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Intra- and Inter-rater Reliability of Coronal Curvature Measurement for Adolescent Idiopathic Scoliosis Using Ultrasonic Imaging Method—A Pilot Study

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Abstract

Study Design: Retrospective reliability study of the coronal curvature measurement on ultrasound (US) imaging in adolescent idiopathic scoliosis (AIS).
Objectives: To determine the intra- and inter-rater reliability and validity of the coronal curvature measurements obtained from US images.
Summary of Background Data: Cobb angle measurements on radiographs are the usual method to diagnose and monitor the progression of scoliosis. Repeated ionizing radiation exposure is a frequent concern of patients and their families. Use of US imaging method to measure coronal curvature in children who have idiopathic scoliosis has not been clinically validated.
Methods: The researchers scanned 26 subjects using a medical 3-dimensional US system. Spinal radiographs were obtained on the same day from the local scoliosis clinic. Three raters used the center of lamina method to measure the coronal curvature on the US images twice 1 week apart. The raters also measured the Cobb angle on the radiographs twice. Intra- and inter-rater reliability of the coronal curvature measurement from the US images was analyzed using intra-class correlation coefficients. The correlation coefficient of the US coronal curvature measurements was compared with the Cobb angles.
Results: The intra-class correlation coefficient (2,1) values of intra- and inter-rater reliability on the US method were greater than 0.80. Standard error of measurement on both of the intra- and inter-rater US methods was less than 2.8°. The correlation coefficient between the US and radiographic methods ranged between 0.78 and 0.84 among 3 raters.
Conclusions: The US method illustrated substantial intra- and inter-rater reliability. The measurement difference between radiography and the US method was within the range of clinically acceptable error (5°). The US method may be considered a radiation-free alternative to assess children with scoliosis of mild to moderate severity.

Keywords: AIS; Coronal curvature; Ultrasound imaging; COL method; Cobb angle

Introduction

Adolescent idiopathic scoliosis (AIS) is a 3-dimensional (3D) deformity of the spine characterized by lateral curvature of the spine and vertebral rotation. It occurs in approximately 3% of adolescents and is especially prominent in females [1]. The Cobb angle [2] measured on standing posterior-anterior radiographs is the reference standard to diagnose and monitor AIS. It also has an important role in

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determining curve progression, treatment options, and assessment of treatment outcome [3-5]. Some studies [6,7] have focused on the intra- and inter-rater reliability of the Cobb angle measurement. It has been reported that measurement errors of the Cobb method based on radiographs are within the range of 3° to 7° [6,7], and usually 5° is considered as a clinically acceptable error as well as the threshold of determining curve progression [2,8].

Although the Cobb method is the most widely used technique in a scoliosis clinic, exposure to ionizing radiation is a significant concern for both patients and their families. These children may require multiple radiographs annually during long-term follow-up, which has been reported to increase risk of breast cancer in female patients [9,10]. Therefore, alternative methods have been investigated to decrease or overcome the potential harm of radiation.

Among many imaging modalities, ultrasound (US) imaging is a promising radiation-free method for scoliosis studies [11-24]. Suzuki et al. [11] identified the spinous processes and laminae on each of the vertebra on US spinal images. They reported that these 2 anatomic landmarks parameters could be used to quantify axial vertebral rotation, which was correlated with the Cobb angle. Furness et al. [12] attempted to use US imaging to identify lumbar intervertebral spaces for anesthetic techniques; they reported that 71% of the lumbar intervertebral spaces were identified correctly. Burwell et al. [13-17] applied US to measure axial vertebral rotation and rib rotation in prone positions. They also reported that repositioning the patient significantly altered measurements. One reasons was that the applied US machine did not have the sensor to track the position and orientation of the transducer. The prone position may also affect spinal deformity measurements.

