### Original Article

# Vertebral Morphometry: Repeat Scan Precision Using the Lunar Expert-XL and the Hologic 4500A. A Study for the 'WISDOM' RCT of Hormone Replacement Therapy

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Abstract. On radiation safety grounds there is concern about the morbidity attributable to routine radiographs of the spine for the identification of new fractures in large-scale trials of fracture prevention. However, the role of the potentially safer low-radiation-dose technique of vertebral morphometry performed by third generation dual-energy X-ray absorptiometry equipment requires evaluation for use in clinical trials. We have therefore investigated the short-term inter-scan imprecision as well as the imprecision attributable to differentday analyses by the same operator and differences in analyses by different operators. The volunteer subjects were participants in a pilot study for a randomized controlled trial of hormone replacement therapy (Women's International Study of long Duration Oestrogen after Menopause, WISDOM). Each subject had two morphometric X-ray analysis scans separated by 2-4 weeks. Exclusions were women with densitometrically defined osteoporosis, as defined by the WHO criterion, and women with a body mass index exceeding 30.9 kg/m<sup>2</sup>. On average, the women were 58.7 years of age and had bone mineral density values in the lumbar spine which were about 0.7 SD units higher than a reference US female age-matched population. Scans were assessed from vertebrae T7

significant differences in performance between the Hologic QDR 4500A and the Lunar Expert XL equipment. Between-scan imprecision was significantly worse than imprecision attributable to reanalysis of the same scan by a different operator or the same operator after an interval. Vertebral level had an effect on measurement uncertainty, especially at the level of the diaphragm and at T7. Coefficients of variation, expressed as percentages of mean values, were better for absolute height measurements than for height ratios, ranging from 1.75% to 3.40% for the three heights measured on three separate machines and from 2.34% to 4.11% for the two height ratios. These results compared favorably with the equivalent figures from a parallel study of morphometry precision undertaken using standard lateral radiographs of the thoracic and lumbar spine (3.1–3.6% and 3.8–3.9%, respectively). We conclude that in trials of prevention therapy in women (or men) selected for not having osteoporosis, low-dose vertebral morphometry using the Hologic 4500A, the Lunar Expert XL or similar equipment is preferable on safety grounds to the classical technique based on standard radiographs, although conventional radiology may still be required in those with prevalent or incident deformities to exclude causes other than osteoporosis. The place of this low-dose technique in trials performed on patients with osteoporosis requires further study.

through L4. In the study there were no clinically

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**Keywords:** Dual X-ray absorptiometry; Osteoporosis prevention; Radiographic vertebral morphometry; Randomised controlled trial; Statistical power

#### Introduction

Vertebral fractures are associated with a high morbidity [1] and are a strong independent risk factor for subsequent fracture [2,3]. Accurate identification of prevalent and incident vertebral fractures is of central importance in epidemiologic studies and in the assessment of interventions for osteoporosis, but definition of vertebral fracture has proved problematic [4,5]. Qualitative assessment of vertebral deformities is inaccurate because of significant inter- and intra-individual variations in vertebral dimensions, and in recent years a number of morphometric approaches have been devised in which individual vertebral heights in the lumbar and thoracic spine are compared with vertebra-specific data from a reference population [5–7].

Traditionally, vertebral morphometry has been applied to lateral radiographs of the spine obtained using conventional radiography; however, this approach has several disadvantages, including the high radiation dose involved [8] and distortion and magnification of the image. The recent development of dual-energy X-ray absorptiometers which employ a fan-beam system has provided a means by which images of the spine of adequate quality can be produced at much lower radiation doses [9,10]; in addition, distortion and magnification of the image can be eliminated by means of a centerline scan which enables a constant distance to be maintained between the X-ray tube and the spine during the scan.

The feasibility of this approach, known as morphometric X-ray analysis (MXA), is now well established but there are few published data on the reproducibility of measurements. This is particularly important in determining the suitability of the method for clinical trials and is also required for calculation of the sample size necessary to demonstrate significant treatment effects on vertebral fracture. In this study we have examined the reproducibility of vertebral height measurements obtained by MXA in healthy postmenopausal women participating in a trial of hormone replacement therapy using the Hologic QDR 4500 and the Lunar Expert-XL dual-energy X-ray absorptiometers. We have compared the precision values obtained with those reported for conventional X-ray morphometry.

