Original Article

A cross-calibration study using a novel dual X-ray absorptiometry system for bone mineral density measurements with the European Spine Phantom

Yaojun Jiang, Yan Wu, Yonggao Zhang, Xiaopeng Yang, Jianbo Gao

Department of Radiology, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China

Contributions: (I) Conception and design: Y Jiang; (II) Administrative support: J Gao; (III) Provision of study materials or patients: Y Jiang; (IV) Collection and assembly of data: Y Jiang, Y Wu, Y Zhang, X Yang; (V) Data analysis and interpretation: Y Jiang; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Jianbo Gao. Department of Radiology, The First Affiliated Hospital of Zhengzhou University, No. 1 Jianshe East Road, Zhengzhou 450052, China. Email: cjr.gaojianbo@vip.163.com.

Background: For bone health assessment, dual-energy X-ray absorptiometry (DEXA) is recommended to measure bone mineral content and areal bone mineral density (aBMD) in the lumbar spine. However, intermachine differences were not taken into account when developing these recommendations. According to the International Society of Clinical Densitometry (ISCD), phantom-based cross-calibration is adequate after replacing the DEXA system from a different manufacturer. For different DEXA equipment, individual calibration equations were found to be necessary to fit the observed values with the given densities.

Methods: The BMD European Spine Phantom (ESP) measurements (L1, L2, and L3) were assessed on 3 machines. We used the Welch test in the one-way analysis of variance (ANOVA) with a *post-hoc* Tamhane T2 test, linear regressions, and Bland-Altman analysis to assess the consistency of measurements and establish cross-calibration equations.

Results: The coefficients of variation (CV)% of the phantom BMD values measured using the 3 systems were less than 3.0%. The 3 DEXA systems were highly correlated with BMD in the lumbar spine, with correlation values ranging from 0.933 to 0.984 (P<0.0001). The cross-calibration regression models of the ESP measurements yielded the highest prediction accuracies with the lowest prediction errors (the standard error of the estimate ranged from 0.004 to 0.008 g/cm^2; P<0.0001). After the regression equations were applied, the differences in BMD values among the 3 systems were negligible. In addition, the Bland-Altman plot showed that almost all data points were within the 95% limits of agreement.

Conclusions: A strong agreement for BMD measurement was established between the 3 DEXA systems. Cross-calibration equations for the lumbar spine BMD values need to be applied to transform the Hologic Discovery A or GE Lunar iDXA measurements into SONIALVISION SMIT measurements to comply with the ISCD standards for patient continuity of care in assessment during clinical diagnosis.

Keywords: Areal bone mineral density (aBMD); European Spine Phantom (ESP); novel dual-energy X-ray absorptiometry; cross-calibration

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Introduction

Osteoporosis is one of the most common bone metabolism diseases. It is associated with decreased bone mass and trabecular thinning, which leads to increased bone fragility and gradually resulting in bone fractures (1-4). Zeng *et al.* (5) reported an osteoporosis prevalence of 29.1% in older women and 6.5% in older men aged >50 years, equating to an estimated population-wide prevalence of 49.3 million and 10.9 million people, respectively. The fragility fracture is the major complication of osteoporosis and is responsible for increased morbidity, mortality, and medical costs. Detecting changes in bone density early and accurately is particularly critical. Dual-energy X-ray absorptiometry (DEXA) is the most commonly used equipment to measure bone mineral density (BMD) for identifying the risk of osteoporosis (6). For DEXA, short-term precision (CV%) and phantom-based accuracy studies are among the most important routine quality control (QC) procedures (7). Furthermore, compared with quantitative computed tomography (CT), DEXA has a low radiation dose and is readily available (3,8-11).

The SONIALVISION SMIT is a fluoroscopic imaging system capable of DEXA using the smart BMD application. Compared to other DEXA implements, the SONIALVISION SMIT includes several notable updates (12). First, this DEXA apparatus contains a novel reference database (Japanese women) that is different from the young adult (age 20–39 years) BMD values for Chinese and White US populations at the spinal and femur skeletal sites. Second, the movement of the examination table and the tube can be adjusted by the console and the buttons beside the examination table so that it can be set quickly to the starting position of the bone densitometer. Furthermore, it is possible to perform simpler and more reproducible positioning by confirming the imaging range using the field light and the low-dose fluoroscopy function. Finally, due to the short scanning time of only about 10 seconds, the risk of patient movement is low, reducing the need for repeated scans.

