

Abstract

This study assessed agreement between the GE Lunar iDXA and Prodigy densitometers for bone measurements and used 3 statistical methods to derive cross-calibration equations: linear regression, the Deming method, and multivariate analysis. Compatibility of machines for the measurements of bone mineral density, bone mineral content, and bone area also was explored. Eighty-five adults, age: 45.5 (SD 12.8) years; body mass index: 25.6 (SD 3.7) kg.m⁻² were measured once at the lumbar spine: L1–L4 and total hip on each densitometer, within 24 hours. Both linear regression and Deming analysis indicated that cross-calibration equations were required at the lumbar spine and total hip but not at the femoral neck. Multivariate analysis identified femur thickness and femur percent fat as predictive variables at the femoral neck and total hip. Bland Altman analysis (Prodigy–iDXA) indicated significant positive bone mineral density bias at the lumbar spine and femoral neck. Significant bone mineral content biases were observed at all 3 sites and bone area biases at both hip sites. These initial results suggest there are small significant differences in the bone parameters and that all 3 bone parameters should be evaluated when comparing densitometers, especially when there are differences in pixel size between the densitometers.

Key Words: DXA; bone; cross calibration; analysis, agreement

Introduction

Bone mineral density (BMD) measurements at the lumbar spine and total hip using dual energy x-ray absorptiometry (DXA) are considered to be the gold standard for osteoporosis diagnosis as defined by the World Health Organisation (1). DXA is also used in both clinical and research settings to monitor long term bone status and/or response to intervention. Of further relevance, BMD can also be incorporated into FRAX algorithms to identify patients' future risk of a major osteoporotic fracture (www.sheffield.ac.uk/FRAX) (2). The consistent and accurate measurement of DXA-derived BMD over time is therefore fundamental. Precision within DXA is high (3,4) but there can be significant differences between densitometers between manufacturers (5,6), and also between models from the same manufacturer (7,8). These issues arise when conducting multicentre studies or when upgrading DXA densitometers and it is advised by the International Society of Clinical Densitometry (ISCD), that in such circumstances, in-vivo cross calibration is performed (9).

The GE Lunar range of DXA densitometers are utilised globally both clinically and for research; the GE Lunar iDXA is the most recent model, advancing on the older Prodigy model. The iDXA uses a higher output x-ray tube than the Prodigy, an identical narrow angle (4.5°) fan beam with 64 high definition CZT detectors and a staggered element array. This improves the image resolution by reducing the dead space between the detectors, giving a near radiographic image and improved spatial resolution (0.30 x 0.25mm compared to 0.60 x 1.05mm) but with a higher radiation dose (Table 1). Several studies have cross calibrated the GE Lunar iDXA with the Prodigy. These studies have generally indicated good agreement for measurements of BMD between the two machines (10-14). However, whilst bone area, along with BMD, is a primary DXA scan parameter, studies to date have only cross calibrated for measures of BMD.

The purpose of this study was to determine if cross calibration was required between two fan beam densitometers from the same manufacturer: the GE Lunar iDXA and the GE Lunar Prodigy, and if so derive calibration equations using different linear regression methods for BMD. Furthermore the level of agreement between bone parameters BMC and bone area at the lumbar spine, femoral neck and total hip were investigated.

Methods

Participants

Eighty five healthy adults were recruited via an intra-university email invitation and participants were excluded from the study if they had received a DXA scan within the previous 12 months, were pregnant or breast feeding. Participant descriptive results are provided in Table 2, and in accordance with ISCD recommendations (9), these groups are representative of those normally scanned at the iDXA facility. Ethical approval for the study was provided by the University Ethics Committee and informed signed consent was attained before scans from all volunteers. All activities performed in this study were in accordance with The Declaration of Helsinki.

