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DXA Body Composition Corrective Factors *between Hologic Discovery models* to Conduct Multicenter Studies

Thibault Sutter*¹, François Duboeuf*³, Roland Chapurlat³, Bernard Cortet⁴, Eric Lespessailles^{1,2}, Jean-Paul Roux³

¹EA 4708 I3MTO Laboratory, University of Orleans, Orleans, France. ²Department of Rheumatology, Regional Hospital of Orleans, Orleans, France. ³INSERM UMR 1033, University of Lyon, Hôpital Edouard Herriot, Lyon, France. ⁴Department of rheumatology, University Hospital of Lille, EA4490, University of Lille, Lille, France.

*Thibault Sutter and François Duboeuf contributed equally to this work.

Conflict of interest: Thibault Sutter, François Duboeuf, Roland Chapurlat, Bernard Cortet, Eric Lespessailles and Jean-Paul Roux declare that they have no conflict of interest.

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Corresponding author: François Duboeuf
INSERM UMR1033
UMR de Medecine Lyon-Est
rue G. Paradin
69372 Lyon Cedex 08
France.
Tel: (33)4-78-78-57-34
Fax: (33)4-78-77-86-63
francois.duboeuf@inserm.fr

Abstract

Background: Dual X-ray absorptiometry body composition measurements are widely used for clinical and research settings. It is well known that measurements vary across instruments, needing caution for longitudinal monitoring or multicentric studies. This study was to quantify intra- and inter-center variability of bone mineral content, bone mineral density, fat and lean body composition measurements **between Hologic Discovery models** in order to calculate the corrective factors to be applied for multicenter research projects.

Materials and Methods: A whole body phantom composed of materials representing the thickness and percentage of bone, lean and fat mass in the human physiological range was analyzed ten times in three different centers using dual energy X-ray absorptiometry scanners (Two Hologic Discovery QDR A and one QDR W). In addition, we used a morphometric vertebral phantom to monitor stability and a three steps block phantom to check accuracy.

Results: We found a good long-term stability and accuracy for the three devices. Intra-center coefficients of variation were within the range of the manufacturer acceptable values (bone mineral density: 1.40%, bone mineral content: 1%, area: 1.50%, fat mass: 0.89%, lean mass: 0.76%, total mass: 0.12%). Whereas the inter-center coefficient of variation exceeded 8% (bone mineral density: 8.18%, bone mineral content: 3.03%, area: 8.63%, fat mass: 3.92%, lean mass: 7.89%, total mass: 2.85%).

Conclusion: Our study showed that the discrepancies across centers remain a major concern, particularly with regard to body composition results. Our study **highlight the need of cross calibration between densitometers and** proposes corrective factors evaluated from a whole body phantom to lead multicentric studies adjustment.

Key words: DXA, Cross-calibration, whole body composition, bone mineral density.

1-Introduction

Dual energy X-ray absorptiometry (DXA) is a reference method for the evaluation of bone mineral density (BMD) [1]. The precision of the BMD measurement by DXA is excellent, with in vitro coefficients of variation (CV) at different sites between 0.4% (lumbar spine) to 1.3% (femoral neck) [2,3] and 2 to 6% for body composition [4]. This technique has been used for the evaluation of the whole body composition or of one of its **sub regions** [4,5]. This assessment yields three distinct components: fat mass, lean mass and bone mineral content.

The wide availability of DXA, its low radiation exposure and its rapid scanning time have led to its use in multicentric trials. However, measurements vary across instruments from the same manufacturer [6,7]. The need of cross-calibration of DXA systems used for body composition has been highlighted by the International Society for Clinical Densitometry (ISCD) in an official positions [8]. It was demonstrated that there were significant in vivo differences in fat composition ($\Delta 3$ kg, $p < 0.0006$) and lean body mass ($\Delta 3.8$ kg, $p < 0.0001$) analyzed by DXA from the same model (Lunar, DPX, Lunar Radiation Corporation, Madison, WI, USA) [9]. Tothill et al. [10] showed that these differences can be as high as 15% for trunk mass measurements using devices from different manufacturers (Norland and Hologic). Consequently, it is necessary to carry out longitudinal analyzes using the same device [10] or to perform cross-calibration in case of multicentric studies.