For the direct measurement of spinal curvature, Li et al. [18,19] used US imaging to determine the optimal location of pressure pads in spinal braces during the brace-fitting process. Instead of using the Cobb angle to quantify the severity of scoliosis, they used the spinous process angle, which they reported was highly correlated with the Cobb angle ($R = 0.98$; $p < .01$) [19]. As a result, 62% of patients (13 of 21 patients) in that study benefited from US assistance. In the US spinal images, the end plates of each vertebra are difficult to identify owing to the acoustic shadowing of posterior structures. Chen et al. [20,21] conducted multiple studies to determine alternative vertebral landmarks that could be used to measure the angle of the tilted vertebrae on the coronal plane [20,21]. They reported that the center of laminar (COL) measurement method on US images was highly correlated with the Cobb angle from radiographs. A pilot study with 5 AIS subjects was performed. The mean absolute difference (MAD) and standard deviation (SD) of measurements between the US and the corresponding radiographs were 0.7 ± 0.5. Cheung et al. [23] developed a freehand 3D US imaging system to assess scoliosis. Based on a series of B-mode ultrasound images (the spatial information and visible vertebral landmarks, ie, spinous process, transverse articular process, and/or superior process), they were able to form a 3D spine model. Their 3D spine model was then projected onto a 2D coronal plane to measure the Cobb angle. The study was validated on a spine phantom with 16 severity configurations. A strong correlation ($R^2 = 0.76$) between the Cobb angle measurements of the radiographic images and US system was obtained, and the intra- and interobserver correlations were 0.99 and 0.89, respectively. Recently, Ungi et al. [24] used the same US system as that of the current authors to measure spinal curvature by using transverse processes as vertebral landmarks. They reported that the MAD ± SD of the differences between the curvature measurements on adult and pediatric spines from the US and the phantoms were 1.27° ± 0.84° and 0.96° ± 0.87°, respectively.

As seen from the literature, although in vitro US measurements have been investigated, in vivo US measurements of spinal deformity have not been fully validated. Therefore, the objectives of this study were to compare the reliability and determine the validity of coronal curvature as measured from standing US images against those measured from standing radiographs on pediatric subjects who have AIS.

Methods

Clinical subjects

The researchers recruited 26 adolescent (22 female and 4 male; mean age, 13.9 ± 2.1 years) who met the following inclusion criteria for the reliability study: 1) they were diagnosed with AIS; 2) they had no prior surgical treatment; 3) they had out-of-brace radiographs on the study day; and 4) the major curve was in the range of 10° to 45°. The time frame of the study was between August and October, 2013. The local health research ethics board granted ethics approval and all participating subjects signed a written consent before being enrolled into the study.

Data acquisition

During the scoliosis clinic visit, each subject was first examined with a posterior-anterior standing radiograph and had a US scan performed within an hour. All US scans were acquired by the same pair of technicians. The US scan was obtained using the SonixTABLET system equipped with 128-element C5-2/60 GPS transducer and the SonixGPS system (Analogic Ultrasound - BK Medical, Peabody, Massachusetts, USA). The applied scan frequency was 2.5 MHz and the penetration imaging depth was set at 6 cm. The gain was set to 10% with linear time gain compensation. The full spine range from C7 to L5 was scanned with the subject in a standing position. Acquisition time was less than 1 minute. Figure 1 shows the subject being scanned using the US device. After scanning, the acquired data were