Measurements

For all measurements, participants wore light clothing with all metal and plastic artefacts removed. Height was measured on a stadiometer and recorded to the nearest millimeter, and body mass was measured on calibrated electronic scales to the nearest gram (both SECA, Birmingham, UK). Each participant received one lumbar spine (L1-L4) and one total hip scan on both the iDXA and the Prodigy within 24 hours. For all lumbar spine scans, positioning was assisted with the GE-Lunar spine positioner which elevates the legs and opens the inter-vertebral spaces to allow clear visualisation of the vertebra. For all total hip scans, patient positioning was assisted

using the GE-dual femur positioning device which allows both legs to be abducted and inwardly rotated 25°. Scans were analyzed using Encore software version 12.5 (Prodigy) and 13.5 (iDXA). The analysis of each scan was performed by the same experienced densitometrist, manually for the lumbar spine for consistent placing of the inter-vertebrae spaces and with auto analysis used for the total hip. Point typing and bone edge profiles were systematically monitored. BMD (mean value of a pixel-by-pixel measurement of the BMD within a defined bone area), BMC (a derived quantity obtained by multiplying BMD by bone area) and bone area data were acquired from each scan. BMD T-scores, BMD Z-scores, percentage tissue fat and thickness parameters were also recorded. Quality assurance and quality control observations were recorded according to manufacturer's guidelines throughout the duration of the study; no equipments drifts or faults were reported during the period of study.

In addition to the in-vivo measurements in-vitro cross calibration investigations were made using three spine phantoms. Measurements were made on both densitometers using the eleven individual vertebrae (BMD range 0.530 to 1.645g.cm⁻²) of three spine phantoms: the GE-Lunar Aluminum (Al) SN9831 (16), the European spine phantom (ESP) (17) and the Leeds paediatric spine phantom (18). The GE-Lunar Al phantom has a wedge construction which simulates four lumbar vertebrae. The phantom was immersed in water to a depth of 15cm which simulates soft tissue (Thickness = 14.5cm: percentage tissue fat = 7.4%). Nominal BMD values for the four simulated vertebrae are 0.920:1.053:1.246:1.386 g.cm⁻². The ESP was specifically developed for cross calibration of DXA scanners. (The ESP comprises of three semi-anthropomorphic calcium hydroxyapatite vertebrae which represent low BMD (0.630g.cm⁻²), medium BMD (1.080g.cm⁻²) and high BMD (1.645g.cm⁻²) embedded in an epoxy resin which simulates soft tissue (Thickness = 17.8cm percentage tissue fat =9.0%). The anthropometric Leeds paediatric lumbar spine phantom is constructed from epoxy resin and bone analogue grade

hydroxyapatite. It consists of six vertebrae embedded in an 11.5cm thick acrylic block. The inner four vertebrae represent regions L1-L4. Nominal BMD values for the four vertebrae are 0.530:0.790:0.950:1.045g.cm⁻² (Thickness = 18.6cm and percentage tissue fat =14.0%). The two vertebrae at the extremities are identical to the adjacent vertebrae this enables the scan to stop and start within a bone region. Ten scans on each densitometer were performed without repositioning.

Statistical analysis

Descriptive statistics are presented as the mean and the standard deviation of the mean (SD). Two tailed paired t-tests were applied to test for significant differences between parameters derived by the two densitometers. To derive the cross calibration equations, we used three statistical methods: linear regression, Deming regression and multivariate analysis. To establish the association and agreement between the two densitometers Bland Altman analysis was performed. All statistical analyses were performed using Analyse-It (Leeds UK) and IBM SPSS Version 19.0 .The level of significance for all statistical tests was p<0.05.

Linear regression makes assumptions about the X and Y variables in the analysis. The X variable (independent) is assumed to be precise and the error in the regression is assumed to be in the Y variable (dependant). We compared two DXA densitometers, and both are inherently subject to measurement error. The 95% confidence intervals (CI) of the intercept were calculated and if not significantly different from zero, the regression was forced through zero. The 95% CI for the slopes were calculated and if the slope was significantly different from one then cross calibration is required. The standard errors of analysis (SEE) for the equations were also compared. In this study, the Prodigy densitometer was the X variable and the iDXA the Y variable, since cross calibration equations are required to predict the iDXA value from the Prodigy value. The Deming

regression method differs from standard linear regression, in that it accounts for errors in the measurements for both X and Y variables. In this method, previously determined BMD precisions for both densitometers at the three measurement sites were used (4,15). Multivariate stepwise regression analysis was performed to determine if the variables age, height, weight, BMI, gender, spine and thickness or percentage fat at the measurement site influenced cross calibration. The differences between the densitometers were analysed using the Bland-Altman analysis (19), the mean difference in the measurements (Prodigy – iDXA) were plotted against the mean value of the measurements. Significance was reached if the 95%CI of the mean difference did not include zero. Limits of Agreement (LOA) were derived from the mean difference ± 1.96 SD. The correlations of the differences and mean values were derived to determine if any observed differences were dependent on the magnitude of the measurement.

