HHS Public Access

Author manuscript

J Clin Densitom. Author manuscript; available in PMC 2017 April 01.

Published in final edited form as:

J Clin Densitom. 2016 April ; 19(2): 220–225. doi:10.1016/j.jocd.2015.04.003.

A DXA Whole Body Composition Cross-Calibration Experience: Evaluation with Humans, Spine and Whole Body Phantoms

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Abstract

New densitometer installation requires cross-calibration for accurate longitudinal assessment. When replacing a unit with the same model, ISCD recommends cross-calibrating by scanning phantoms 10 times on each instrument and states spine BMD should be within 1%, while total body lean, fat and %fat mass should be within 2% of the prior instrument. However, there is limited validation that these recommendations provide adequate total body cross-calibration. Here we report a total body cross-calibration experience with phantoms and humans.

Cross-calibration between an existing and new Lunar iDXA was performed using three encapsulated spine phantoms (GE-Lunar, BioClinica and Hologic), one total body composition phantom (BioClinica) and 30 human volunteers. Thirty scans of each phantom and a total body scan of human volunteers were obtained on each instrument.

All spine phantom BMD means were similar (within 1%; < −0.010 g/cm^2 bias) between the existing and new DXA unit. The BioClinica Body Composition Phantom (BBCP) BMD and BMC values were within 2% with biases of 0.005 g/cm^2 and −3.4g. However, lean and fat mass and %fat differed by 4.6 to 7.7% with biases of +463g, −496g and − 2.8%, respectively. *In vivo* comparison supported BBCP data; BMD and BMC were within ~2% but lean and fat mass and %fat differed from 1.6 to 4.9% with biases of +833g, −860g and −1.1%. As all body composition comparisons exceeded the recommended 2%, the new densitometer was recalibrated. Following recalibration, *in vivo* bias was lower (<0.05%) for lean and fat; −23g and −5g. Similarly, BBCP lean and fat agreement improved.

In conclusion, the BBCP behaves similarly, but not identical, to human *in vivo* measurements for densitometer cross-calibration. Spine phantoms, despite good BMD and BMC agreement, did not detect substantial lean and fat differences observed using BBCP and *in vivo* assessments. Consequently, spine phantoms are inadequate for DXA whole body composition cross-calibration.

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Keywords

dual-energy x-ray absorptiometry; cross-calibration; whole body phantom; spine phantom; in vivo

INTRODUCTION

The need to cross-calibrate replacement DXA scanners is well recognized (1). More recently, the ISCD has published Official Positions describing recommendations for cross-calibration of DXA systems used for body composition (2) which are as follows:

- When changing hardware, but not the entire system, or when replacing a system with the same technology (make and model), cross-calibration should be performed by having one technologist scan one phantom 10 times, with repositioning, before and after hardware change.
- If a greater than 1% difference in mean BMD is observed, contact the manufacturer for service/correction.
- If a greater than 2% difference in mean percent fat, fat mass or lean mass is observed, contact the manufacturer for service/correction.

However, there are only limited data validating this approach in practice. Moreover, as total body composition phantoms are not widely available, it is logical to assess if it is possible to utilize the much more widely available spine phantoms for this purpose.

Phantoms are at best “patient mimics,” and have constraints (3). For example, it is logical that the ideal body composition phantom, would be designed along the lines of the Hologic Total Body phantom which is the size of a human but therefore is large, heavy, costly to ship, and cumbersome for the operator to use (4), thus making it less than ideal in both the clinical setting and clinical trials. For the latter a semi-portable phantom is required that, preferably, can be carried and used by a single operator. The BioClinica Body Composition Phantom (BBCP), (BioClinica Inc, Princeton, NJ) is a design compromise between size and weight, to allow reasonably easy transit and the criteria of being managed by a single operator versus being anthropomorphically correct. Importantly, the BBCP can be scanned and analyzed using all major DXA platforms, thus making it suitable for multicenter clinical trials. To the authors knowledge this is the first publication evaluating this new body composition phantom.

Here, cross-calibration of a new DXA scanner of the same manufacturer and model as an existing (GE Lunar iDXA) unit is presented. The underpinning concept is that human *in vivo* measurements constitute the gold standard for densitometer cross-calibration and that spine phantoms would be less representative of fat and lean mass than either a total body phantom or human *in vivo* total body measurements. Additionally, we evaluated whether the BBCP has the potential to replicate human *in vivo* data for this purpose.