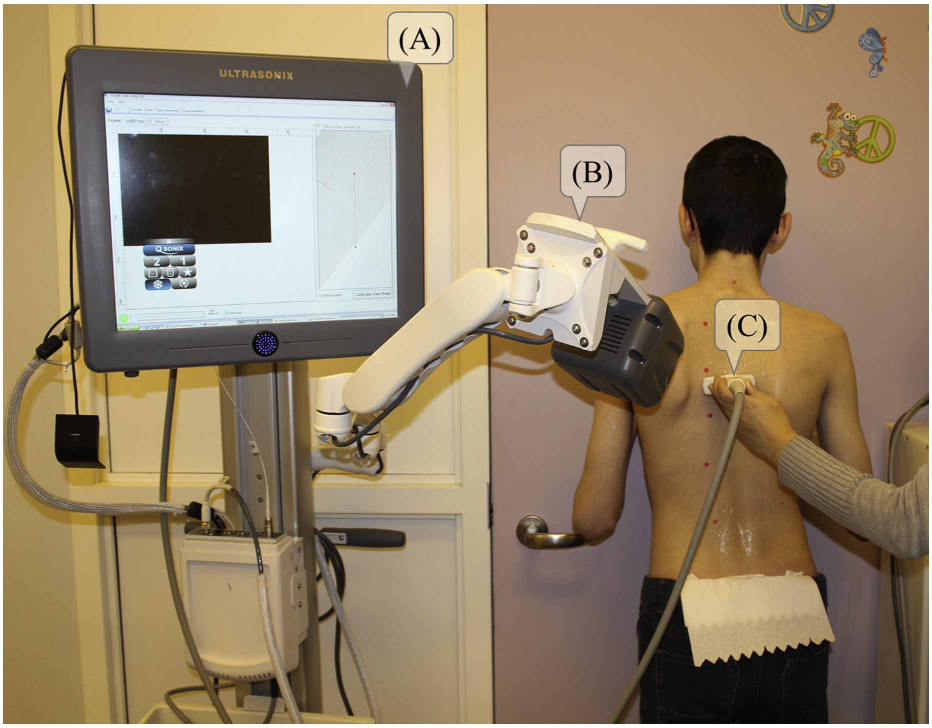

Fig. 1. Subject being scanned using ultrasound devices: (A) SonixTABLET, (B) SonixGPS, and (C) C5-2/60 GPS transducer.

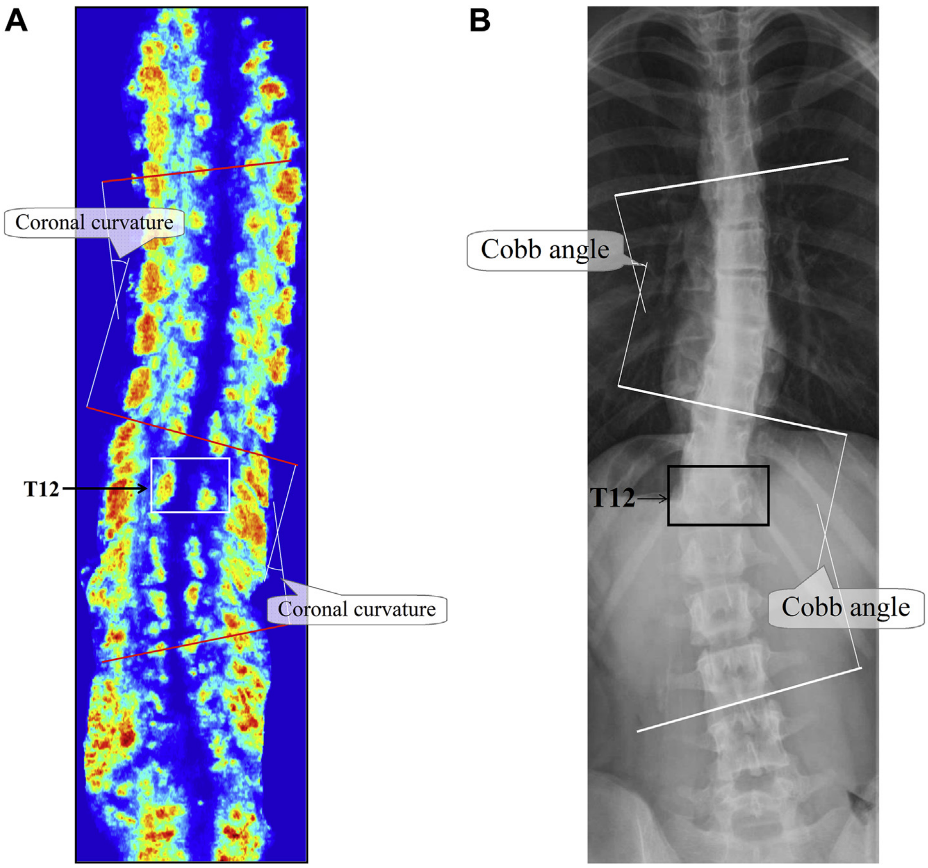

Fig. 2. Curvature measurement: (A) using the center of laminar method on ultrasound image in the coronal plane and (B) using the Cobb method on radiograph.