The rationale of this study was to highlight the importance of well-conducted cross-calibration in multicenter studies. We propose corrective factors calculated from sub-regions of a whole body phantom to be applied for body composition measurements (BMD, fat and lean mass) in multicenter research projects.

2-Materials and Methods

2-1 Materials

Three **collaborative** investigating centers were included: center A (Hospital Edouard Herriot, Lyon, INSERM UMR 1033, University of Lyon, France), center B (Lille University Hospital, France: Bone Densitometry Service, Rheumatology) and center C (Orléans Regional Hospital, France: Department of Rheumatology: Institute for Prevention and Research on Osteoporosis). Measurements were performed using Hologic Discovery QDR A devices at Center A and C and with a Hologic Discovery QDR W (Hologic, Bedford, MA) at the center B. Standard adult whole body scans were performed using fan beam technology.

To assess long-term stability and variability, three different calibrated manufacturer anthropometric phantoms consisting of four "vertebrae" (L1-L4) mimicking the characteristics of a human lumbar spine embedded in epoxy resin (respectively for devices #85051, #87188, #81563, Hologic®, USA, Bedford, MA) were used.

The accuracy, linearity and differences between centers were checked with a phantom (No. 010-1146, serial number: 3513, From Hologic®, USA, Bedford, MA) composed of three blocks of hydroxyapatite of respective surface density of 0.608, 0.993 and 1.579 g / cm² placed in a block of epoxy resin simulating the soft tissue.

Whole body measurements differences between centers were measured using a whole body phantom (No. 1206, Hologic®, USA, Bedford, MA) containing compartments of known amounts of bone and soft-tissue equivalent. This phantom design was modular, consisting of six white high-density polyethylene (HDPE) rectangles of varying length and width. Various combinations of HDPE (« fat ») and polyvinylchloride (« lean ») were used to mimic fat tissue. Simple geometric shapes of aluminum were embedded in the base HDPE layer to

simulate the bone tissue. The whole body phantom dimensions were 76 cm in length, 36 cm in width, 14 cm in height, and weighted 28 kg (Figure 1).

2-2 Methods

The three anthropometric phantoms were scanned every day according to the manufacturer's recommendation, using a specific automatic procedure. The phantom used for accuracy and linearity control, composed of three hydroxyapatite blocks, was scanned according to the manufacturer's in vivo procedure; we performed 10 scans over one day without repositioning on each device.

The same operator (TS) carried out the acquisitions of the whole body phantom in the three centers, with fan beam machines on a standard mode whole body scanning. According to the manufacturer procedure, the phantom was placed in the center of the table, with the top of the phantom positioned upwards of the table about 20 cm of the edge, parallel to the length of the table so that the distances between the sides of the phantom and the edges of the table were equal. The whole body phantom has been analyzed 10 times without repositioning according to the recommendations of the international society of densitometry [11]. The Hologic APEX Software with Windows XP operating system was used on all three devices (version 13.3.01) for the analysis of the data by the same operator (TS). The whole body mode was selected to scan the phantom. The duration of the whole body analyses in the three centers was 3 minutes for Lyon and Orléans (Hologic Discovery QDR A) and 6 minutes for Lille (Hologic Discovery QDR W).

The sub-regions of whole body phantom analysis were selected as recommended by the manufacturer. Measurements were done for fat and lean mass in six sub regions of the whole body phantom: total whole body, whole body less head, trunk, head, right leg and left leg (Figure 2) and in 10 sub-regions for BMD assessment.