METHODS

Study design

Division 1 athletes were being longitudinally scanned on a GE Healthcare Lunar (Madison, WI) iDXA densitometer for body composition assessments to facilitate athletic training and injury rehabilitation. As a new iDXA densitometer was acquired, future scanning of this cohort was transferred to this new instrument. Consequently, it was recognized that cross-calibration for body composition measurement was required for accurate longitudinal assessment. To this end, phantoms and healthy volunteers were scanned on these two iDXA instruments. All scans were acquired and analyzed with enCORE software; version 13.31 for the existing scanner and version 14.1 for the new scanner. Thirty human volunteers were scanned on both instruments on the same day over a 36-day timespan. This exercise was categorized as a quality assurance activity and consequently determined IRB exempt by the University of Wisconsin Health Sciences Human Subjects Committee.

Phantoms

Three DXA spine phantoms and one prototype body composition phantom, detailed below, were measured thirty times on each densitometer without repositioning five days after the last human scans were obtained. These encapsulated spine phantoms were: 1. Lunar spine phantom, (GE Lunar, Madison WI); 2. Hologic Spine phantom, (Hologic Inc. Bedford MA) and 3. Bone Fide Phantom (BFP) (BioClinica, Princeton, NJ), see Figure 1. These three phantoms are of similar size and weight but have some characteristic differences. The Lunar phantom has an aluminum bar embedded in acrylic representing approximately 35% fat. The bar is straight edged, but each vertebra provides a different density value. The Hologic spine phantom is a true anthropomorphic phantom that mimics human spine anatomy, however, each vertebral body has similar densities. The insert is made of calcium hydroxyapatite, and the clear acrylic surround is hyper-physiological, being around 60% fat. The BFP is a shaped calcium hydroxyapatite bar with 4 “vertebrae,” each one of separate density and size. The acrylic is a two-phase mixture that provides a normal physiological soft-tissue of approximately 24%. The BFP is the only phantom that has been shown to match subject data for spine BMD by linear regression (5,6).

A prototype total body phantom, the BioClinica Body Composition Phantom (BBCP), (Figure 2) was also scanned. This phantom measures 60 cm in length, 36 cm in width, 9 cm in height and weighs approximately 16 kg and therefore does not replicate the adult human body mass or size. However, the phantom does replicate human body composition proportionally in that it contains high-density polyethylene, polyvinyl chloride and an aperture of aluminum to simulate different human soft tissue and bone compositions.

Participants

Thirty adult volunteers (15 male/15 female) were scanned once on each densitometer. Their mean (SD) age was 31.1 (10.8), range 20-60 years; and mean (SD) BMI was 24.1 (2.8), range 19.7-30.7 kg/m^2. The entire body of all volunteers was contained within the scan field and positioning was per ISCD recommendations, i.e. NHANES style.(2) Both scans in each

individual were obtained on the two scanners within 60 minutes and food ingestion and voiding were prohibited between scans.

Statistical Analysis

Agreement between the two densitometers was evaluated by linear regression and Bland-Altman analysis using Analyze-it software v2.3 (Leeds, UK).

RESULTS

Spine Phantoms

All three spine phantoms demonstrated a < 1% difference in L1-L4 mean BMD and BMC between the new and existing densitometer (Figure 3 and Table 1). The L1-L4 BMD mean biases between instruments were ≤ −0.010 g/cm^2 with each phantom (Table 1).

Total Body Phantom

The total body mean BMD and BMC were < 1% different between the existing and new densitometer using the BBCP (Table 1). Mean total body BMD and BMC bias was 0.005 g/cm^2 and 3.4 g respectively (Table 1). Total body mean lean and fat differed by 4.6% and 7.8% respective with corresponding mean biases of +463 g and −496 g (Figure 3a/b).

Human *In Vivo* Measurement

The total body lean and fat mass initially differed by 1.6% and 4.2% between the two densitometers with respective biases of +833 g and −860 g (Figure 3c-d and Table 1). As the total body fat value difference between instruments exceeded the recommended 2%, the manufacturer was contacted and the new densitometer was recalibrated to improve lean and fat mass agreement with the existing scanner. No adjustment was made to BMC or bone area.