Significant differences have been observed in bone density measurements achieved using densitometers from different vendors compared to when using different models from the same vendor. Hence, the International Society for Clinical Densitometry (ISCD) recommends that any hardware upgrade or replacement of an old DEXA system by the same or different vendor should be preceded by cross-calibration of the DEXA, especially for implementations of the DEXA systems such as the SONIALVISION SMIT.

It is well known that the clinical routine includes calibration of the DEXA systems only with a manufacturer's phantom for daily QC, making it necessary to verify the reliability of BMD measurements in human participants. In this study, we carried out cross-calibration between the SMIT, Discovery A, and Lunar iDXA for BMD measurements of an anthropomorphic European Spine Phantom (ESP) (4,13). Furthermore, we transformed BMD measurements made with the Discovery A and Lunar iDXA to SMIT measurements to allow for consistent assessment of bone density across the DEXA measurement systems.

In this study, BMD measurement with SONIALVISION SMIT has shown good short-term precision in the lumbar spine. Compared with the Discovery A or iDXA, small but significant differences in BMD have been observed at the lumbar spine, and cross-calibration equations may be required for the spine. This suggests that a follow-up study should be performed using novel DEXA equipment because of the longitudinal stability over time of the SMIT, or an investigation into interoperator measurement precision with increased experience using the SMIT should be conducted. Therefore, this study aimed to establish cross-calibration equations and verify the SONIALVISION SMIT via the cross-calibration of different DEXA scans.

Methods

Phantom

An anthropomorphic ESP (QRM GmbH, Möhrendorf, Germany) consists of water-equivalent resin containing 3 vertebral inserts with different BMD quantities. The BMD was defined as the amount of calcium hydroxyapatite (HA) per volume unit of bone. When measured on DEXA, these lumbar spine vertebral inserts (L1–3) represent an areal bone mineral density (aBMD) of 0.5 (osteoporosis), 1.0 (osteopenia), and 1.5 g/cm^2 (normal bone mass) HA (14). The International DEXA Standardization Committee recommended the ESP as a possible standard for use in DEXA (15).

BMD measurement

The BMD measurements using Smart BMD software (version 01.13.03; Shimadzu, Kyoto, Japan) of the SONIALVISION SMIT system (Shimadzu, Kyoto, Japan), the Discovery A Pencil Beam DEXA scanner (software version 13.5.3.3;

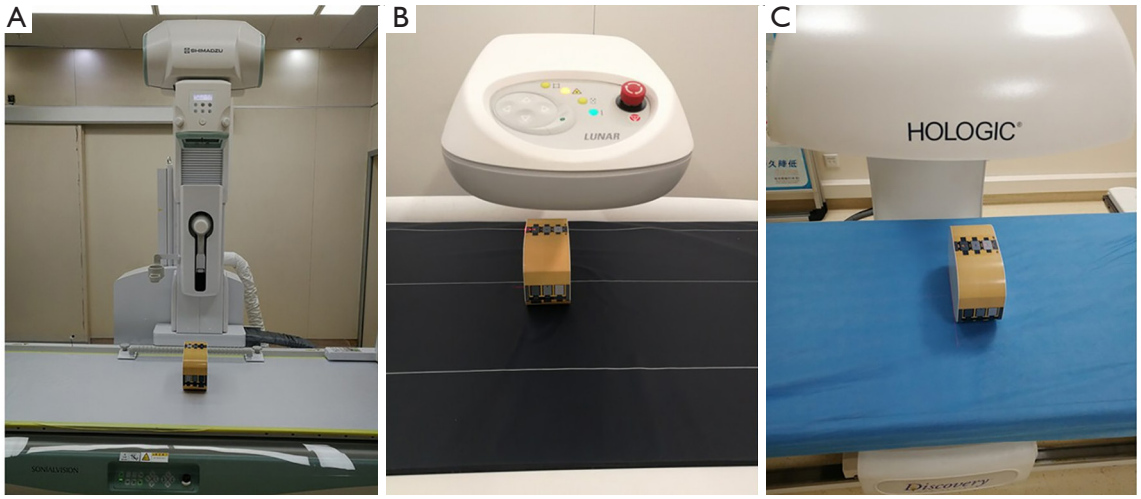

Figure 1 Phantom setup. An anthropomorphic European Spine Phantom on the equipment examination bed with the SMIT (left), Lunar iDXA (middle), and Discovery A (right). SMIT, SONIALVISION SMIT; iDXA, Lunar iDXA.