Results

In-vitro cross-calibration

There were no significant differences between the Prodigy and iDXA for BMD, BMC and bone area measurements of the eleven simulated vertebrae of the three phantoms. Linear regression analysis of BMD indicated excellent agreement between the two densitometers with intercept and slope not significantly different from zero and one respectively (Figure 1), this would suggest that cross calibration is not required.

In-vivo cross-calibration

The mean (SD) values for BMD, BMC, bone area, T-scores, Z-scores, percentage fat tissue and body thickness at the measured sites are presented in Table 2. Across the cohort no significant differences were observed between right and left hip measurements so only the right hip data

are reported here. The iDXA lumbar spine BMD and BMC were lower than the Prodigy values ($p<0.05$; $p<0.01$ respectively). At the femoral neck, although iDXA BMD was lower ($p<0.01$) than the Prodigy BMD values, BMC and bone area were higher ($p<0.05$ and $p<0.0001$ respectively). At the total hip no difference was observed in BMD, however, the iDXA values for BMC and bone area were higher than the Prodigy values (both $p<0.0001$). At the lumbar spine there was no differences in percentage tissue fat but a difference was found in the estimation of tissue thickness ($p<0.005$). At the total hip differences were observed for percentage tissue fat ($p<0.05$) and tissue thickness ($p<0.01$).

The results of the linear regression and Deming analyses of BMD measurements are given in Table 3. Linear regression and Deming analysis of lumbar spine BMD indicated an intercept and slope different from zero and unity (Figure 2) suggesting difference between the densitometers using both linear regression methods. The 95%CI indicated no differences between the intercept or slope between the two analysis methods. For femoral neck BMD, linear regression analysis (Figure 3) and Deming analysis had a zero intercept and unity slope suggesting agreement using both linear regression methods. For total hip BMD, linear regression analysis (Figure 4) had a significant intercept and slope less than unity. For the Deming analysis, the intercept was not significant and the slope was not different from unity at the 95%CI level.

Multivariate regression analysis indicated that age, gender, height, weight, BMI, tissue thickness and percentage tissue fat at the measurement site did not effect cross calibration at the lumbar spine. Tissue thickness had an effect at the femoral neck ($p<0.01$) and percentage tissue fat at the total hip ($p<0.0001$) (Table 4). The effect of tissue thickness on femoral neck BMD differences (Prodigy – iDXA) had a negative slope ($r = -0.25$, $p<0.02$) (Figure 5). A stronger relationship was observed at the total hip between BMD differences and percentage tissue fat ($r = -0.45$, $p<0.0001$) (Figure 6).

Results from the Bland Altman analysis are shown in Table 5. At the lumbar spine, BMD and BMC had a significant positive bias of 0.005g/cm² and 0.48g respectively, with positive correlations of $r = 0.35$ and $r = 0.22$ respectively. Femoral neck BMD showed a significant positive bias of 0.007g/cm² while both BMC and bone area had small significant negative biases (-0.03g and -0.06cm²). Bone area also had a negative correlation ($r = -0.21$, $p < 0.05$). Total hip BMD had no bias but a positive correlation ($r = 0.24$, $p < 0.05$). Both Total hip BMC and bone area had a negative bias (-0.74g and -0.73cm²; $p < 0.001$) (Figures 6 and 7). Only the spine area and right total hip showed no significant difference suggesting good agreement between densitometers for parameters at these sites.

Discussion

The aim of this study was to determine the necessity of using BMD cross calibration equations on the GE iDXA and Prodigy densitometers and whether the linear regression method used influences the equations generated. The bone parameters BMD, BMC and area were also reviewed to determine if differences in these parameters occurred using Bland Altman analysis.

In-vitro cross calibration was performed to compare the linearity of the two densitometers. From this study, excellent linearity was observed with no significant intercept and unity slope implying that no cross-calibration was necessary, however the *in-vivo* cross calibration study suggested that cross calibration equations were required for the spine and the total hip. The difference between the *in vitro* and *in vivo* findings may be that calibration phantoms do not reflect the variability in body size of human subjects (20). In this study, the participant group varied widely in terms of body thickness: 15.5 to 27.6cm (lumbar spine), 14.7 to 21.6cm (hip) and percentage tissue fat: 7.5 to 49.4% (lumbar spine) and 9.4 to 36% (hip), and it is known that this can affect BMD measurements (21). This has been demonstrated by two recent studies, which

reported errors in BMD due to regional changes of body composition at the lumbar spine (22) and the lumbar spine and femoral neck (23).