2-3 Statistical analyses

Assessment of linearity were performed using linear regression between the actual values of the three blocks of hydroxyapatite and their measured values. Accuracy of the three devices (differences between the measured values and the actual values) were evaluated. **Bland Altman analysis was performed to verify the stability of the accuracy according to the density values.** The differences between the DXA measurements from the three centers were assessed by Kruskal–Wallis test, followed by **Mann-Whitney U-test for two-by-two centers comparison.** Results were expressed as mean and standard deviation (SD). The intra and inter-center coefficients of variation (intra-CV = mean of the 10 measurements divided by the corresponding standard deviation; inter-CV = mean of the tree centers values divided by the corresponding standard deviation). The percentage of error between the centers (inter-center mean - intra-center mean / inter-center mean x 100) were calculated. The significance threshold was set at $p < 0.05$.

Cross-calibrations equations were obtained using the different sub-regions of the phantom for BMD, fat and lean mass. All analyses were performed using IBM SPSS (version 22.0.00, IBM, Chicago, IL, USA).

3-Results

The mean values and coefficients of variation of one-year quality control performed every day on lumbar spine phantom in each center are displayed in table 1. The intra center CVs remained below one percent (0.3 to 0.6%). For each center, accuracy and linearity were analyzed using the phantom composed of three blocks of hydroxyapatite. We compared the constructor references values with the measured values. Accuracies of the centers A, B and C were respectively -7.1%, -6.2%, -8.3% with non-significant Bland et Altman tests (**Figure 3**)

Excellent linearity was found **between measured and real values** ($r^2 = 0.999$; 0.999 ; 0.857 ; respectively for center A,B,C).

The average of intra-center CVs (BMD: 1.40%, BMC: 1%, area: 1.50%, fat mass: 0.89%, lean mass: 0.76%, total mass: 0.12%) were lower than the inter-center CVs (BMD: 8.18%, BMC: 3.03%, area: 8.63%: fat mass: 3.92 %, lean mass: 7.89%, total mass: 2.85%). These results showed that the intra-center coefficient of variation remained $<1.5\%$ (Table 2). The inter-center coefficients of variation were higher for BMD, area, lean mass and fat mass variables with respective values of 8.18%, 8.63% and 7.89% (Table 2) for the total whole body. All measurements were significantly different between centers ($p < 0.01$). From the whole body sub-regions BMD, lean and fat mass measurements, linear regressions between the three centers were calculated. The equations showed a good linearity (r^2 from 0.86 to 0.99) and were used to determine the respective corrective factors (Figure 4).

4-Discussion

In this study, as expected we have found an excellent reproducibility of intra center measurements of body composition ($<2\%$), whereas it was much poorer across centers, despite the use of devices from the same manufacturer (2.85% to 8.63% from total mass to fat mass).

For each center, a good **long-term** stability ($CV < 0.6\%$) was observed as demonstrated by the annual values and variation of the anthropomorphic phantom of vertebrae. Similarly, for each center, accuracy was found from 6 to 9%. The intra-center variability appears of the same order of magnitude ($CV < 2\%$) for the BMD, BMC and soft tissue values. Concerning the inter-center variability, coefficient of variation and percentage error were high for BMD, area and lean mass for whole body results. These results, **acquired and analyzed by the same operator (TS)**, are in agreement with several studies [12–14], which showed much higher

inter-center variations than intra-center variations despite devices of the same brand and same generation (QDR 4500 Hologic). Validation studies have shown that DXA measurement of body composition was accurate when compared with reference methods [1,15,16]. However whole body soft-tissue measurements differ between DXA machines from different manufacturers [15] but also between different machines from the same manufacturer [17].

The goal of our study was to propose corrective cross-calibration equations using the different sub-regions of a Hologic whole body phantom to adjust inter-centers variations for bone and soft tissues.