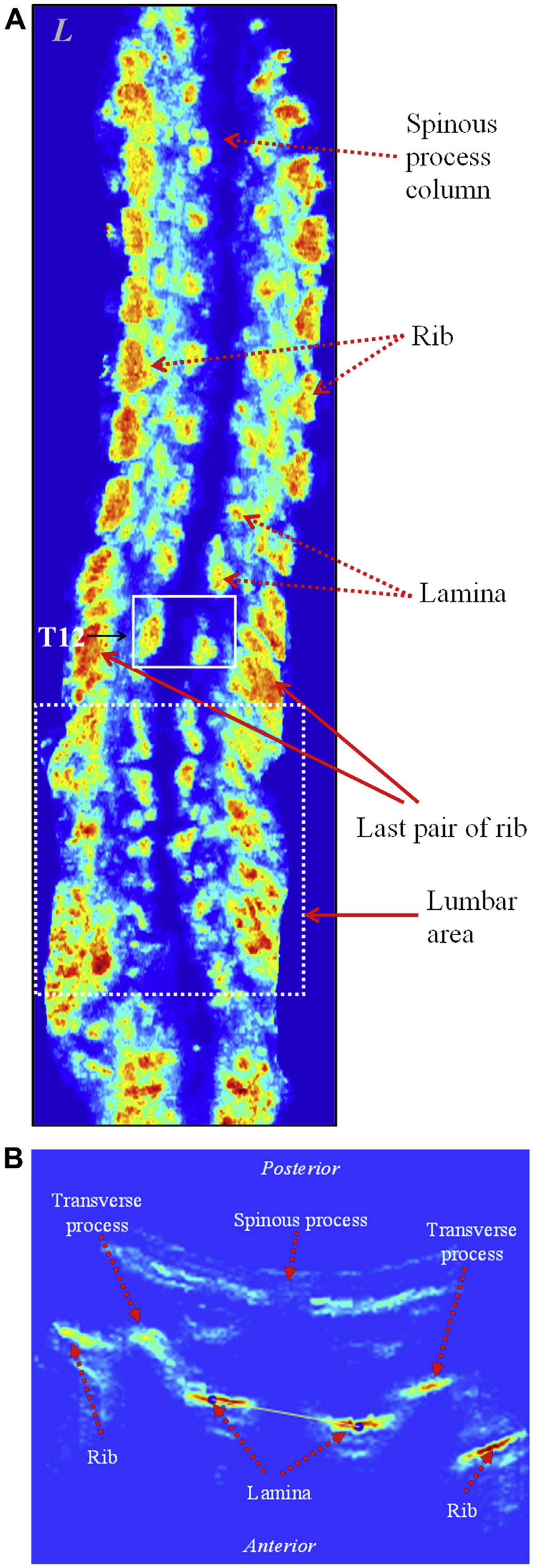

Fig. 3. Landmarks, spinous process column, rib, lamina, and transverse process on (A) coronal plane and (B) transverse plane of the ultrasound image.

exported to a 3D image file using a custom-developed in-house program. One research associate then prepared the image files, which were used by all raters to perform US measurements.