#### **Materials and Methods**

Subjects

The subjects were participants in the feasibility studies for a long-term randomized controlled trial of hormone replacement therapy – 'WISDOM' (Women's International Study of long Duration Oestrogen after

Menopause) - and had been recruited for the trial through general practices in the Medical Research Council General Practice Research Framework. One hundred and eighty-five women (mean age 58.7 years, range 46-68 years) from general practices close to one of three British scanning centers: Solihull (center 1); Addenbrooke's Hospital, Cambridge (center 2); and Guys and St Thomas's Hospitals, London (center 3) were approached. The ethics review committees at all three centers approved the study prior to starting. Women with a body mass index (BMI: weight in kg/ height in meters<sup>2</sup>) greater than 30.9 or with clinical evidence of spinal scoliosis were excluded. All participants gave informed written consent before inclusion in the study. At the first visit each woman had an anteroposterior spine bone mineral density (BMD L1-L4) and a vertebral morphometry (MXA) measurement. After a 2- to 4-week interval the MXA measurement was repeated. The BMD measurements were analyzed and reported locally. Women with a BMD more than 2.5 SD below the young US adult mean were referred to their primary care physician.

#### Equipment

Two of the centers used a Hologic QDR4500A (Hologic, Waltham, MA). A centerline scan was done in turbo mode followed by a 14 min high-definition lateral scan (single and dual energy protocol). The subjects were instructed to exhale fully and then to breathe shallowly. The scans were analyzed using software version 8.17. The third center used a Lunar Expert-XL (Lunar, Madison, WI). A 37 s 5 mA fast lateral scan was performed in under 40 s. Subjects were asked to exhale fully and then hold their breath. The data was acquired using software version 1.63 and analysis was performed with v.1.64.

The MXA images were sent to Cambridge for centralized analysis. Both single-energy and dual-energy images were used in the analysis of the Hologic scans, depending on which gave the greater clarity in defining the vertebral body outlines. The Lunar scan images were dual energy and contrast was optimized to give the maximum gray levels for each scan. Further image enhancement was undertaken with the image analysis tools and filters before point placement. No 'Compare' facility was available with the Lunar software at the time this work was done.

#### Intra-operator Precision

The intra-operator precision was evaluated using the results from a single fully trained operator and based on the scans from Cambridge and Solihull. Vertebrae from T7 to L4 were analyzed three times by the operator, who each time remained masked to the previous analyses. The re-analyses were performed after intervals of approximately 22 days (center 2) and 76 days (center 1).

#### Inter-operator Precision

The inter-operator precision was measurd for the Lunar and one of the two Hologic centers. Each of the initial MXA scans was analyzed by four different trained operators. General guidelines based on the manufacturer's procedures were specified prior to the analysis so that there was agreement on the correct positioning of the six points required for vertebral height measurement. However, the actual analysis of each subject's scan was performed independently by each operator.

#### Between-Scan Precision

All the subjects who had repeat MXA scans were used for the between-scan precision analysis. Each image was analyzed by a single fully trained operator. The second scans from both center 1 and center 2 were analyzed with the operator debarred from reviewing the first scan analysis at any time after completion, so that there was an average interval of 22 days in center 2 and 76 days in center 1 between analyses. Subsequently, the scans from centers 2 and 3 acquired using the Hologic QDR 4500A were reanalyzed using the 'Compare' facility so that the operator could adjust point positioning in the light of the previous scan evaluation. At the time of the study, no 'Compare' facility was available for the Lunar system.

#### Statistical Analysis

The results were evaluated using SPSS (SPSS, Chicago, IL), using the general principles described by Glüer et al. [11]. To calculate the precision of repeat analysis and repeat measurment, general analyses of variance (ANOVAs) were performed with subject, vertebral levels and subject interacting with vertebral levels as three categorical variables in the analysis. Precision in units of measurment was calculated as the root mean square of the residual variance and precision was also calculated as percentages (%CV) of the mean calculated vertebral heights and height ratios. Analyses were repeated for each vertebral level from T7 to L4 in order to study the effect of vertebral level on precision.

