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Cross-Calibration Study of The Stratos And Hologic QDR4500 A Dual-Energy X-Ray Absorptiometers to Assess Bone Mineral Density And Body Composition

Laurent Maïmoun,1,2* Sandrine Alonso,3 Krishna Kunal Mahadea,4 Vincent Boudousq,5 Thibault Mura,3 and Denis Mariano-Goulart1,2

1 Service de Médecine Nucléaire ,Hôpital Lapeyronie, CHU Montpellier, France;

2 Physiologie et Médecine Expérimentale du Cœur et des Muscles (PhyMedExp), INSERM, CNRS, Université de Montpellier (UM);

3 Département d'Information Médicale, CHRU Nîmes et UM, Nîmes, France;

4 Université de Montpellier, Montpellier, France;

5 Service de Médecine Nucléaire, Hôpital Carémeau, CHU de Nîmes, France

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Cross-calibration; Dual X-ray absorptiometry (DXA); Stratos; QDR4500A; Areal bone mineral density (aBMD); Body composition; Body mass index.

*Corresponding author at:

Département de Biophysique, Université Montpellier Service de Médecine Nucléaire, Hôpital Lapeyronie 371, avenue du Doyen Gaston Giraud. 34295Montpellier cedex5.

E-mail:

l-maimoun@chu-montpellier.fr

Abstract

The objective of the study was to assess the agreement between the Stratos (DMS) and QDR 4500A (Hologic) DXAs in determining whole body and regional aBMD, as well as whole body composition.

Fifty-five individuals (46 women: 84%) with a mean age of 41+/-13.0 years (range: 20 to 64) and a mean BMI of 31.9+/-10 kg/m² (range: 12.2 to 49.5) were consecutively scanned on the same day using the two devices. Predictive equations for a real bone mineral density (aBMD) and whole body composition (WBC) were derived from linear regression of the data.

The two DXAs were highly correlated (p<0.001 for all parameters) with a correlation coefficient (r) ranging from 0.89 to 0.99 for aBMD (r=0.89 for whole body, r=0.92 for radius, r=0.95 for femoral neck, r=0.96 for total hip, and r=0.99 for L1-L4). For WBC, the r value was 0.98 for lean tissue mass (LTM) and 1.0 for fat mass (FM). Paired t-tests indicated a statistically significant bias between the two DXAs for the majority of measurements, requiring the determination of specific cross-calibration equations .Compared to QDR 4500A, Stratos underestimated whole body aBMD and LTM and overestimated neck and hip aBMD and whole body FM. Conversely, no significant bias was demonstrated forme an aBMD at L1-L4 and radius. For whole body aBMD and FM, the concordance between the two DXAs was influenced by BMI.

Despite a high concordance between the two DXAs, the systematic bias for aBMD and WBC measurements illustrates the need to define cross-calibration equations to compare data across systems.

Introduction

Dual-energy X-ray absorptiometry (DXA) is the reference technique for the evaluation of areal bone mineral density (aBMD). It is noninvasive and characterized by low radiation and high precision and reproducibility, making it useful to monitor changes in aBMD over time and to determine treatment efficacy (1). However, a difference in aBMD calibrations between manufacturers has been well documented (234). Typically, it has been reported that a measurement of spine aBMD on a system from Hologic is lower than on the GE Healthcare Lunar system (23). Moreover, aBMD variations have also been observed for different scanners within the same manufacturer's product lines (56). The official guidelines of the International Society for Clinical Densitometry (ISCD) (7) therefore recommend that patient follow-up be performed with the same device. However, in situations where an old DXA is replaced by a newer one, or to meet the needs of a multicenter study, the ISCD recommends a cross-calibration study between devices to ensure consistent results (7).

In addition to aBMD, there is growing interest in evaluating body composition with DXA, which is today the gold standard in clinic for determining WB, regional lean tissue mass (LTM) and fat mass (FM) (8). Indeed, DXA use for patients with various conditions was advocated in the last ISCD recommendations, published in 2013⁹. These included patients living with HIV and taking antiretroviral agents, obese patients undergoing bariatric surgery (*1011*), patients with other conditions that induce significant weight loss, and patients with weakness or poor physical functioning. For example, when LTM is evaluated with DXA in weak or poorly functioning patients, it contributes to the sarcopenia diagnosis by adding the concomitant evaluation of muscle quantity or mass to the measurements of muscle strength by handgrip strength and physical performance by gait speed (*12*). Thus, low LTM can be defined by different cut-offs using appendicular lean mass evaluation 12, 13, 14, which requires the capacity of the device to perform segmental analysis – only possible with DXA technology. As for aBMD, the ISCD recommends a cross-calibration study between devices to ensure consistent results for body composition analysis (*7*).