Post Recalibration Analysis

Following manufacturer recalibration, re-analysis of the human *in vivo* scans revealed lower bias for lean and fat down to a mean difference of −23 g and −5 g respectively (Figures 4a/b & Table 2) thereby decreasing the between-scanner difference to < 0.05%. Similarly, agreement of the body composition phantom lean and fat improved, although still exceeded the ISCD recommendation of <2% difference in body composition in that, despite recalibration, the BBCP biases for lean and fat were reduced to 265 g (2.5%) and −298 g (−4.8%) respectively. As spine BMD did not differ between instruments and the intended use of this instrument was soft tissue body composition assessment, BMD was not recalibrated and therefore the spine phantom re-analysis was not performed.

DISCUSSION

In this study, the ISCD recommendations (1,2) for body composition cross-calibration when replacing a densitometer were implemented. To the authors' knowledge, this study is the first to compare data from spine phantoms and a total body phantom, with in vivo cross-calibration. Although spine phantoms are commonly used due to their wide accessibility,

these data demonstrate that using of any of these three encapsulated spine phantoms does not adequately cross calibrate densitometers for body composition measurement. Importantly, even though the L1-L4 mean BMD differed by <1%, thus meeting the ISCD recommendations, spine phantom data did not detect the need for manufacturer recalibration for total body fat and lean mass measurement. This is not surprising given that spine phantoms are designed to mimic spine BMD, not total body fat/lean mass and moreover are not representative of total body size. This study suggests that human *in vivo* measurement is necessary for optimal total body DXA cross-calibration despite the same make and model densitometer. Utilization of these *in vivo* data demonstrated a need for manufacturer recalibration, which resulted in total body fat and lean mass measurements that were virtually identical between the two instruments in the *in vivo* sample, differing by much less than the recommended 2%.

The ISCD also recommends cross-calibration using an adequate total body phantom for lean and fat measurement before and after hardware change of the same make and model instrument.(2) Although there are limited data regarding cross-calibration for body composition with phantoms, to our knowledge, none of the existing studies were compared with *in vivo* cross-calibration.(7,8) Indeed, the ISCD Position Development Conference noted that additional research was needed to evaluate the link between in vivo cross-calibration and phantom measurements.(2) The data presented here are the first to compare phantom and in vivo evaluation for body composition cross-calibration assessment. In this study, data from the BioClinica prototype total body phantom were similar, but not identical to, the *in vivo* results in that fat and lean mass differences still exceeded 2% following instrument recalibration while the *in vivo* data were virtually identical. While not reaching the recommended level of agreement, it is notable that recalibration did substantially improve between scanner phantom agreement. To summarize, these data demonstrate that body composition results of this prototype BBCP body composition behaved similar to, but did not perfectly replicate, human data. It is noteworthy that this prototype phantom is designed to replicate percent fat of the average human, not the relatively low body fat proportion observed in this population (24%) which was selected to be similar to athletes, (~20% at UW).

It is possible that phantoms do not reproduce human *in vivo* results because current total body phantoms do not allow measurement of various mass ranges such as are generated with *in vivo* sampling. The fact that the single data point for lean and fat mass generated by this phantom are close to the *in vivo* regression lines, does suggests that phantoms, such as the BBCP, might be suitable for densitometer cross-calibration if the mass measured spanned a clinically relevant range. Emphasizing this important point, the ISCD Position paper states “An adequate phantom for scanner cross-calibration would have to show a similar range of relevant values as the patient cohort of interest.” (2) Further evaluation of phantoms that can be configured to a variety of mass and composition seems indicated and are in development. To this end, the results from this phantom are encouraging and provide support for the further development of the BBCP.

It is worthy of comment that two versions of software were utilized between the existing and new instruments. As new instruments are installed with the most current software, cross

calibration between existing and new instruments will routinely occur using different software versions, consequently, this approach replicates a true clinical environment. One could postulate this would contribute to the bias as there can be measurement differences between software versions, however, recalibration of the new instrument, if needed, will address this off-set should it exist.