#### **Results**

#### **Subjects**

In total 185 women were approached, and of these 125 were scanned. The remainder either refused (n = 26), cancelled their appointment (n = 6), were considered scoliotic (n = 1) or had a high BMI (>30.9; n = 27). Of those who were scanned, a further 9 were rejected on the basis that the time delay between each scan was too long (n = 2), the images were unanalyzable (n = 4), no repeat scan had been acquired (n = 2) or that there was evidence of scoliosis (n = 1). Precision analysis was performed on 32 subjects in center 1, 31 in center 2 and 46 in center 3.

The average time interval between scans was 24 days (range 13–27 days). The women were a mean of 58.7 years of age (range 44–68 years).

#### Bone Density

One subject in Cambridge, 3 in London and none in Solihull had BMD values in L1–L4 which were more than 2.5 SD below the young normal mean. They were therefore referred to their primary care physician and excluded from this study. The prevalence rate of osteoporosis diagnosed by densitometry as a BMD more than 2.5 SD below the young normal mean [12] was therefore 3%. Thirty-seven percent of the women had a *T*-score that was more than 1 SD below the young normal mean but above the threshold for a diagnosis of osteoporosis. There was no significant difference between centers in mean BMD. Mean *T*-score in the three centers combined was -0.44 (SD 1.41).

#### Operator Precision

Intra-operator precision was found to be similar on the two systems (Table 1). For the Lunar system the point placement appeared to be less precise for the posterior height compared with the other two heights (2.14%), whereas for the Hologic system the posterior height (1.67%) was the most reproducible and the anterior height (2.14%) the least reproducible. As expected, inter-operator variation was larger than variation arising from repeat analyses performed by a single fully trained operator (Table 2). Between operators, the least

Table 1. Intra-operator precision

	Lunar Exp	ert-XL	Hologic QDR 4500A		
	RMSE	%CV	RMSE	%CV	
Anterior	0.451	2.02	0.507	2.14	
Posterior	0.490	2.14	0.407	1.67	
Mid-body	0.428	2.00	0.471	2.04	
AP ratio	0.028	2.85	0.026	2.65	
MP ratio	0.026	2.78	0.023	2.43	

RMSE, root mean square error (mm for heights); AP, anterior:posterior; MP, mid:posterior.

Table 2. Inter-operator precision

Vertebral height or height ratio	Lunar Exp	ert-XL	Hologic QDR 4500A		
or neight ratio	RMSE (mm)	%CV	RMSE (mm)	%CV	
Anterior	0.630	2.84	0.721	3.18	
Posterior	0.624	2.73	0.812	3.47	
Mid-body	0.556	2.64	0.679	3.10	
AP ratio	0.032	3.31	0.036	3.66	
MP ratio	0.030	3.30	0.033	3.53	

RMSE, root mean square error; AP, anterior posterior; MP, mid posterior.

imprecision was seen for the mid-body height, and this was reflected in the slightly larger error seen in the anterior:posterior than the mid:posterior ratios (Table 2).

#### Between-Scan Precision

Re-scanning the patient resulted in increased variation, presumably due to the repositioning. The lowest levels of variation were observed from one of the Hologic centers when the analysis was completed using the onscreen 'Compare' facility. For all three heights it can be seen (Table 3) that the coefficient of variation was consistently below 2%. At center 3 slightly higher measurement error was recorded for those scans

analyzed using 'Compare'. Analysis of the Hologic scans blind, without using the 'Compare' function, resulted in slightly higher variation (posterior 2.15%, mid-body 2.31% and anterior 2.56%) at center 2. When we examined the variation observed at center 2 with and without 'Compare' a small but significant improvement could be seen in the point placement for all three heights (anterior, p<0.00001; posterior, p = 0.0004; mid-body, p=0.0001).