To date, no data have been published on the cross-calibration between the Stratos (DMS®) and the QDR 4500A (Hologic Inc.®). To our knowledge, Stratos was only cross-calibrated with Discovery A, another device from Hologic®, but only lumbar spine and hip regions were analyzed, with no information on body composition(15).

The purpose of this study was to perform an in vivo calibration of total and regional body scans between two DXA devices: Stratos (DMS-APELEM; pencil-beam technology) and QDR 4500A (Hologic, Inc.; fan-beam technology), with a focus on aBMD and body composition.

Section snippets

Subjects

Fifty-five adults were recruited via an intra-hospital email invitation or from among patients referred to the Department of Nuclear Medicine, Lapeyronie Hospital (Centre Hospitalier Universitaire de Montpellier, CHRU Montpellier, France) for evaluation of aBMD and body composition. 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 <160 kg (table weight limit restriction of the QDR 4500A 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 breast feeding. In accordance with the ISCD recommendations (7), these participants were representative of our patients and represented the full spectrum of scans performed 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 Méditerranée III on 9 July 2015: reference 2015-06.02 bis), and permission for the clinical trials was granted by the French Medicine and Health Care Products Regulatory Agency (ID RCB: 2015-A00596-43, on 21 September 2015). All study participants were volunteers and gave specific signed consent before the scans. All activities performed in this study were in accordance with the Declaration of Helsinki.

Standing height was measured with a stadiumeter to the nearest 0.1cm and recorded as the mean of two consecutive measurements. Body weight was measured with a calibrated scale with a precision of 0.1kg. 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 located at the same site, each participant was scanned consecutively on the QDR 4500A (Hologic, Inc.) and immediately after on the Stratos (DMS, Mauguio, France). They wore the same light clothing with all metal and plastic artifacts removed. The QDR 4500A was used as the reference device. The lumbar spine (L1-L4) in the posterioranterior projection, the left proximal femur, the radius and the whole body were scanned on both DXA scanners. This was done after following the procedures described in each densitometer's operating manual. For aBMD analysis, the regions of interest (ROIs) were defined for the lumbar spine, femoral neck, total hip, radius and whole body, while for body composition [i.e., LTM and FM], the ROIs were defined for legs, arms and whole body. Moreover, appendicular lean tissue mass (ALM) was defined as the sum of LTM of the arms and legs ,as described by Heymsfield et al.(13).

Specificity of the DXA

-*Stratos* employs pencil-beam DXA technology. 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 (35 and 65 keV) filtered by a k-edge filter (samarium). A pencil-shaped beam is obtained when the raw X-rays pass through by a circular collimator. Photon counting is done with a scintillation crystal (LaCl₃) coupled to a photomultiplier. 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 brasscollimator placed in front of the detector. The X-ray source and the detector move. Simultaneously along the x and y axes and the maximum scan area is 200 x $65cm^2$. The scanned image is a projection of the object with no magnifying effects and independent of the position of the object along the source/detector axis. Software version V5.2.1.2 was used. Other details and dosimetry were previously published (15). The least significant change (LSC) for Stratos was previously reported, with values of 3.39% for lumbar spine (L1-L4), 5.84% for femoral neck, and 2.38% for total hip (15).

-QDR 4500A employs fan-beam DXA technology. Briefly, the X-ray source has a continuous spectrum with two energy peaks (100 and 140 keV). The detector system is composed of a 216-multichannel detector consisting of CdWO4 scintillators coupled to silicon diodes. Software version 12.6 was used. Other details and dosimetry were previously published (16).