Hologic Inc., Bedford, MA, USA), and the Lunar iDXA Fan Beam DEXA scanner with a 64-channel detector (software version encore 16; GE Healthcare, Chicago, IL, USA). All scans were performed by the same operator to decrease the potential introduction of interoperator differences.

Imaging protocols

The 3 DEXA scanners used a linear X-ray fan beam with switched-pulse dual-energy (100/140 kVp) and a multielement detector array. The standard mode was used for measurements. The scan times were 10, 10, and 47 seconds with an exposure of 0.62, 0.04, and 0.146 mGy for the lumbar spine scans, respectively.

Study design

The ESP (ESP-145) was placed on the scanner table and aligned along the long axis of the table, as shown in *Figure 1*. To minimize the potential operator bias, all scans on the 3 devices were performed by the same examiner. ESP was carefully scanned 10 times with repositioning to calculate the short-term precision error [coefficients of variation, CV% = (SD/mean) ×100%] of the equipment. Linear regression equations were applied to cross-calibrate the Discovery A and iDXA to the SMIT in terms of the densitometric standards in the ESP with BMD value. This study was approved by the local institutional review board (No. 2021-KY-1222-002).

Image analysis

For analysis, a rectangular region of interest (ROI) was automatically drawn over each vertebral of ESP to segment the bone region and quantify the aBMD in g/cm^2. However, all BMD analyses were thoroughly checked for random measurement errors (i.e., ROI errors, metal artifacts, and misidentification of the vertebral body) and were manually corrected if needed. In this study, the QC procedures on the phantom were carried out according to the manufacturer's recommendations.

Statistical analysis

Data analysis was performed using GraphPad Prism version 8.0 for Windows (GraphPad Software Inc., La Jolla, CA, USA). The data were checked for normality using a Shapiro-Wilk test and are presented as the mean and SD. The Welch test in a one-way analysis of variance (ANOVA) with a *post-hoc* Tamhane T2 test was used to analyze the difference in ESP BMD measurements with the SMIT, Discovery A, and Lunar iDXA.

By constructing linear regression models around the ESP measurements by SMIT, Discovery A, and Lunar iDXA, we generated equations for BMD cross-calibration with each of the instruments. The statistical quality of the model was evaluated by the appropriate statistical term and standard error of the estimate (SEE). The multiple regression models were assessed using correlation (r) and SEE. A Bland-Altman analysis plotted the average of the 2 measurements

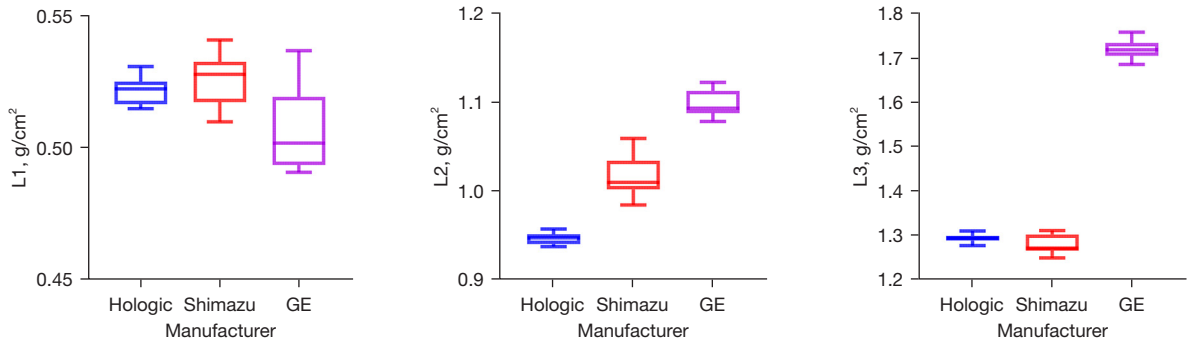

Figure 2 Boxplots showing the BMD measurements in L1, L2, and L3 between the Discovery A, SMIT, and Lunar iDXA. BMD, bone mineral density; SMIT, SONIALVISION SMIT; iDXA, Lunar iDXA.