#### Precision at the Different Vertebral Levels

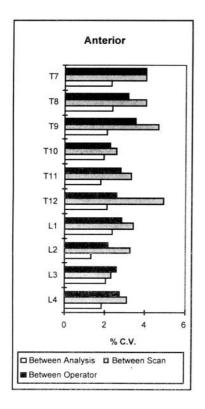
Figure 1 illustrates the variation at the different vertebral levels for the intra-observer, inter-observer and between-

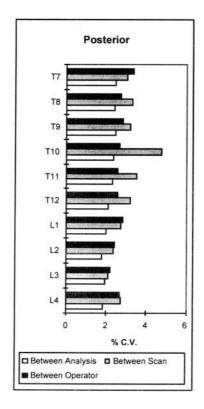
Table 3. Between-scan precision

Vertebral height or height ratio	Lunar Expert-XL Center 1		Hologic QDR 4500A (without 'Compare') Center 2		Hologic QDR 4500A (with 'Compare') Center 2		Hologic QDR 4500A (with 'Compare') Center 3		Radiography <sup>a</sup>
	RMSE	%CV	RMSE	%CV	RMSE	%CV	RMSE	%CV	%CV
Anterior	0.796	3.40	0.607	2.56	0.417	1.76	0.606	2.56	3.1
Posterior	0.698	3.06	0.524	2.15	0.434	1.78	0.596	2.43	3.2
Mid-body	0.662	3.09	0.535	2.31	0.432	1.86	0.505	2.18	3.6
AP ratio	0.040	4.11	0.032	3.26	0.023	2.34	0.029	2.97	3.8
MP ratio	0.037	3.90	0.027	2.80	0.023	2.39	0.025	2.66	3.9

<sup>&</sup>lt;sup>a</sup> Results from Weber et al. [13].

AP, anterior:posterior; MP, mid:posterior.





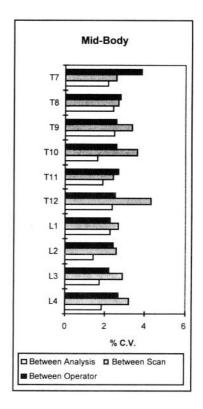
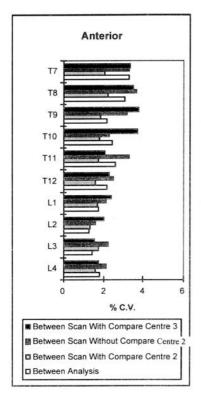
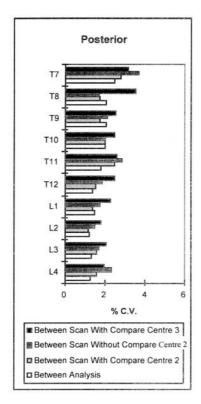


Fig. 1. Variation in precision of vertebral height measurements at 10 vertebral levels of the spine. Data presented are between-analyses (same scan), between-operators (same scan) and between-scans for the Lunar Expert-XL.





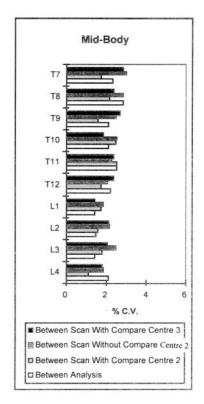


Fig. 2. Variation in precision of vertebral height measurements at 10 vertebral levels of the spine. Data presented are between-analyses (same scan), between-scans (with and without 'Compare') for Hologic QDR 4500A.

scan analyses using the Lunar Expert-XL. For the anterior heights the largest errors were associated with re-scanning the patient and these reached a peak of T12 and T9, remaining relatively high in the whole upper thoracic region. Repositioning appeared to have little effect on precision in the lower lumbar (L2) and thoracic (T10) vertebra. When a single scan was reanalyzed by the same or a different operator the best precision was again seen in the lower lumbar region (L2), with a gradual rise in imprecision moving towards the thoracic vertebrae. A similar pattern was seen for the posterior heights. At T10 repositioning had a greater effect on posterior height measurement than that observed for the anterior height (anterior, 2.54%; posterior, 4.79%). The precision at the different levels for the mid-body heights was more consistent, but again the largest imprecision occurred at T12 and T10.