The need for correction is suggested by several studies that showed that inter-center variations can reach up to 7% for whole-body measurements between devices of different manufacturers [6,7]. Diessel et al (6) tested the Lunar variable composition phantom (VCP) in which blocks and sheets are used in various combinations to simulate five different soft tissue composition. These authors conclude that VCP is a simple, easy-to-use tool that shows good potential for use in longitudinal quality control of percent body fat measurements by DXA devices (Hologic QDR-4500;and QDR1500; Lunar Expert, DPX-IQ, and DPX-L.). This phantom measured similar percent fat values between DXA scanners of the same make and model. However, when comparing DXA scanners of different make in vivo cross calibration appeared still needed.

Although more moderate, these significant variations can reach 5.6% between devices produced by the same manufacturer [12,17,18]. These inter-machine variabilities represent a major concern and a limitation in the use of this technique, especially in multicentric studies. Abrahamsen et al [18] showed that the Hologic QDR-2000 gives a 3.2% ($p < 0.001$) higher fat mass and a 2.3% lower lean body mass compared to a Hologic QDR-1000W. The total tissue mass was significantly lower with QDR-2000 (0.6%, $p < 0.001$). Similarly, by comparing a QDR 4500W with a Discovery W, Covey et al. [17] found significant differences for inter

center values. The QDR 4500W tends to overestimate the lean mass and underestimate the fat mass compared to the Discovery Wi. Differences observed between centers with devices of the same manufacturer could be explained in several ways. The first one is that the software used can lead to different calculation techniques or used segment detection factors [10]. Kohrt et al. [1], was interested in these different versions of analysis software and showed that the results obtained with the same machine (Hologic QDR-1000W) but with different versions of software did not give the same results. Indeed, version 5.50 (Hologic software) underestimated the percentage of soft tissues in the central region of the body (55%) while an updated version (version 5.64, Hologic software) corrected these variations and quantified 96% of soft tissues in the same region. Several studies have shown that these errors were higher in areas of low bone density such as fingers, pelvis or ribs. The results of Economos et al. [19] validated this hypothesis. The second one should be due to the different calibration settings and to the particularity of the X-tube of the device. Studies have shown that the differences were beam- [18,20] and scanning mode dependent [21]. According to Paton et al [9], the lack of consensus on machine calibration and the difficulty of including calibration constants in analysis software affect BMD results and thus the quantification of soft tissues.

In our study, the observed variations are mainly due to absolute calibration and the specificity of the X-tube of the device, since only one operator has performed the acquisition and analyses. The machines were from the same brand and of the same model. These variations between devices could induce a fluctuation of **the threshold** between the different tissues (bone, muscle and fat) (Table 2).

If BMD cross-calibration recommendations are largely documented using standardized phantoms, cross-calibration recommendations for body composition remains more limited, as total body composition phantoms are not widely available. One study from Krueger et al. [22] shows that none of the existing three encapsulated spine phantoms does adequately cross-

calibrate densitometers for soft tissue body composition measurement. Moreover using the Bioclinica Body composition phantom with GE Lunar iDXA instrument, these authors conclude that in vivo cross calibration is needed to ensure comparable body composition results. **Nevertheless, these results** are limited to GE Lunar iDXA instruments and BBCP. In this present study, we used Hologic instruments with a Hologic whole body phantom.

They state that a single data point for lean and fat mass generated by the phantom, such as BBCP, close to the in vivo mass range, might be suitable for densitometer cross-calibration if the mass measures spanned a clinically relevant range.

We have showed that the use of corrective factors could be deducted from an easy available whole body phantom segmented in different sub-regions giving sufficient clinical range at different tissue thicknesses in order to represent in-vivo variations. The limit of our study is that, from a clinical-point of view, the whole body phantom is only a representation of a human body and therefore does not represent human full variability. The differences observed in vitro should be validated in-vivo.

aBMD and DXA body composition imaging are now widely used to clinically evaluate the efficacy of new medications targeting bone and muscle diseases [5,23,24]. The measurement by DXA also allows to study the relationships between body composition (fat mass, lean mass) and BMD both at the whole body level and at specific bone sites [25].