Procedure for analysis of femoral regions

Shared procedure: For the two DXAs, the left hip that is scanned is internally rotated using a hip positioner. Hip is internally rotated because it will open up the femoral neck area, putting

the femoral shaft in line with the scanner bed and minimizing the lesser trochanter. Specific procedures: For QDR-4500A, the bottom of the global ROI should be 10 lines below the bottom of the lesser trochanter, 5 lines above the top of the head of the femoral neck, 5 lines laterally to the head of the 5 lines above the top of the head of the femoral neck, 5 lines laterally to the head of the femoral neck, and 5 lines laterally to the great trochanter. When the global ROI is defined, the software automatically places the different ROIs (i.e., head of the femur, greater trochanter and bottom of the lesser trochanter) and the femoral midline. By default, the width of the femoral neck box is a rectangular region of 1.5 * 5 cm and is placed tangent to the crest of the greater trochanter. For Stratos, the bottom of the global ROI is automatically positioned 6 cm below the insertion between the femoral neck axis and the lower limit of the femoral neck ROI (yellow line). The red line defines the femoral neck's axis and cuts the femoral neck in half. The femoral neck box in blue is positioned tangent to the crest of the greater trochanter. Last, the green line should be placed from the inflection point of the trochanter edge up to the boundary of the trochanter. Fig.1 presents the left proximal femur images of both bone densitometers, including their respective ROIs.



Fig. 1. QDR 4500A (Left) and Stratos (Right) left proximal femur images with the different regions of interest in the same 35-year-old women.

Characteristics of the 55 participants.						
Participants	$Mean\pm SD$	Range				
% Female	46 (84%)	Sam				
Age (years)	41 ± 13	20-64				
Weight (kg)	87 ± 28	30 - 135				
Height (m)	1.65 ± 0.09	1.51 - 1.9				
Body mass index (kg/m ²)	31.9 ± 10	12.2 - 49.5				

 Table 1

 Characteristics of the 55 participants.

Data are given by mean ± SD. BMI: body mass index.

Statistical analysis

Characteristics are expressed as mean \pm standard deviation (SD) and frequency with percentage. Correlations between the QDR 4500A and Stratos measurements were calculated using Pearson correlation coefficients (with 95% CI). Inter-scanner differences were evaluated by calculating the systematic difference between the QDR 4500A and Stratos measurements (systematic bias) and tested against the 0 value using a paired Student's t-test. Agreement was analyzed using a Bland-Altman plot.

Cross-calibration equations were estimated using linear regression. Systematic bias and agreement between the Stratos and QDR-4500A measurements converted using the cross - calibration equations were assessed using paired Student's t-tests and Bland-Altman plots.

The BMI effect and effect modification on the cross-calibration model were evaluated by adding an effect and an interaction term with a "Severe-Obesity" variable to the linear regression model. This dichotomization was chosen because it best fit the data for the interaction effects under consideration. All the analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC).

Results

The characteristics of the participants are described in Table 1. Fifty-five individuals (46 women: 84%) with a mean age of 41 ± 13.0 years (range: 20 to 64) and a mean BMI of $31.9 \pm 10 \text{ kg/m}^2$ (range: 12.2 to 49.5) were included in this study. The repartition of participants according to BMI class is presented in Table 2.

Cross-calibration

Results of the comparisons of mean bone mass parameters and body composition parameters measured by the Stratos and QDR 4500A are given in Table 3. Values of aBMD on the two DXAs were highly correlated (p<0.001 for all) with a coefficient of correlation (r) ranging from 0.89 to 0.99 (r=0.89 for whole body, r=0.92 for radius, r=0.95 for femoral neck, r=0.96 for total hip, and r=0.99 for L1-L4 aBMD). For whole body composition, r ranged from 0.96 for ALM to 1.0 for FM (all p<0.001). All these correlations are presented in Table3 and Figs.2 and 3.



Fig. 2. Correlations between measures obtained with QDR 4500A and Stratos for areal bone mineral density. aBMD: areal bone mineral density; BMC: bone mineral content; L1-L4: lumbar spine. Solid line is regression line, gray zone is 95% confidence interval of regression line, dashed line is line of identity, r is Person correlation coefficient.

However, although the two measures were highly correlated, the paired t-test indicated a statistically significant bias between the Stratos and QDR 4500A for most of the measurements. Compared to QDR 4500A, Stratos under estimated whole body aBMD with a difference of 0.116 g/cm², corresponding to a mean relative change of 10.4%. Specifically, the mean femoral neck and total hip aBMD were, respectively, a mean 0.07 g/cm² and 0.04 g/cm² lower with QDR 4500A than Stratos, corresponding to mean relative changes of 9% and 4.5. No significant bias was demonstrated for mean aBMD at L1-L4 and radius between the two DXAs .Compared to QDR 4500A ,Stratos over estimated FM (kg and %) and underestimated LTM (p< 0.001 for the three parameters) .The systematic differences for bone parameters and body composition parameters are depicted in Figs.4a and 5a with Bland-Altman plots (Stratos versus QDR 4500A).