The vertebral level variation is demonstrated in Fig. 2 for the Hologic QDR 4500A measurements. Poor visualization of the vertebrae around the diaphragm and of the upper thoracic vertebrae resulted in larger measurement imprecision posteriorly at these locations. In general the precision results were rather similar to those obtained with the Lunar Expert-XL.

## Comparison of Precision Obtained using MXA and Conventional Lateral Spinal Radiographs

Weber et al. [13] have recently presented precision data calculated in the same way obtained on a populationbased cohort of subjects studied with two interval thoracic plus lumbar spine radiographs taken 2 years apart. When the small number of incident deformities were excluded, the precision data were similar to those we obtained with MXA in the present study and are included in Table 3 for comparison.

#### Discussion

Compared with some previously published precision data for MXA performed with both Lunar Expert-XL and Hologic QDR 4500 machines the present data are reassuring. The differences between the results from the three centers, while in some cases statistically significant, do not necessarily reflect differences in the results achievable with the different technologies provided by the two manufacturers. In one center it was routine practice to have several operators using the equipment whereas in another a single operator performed all the MXA scans. There may also have been differences in the populations studied, although this is thought not to have been a major source of variation because their BMDs were similar. The precision obtainable in an individual is highly dependent on the subject's cooperation – another potential source of variation between study populations.

When these data were compared with those derived from conventional radiographs of a population-based sample of volunteers [13] the precision in point placement obtained was remarkably similar by MXA N. Crabtree et al.

and conventional radiology. The recent study by Rea et al. [14] concerned the reproducibility of quantitating morphometric measurements from the same subjects, using conventional radiographic and MXA images respectively [14]. In our radiographic study [13] we did not evaluate the reproducibility of re-measuring the same radiograph. Instead, we examined the reproducibility of measurements obtained from sequential radiographs. Therefore the measurement uncertainties in the study by Weber et al. [13] included a contribution attributable to the repositioning of the subject. Because in Rea et al.'s study [14] there was an advantage in using conventional radiographs, which was no longer evident when the results of the present study were compared with the study by Weber et al. [13], we suggest the explanation that the effects of repositioning the subject in the less comfortable and reproducible lateral decubitus position might have been sufficient to mask the inherent technical advantages in image clarity obtainable with radiographs.

Our results are reassuring because MXA offers substantial advantages in terms of radiation dose compared with conventional radiographs. Shrimpton et al. [8] have calculated that there might be one radiationrelated death in their remaining lifetime among 60-yearold women for every 25 000 who have a lateral radiograph of the lumbar spine combined with a lateral radiograph of the thoracic spine in Britain. With the technology employed with MXA the radiation hazard of large-scale studies of spinal morphometry can be improved very substantially since the estimated radiation doses recorded both for the Lunar Expert-XL and for the Hologic QDR 4500 were less than 20% of that attributable to a representative British lumbar and thoracic lateral spine radiographic examination. With the increasingly widespread availability of MXA technology, the safety of large-scale studies on spinal osteoporosis in epidemiology and clinical trials should be considerably enhanced.

The use of MXA and fan-beam technology offers a number of technical advantages to compensate for the loss of definition through the use of a smaller X-ray dose. The MXA equipment uses a fan beam rather than a cone beam of X-rays. This gives greater collimation of the X-ray beam, which cuts out much of the scattered radiation that degrades image quality on cone-beam images. Secondly, the MXA machines acquire their images with high-quality semiconductor detectors with a dynamic range an order of magnitude greater than conventional planar radiography, where the optical density is linearly proportional to film exposure. These modern detector systems permit post-acquisition image optimization that was not possible previously. Finally, the patient lies supine for MXA scans rather than in the decubitus position. Because of the greater discomfort (for some patients) and inherent gravitational instability of the decubitus position, there is an advantage in reproducibility favoring the supine position.

It should be noted that the women studied here were a population-based sample of normal volunteers for

hormone replacement therapy after the menopause. These women were therefore not typical of the patients who are frequently studied in trials of treatment for established osteoporosis. This is reflected in their lumbar spine BMD, the T-score of which averaged -0.44 compared with an expected mean for a normal US population of the same age distribution of -1.1 (Hologic reference population). Furthermore, a densitometric diagnosis of osteoporosis was a criterion for the exclusion from the study. The results obtained in our cohort may therefore not be representative of measurements obtained in subjects with lower BMD, in whom precision would be expected to be lower, and further assessment of MXA technology in osteoporotic patients with and without vertebral fractures is required.