Data measurement

Figure 2 shows a US image (A) compared to the corresponding radiograph (B) from a recruited subject. The US and radiographic images were measured using the same custom-developed software. The radiographic images from clinical records were exported into JPEG format with 100% image quality and then imported into the software. The Cobb angles were measured simply by drawing 2 lines in the radiographs: one parallel to the top edge of the cephalad vertebrae with the greatest degree of tilt and the other parallel to the bottom edge of the caudal vertebra with the greatest degree of tilt. To measure the coronal curvature on the corresponding US image, the COL method introduced by Chen et al. [21,22] was applied. The COLs at each vertebra level were first manually selected on the coronal plane of the US image by the user (Fig. 3A). Two points, on the left and right, were selected at each level. The in-house program linked the left and right COL on the coronal view image. The user used the mouse to select the vertebral level and the corresponding transverse view image was displayed. The user could fine-tune the COL by moving the landmarks at the laminae (Fig. 3B). Because the US data were 3D, the adjustment of the COL on the transverse view would be reflected on the coronal view. Similar to the radiographic method, the last pair of ribs was used to identify the T12 vertebra. As shown in Fig. 3A, the ultrasound signals reflected from the ribs are always stronger and larger as the result of a relative large flat surface. Therefore, the ribs can be easily identified pair by pair in the thoracic area, whereas there are no evident signs of rib pairs in the lumbar area. In this study, all 3 observers agreed on the T12 level before the measurements and then labeled other vertebral levels accordingly. After marking all the levels, the in-house program automatically calculated the tilt angle at each vertebral level relative to the horizontal line on the coronal plane. The program then displayed the proxy Cobb angle by using the 2 most tilted lines at the end points of the curve.

Three raters were involved in this study. Raters 1 and 2 were novice researchers with approximately 6 months' experience in scoliosis research, whereas Rater 3 had 15 years' experience in measuring Cobb angles on radiographs. Because this US method was new to all raters, before the study, all raters were required to measure 15 practice US images acquired from children with AIS. The practice measurements were not used for analysis but primarily to develop a standard measurement protocol. All 3 raters were blinded to clinical information about the subjects, and the measurements were conducted independently without communication among raters. The US and radiographic images were randomly assigned code numbers and the 2 types of image were measured 3 days apart to

Table 1
Intra-rater difference of curvature measurement using ultrasound and radiographic methods.

Methods	Observers	Measurements, n	Mean absolute difference between measurements (degrees)	Standard deviation of absolute difference between measurements (degrees)	Intra-class correlation coefficient (2,1)	Standard error of measurement calculated from standard deviation of second measurement (degrees)
Radiograph	R1	48	1.5	1.6	0.95	1.6
	R2	47	1.3	1.2	0.96	1.5
	R3	47	1.2	1.3	0.97	1.2
Ultrasound	R1	42	3.1	2.4	0.84	2.8
	R2	44	3.4	2.0	0.86	2.5
	R3	41	1.9	1.9	0.93	1.6

minimize memory effects. Each rater measured the coronal curvature on both of the US and radiographic images twice, and the time interval between the 2 trials was at least 1 week apart to further reduce recall bias. There was no specific order for the US or radiographic measurements.

Statistical analysis

The researchers performed statistical analysis with IBM SPSS Statistics (IBM, Armonk, New York, USA), version 21. The MAD and SD were used to evaluate the differences among trials, raters, and methods. Intra- and inter-rater reliabilities were assessed by calculating the standard errors of measurement (SEM) and the intra-class correlation coefficients (ICC[2,1]) using a 2-way random model and absolute agreement with a 95% confidence interval. According to Currier [25], the ICC value was characterized as very reliable (0.80−1.00), moderate reliable (0.60−0.79), and questionable reliable (0.60 or less). To evaluate the reliability and agreement among raters and the different imaging methods, the average value of the 2 trials in each method from each rater was applied to the analysis.

Results

Many subjects had multiple curves that were detected on both the US and radiographic images. Because the radiographic method is still the reference standard for measuring curve severity, the curves detected on radiographic images in both trials by at least 2 of the 3 raters were chosen for assessment. All US comparisons and analysis were limited to these curves.

There were 49 curves eligible for the reliability assessment. The Cobb angles of these curves ranged from 12° to 45° and the average value was 23.6° ± 7.0°. Table 1 lists intra-rater variation and reliability for both US and radiographic measurements. Compared with the radiographic measurement, the US method showed larger MAD and SD values for all raters, which were 3.1° ± 2.4°, 3.4° ± 2.0°, and 1.9° ±1.9° for rater 1, 2, and 3, respectively. However, the mean difference in US measurements among all intra-rater measurements was less than the commonly accepted intra-rater variability (4.9°) [6]. The ICC values of the US method from all 3 raters were above 0.80, which demonstrated high reliability. Of all 3 raters, the most experienced one (R3) reported the best statistical results, including the highest ICC value and the smallest MAD, SD, and SEM on both measurement methods.