This work underline the attention to pay to the homogeneity of the data in case of multicenter studies. Inter center precision of whole body composition DXA measurements is poor, **and cross calibration mandatory, even when densitometers of the same manufacturer are used.** We have found that it is possible to calculate corrective factors from sub-regions of a whole body phantom **to improve feasibility** in conducting multicenter studies.

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Table 1

Mean of the daily values of the respective "lumbar spine" phantom of each center from 17.11. 2016 to 17.11.2017.

	Center A	Center B	Center C
L1-L4 BMD (g/cm ²)			
Mean ± SD	0.99± 0.006	0.98± 0.003	1.013± 0.005
CV %	0.6	0.3	0.4

BMD: bone mineral density; SD: standard deviation; CV: coefficient of variation

Table 2

Variability of the BMD, BMC and body composition assessed by the whole body phantom between the different centers (n= 10)

		Center A	Center B	Center C	P*	All centers
		n=10	n=10	n=10		n=30
BMD (g/cm ²)	Mean	1.06 ^{b,c}	1.24 ^{a,c}	1.12 ^{a,b}	<0.01	8.18
	SD	0.02	0.02	0.01		
	CV intra-center (%)	1.88	1.61	0.89		
	CV inter-center (%)					
BMC (g)	Mean	729.16 ^{b,c}	723.90 ^{a,c}	689.32 ^{a,b}	<0.01	3.03
	SD	4.11	12.47	4.97		
	CV intra-center (%)	0.57	1.72	0.72		
	CV inter-center (%)					
Area (cm ²)	Mean	689.00 ^{b,c}	582.03 ^{a,c}	618.55 ^{a,b}	<0.01	8.63
	SD	13.10	8.74	6.81		
	CV intra-center (%)	1.90	1.5	1.10		
	CV inter-center (%)					
Fat Mass (g)	Mean	12681.38 ^{b,c}	13543.91 ^{a,c}	13618.30 ^{a,b}	<0.01	3.92
	SD	162.08	135.48	52.39		
	CV intra-center (%)	1.27	1.00	0.38		
	CV inter-center (%)					
Lean Mass (g)	Mean	17019.85 ^{b,c}	14547.02 ^{a,c}	15597.41 ^{a,b}	<0.01	7.89
	SD	158.15	129.42	74.13		
	CV intra-center (%)	0.92	0.88	0.47		
	CV inter-center (%)					
Total Mass (g)	Mean	29701.24 ^{b,c}	28090.93 ^{a,c}	29215.72 ^{a,b}	<0.01	2.85
	SD	34.97	19.49	50.37		
	CV intra-center (%)	0.11	0.06	0.17		
	CV inter-center (%)					

BMD: Bone Mineral Density; BMC: Bone Mineral Content; CV: coefficient of variation; SD: standard deviation; * Kruskal and Wallis test. Orleans versus Lille (a); Orleans versus Lyon (b), Lille versus Lyon (c); Mann and Whitney U-Test : p ≤0.01.

Figure 1:

Description of the whole body phantom (Hologic®, USA, Bedford, M)

Figure 2:

