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Comparison of the Lunar Prodigy and Stratos DR dual-energy X-ray absorptiometers to assess regional bone mineral density

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Abstract

Purpose: The first objective of the study was to assess the agreement between the Stratos DR (DMS) and the GE Prodigy (GE) DXAs in determining femoral neck, total hip and lumbar spine aBMD. The second objective was to assess the potential impact of leg positioning (hip flexed at 90° or not) on lumbar spine aBMD. **Methods:** Forty-six individuals (n=42 women, 91.3%), with a mean age of 59.7 ± 13 years and mean BMI of 23.8 ± 4.7 kg/m², were scanned consecutively on the same day using the two devices. In a subgroup (n=30), two consecutive Stratos DR scans (with hip flexed at 90° or not) at the lumbar spine were conducted. Predictive equations for hip and lumbar spine aBMD were derived from linear regression of the data. **Results:** Correlation coefficients for aBMD measured with the two DXAs were characterised by an R² of 0.76 for the femoral neck, 0.89 for the total hip, and 0.86 for the lumbar spine. However, the derived equations for aBMD determination showed an intercept significantly different from 0 for hip aBMD, and a slope significantly different from 1 for lumbar spine aBMD. These results highlight a bias between the two measurements, thus requiring the determination of specific cross-calibration equations for hip and lumbar spine, femoral neck excepted. When compared with values on the Prodigy, mean aBMD on the Stratos DR was higher at the femoral neck (+4.8%, p<0.001) and total hip (+9.6%, p<0.001) and lower at L2-L4 (-8.8%, p<0.001). The coefficient of variation (CV%) for the two consecutive measures at lumbar spine (with different positioning) with the Stratos DR was 2.9%. **Conclusions:** The difference in aBMD measured with the two DXAs illustrates the need to define cross-calibration equations when comparing data across systems in order to avoid erroneous conclusions.

Key Words: Cross-calibration; Dual X-ray absorptiometry (DXA); Stratos DR; Prodigy; Areal bone mineral density (aBMD).

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Introduction Dual-energy X-ray absorptiometry (DXA) is a safe, accurate and precise technique to assess areal bone mineral density (aBMD), the parameter used to diagnose osteoporosis (1,2). The indications are set out and updated in the official guidelines of the International Society for Clinical Densitometry (ISCD) (3). However, commercialised DXA systems may have different photon sources (4), hardware (filters, collimators, detectors) and software (analysis algorithms) (5), all of which can generate differences in the aBMD results of densitometers from different manufacturers. Thus, it was reported that a measurement of spine aBMD on a system from Hologic is typically 11.7% lower than on the GE Healthcare Lunar system (6). In a recent report, Reitshamer et al. (7) confirmed systematically lower mean aBMD values of 0.136 g/cm² at the femoral neck and 0.169 g/cm² at the lumbar spine on the Horizon A (Hologic) compared to Prodigy (GE Lunar). Moreover, aBMD variations have also been reported for various DXA models from the same manufacturer (8,9). For example, although the Prodigy and iDXA from GE Healthcare Lunar showed a close linear relationship over the entire range of aBMD values (correlation coefficients ranging from 0.96 for whole body and 0.99 for lumbar spine), a discrepancy between the absolute aBMD measurements was observed, with the size of the discrepancy depending on the region of interest (ROI) (8,10).

These differences in characteristics suggest that patient follow-up should be performed in the same unit with the same device (3). Yet this recommendation cannot always be followed because ageing densitometers are regularly replaced by newer-generation technologies with better performances and reduced radiation (11). In this situation, the official position of the ISCD(3) is that cross-calibration studies should first be performed at anatomic sites commonly measured in clinical practice typically the lumbar spine and proximal femur to allow the comparison of data collected on the different systems. Cross-calibration equations are therefore recommended to compare the results between systems (3). To date, there are no published data on the cross-calibration between the Stratos DR (DMS) and the Prodigy (GE Healthcare).