Table 1 Repeated phantom measurements at L1–L3 (n=10), which were measured by the SMIT, Hologic Discovery A, and Lunar iDXA with the ESP phantom

Vertebra	BMD, ESP-145 (g/cm^2)	BMD		
		SMIT	Discovery A	Lunar iDXA
L1	0.5			
Mean (SD) (g/cm^2)		0.526 (0.010)[a]	0.522 (0.005)[a]	0.508 (0.015)[a]
CV%		1.901	0.958	0.958
L2	1.0			
Mean (SD) (g/cm^2)		1.016 (0.023)[b]	0.947 (0.007)[b]	1.098 (0.015)[b]
CV%		2.264	0.739	1.366
L3	1.5			
Mean (SD) (g/cm^2)		1.281 (0.021)[c]	1.295 (0.009)[c]	1.721 (0.022)[c]
CV%		1.639	0.695	1.278

[a,b,c], one-way ANOVA between the SMIT, Discovery A, and Lunar iDXA in the L1, L2, and L3, respectively (P<0.05). ANOVA, analysis of variance; SMIT, SONIALVISION SMIT; iDXA, Lunar iDXA; BMD, bone mineral density; ESP-145, European Spine Phantom no.1 45; SD, standard deviation; CV, coefficients of variation.

on the x-axis and the difference between them on the y-axis. To help identify statistical population trends, the mean and 95% confidence intervals (CIs) were overlaid on the plot. The Bland-Altman method was applied to evaluate the bias among the 3 devices. A two-tailed P value <0.05 was considered statistically significant.

Results

As shown in *Figure 2*, the boxplot analysis indicated that the data did not include any outliers. The data in each group followed a normal distribution according to the Shapiro-Wilk test (P>0.05). There were statistically significant differences in L1 (Welch F=4.896; P=0.023), L2 (Welch F=447.9; P<0.0001), and L3 (Welch F=1,621; P<0.0001) among the different devices. The ESP scans indicated that SMIT BMD value measured 0.8% higher (P=0.696), 7.2% higher (P<0.0001), and 1.1% lower (P=0.201) than did the Discovery A in L1, L2, and L3, respectively. The SMIT BMD value also measured 3.5% higher (P=0.019), 7.4% lower (P<0.0001), and 25.6% lower (P<0.0001) than did the Lunar iDXA in the L1, L2, and L3, respectively (*Table 1*). The CV% of the phantom BMD value was slightly higher when measured with the SMIT (1.901–2.264%) than with the Discovery A (0.695–0.958%) or Lunar iDXA (1.278–1.366%).

Table 2 Linear regression equations to cross-calibrate the Discovery A and iDXA to SMIT in terms of the densitometric standards in the ESP

Vertebra	Equation	r	SEE	P
L1	BMD SMIT =1.881 × Discovery A – 0.457	0.941	0.004	<0.0001
	BMD SMIT =0.604 × Lunar iDXA + 0.219	0.933	0.004	<0.0001
L2	BMD SMIT =3.276 × Discovery A – 2.087	0.948	0.008	<0.0001
	BMD SMIT =1.534 × Lunar iDXA – 0.668	0.984	0.004	<0.0001
L3	BMD SMIT =2.170 × Discovery A – 1.529	0.945	0.007	<0.0001
	BMD SMIT =0.906 × Lunar iDXA – 0.278	0.941	0.007	<0.0001

BMD, bone mineral density; SEE, standard error of the estimate; ESP, European Spine Phantom; SMIT, SONIALVISION SMIT; iDXA, Lunar iDXA.

As shown in *Table 2*, the cross-calibration equations indicated r ranging from 0.933 to 0.984 and SEE ranging from 0.004 to 0.008 for the L1-3 on the different devices (P<0.0001).

Bland-Altman analysis revealed good agreement between the SMIT and Discovery A or Lunar iDXA for BMD measurement at the L1-3 (*Figure 3*). Almost all data points were within the 95% limits of agreement of the ESP BMD measurements.

Discussion

The QC of BMD measurements is essential to maintaining consistency and mainly involves the inspection of equipment and assessment of the radiographer's expertise. The QC process of a device includes both the short-term daily QC and the long-term dynamic QC (16,17). Daily QC involves inspecting the device condition every day using the manufacturer's device-specified phantom. However, changes in the BMD value should be followed-up by a general phantom, such as the ESP. Zemel *et al.* (18) reported that most hospitals do not know where their machine falls within the range of intermachine variability, which may affect the diagnosis of bone-threatening conditions in patients. Based on the ESP BMD measurements, this paper highlighted the systematic differences between the SMIT, Discovery A, and Lunar iDXA devices (P<0.0001). Zemel *et al.* (18) reported that the coefficient of variation of aBMD values was 1.8% in different clinical centers. Patel *et al.* (19) reported that the CV% for different generations of Hologic scanners varied from 0.7% to 1.34% for the lumbar spine. Similar to the findings of a previous study (20), the CV% of the BMD value was slightly higher when measured with the SMIT (1.901–2.264%) than with the Discovery A (0.695–0.958%) and Lunar iDXA (0.278–1.366%). The ISCD recommends correction equations be used if the difference between 2 densitometers exceeds 1% (21). In this paper, the CV% of all BMD values with the SMIT were beyond 1% (1.901–2.264%); therefore, calibration should be carried out again to set the difference within 1%. Kim *et al.* (22) reported that the quantitative comparison of 3 devices should be carried out via cross-calibration. In this study, cross-calibration was carried out by a single radiologic technologist. This study aimed to establish cross-calibration equations and verify the SMIT by cross-calibration with different DEXA scans. The BMD of the ESP was measured using the existing (Discovery A and Lunar iDXA) and replaced (SMIT) devices 10 times each to obtain the mean BMD values.