As the subjects included in this study presented a large dispersion of BMI (range 12.2 to 49.5 kg/m²), the concordance of measurements between QDR 4500A and Stratos was analyzed according to BMI class (see Supplementary Table1). For most parameters, the bias between the two measurements obtained by the two DXAs was not influenced by BMI. Only limited significant interactions of BMI with whole body aBMD, whole body BMC and whole body FM (kg and %) were found (see Supplementary Table1 and Supplementary Fig.1).

Due to the observed differences between the two densitometers, linear cross-calibration equations were derived for bone mass parameters and body composition parameters. These equations are presented in Table4. The agreement between the Stratos measurements and the QDR 4500A measurements after conversion using the cross-calibration equations is depicted in Figs. 4b and 5b with Bland-Altman plots. Specific cross-calibration equations for parameters influenced by BMI are presented for the two classes of BMI (>/=35kg/m² or >35kg/m²) in Table 5.

Discussion

For a group of participants presenting a large range of BMI values, in vivo cross-calibration demonstrated good linear agreement between the Stratos and the QDR 4500A for both bone and body composition parameters. However, the regression slope in most of the ROIs was significantly different from unity, demonstrating the need to cross-calibrate these two DXAs from different manufacturers.

aBMD

Although all the aBMD measurements were significantly correlated between the two densitometers, the aBMD values with the Stratos were significantly lower for whole body and higher for femoral neck and total hip compared to QDR 4500A. For the latter two skeletal sites, mean 0.07 g/cm² and 0.04 g/cm² differences were, respectively, observed, which amounted to percentage variations of 9% and 4.5%. In cases of differences exceeding 1%, the ISCD recommends (7) the development of cross-calibration equations to ensure comparability between the two densitometers; for example, to ensure correct patient management when a currently commercialized Stratos replaces an older QDR 4500A, or to ensure the consistency of measurements when a multicenter study is being conducted. Various technological reasons have been proposed to explain the aBMD offsets ,including differences in the

manufacturers' calibration processes, computing algorithms, and detection technologies (17-19). In the current study, the type of beam (i.e., fanorpencil) may also be implicated. However, in a recent meta-analysis based on 14 studies, Yoon et al. (20) concluded that here was no significant difference in aBMD at the hip region between the two modes of DXA scanners, although pencil-beam underestimated aBMD in whole body compared to fan-beam, as was found in our study. It is never the less interesting to note that only studies comparing DXAs from the same manufacturer (i.e., Prodigy vs iDXA from Lunar or QDR 2000W vs QDR 4500A from Hologic) had been compiled (20). This methodology may have introduced a selective bias because an intra-device cross-calibration may have been performed by the manufacturers to limit aBMD differences within their range of densitometers. Other studies comparing pencil-beam (DPX-NT) and fan-beam (QDR 4500C) DXAs from two different manufacturers reported that, although the two DXAs were highly correlated, pencil-beam overestimated aBMD at the femur (0.082 g/cm²) (21). Our results at the femoral region confirmed these findings.

Conversely to hip regions, no aBMD difference between the two DXAs was detected for lumbar spine or radius. For lumbar spine, divergent results concerning the agreement between pencil- and fan-beam have been reported, including no difference (20) or an

overestimation of pencil-beam aBMD (21). The accuracy of aBMD measurements at lumbar spine and the determination of cross-calibration equations are important because bone loss after menopause preferentially affects lumbar spine, which is an essential bone site for diagnosing osteoporosis(22) and for monitoring the effectiveness of osteoporotic drugs (23). Concerning the radius, the ISCD recommends measuring this bone site (7,24) in certain circumstances, such as to diagnose osteoporosis when hip and/or spine cannot be measured or interpreted and in cases of hyperparathyroidism or very obese patients (over the weight limit for the DXA table). Until now, few data have been available concerning the cross-calibration at this bone site. Pearson et al. (25) found a 15% higher aBMD value measured by Prodigy compared to QDR 2000. Dowthwaite et al. (26) reported lower aBMD values (-0.002 g/cm²) with Discovery A compared to QDR 4500W. Last, Abrahamsen et al. (27) reported that aBMD values were significantly lower (-3.3%) with the QDR 2000 compared to QDR 1000W.