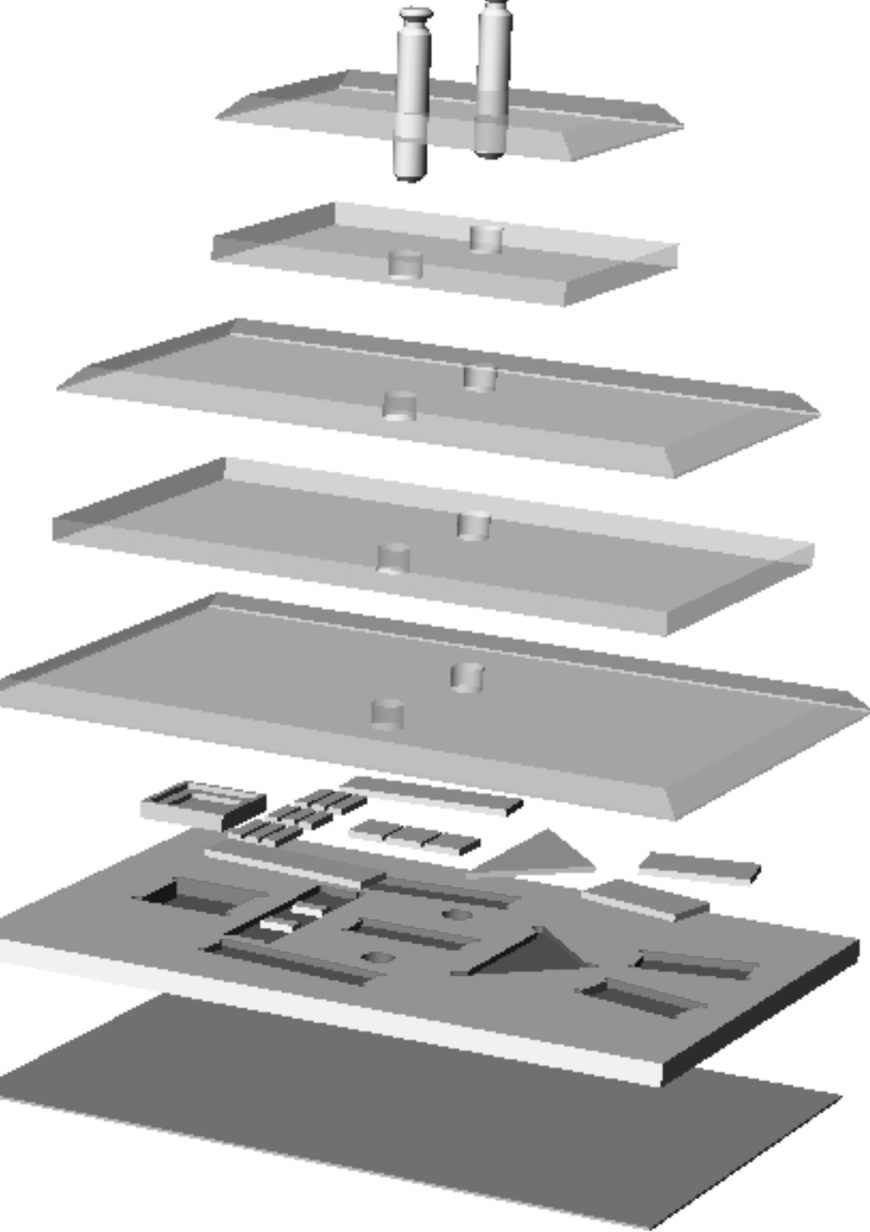
Sub-regions of the whole body phantom: 1 total whole body; 2 whole body without head; 3 Trunk; 4 Head; 5 right leg; 6 left leg.

Figure 3:

Regression of the accuracy (%) according to the density (g/cm²) estimated on a three blocks hydroxyapatite phantom.

Figure 4:

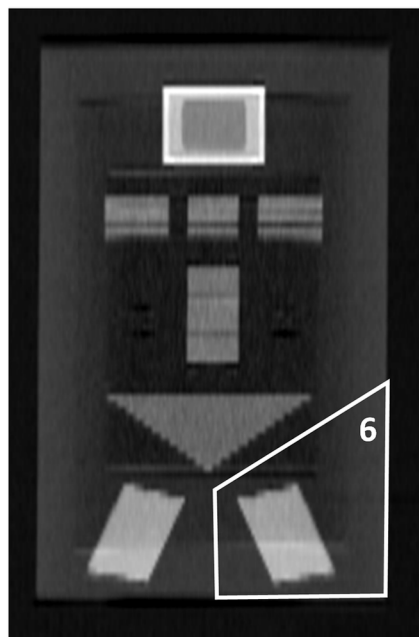
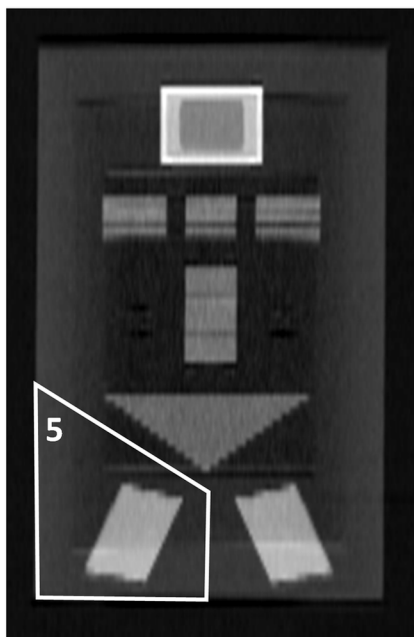
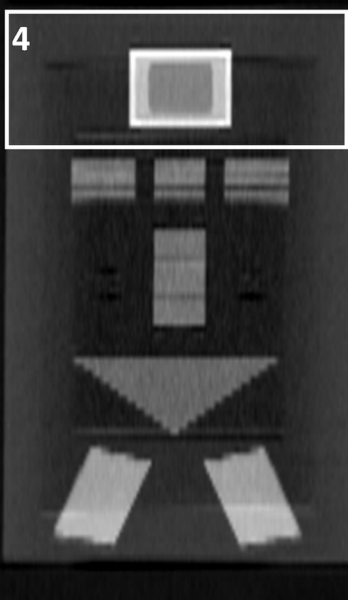
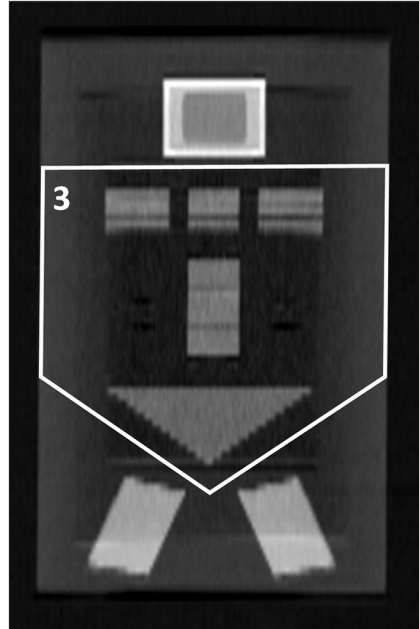
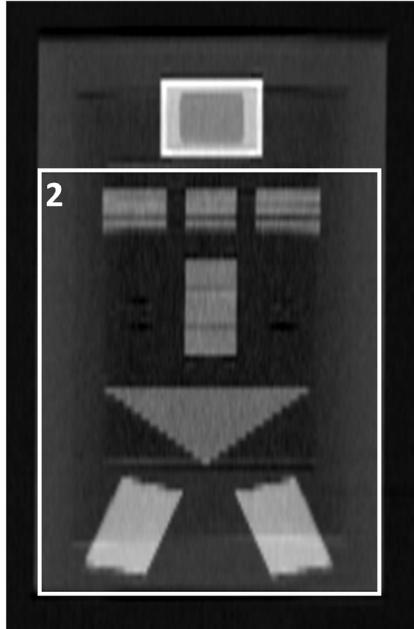
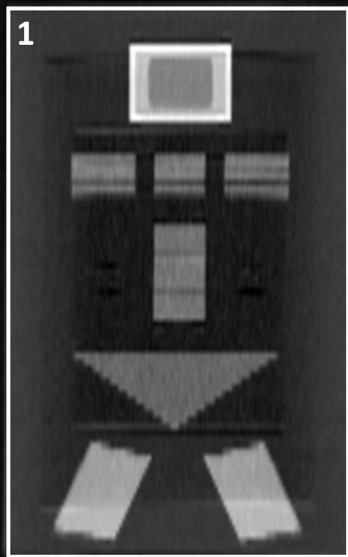
Cross-calibration equations, **obtained by single linear regression**, for the three centers calculated from the whole body sub-regions BMD, lean and fat mass measurements, to determine the corrective factors.