Saarelainen *et al.* (20) reported that the iDXA showed higher values than did the Lunar Prodigy at high BMD values, whereas the opposite was found at low BMD values. Similar to a previous study, the iDXA-measured BMD values in L1, L2, and L3 were 3.5% (0.018 g/cm^2) lower, 7.4% (0.082 g/cm^2) higher, and 25.6% (0.44 g/cm^2) higher than those measured with the SMIT in this paper. Reid *et al.* (23) reported that Hologic scanners tended to underestimate the nominal BMD, while Lunar scanners overestimated this value. Similar to a previous study, the Discovery A-measured BMD values in the L1, L2, and L3 were 0.8% (0.004 g/cm^2) lower, 7.2% (0.069 g/cm^2) lower, and 1.1% (0.014 g/cm^2) higher than those measured using the SMIT in this paper. This study indicated that the SMIT and Discovery A tended to be lower at high BMD values compared to the Lunar iDXA. The ISCD recommends that phantom-based cross-calibration system from different devices is essential after replacement of the DEXA. To obtain more accurate measurements, individual calibration equations were derived for each machine in previous

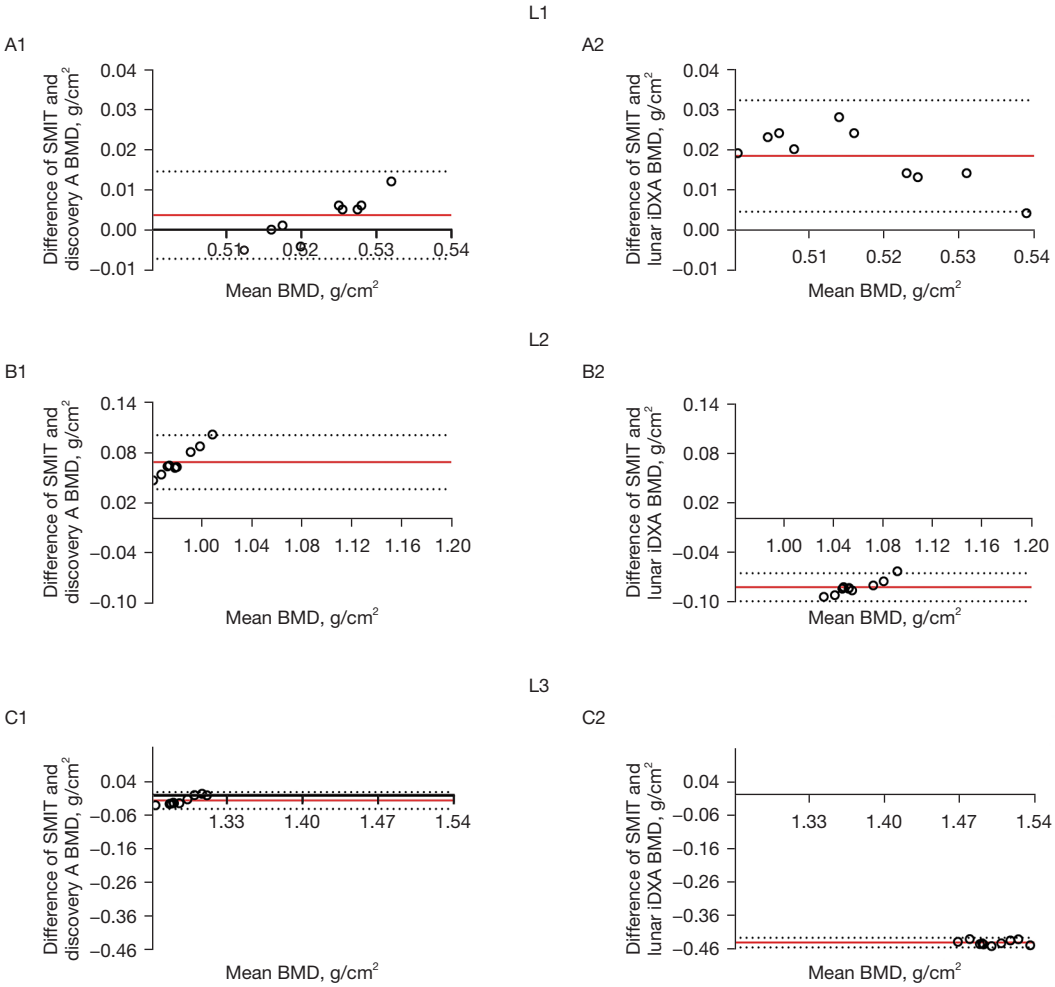

Figure 3 The mean difference (red solid line) and limits of agreement (dotted line) were used for the 95% limits of agreement of the Bland-Altman analysis in this study. (A1, B1, C1) Bland-Altman plots display the comparison of the BMD measurements in the L1, L2, and L3 between the SMIT and Discovery A. (A2, B2, C2) Bland-Altman plots show the comparison of the BMD measurements in the L1, L2, and L3 between the SMIT and Lunar iDXA. BMD, bone mineral density; SMIT, SONIALVISION SMIT; iDXA, Lunar iDXA.

studies (4,5,24). Similar to the findings of Genant *et al.* (4), the correlation of the patients' spinal BMD values was excellent for each of the 3 scanner pairs. In this study, the regression models of the ESP measurements for the SMIT showed a strong positive correlation with the BMD values (*vs.* Discovery A, r=0.941–0.948; *vs.* iDXA, r=0.933–0.984). However, the regression slope and intercept were different, demonstrating the need for cross-calibration. For different DEXA devices, individual calibration equations were found to be necessary to fit the observed values with the given densities (25). Cross-calibration also decreased the systematic errors between the 3 instruments.