Table 2 shows the assessment of inter-rater variation and reliability in both measurement methods. Similar to the intra-rater analysis, the results between raters using the US method were less consistent than those measured by the radiographic method. The MAD ranged from 2.3° to 3.4°, which was twice the value from the radiographic measurement; the SEM ranged from 2.2° to 2.7°, which was also 2 times the

Table 2
Inter-rater difference of curvature measurement using ultrasound and radiographic methods.

Methods	Observers	Measurements, n	Mean absolute difference between raters (degrees)	Standard deviation of absolute difference between raters (degrees)	Intra-class correlation coefficient (2,1)	Standard error of measurement calculated from standard deviation of measurement from R3 (or R1) (degrees)
Radiograph	R1 versus R2	45	1.2	1.3	0.97	1.2
	R1 versus R3	46	1.5	1.1	0.96	1.4
	R2 versus R3	45	1.4	1.0	0.97	1.2
	R1 versus R2 versus R3	44			0.97	1.2
Ultrasound	R1 versus R2	41	2.3	2.3	0.90	2.2
	R1 versus R3	39	3.4	2.6	0.80	2.7
	R2 versus R3	39	2.8	2.1	0.86	2.2
	R1 versus R2 versus R3	39			0.85	2.3

Table 3
Difference in curvature measurement between ultrasound and radiographic methods.

Observer	Measurements, n	Mean absolute difference between ultrasound and radiographic measurements (degrees)	Standard deviation of absolute difference between ultrasound and radiographic measurements (degrees)	R	Intra-class correlation coefficient (2,1)	Standard error of measurement calculated from standard deviation of radiographic measurement (degrees)
R1	41	3.3	2.3	0.84	0.83	2.9
R2	44	3.8	2.7	0.78	0.78	3.4
R3	40	3.3	2.3	0.83	0.82	3.0

radiographic results. The ICC value from the US method ranged between 0.80 and 0.90, which was about 0.10 lower than the radiographic method but is still characterized as very reliable. The largest MAD of the coronal curvatures between different raters on the US method was 3.4°, which was below the clinically acceptable error rate.

Table 3 lists the results of reliability analysis between the US and radiographic methods. All 3 raters detected fewer curves using the US method; the number of curves that were used for further analysis including intra- and inter-rater reliability study and comparisons with radiography for the 3 raters were 42, 44, and 41, respectively. The MAD between the 2 methods (range, 3.3°−3.8°) was larger than either the intra- or inter-rater differences of either measurement method. The correlation coefficient between the US and the radiographic methods of the 3 raters ranged from 0.78 to 0.84, which indicated moderate correlation. The SEMs between the US and the radiographic measurements ranged from 2.9° to 3.4°.

Discussion

Currently, a 5° variation in Cobb angle measurement is widely accepted as the acceptable clinical error [2]. The literature reports that the intra- and interobserver reliability (ICC) of Cobb measurements is 0.87 to 0.99 and 0.87 to 0.98, respectively [26-28]. In this study, the US method showed comparable results to the literature. The mean differences from trials and raters ranged from 1.9° to 3.4°, within the commonly accepted variance of the Cobb method (5°), and the ICC values of intra- and inter-rater measurements (0.80−0.93) were all in the very reliable range. The inter-rater reliability was comparable to the corresponding intra-rater reliability from a single rater, which suggests that no rater bias or learning effect existed.