The lumbar spine is one of the key sites used in the clinical evaluation of patients with osteoporosis (1). To estimate lumbar spine aBMD, most but not all manufacturers recommend placing the patient with the hip joints flexed to 90° to keep their thighs perpendicular to the scanning table (12). The aim of this procedure is to reduce the lumbar curvature and thus achieve a better separation of the individual vertebrae. It was also demonstrated that vertebral positioning may modify aBMD measurement (13). To date, however, no data concerning the effect of patient positioning on lumbar spine aBMD measurements are available for the Stratos DR.

The first objective of this study was to determine the extent of agreement for regional measures of aBMD (femoral neck,

total hip and lumbar spine) between the following DXA devices: (i) Stratos DR (DMS) and (ii) Prodigy (GE Healthcare). The second objective was to assess the potential impact of leg positioning (hip flexed at 90° or not) on lumbar spine aBMD.

Materials and methods

Subjects

The sample consisted of patients referred to the Department of Nuclear Medicine, Gui de Chauviac Hospital (Centre Hospitalier Universitaire de Montpellier, CHRU Montpellier, France) for evaluation of aBMD. Forty-six individuals (n=42 women, 91.3%) with a mean age of 59.7 ± 13.0 years (range: 28.9 to 85.5) and a mean BMI of 23.8 ± 4.7 kg/m² (range: 14.6 to 39.8) were included in this study. All participants were Caucasian and, to be eligible, they had to be over 18 years old, able to lie supine for 10-15 minutes, and have body weight <140 kg (table weight limit restriction of the Prodigy system). Participants were excluded from the study if they had a history of lumbar spine or proximal femur fracture, hip replacement or osteosynthesis and cementoplasty at the lumbar spine, or were pregnant or breastfeeding. In accordance with ISCD recommendations (3), these groups are representative of those routinely scanned in our department.

Study procedures

Ethics approval for the study was obtained from the Ethics Review Committee of Nîmes, France (Commission de Protection des Personnes, Sud Mediterranee III on 7 February 2011), and permission for the clinical trials was granted by the French Medicine and Health Care Products Regulatory Agency (ID RCB: 2010-A01411-38, on 27 January 2011). All study participants were volunteers and gave specific signed consent before the scans for either the cross-calibration only or the cross-calibration with additional scanning at the lumbar spine (leg positioning). All activities performed in this study were in accordance with the Declaration of Helsinki.

Standing height was measured with a stadiometer to the nearest 0.1 cm and recorded as the mean of two consecutive measurements. Body weight was measured with a calibrated scale with a precision of 0.1 kg. Body mass index (BMI) was calculated as weight (kg) divided by the square of height (m).

Dual-energy X-ray absorptiometry measurements

As the two systems were situated at the same site, each participant was scanned consecutively on the Prodigy DXA (GE-Lunar Corp., Madison, WI) and the Stratos DR (DMS, Mauguio, France) within a 2-hour period. They wore the same light clothing with all metal and plastic artefacts removed. The Prodigy was used as the reference device. The lumbar spine (L1-L4) in the posterioranterior projection and the left proximal femur were scanned on both DXA scanners. This was done after following the procedures described in each

densitometer's operating manual. Array scan mode was used for the Prodigy (software version 3.6), whereas standard mode was used for the Stratos DR (software version 2.0.2.3). ROIs were defined for the lumbar spine, femoral neck and total hip.