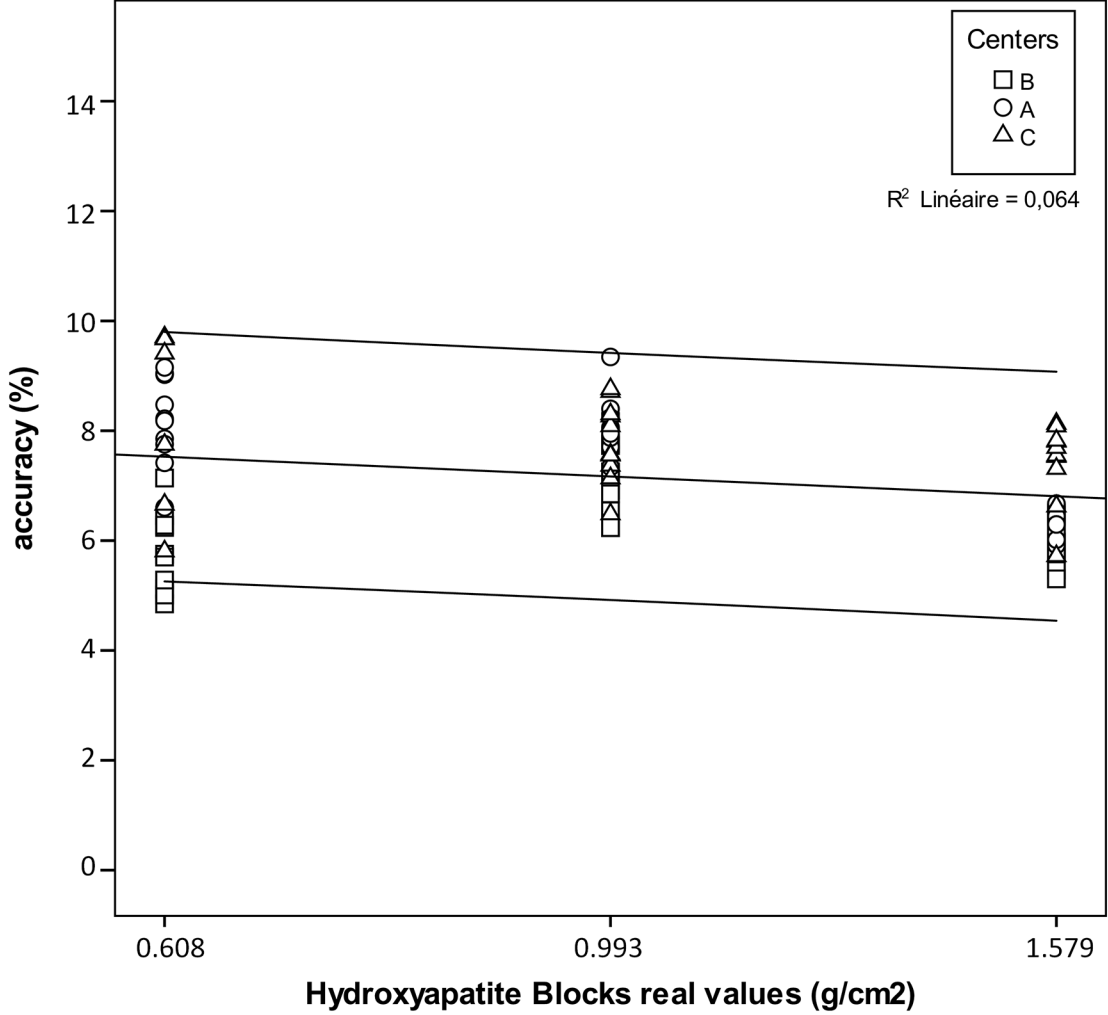


Fat Tissue

Bone Tissue

Lean Tissue





FAT (g)**LEAN (g)****BMD (g)**