A number of conditions other than osteoporosis may result in vertebral deformity and in both clinical practice and clinical trials visual assessment is important to determine the underlying cause. Such assessment can only reliably be performed using conventional radiographs and these should therefore be performed in individuals in whom a prevalent or incident deformity is identified on MXA, since up to 10% of such deformities may be due to nonosteoporotic causes. This will apply to relatively few subjects in population-based studies but will occur more frequently in clinical trials in patients with osteoporosis. Another potential limitation of MXA, and to a lesser extent of conventional radiographs, is the relatively poor visualization of the upper thoracic vertebrae; for the purposes of the present study, it was decided to exclude T3-T6 from measurment to reduce errors associated with poor-quality images. However, since osteoporotic fractures occur in this region it will be important in the future to assess the precision of MXA in these vertebrae, in both normal and osteoporotic subjects.

The present study was undertaken to enable power calculations for a proposed large-scale study of the magnitude of the effect of long-term continuous combined hormone replacement therapy in preventing incident vertebral deformities. The results we have obtained have demonstrated that on dosimetric grounds the use of MXA technology is clearly to be preferred to the use of conventional radiographs, but that no clear preference emerged between the Hologic and Lunar equipment. Further studies are required to determine how precision might be optimized using both types of equipment; however, it seems likely that the best precision will be obtained with one or perhaps two operators per center with expertise in MXA using the equipment, so that consistency is sustained both in patient positioning and in operator interaction with the computer software at the time of point placement on the MXA images. In multicenter research studies there will be clear advantages in centralizing quality assurance and the finalizing of analyses.

In conclusion, in prospective studies of vertebral deformity incidence in populations of women who are relatively unaffected by osteoporosis at the start of the study, MXA now seems to be the method of choice,

given dosimetric considerations, the similar performance of morphometry using the two technologies and the uncertainties of qualitative assessment using conventional radiographs when expert radiographic assessors report the results in isolation from each another [4]. It may be wondered why a low radiation dose technology should peform so well in comparison with a higher-dose technology which achieves much better pictorial definition. The answer may in part lie in the fact that conventional radiographs use cone-beam technology leading, by comparison with fan-beam technology, to an increase in rotation-associated artifacts affecting the orientation of the end plates. MXA always visualizes the end plates at right angles to the sagittal axis of the patient so that in the absence of scoliosis these artifacts are avoided. Other advantages of fan-beam technology include reduction of image degradation attributable to scattered radiation, due to the higher collimation of the X-rays; broader dynamic range; and the potential for simultaneous single- and dual-energy acquisition. Disadvantages include poor resolution of the upper thoracic vertebrae, difficulty in identification of minor vertebral deformities and distortion of vertebral body images by breathing artifacts. Overall, however, it appears that MXA is a real advance for the study of vertebral deformity in population-based studies. Further studies are needed before the place of this technology in clinical diagnosis can be defined.

Acknowledgements. This study was supported by a MRC Project Grant, no. G9608230. We thank the following doctors and nurses in the participating general practices in Bath, Bromsgrove, Bracknell, Bungay, Coleford and South Harrow for their help with the recruitment, and their patients in these practices who agreed to participate in the study: Bath: Dr G. Walker, Dr R. Rolls, Dr P. Booth, Mrs M. Goldsborough, Mrs F. Round; Mrs M. Allen; Coleford: Dr W. Insh, Mrs B. Hinton; Bracknell: Dr C. Kada, Mrs P. Allen; Bungay: Dr C. Hand, Mrs L. Hand; Bromsgrove: Dr M. Leci, Mrs A. Hall; Harrow: Dr J. Justice, Mrs L. O'Grady. We also acknowledge the contribution of Sister Shirley Love, who helped to organize the study.

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Received for publication 29 January 1999 Accepted in revised form 15 December 1999