The Prodigy employs a narrow fan beam at an angle of 4.5° oriented parallel to the long axis of the body using a peak X-ray energy of 80 kVp, a current of 3 mA, and a Kedge filter to produce energies at 43 and 70 keV. The Prodigy system employs 16 5-cm long detectors with energy-sensitive cadmium zinc telluride, thus allowing for rapid photon counting (14). The Stratos DR uses fan beam DXA technology with a 5° angle. The generator operates on a 90-kV power supply and a 0.1- to 2-mA current depending on the type of scan and the patient's morphology. The X-ray source has a continuous spectrum with two energy peaks (43 and 70 keV) filtered by a kedge filter (samarium). The fan beam is obtained when the raw X-rays pass through a rectangular lead collimator. Photons are counted with a direct digital detector consisting of cadmium telluride (CdTe) crystals pixelated in a 2D array (4 × 64 pixels). The X-ray tube is placed beneath the patient's table and the detector is lodged in the arm. Scattered rays are stopped by a brass collimator placed in front of the detector. The source of the detector moves simultaneously along the x and y axes and the maximum scan area is 200 × 65 cm². The scanned image is a projection of the object along the source/detector axis.

To test the possibility that leg positioning and the curvature of the lumbar spine might have modified the aBMD, two measurements were successively performed in a subgroup of participants (n=30). First, the scan was done with the hip joints flexed 90° to keep the thighs perpendicular using a cushion provided by the manufacturer. Then, the same L2-L4 ROI was scanned in the posterioranterior projection but with the legs flat on the table. All scans were done by the same technician who analysed each scan individually.

Statistical analysis

Descriptive statistics including means and standard deviations were calculated for all variables. To assess the agreement between the pairs of measurement, t-tests, linear regression analysis and the Bland & Altman plot were used (15). Limits of agreement, between which approximately 95% of the difference in two measures lie, were calculated as ± 1.96 SD of the mean difference. A simple Pearson correlation was performed between the difference (Stratos DR-Prodigy) and the corresponding average ((Stratos DR+Prodigy)/2) for each estimate; a significant association was indicative of a bias between instruments.

The t-test allowed us to reject the hypothesis that the differences between the two measures were related only to chance. We used linear regression analysis to estimate the cross-calibration equations for the Prodigy DXA and Stratos DR. The coefficient of determination R² measured the

strength of the linear relationship between the two measures. The intercept and the slope of the regression line evaluated the systematic (and correctable) bias between the two measures. Inter-device precision after cross-calibration was assessed by computing the generalized least significant change (GLSC%) using the method proposed by Sheperd et al.(16). As recommended, given that only two measurements were available in a subset of patients for the Stratos DR, we used for the previously cited calculation of the estimated precision of the Stratos DR for the intra-device precision of both devices (see below). If the percentage of change between a patient's baseline aBMD measure on the Prodigy device and their follow-up aBMD measure on the Stratos DR was greater than the GLSC (after cross-calibration), we assumed with 95% confidence that a true change in aBMD had occurred.

To assess the influence of leg positioning on aBMD measurement at the lumbar spine (L2-L4), we measured aBMD at the spine in 30 volunteers two times: with and without the positioning cushion. The coefficients of variation (CV%) were estimated and defined as follows: "the percentage of change of a measurement relative to the true value of the measurement will be expected to be less than CV (%) for 95% of the observations" (15,17).

$$CV(\%) = \sqrt{\frac{\left(\frac{\sum(a-b)^2}{2n}\right)}{\frac{\sum(a+b)}{2n}}}$$

We computed the least significant change as LSC=2.77*CV (%). The percentage of change between the two measurements for the same participant was expected to be less than the LSC for 95% of the pairs of observations. Thus, the percentage of change was considered significant if it exceeded the LSC.

Our sample size was established according to the ISCD recommendations (3): a minimum number of 30 subjects that may be preferentially included to perform a crosscalibration between two devices (primary objective) or to perform a precision analysis (30 patients scanned two times with leg repositioning between scans) of a single device (secondary objective).

Statistical analyses were performed at the conventional two-tailed a level of 0.05 using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Characteristics of the study populations are given in Table 1. Forty-six individuals with a mean age of 59.7 ± 13.0 years and BMI ranging from 14.6 to 39.8 kg/m² were included in this study. Comparisons of mean aBMD at the femoral neck, the total hip and lumbar spine as measured by the Prodigy and Stratos DR are given in Table 2 and the mean difference is presented in

Table 3. Paired ttests indicated that aBMD measured by the two devices Table 1

Characteristics of the 46 participants (91.3% female).