Limitations of the study include use of only a single total body phantom, that this phantom was a prototype, and that only a single make and model of densitometer was evaluated. The ability to evaluate other commercially available whole body phantoms would have been a substantial advantage. However, to our knowledge, such comparisons do not exist. Whether these findings would apply to other comparisons of like-model densitometers is not known. It is worthy of note that this study, and the ISCD recommendations cited in the introduction, apply to cross-calibration of the same make and model of densitometer. As DXA technology differs between manufacturers, ISCD does recommend *in vivo* cross-calibration when evaluating instruments for densitometers from different manufacturers.(2) Finally, as the *in vivo* sample used in this trial was a relatively young and non-obese group, these data might not be replicated using other populations. However, the sample in this exercise was selected, as it closely resembled the population that will be scanned on these instruments.

In conclusion, standard spine phantoms are inadequate for densitometer cross calibration for total body fat and lean measurements. Additionally, when replacing DXA scanners for the purpose of total body composition assessment, even with the same make and model instrument, *in vivo* cross-calibration is needed at this time to ensure comparable body composition results.

References

1. Baim S, Binkley N, Bilezikian JP, et al. Official positions of the International Society for Clinical Densitometry and Executive summary of the 2007 ISCD position development conference. J. Clin. Densitom. 2008; 11:75–91. [PubMed: 18442754]
2. Hangartner TN, Warner S, Braillon P, Jankowski L, Shepherd J. The Official Positions of the International Society for Clinical Densitometry: acquisition of dual-energy X-ray absorptiometry body composition and considerations regarding analysis and repeatability of measures. J. Clin. Densitom. 2013; 16(4):520–36. [PubMed: 24183641]
3. Miller, CG. Organization of the clinical trial by the sponsor.. In: Pearson, D.; Miller, CG., editors. Clinical Trials in Osteoporosis. Second ed.. Springer-Verlag; London: 2007. p. 75-90.
4. Anonymous. 2011-2012 Body Composition Procedures Manual National Health and Nutrition Examination Survey (NHANES). CDC; Atlanta, GA: p. 6-27-6-30.
5. Pearson D, Cawte SA, Green DJ. A comparison of phantoms for cross-calibration of lumbar spine DXA. Osteoporos. Int. 2002; 13:948–954. [PubMed: 12459937]
6. Pearson, D. Standardization and pre-trial quality control.. In: Pearson, D.; Miller, CG., editors. Clinical Trials in Osteoporosis. Springer; New York: 2002. p. 43-65.
7. Guo Y, Franks PW, Brookshire T, Antonio Tataranni P. The intra- and inter-instrument reliability of DXA based on ex vivo soft tissue measurements. Obes. Res. 2004; 12(12):1925–9. [PubMed: 15687392]
8. Diessel E, Fuerst T, Njeh CF, et al. Evaluation of a new body composition phantom for quality control and cross-calibration of DXA devices. J. Appl. Physiol. 2000; 89(2):599–605. [PubMed: 10926643]

Figure 1. Encapsulated spine phantoms

Three spine phantoms were evaluated for cross-calibration, A. GE Lunar (Madison, WI), B. Hologic (Bedford,MA) and C. BioClinica Bona Fide Phantom (Princeton, NJ)