Even though the US method showed good intra- and inter-rater reliability, there were still slightly higher discrepancies compared with the reliability of the radiographic method; the ICC values were 4% to 12% lower and the SEMs were 0.4° to 1.3° larger. The possible reasons for these discrepancies are the lower resolution of US images and less experience using this new technique compared with the conventional radiographic method. Extensive use of radiography has led to optimization in potential sources of error such as the subject's posture during acquisition. One suggestion is to use a standing frame during US scan to standardize the standing posture. Among 3 raters, the most experienced one with experience in scoliosis (R3) showed better agreement between trials than the 2 new researchers. It implies that measurement using the US method may be improved by observers acquiring better skills. Furthermore, it was reported that a main source of Cobb angle error was in the selection of the end vertebrae [28]. A phantom spine model study [22] that used the COL method to measure the proxy Cobb angle in US images had been reported. The error index [6] used to assess the impact of the end-vertebra selections was analyzed and results showed no significant difference for the error index between the Cobb and COL methods [22]. Therefore, similar error as with the radiograph and Cobb angle may exist for US COL measurements. Future studies should evaluate the effect of Cobb angle reliability using the same end points of the curve.

As shown in Table 3, the difference between the coronal curvatures measured on US images and the Cobb angles measured on radiographs were 3.3°, 3.8°, and 3.3° for the 3 raters, respectively, which were all in the range of common acceptance for scoliosis assessment. Furthermore, the US method presented an average of 3.1° SEM for all 3 raters. These results demonstrate substantial agreement between the 2 methods. There are several possible reasons for the inconsistency between methods. First, the US scan and radiographs were not acquired simultaneously, but were taken within 1 hour and in different locations; thus, the posture of the subjects may have changed between the 2 examinations. For the radiographic examination, subjects stand in a positioning chariot whereas they are freestanding during the US examination. Second, the 2 methods used different landmarks to calculate the coronal curvature. Although the COL method is highly correlated to the Cobb method [21,22], identifying the center of lamina was less accurate than identification of the end plate of the vertebra.

Another noticeable issue with the US measurement was that some curves were not detected on the US images. For the 3 raters, 7, 5, and 8 curves, respectively, were not observed referring to the 49 overall curves determined from the radiographs. The missing curves were defined as those not detected by at least 2 of 3 raters. A total of 8 missing curves were identified, none which were the major curve of the subjects. The mean and SD of the severity of all missing curves were 22.4° ± 7.0° (range, 13°–30°) and the apices of these curves were located at T3–T6 (5), T7 (1), T12 (1), and L3 (1). Most of the missing curves were in the upper thoracic region (63%) and were the compensation curves. In addition to the missing curves, 8 false curves were observed by US but were not visible on radiographs. The false curves were mainly mild curves in which 75% (6 of 8) were less than 20°. The apices were distributed at T3–T6 (4), T7–T9 (2), and L2–L3 (2); therefore, 50% of curves were once again in the upper thoracic regions. The freestanding posture employed during the US examination may have created these missing and false curves. Therefore, a standing posture frame similar to that used in radiography is proposed in future studies to reduce the standing posture variation.

In this study, 4 of 30 subjects scanned within the study period were excluded. The primary reason was the unclear US images in which the researchers were unable to identify the lamina confidently. Possible reasons for loss of the US information may be thicker muscles that reduce signal penetration and a large rib hump that may create bad contact between the transducer and the back of the subject.

Furthermore, US apparatuses exist in most hospitals worldwide, but using US to diagnose scoliosis is still limited. The primary reason is that most US manufacturers do not allow users to export the raw US data. A stack of standard B-mode US images that are missing the position and orientation of these image frames cannot be used to reconstruct the 3D information of the spinal deformity accurately. The US equipment in this study had a specific research mode that allowed users to export raw data. A custom in-house program was needed to process the information to reconstruct the 3D spinal deformity and display in 3 orthogonal views (coronal, transverse, and sagittal).

In conclusion, the intra- and inter-rater measurement reliability of the US measurement showed substantially reliable results. The US measurement errors from different raters compared with the radiographic measurement were all within the range of acceptable accuracy for the scoliosis clinic. The US method has shown promise as a complementary radiation-free tool for monitoring children who have AIS. A single US scan can provide 3D information about the spinal deformity that a single plain radiograph cannot provide. However, the US technique cannot be used on subjects who have had spinal surgery. Metal implants inside the body make strong US reflections that may block required landmarks on the vertebra. Second, children who have severe AIS (major curve 45° or greater) with large vertebral rotation will have significantly reduced image quality that results in inaccurate measurements.

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