Participants	Mean or n (%) SD	Range
Number of women		
Age (years)	28.9	15-85.5
Weight (kg)	65.763	22.3-126
Height (cm)	§§§§	150-178
Body mass index (kg/m ²)	13.015	0.7-24.7
		14.6-39.8

Data are given by mean § SD.

Table 2

Comparison of mean areal bone mineral density (g/cm²) at femoral neck, total hip and lumbar spine measured by the Prodigy and Stratos DR DXAs.

Regions	Prodigy	Stratos DR	p-value
Femoral neck	0.8000	0.8431	0.052
Total hip	§§§	§§§	0.979
L2-L4	0.1050	0.1270	0.173
	0.1280	0.1290	0.151

Data are given by mean § SD. p-values for paired t-tests.

was significantly different for all bone sites. Specifically, aBMD measurement with the Stratos DR was significantly higher at the femoral neck (+4.8%, p<0.001) and the total hip (+9.6%, p<0.001) compared to the Prodigy, whereas aBMD measurement with the Stratos DR was lower at L2-L4 (-8.8%, p<0.001). These systematic differences are depicted in Figure 1 with aBMD scatter plots (Prodigy versus Stratos DR).

Regional cross-calibration equations

Results of the linear regression analysis are shown in Table 4 and Figs. 1 and 2. A high degree of correlation was observed

Table 3

Limits of agreement for femoral neck, total hip and lumbar spine aBMDs measured by Prodigy and Stratos DR.

Region	Mean aBMD difference (Stratos DR-Prodigy)	Percent aBMD difference (Mean difference)/ Stratos DR)	Limits of agreement (Difference § 2SD)	Correlation r ^a between difference & mean	p ^a for r ^a =0
Femoral neck	-0.0840	-8.769	-0.080 to 0.170	0.38	0.01
Total hip	0.0890	5.84	0.005 to 0.173	0.10	0.51
L2-L4	§§§ 0.0630	6.294	0.210 to 0.042	0.32	0.03

between regional aBMD measured with the two DXAs, characterised by an R² of 0.76 for the femoral neck, 0.89 for the total hip and 0.86 for the lumbar spine. However, the derived equations for aBMD determination showed an intercept significantly different from 0 for hip aBMD and a slope significantly different from 1 for lumbar spine aBMD. These results indicated a bias between the two measurements for both bone sites, femoral neck excepted, and required the determination of specific cross-calibration regression equations for the two DXAs at all bone sites. The cross-calibration equations linking the two DXAs are detailed for each bone site in Table 4. After cross-calibration, inter-device GLSC (%) was 16.1%, 10.0% and 16.2% for femoral neck, total hip and L2-L4, respectively.

Concerning the lumbar spine between the two positions (with and without cushion), the mean (SD) difference (g/cm²) was -0.018 (0.040), the CV (%) was 2.9% (Table 5), and the LSC was 8.2%. Non-significant variation between the first and second measures was demonstrated.

Discussion

This study aimed to cross-calibrate the GE Prodigy and Stratos DR for measurements of the most frequently analysed bone sites (i.e. hip and lumbar spine) using a group of participants that was representative of the patients routinely scanned in our department. Our results showed the close linear relationship of the aBMD measurements at each bone site. However, in most of ROIs the regression slope was significantly different from unity, demonstrating the need to cross-calibrate the two DXAs from different manufacturers.

As opposed to other DXA devices that have benefited from numerous cross-calibration evaluations, such as the iDXA versus Prodigy (8,10,18), this is the first study to our knowledge to compare the Stratos DR with Prodigy. We observed significant differences between the Stratos DR and Prodigy for aBMD at all evaluated bone sites, i.e. the femoral neck, total hip and lumbar spine, which may be of great research and clinical relevance. The Stratos DR overestimated aBMD at the femoral neck and total hip and underestimated it at the lumbar spine (L2-L4)

Data are given by mean \pm SD, a Pearson correlation coefficients and levels of significance for Bland & Altman plots. aBMD: areal bone mineral density.