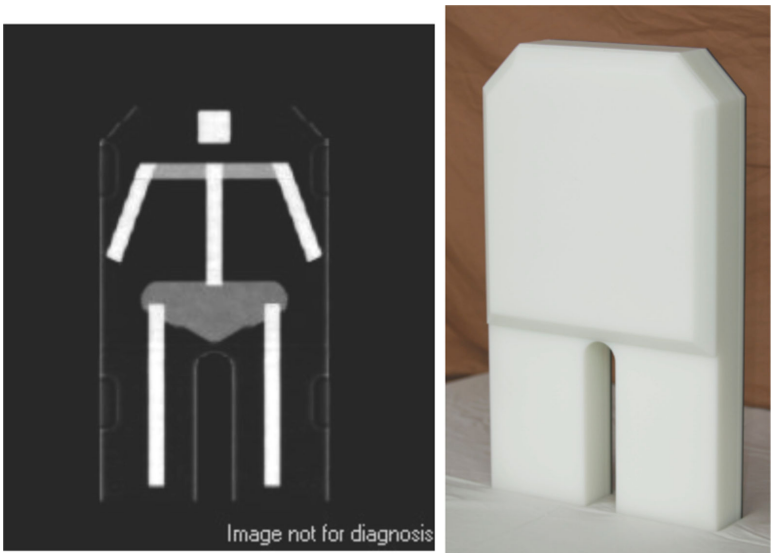
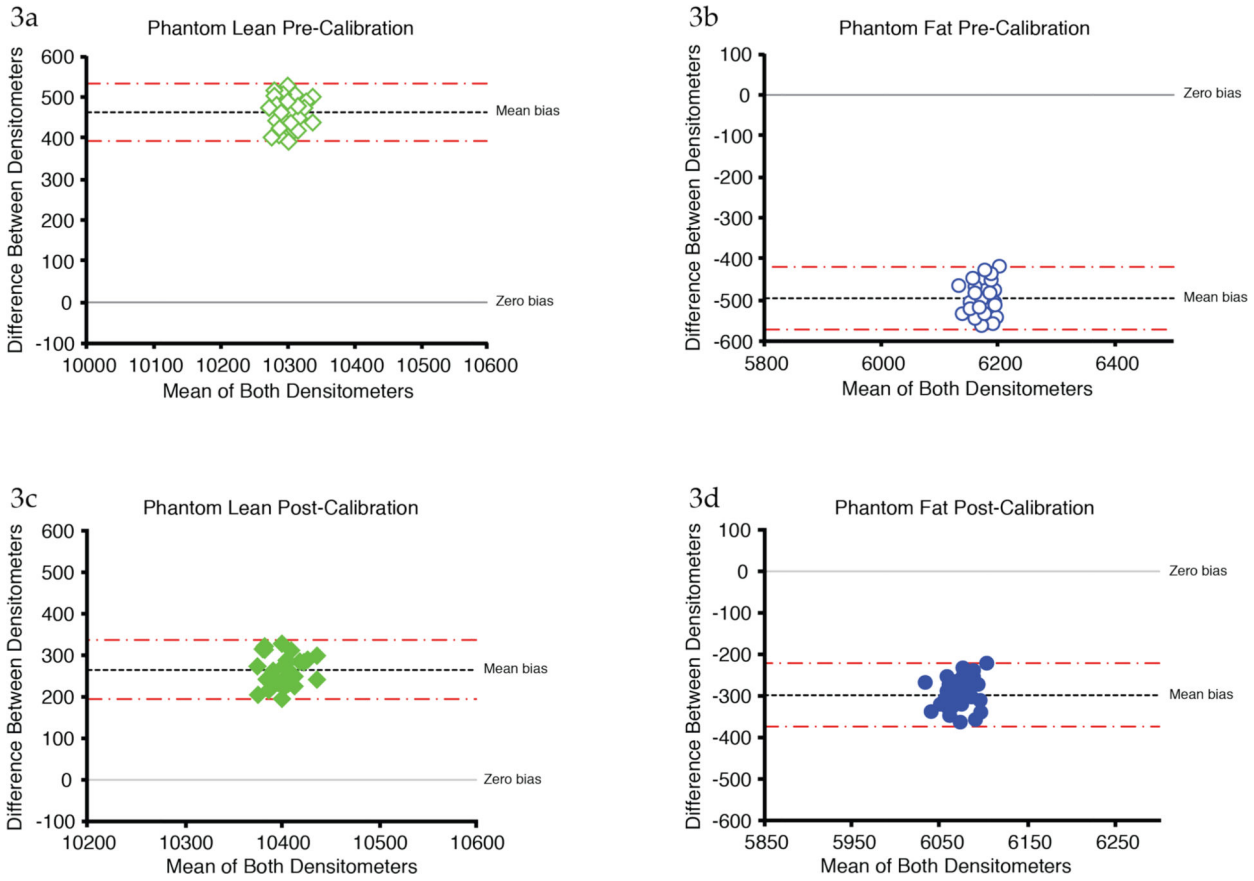


Figure 2. Body Composition Phantom

BioClinica Body Composition Phantom Prototype (BBCP). Whole body phantom designed to emulate bone, lean and fat mass for the purpose of monitoring DXA scanners for body composition. The phantom measures 60 × 36 × 9 cm and weighs ~16 kg.