To date, four studies have cross calibrated BMD measurements between the iDXA and Prodigy densitometers (11-14); only two of the four studies recruited more than 60 subjects. The two larger studies, Choi et al (13) and Kruger et al (14) utilised linear regression and the Deming method respectively in the generation of their cross calibration equations. Choi et al generated cross calibration equations for BMD using linear regression derived from 60 Korean adults for the lumbar spine (range 0.544 to 1.488g/cm²) femoral neck (range 0.573 to 1.235g/cm²) and total hip (range 0.570 to 1.294g/cm²); these were then applied to a validation group. Bland Altman analysis indicated nonsignificant biases for the three sites of 0.013, 0.017 and -0.004 g/cm². In a second major study of 345 adults, similarly, Krueger et al (14) derived cross calibration equations for lumbar spine (range 0.658 to 2.066 g/cm²), femoral neck (range 0.588 to 1.631 g/cm²) and total hip (range 0.592 to 1.603g/cm²) BMD using the Deming regression. Bland Altman-derived biases of -0.003, -0.007 and 0.001g.cm⁻² for the three sites were reported. In 85 adults, our findings only indicated a requirement for the use of cross calibration equations at the spine (range 0.837 to 1.658 g/cm²) and total hip (range 0.74 to 1.473 g/cm²) however calibration equations were not needed at the femoral neck (range 0.762 to 1.531 g/cm²). Choi and Kruger reported a greater BMD range in the femoral neck which included a lower BMD limit than our study which may have contributed to the necessity for calibration equations at this site. From the multivariate analysis on the femoral neck and total hip, with the exception of Prodigy BMD, the only parameters that were found to have a significant effect on the cross calibration were thickness at the femoral neck and percentage tissue fat at the total hip.

With Bland Altman analyses of BMD outcomes, there were small but significant positive biases at the lumbar spine (0.4%) and femoral neck (0.7%), comparable to those reported by

previous studies.(13,14). Comparison between the Bland Altman LOA and iDXA LSC for BMD values indicated that at the spine LOA = $\pm 0.040\text{g/cm}^2$ compared to iDXA LSC = $\pm 0.014\text{g/cm}^2$ and at the total hip LOA = $\pm 0.041\text{g/cm}^2$ compared to iDXA LSC = $\pm 0.020\text{g/cm}^2$ therefore cross calibration equations should; be applied to the spine and total hip to reduce the LOA below LSC. The Bland Altman results also suggest that cross calibration equation maybe necessary at the femoral neck due to differences between the LOA = $\pm 0.045\text{g/cm}^2$ and the iDXA LSC = $\pm 0.038\text{g/cm}^2$ at this site; this results contradicts the linear regression which indicated that cross calibration was not necessary.

Bland Altman results for bone parameters area and BMC also reported here. Although the spine area bias was not significant both area values at the femoral neck and total hip had a significant negative bias. Although the largest of the three sites, bone area of the lumbar spine had the lowest bias indicating good agreement between densitometers this was not the case for the hip sites. This indicates that the agreement of bone area measurements between the densitometers was closer at the spine than at the femoral neck and total hip, which has a more complex and variable area and a more accurate measurement may be made with the iDXA due to the smaller pixel size. BMC at the lumbar spine had a significant positive bias and correlation indicating a magnitude effect which was not observed with BMC at the hip sites. At the hip sites BMC had significant negative bias but with no magnitude effect. The Bland Altman confirms the comparison data suggesting that the iDXA is measuring higher values of BMC than the prodigy at the hip sites but not at the spine.

Limitations of this study include using precision data that had been previously acquired for these densitometers and using subjects who provided a smaller range of BMD values than comparable studies. Whilst it would have been ideal to conduct a simultaneous precision investigation and recruit a broader range of subjects the study group for the current cross

calibration study and our previous precision studies are comparable and reflect our usual research participants in the DXA Unit.

In conclusion, this study determined close comparability between the GE Lunar Prodigy and the iDXA densitometers however cross calibration equations are required for the spine and total hip. The predictive cross calibration equations generated in this study are not comparable therefore suggesting that choice of linear regression affects the generated predicate value. This is of interest when updating densitometers when longitudinal monitoring of patients is ongoing and therefore cross calibrations equations are required. A comparison study should be initiated to determine which of the cross calibration equations predicts the measured iDXA value.