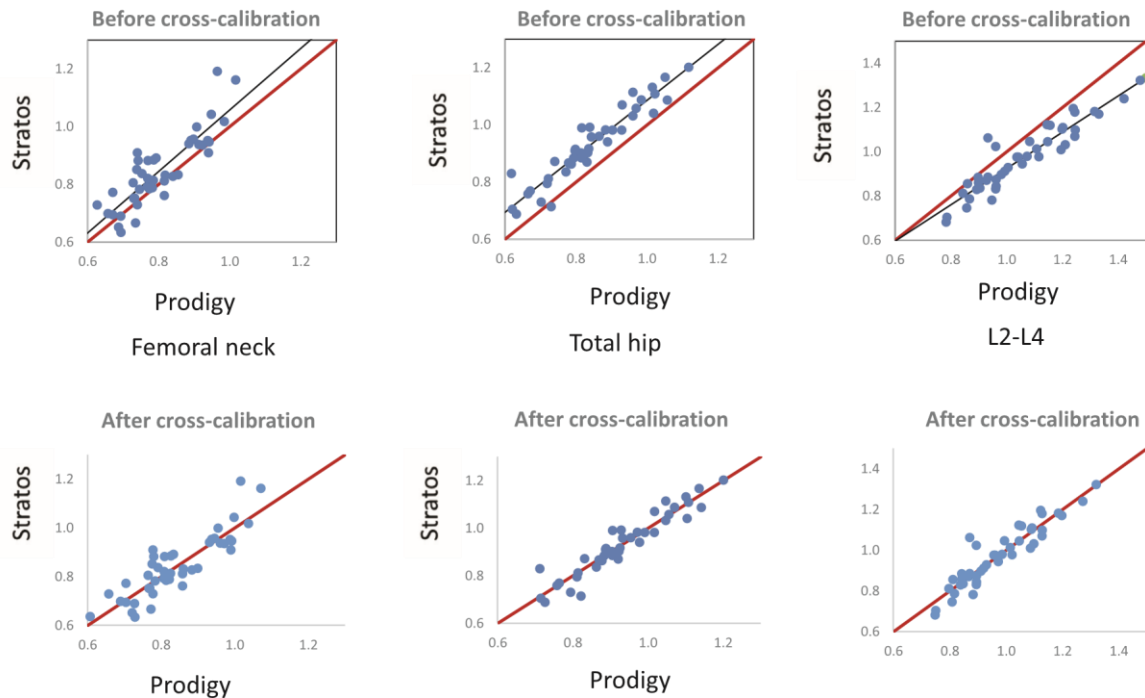


Fig. 1. Scatter plot for femoral neck, total hip and lumbar spine (L2-L4) aBMD measured using a Prodigy (GE Lunar) versus a Stratos DR (DMS). Up panel before cross-calibration, and down panel before cross-calibration. The red line is the line of equality on which all points would lie if both devices gave exactly the same value. The black line is the linear regression line. The unit of measure is g/cm^2 .

compared to the Prodigy. Inter-device differences were greater for hip (+9.6 \pm 4.6%) than for lumbar spine (-8.8 \pm 6.3%). As the differences exceeded the 1% that is recommended by the ISCD, this pointed to the need for correction equations (3). These results are in agreement with previous findings that showed a similar range of differences between DXA devices produced by different manufacturers using fan beam technology, like the Discovery A from Hologic, and those using pencil beam technology, like the Stratos from DMS (11). It should be noted that the difference in aBMD measurements is lower when the two DXAs are produced by the same manufacturer (less than 1.5%) (8,10,19). Other technological factors have been identified that may also account for the differences in the aBMD results, including differences in the procedures for image acquisition and software analysis

between the two bone densitometers (4,5,20). The mean systematic difference between the two devices largely exceeded the annual biological aBMD changes evaluated in women after menopause, the main class of patients usually evaluated by DXA (21). It may also have exceeded the bone loss observed in patients with spinal cord injury, a group that is considered a “clinical model” of an extremely intensive bone demineralisation process (22).