In comparison to other DXAs like Prodigy or QDR 4500A, which have benefited from many cross-calibrations with other DXAs from both the same and different manufacturers (3,4,26,28,29). Stratos has only been

compared to the fan-beam Discovery A (Hologic), and the results demonstrated good agreement between the two(15). It is interesting to note that close results were obtained particularly at the hip region, where Stratos aBMD measures were 0.080 g/cm² higher for femoral neck and 0.069 g/cm² higher for total hip. Conversely to the current study, a significant 0.028 g/cm² lower value for L1-L4 was reported for Stratos, whereas no data on radius aBMD and body composition were available (15).



Fig. 4. a. Bland-Altman analysis to compare measures obtained with QDR 4500A and Stratos for bone mass parameters. aBMD: areal bone mineral density; BMC: bone mineral content; L1-L4: lumbar spine. Plots present mean of QDR 4500A and Stratos measurements (x axis) plotted against the difference between QDR 4500A and Stratos measurements (calculated as QDR 4500A - Stratos). Solid line represents the mean difference, dashed lines represent ±1.96 SD of the mean difference.

Fig. 4b. Bland-Altman analysis to compare measures converted using the cross-calibration equations for QDR 4500A and measures obtained with Stratos for bone mass parameters. aBMD: areal bone mineral density; BMC: bone mineral content; L1-L4: lumbar spine. Plots present mean of QDR 4500A and Stratos measurements (x axis) plotted against the difference between QDR 4500A and Stratos measurements (calculated as converted (c) QDR 4500A - measured (m) Stratos). Solid line represents the mean difference, dashed lines represent ±1.96 SD of the mean difference.



Fig. 4 Continued

BMI ≤35									
1						After conversion			
	N	Equation	R-square RM	RMSE	Intercept p-value	Bias	p paired t-test		
Stratos Whole body aBMD	28	-0.1461+ (1.0205* QDR 4500 A Whole body aBMD)	0.8001	0.064	0.1926	0±0.063	0.9953		
Stratos Whole body BMC	28	-7.4075+ (1.0345* QDR 4500 A Whole body BMC)	0.8861	173.940	0.9638	0.066 ± 170.688	0.9984		
Stratos Whole body FM (%)	28	-1.7232+ (1.1535* QDR 4500 A Whole body FM (%))	0.9843	1.733	0.0591	0±1.701	0.9993		
Stratos Whole body FM (g)	28	-1030.0636+ (1.0923*QDR 4500A Whole body FM (g))	0.9930	1223.03	0.0300	-1.063 ± 1200.171	0.9963		
Stratos Whole body aBMD	25	0.2101+ (0.7266* QDR 4500A Whole body aBMD)	0.7421	0.047	0.0548	0±0.046	0.9940		
Stratos Whole body BMC	25	862.3993+ (0.7998* QDR 4500 A Whole body BMC)	0.8489	139.838	<.0001	-0.029 ± 136.894	0.9992		
Stratos Whole body FM (%)	25	7.1903+ (0.9652* Q DR 4500A Whole body FM (%))	0.8853	1.839	0.0382	-0.001 ± 1.8	0.9985		
Stratos Whole body FM (g)	25	5497.2.532+ (0.9718*QDR 4500A Whole body FM (g))	0.9386	2124.42	0.0465	2.109±2079.692	0.9960		

Table 5 Specific cross-calibration equations according to body mass index status (< 35 kg/m²>).

aBMD: areal bone mineral density; BMC: bone mineral content; SD: standard deviation; L1-L4: lumbar spine; g: gram; RMSE: root mean square error.

Body composition

DXA analysis of total and regional body composition has progressively become important in the diagnosis and follow-up of patients with a range of pathologies or clinical condition s(9), including patients with HIV, obese patients undergoing bariatric surgery (1011), and patients with muscle weakness or poor physical function (1213)[•] (30). However, as DXA findings for body composition differ across the scanning systems produced by different manufacturers (3), the development of cross-calibration equations based on in vivo analysis, instead of in vitro phantoms that may be misleading (31), is required and recommended by the ISCD (9).