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Table 1: GE Lunar Prodigy – iDXA scan parameters

	Prodigy	iDXA
Fan beam angle	4.5°	4.5°
Spine/femur scan mode	Standard	Standard
X-ray tube		
Voltage (kV)	76.0	100
Current (mA)	3.00	2.50
Reference counts : High	131902	170911
: Low	159964	263860
Pixel size (mm)	0.60 x 1.05	0.3 x 0.25
Pixel area (mm ²)	0.63	0.075
Time (min)	0.50	0.52
Dose (uGy)	37.0	146.0

Table 2: Comparison of GE Lunar iDXA and Prodigy Results

		BMD (g/cm²)	BMD (Range)	BMC (g)	Area (cm²)	T-score	Z-score	Tissue % fat	Th
Spine	Prodigy	1.221(0.162)	0.837 to 1.658	71.02(13.01)	58.14(7.0)	0.2(1.4)	0.6(1.3)	24.1(10.2)	20.
	iDXA	1.216(0.154)†		70.53(12.63)††	58.01(7.1)	0.2(1.3)	0.5(1.3)	24.2(10.2)	20.
Neck	Prodigy	1.027(0.158)	0.762 to 1.531	5.18(0.99)	5.04(0.49)	0.1(1.2)	0.7(1.6)	23.1(6.6)	17.
	iDXA	1.020(0.155)††		5.21(1.00)*	5.10(0.52) ***	0.0(1.2)	0.5(1.1)	23.4(6.9)*	17.
Hip	Prodigy	1.057(0.157)	0.740 to 1.473	34.92(6.74)	32.99(3.51)	0.2(1.2)	0.5(1.1)		
	iDXA	1.055(0.152)		35.66(6.66)***	33.72(3.50))***	0.2(1.2)	0.5(1.1)		

*p<0.05, **p<0.005 ***p<0.0001 significantly higher than Prodigy

†p<0.05, ††p<0.01 significantly lower than Prodigy

Table 3: Linear and Deeming regression analysis for BMD

Site	Regression Method	Intercept	95%CI	Slope	95%CI	r ²	SEE
Spine (L1-L4)	Linear	0.065	0.031 to 0.100	0.942	0.913 to 0.970	0.98	0.021
	Deeming	0.050	0.010 to 0.090	0.960	0.920 to 0.990		0.016
Femoral Neck	Linear	0.024	-0.008 to 0.056	0.970	0.939 to 1.000	0.98	0.022
		0*		0.993	0.988 to 0.998	0.99	0.022
	Deeming	0.010	-0.030 to 0.050	0.980	0.940 to 1.020		0.019
Total Hip	Linear	0.039	0.010 to 0.069	0.961	0.933 to 0.989	0.98	0.020
	Deeming	0.030	0.000 to 0.060	0.970	0.940 to 1.000		0.015

* Intercept forced through zero

Table 4: BMD cross-calibration multivariate analysis

iDXA BMD Region	Intercept (95% CI)	Variable	Coeff(95%CI)	p	SEE
Right Femoral Neck	-0.059 (-0.124 to 0.007)	Prodigy BMD	0.962 (0.932 to 0.992)	<0.0001	0.0215
		Femur thickness	0.0051 (0.0015 to 0.009)	0.005	
Right Total Hip	-0.003 (-0.032 to 0.026)	Prodigy BMD	0.980 (0.958 to 1.002)	<0.0001	0.0152
		% femur fat	0.001 (0.0005 to 0.0015)	<0.0001	

None of the parameters had any effect on the lumbar spine (L1-L4) cross calibration

Table 5: Bland Altman agreements for BMD, BMC and Area at the three measurement sites

Site		Mean Bias	95%CI	Limits of Agreement	Correlation (r)
Spine (L1-L4)	BMD	0.005*	0.000 to 0.010	-0.040 to 0.051	0.35**
	BMC	0.48**	0.12 to 0.85	-2.82 to 3.79	0.22*
	Area	0.13	-0.08 to 0.34	-1.80 to 2.06	-0.11
Femoral Neck	BMD	0.007**	0.002 to 0.011	-0.038 to 0.051	0.14
	BMC	-0.03*	-0.06 to 0.00	-0.28 to 0.22	-0.09
	Area	-0.06***	-0.08 to -0.03	-0.29 to 0.18	-0.21*
Total Hip	BMD	0.0005	-0.003 to 0.004	-0.033 to 0.034	0.24*
	BMC	-0.74***	-0.88 to -0.61	-1.951 to 0.464	0.13
	Area	-0.73***	-0.874 to -0.62	-1.75 to 0.29	0.01