Although the aBMD values of the Stratos DR and Prodigy were significantly different, scatter plots showed a close linear relationship over the range of aBMD values for the femoral neck, total hip and lumbar spine with a coefficient of correlation (R) of 0.87, 0.94 and 0.93, respectively. Our results are fully comparable to those of Reitshamer et al. (7), who compared the Horizon A and Prodigy. In their study, a R of 0.88, 0.94 and 0.98 was

Table 4

Linear regression analysis for femoral neck, total hip and lumbar spine aBMDs measured by Prodigy and Stratos DR.							
Region	Regression equation	Slope 95% CI	p for slope	Intercept 95% CI	p for intercept	R ₂	p for R ²
Femoral neck	ST = 1.065PR -0.007	0.879-1.250	0.48	-0.156-0.142	0.92	0.76	<0.001
Total hip	ST = 0.980PR +0.106	0.872-1.086	0.70	0.015-0.197	0.02	0.89	<0.001

L2-L4 ST = 0.822PR + 0.104 0.720-0.924 <0.01 -0.005-0.213 0.06 0.86 <0.001

Stratos DR: ST and PR: Prodigy.

p-values are displayed for the following null hypothesis: slope=1, intercept=0 and R2=0.

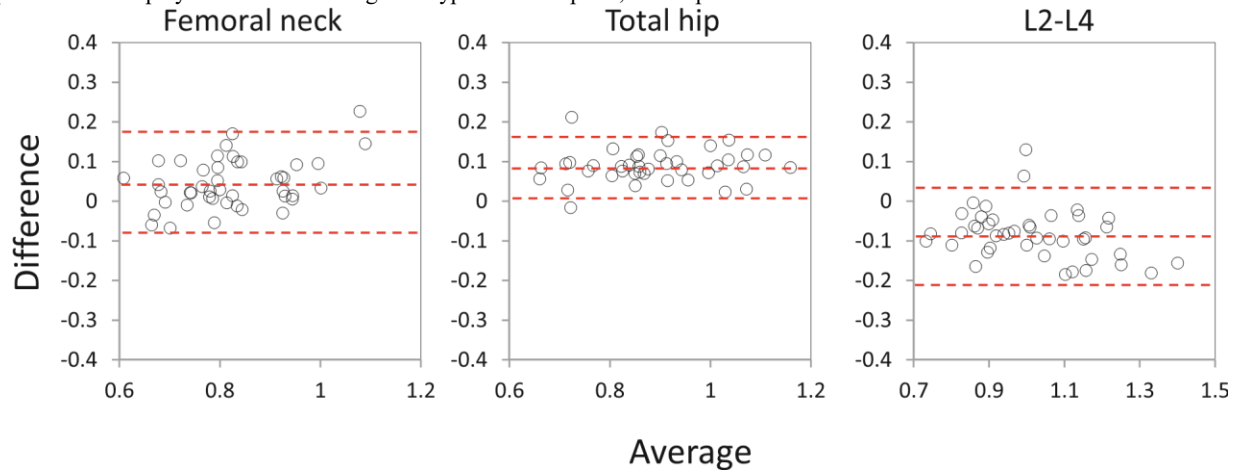


Fig. 2. Bland & Altman plots comparing the Prodigy (GE Lunar) and Stratos DR (DMS) for femoral neck, total hip and lumbar spine (L2-L4). The unit of measure is g/cm².

reported at the femoral neck, total hip and lumbar spine, respectively. Shepherd et al. (23) reported a better correlation when they compared the Prodigy to Delphi, with specific values of 0.95, 0.98 and 0.99, respectively. In the total hip and lumbar spine ROIs (femoral neck excepted), the intercepts and regression slopes were respectively significantly different from zero and unity, demonstrating the need for cross-calibration. We thus developed translational equations to enable the conversion of Stratos DR values to Prodigy values to ensure the comparability of the acquired data. Nevertheless, as previously described for other cross-calibrations, the correction equations may differ somewhat, depending on the identification of patient-related parameters like gender, ethnicity and mean aBMD (8,10,18). Consequently, regression equations for translating scans between the Stratos DR and Prodigy are valid only for the conditions presented in this study.