As expected, although both DXAs showed excellent reliability for whole body LTM and FM (r=0.98 to 1), there were significant differences between the Stratos and QDR 4500A for body composition evaluation. The whole body LTM determined by Stratos was lower (bias of 4.2 kg corresponding to a mean relative change of 7.8%)

while the fat mass was higher (bias of 2.4 kg corresponding to a mean relative change of 4.7%) compared to QDR 4500A. These results demonstrate an unavoidable difference between the pencil-beam and fan-beam techniques. To date, no study has compared body composition parameters between Stratos and another densitometer, and therefore we have no elements of comparison. However, most studies that have compared pencil- and fanbeam DXAs reported similar findings (21,32), although no difference or only specific differences have also been reported (28,33-35). For example, in a sample of 47 subjects composed of children and adults, Ellis and Shypailo (32) reported a higher value of whole body LTM and lower FM measured with fan-beam QDR 4500A compared to pencil-beam QDR 200W. The smaller difference (1 kg and 0.7 kg, respectively) may be explained by the comparison of two DXAs from the same manufacturer. The same small difference was also observed when DPX and PRODIGY, two DXAs produced by GE/Lunar, were compared (28). However, this difference was not found in a second study comparing the same pencil- and fan-beam densitometers in a heavier population with greater fat mass (35). These findings suggest that a machine miscalibration or a population effect (28) may have influenced the result.

The difference in LTM values with the two DXAs consequently influenced the ALM values, which were also higher with QDR 4500A. However, taking into account the small difference between the two DXAs (594 g), the clinical implication of this difference in the diagnosis of

sarcopenia remains to be demonstrated in a large older population.

We are aware that the mean BMI (i.e., 31.9 kg/m²) of our population can be classified as overweight. However, these patients strongly reflect those currently evaluated in our Department for medical care of anorexia nervosa or obesity with a nutritional or surgical approach. In addition, the inclusion of participants with a large range of BMI (i.e., from severely underweight [12.2 kg/m2] to obesity class III [49.5 kg/m2]) was an excellent opportunity to determine that the concordance between the two DXAs is poorly influenced by BMI at bone sites with clinical importance for osteoporosis diagnosis (i.e., hip, lumbar spine and radius). This suggests that our cross-calibration equations may be generalized to different populations, except for whole body BMD, BMC and FM (%, kg), where BMI correction should be used with a specific cross-calibration equation. When it was studied, some (19,32,36,37), but not all works (3,32,38) had previously reported that BMI or other anthropometric parameters such as abdominal thickness were correlated with some inter-device differences. The concomitant analysis of aBMD and body composition in various commonly and uncommonly (i.e., radius) analyzed sites is a strength of

this study. However, to be more comprehensive, visceral adipose tissue should also have been compared between the two DXAs, but unfortunately this function was not available with the QDR 4500A.



Fig. 5. a. Bland-Altman analysis to compare measures obtained with QDR 4500A and Stratos for body composition parameters. FM: fat mass; LTM: lean tissue mass. Plots present mean of QDR 4500A and Stratos measurements (x axis) plotted against the difference between QDR 4500A and Stratos measurements (calculated as QDR 4500A - Stratos). Solid line represents the mean difference, dashed lines represent ±1.96 SD of the mean difference.

Fig. 5b. Bland-Altman analysis to compare measures converted using the cross-calibration equations for QDR 4500A and measures obtained with Stratos for body composition parameters. FM: fat mass; LTM: lean tissue mass. Plots present mean of QDR 4500A and Stratos measurements (x axis) plotted against the difference between QDR 4500A and Stratos measurements (calculated as converted (c) QDR 4500A – measured (m) Stratos). Solid line represents the mean difference, dashed lines represent ±1.96 SD of the mean difference.



Fig. 5 Continued

Conclusion

To summarize, the study showed good linear agreement between a currently commercialized pencil-beam Stratos and an older fan-beam QDR 4500A. Using the cross-calibration equations generated from a population presenting a large range of BMI, an accurate transformation of the Stratos values was obtained, removing all significant differences between the two DXAs. These results can now be used to assess aBMD or LTM and FM in multicenter studies or when a change from QDR 4500A to Stratos is necessary.

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