Figures 3. a-d: Bland-Altman Plots of Lean and Fat BioClinica Body Composition Phantom Data Before and After Recalibration

Lean and fat differed between instruments by 4.6% & 7.8% with biases of +463 g & −496 g (3a-b). After recalibration, instrument agreement improved to 2.6% for lean and 4.8% in fat, with biases of +265 g and −298 g respectively (3c-d).

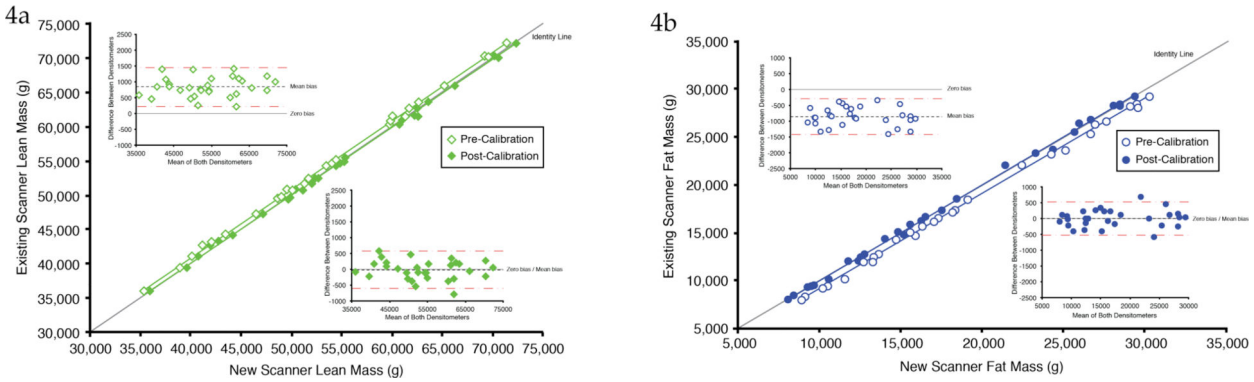


Figure 4. a-b: Lean and Fat In Vivo Data Before and After Recalibration

Figure 4a depicts the total body lean mass agreement as assessed by linear regression and Bland-Altman plots prior to (open circles) and following densitometer re-calibration (closed circles). Figure 4b depicts the same evaluations for total body fat mass prior to (open diamonds) and following recalibration (closed symbols). Pre-recalibration the regression equations were y = 1.0037x + 637.37 for lean and y = 0.9953x – 774.61 for fat. Following re-calibration the regression equations were y = 0.9948x = 259.91 and y = 1.0034x – 64.702 respectively. There was a change in the slope and bias of 0.009 and 855.6 g respectively in lean and −0.008 and −855.6 g respectively in fat.

Table 1

d Comparisons on the Existing and New Instrument

L1-L4		BonaFide Phantom (BFP) L1-L4			Hologic Phantom L1-L4			Bioclinica Body Composition Phantom (BBCP) Total Body			Human *In Vivo* Total Body		
New Unit Mean		Bias	Existing Unit Mean	New Unit Mean	Bias	Existing Unit Mean	New Unit Mean	Bias	Existing Unit Mean	New Unit Mean	Bias	Existing Unit Mean	New Unit Mean
1.195		−0.008	1.070	1.079	−0.003	1.105	1.108	0.005	1.081	1.086	0.026	1.250	1.276
51.04		0.269	44.77	44.51	0.512	52.46	51.95	0.067	497.6	497.7	−11.3	2432	2420
61.00		0.085	47.92	48.00	0.425	57.99	57.56	−3.367	537.7	541.1	−50.9	3051	3102
-		-	-	-	-	-	-	462.9	10534	10071	832.9	54230	53397
-		-	-	-	-	-	-	−496.4	5924	6420	−860.2	17507	18267
-		-	-	-	-	-	-	−2.84	34.9	37.7	−1.14	23.4	24.6

Table 2

BBCP Phantom and Human Comparisons on the Existing and New Instrument Post Recalibration

	BBCP After Recalibration			Human *In Vivo* After Recalibration		
	Bias	**Existing Mean**	**New Mean**	**Bias**	**Existing Mean**	**New Mean**
Lean (g)	264.7	10534	10269	−22.7	54230	54252
Fat (g)	−298.1	5924	6222	−4.6	17507	17512
%Fat (%)	−1.675	34.9	36.53	0.98	23.4	23.4