Evaluation of lumbar spine aBMD is essential for diagnosing osteoporosis because this bone site is preferentially

Table 5

Comparison of two measurements (flexion of hips to 90° and legs-down position) of lumbar spine aBMD performed by Stratos DR.

aBMD (g/cm ²)	Lumbar spine
---------------------------	--------------

Coefficient of variation (%)	2.02
Mean difference (mean % Mean difference)	0.015
(mean 1nd measure (meanst measure (mean §§SD)SD)§ SD)§ SD)	0.997-2.022.9§§§§§3.40.1640.1580.040

Data are given by mean § SD. aBMD: areal bone mineral density. Mean difference: mean of the difference between the first and second aBMD measurements.

affected by demineralisation after menopause(21) and also because the effect of osteoporotic drugs is particularly marked at this bone site (24). Experimental study has demonstrated that projectional DXA measurements in human cadaveric spine phantom are significantly affected by the positioning of the lumbar spine, but more severely by kyphotic than lordotic curvature (13). In our study, we found a moderate (0.018 gr/cm²) but non-significant difference in the aBMD measured in the same patient after repositioning with or without the leg elevation that modified the curvature of the lumbar spine. This difference appeared slightly increased but close to the value generally reported (CV around 2%) by most manufacturers for lumbar spine repositioning in the recommended condition (i.e. 90° hip flexion) (17,25,26). Our results confirmed those of Lekamwasam et al. (12), who also reported no significant difference in total spine aBMD or T-score measured with hip flexion compared to without hip flexion using a Hologic Discovery DXA scanner. The concomitant variation in the ROI and the bone mineral content (BMC) to the same extent may explain why no modification in aBMD and T-score was observed between the two situations, thus consequently not compromising the diagnostic stratification of osteoporosis. We also had too few men in the reproducibility as-sessment to assess the effect of sex. It is possible that measurement

errors in men may be worse than in women because of a relatively high prevalence of anatomic abnormalities such as degenerative sclerosis. We also had too few men in the reproducibility assessment to assess the effect of sex. It is possible that measurement errors in men may be worse than in women because of a relatively high prevalence of anatomic abnormalities such as degenerative sclerosis.

Our study presents some limitations, particularly the low proportion of men in the reproducibility assessment, which did not allow us to evaluate the effect of sex. It is possible that measurement errors in men may differ from those in women, particularly at the lumbar spine, due to a difference in body fat repartition (android vs gynoid), as this factor is known to influence aBMD measurement (27). Moreover, it should be underlined that the main limitation of the cross-calibration approach is that the resulting cross-calibration estimate is generally more variable than an actual measurement made by the target device. Thus, to be considered a true clinical change, the change between a patient's baseline aBMD measurement on the Prodigy device and the follow-up aBMD measurement on the Stratos DR must be greater than a change between two aBMD measurements on the Stratos DR. Clinicians should take this greater variability (larger random error) into account, especially by using GLSCs (such as those calculated in our study) as the threshold of clinical interest, and not the conventional LSCs of the target device. These thresholds can sometimes be very large and may limit the clinical interpretability of the cross-measurement estimate.

Conclusion

The difference in aBMD measured with the Prodigy and Stratos DR DXAs illustrates the need to define cross-calibration equations to compare data across systems in order to avoid erroneous conclusions. The positions with and without leg elevation did not significantly affect the lumbar spine aBMD.

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