*p<0.05, **p<0.01, ***p<0.001 significantly different from zero

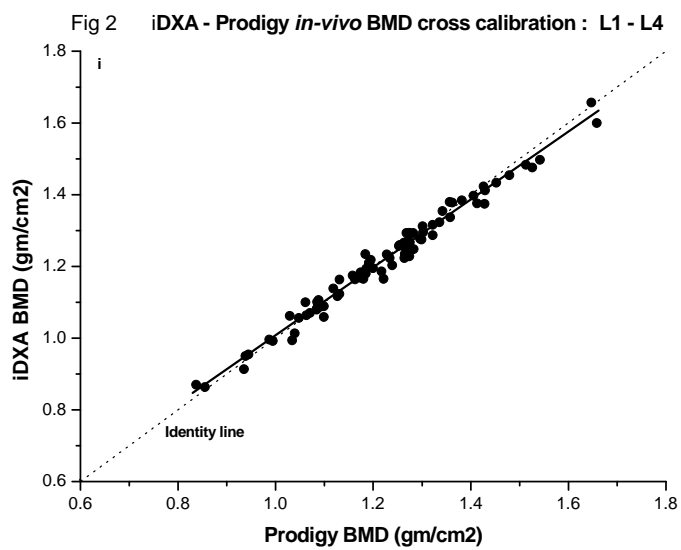
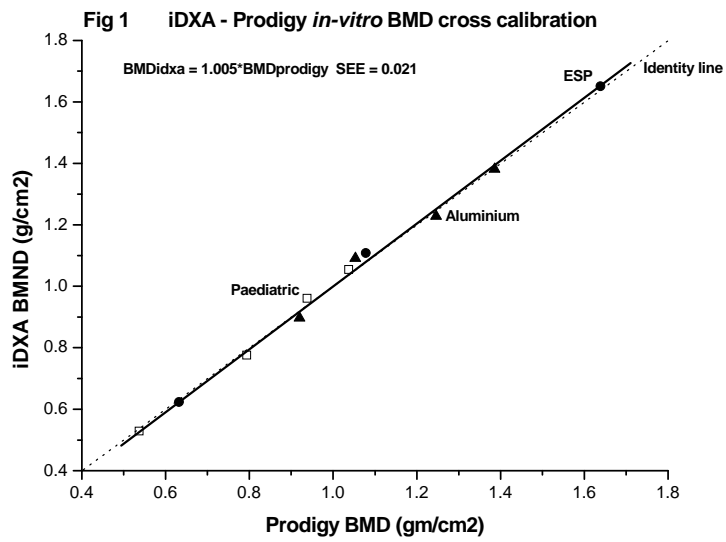


Fig 3 iDXA - Prodigy *in-vivo* BMD cross calibration : Femoral neck

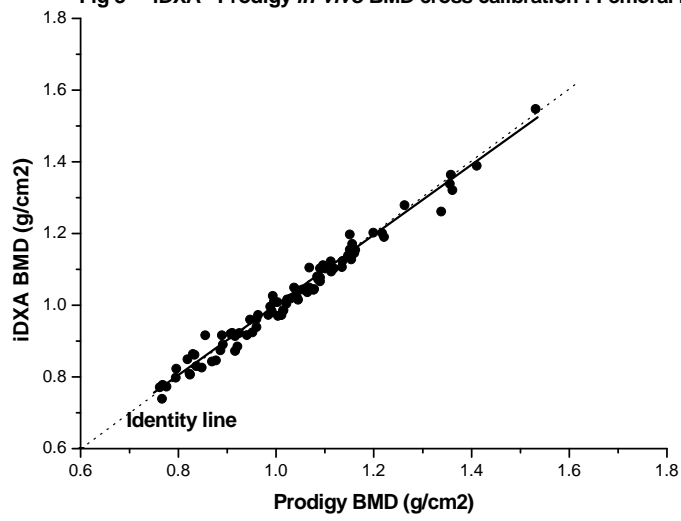


Fig 4 iDXA - Prodigy *in-vivo* BMD cross calibration : Total Hip