Hind *et al.* reported that Bland-Altman analyses on BMD values showed small but significant positive biases at the lumbar spine (0.005) (26). The Bland-Altman analysis conducted by Choi *et al.* (27) showed good agreement between the Prodigy and iDXA. Krueger *et al.* (28) reported that the lumbar spine BMD was highly correlated with a correlation coefficient (R^2) of 0.98. Additionally, Bland-Altman analysis demonstrated an aBMD bias of –0.003 g/cm^2, confirming equipment similarity. In this paper, Bland-Altman analyses showed small biases in the BMD measurements (g/cm^2) of the ESP (SMIT *vs.* Discovery A range –0.014 to 0.069; SMIT *vs.* iDXA range –0.440 to 0.018), which were

comparable with those reported by previous studies. The Bland-Altman results also indicated that cross-calibration equations may be required at this site.

The increasing incidence of osteoporosis and fractures partly reflects the rapid aging of China's population (3). In the Asian esophageal cancer belt, most of the published findings on esophageal cancer risk factors have come from Chinese studies (29-31). In China, gastric cancer is the main malignancy of the digestive tract, which seriously threatens the health of Chinese people (32). In this study, the novel DEXA is suitable for older adults who have gastrointestinal disease indications and can be used to perform BMD screening during the gastrointestinal examination. This study showed that cross-calibration is essential, especially novel DEXA equipment is used to measure BMD. This is particularly beneficial for long-term follow-up epidemiological studies on osteoporosis and multisite equipment studies based on bone densitometry.

This study had several limitations that should be noted. First, we only considered 1 operator and only collected the scans in 1 session. In real-world clinical practice, different technicians perform the inspections. Therefore, an assessment of the technician's operating error is required. The DXA technologist precision assessments, least significant change (LSC) calculations, and recommended precision thresholds were derived from the Adult Official Positions of the ISCD (as updated in 2019). Second, human participants were not included in this study. We appreciated it not only focus directly on BMD measures but also on osteoporosis diagnosis. In this study, only BMD measures were studied through ESP.

In conclusion, a strong agreement for BMD measurement was established between the 3 DEXA systems. Cross-calibration equations for lumbar spine BMD values need to be applied to transform the Hologic Discovery A or GE Lunar iDXA measurements into SONIALVISION SMIT measurements, so as to comply with ISCD standards for patient continuity of care in assessment during clinical diagnosis.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-22-619/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was approved by the local institutional review board (No. 2021-KY-1222-002).

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