

1 **A novel method to measure the sagittal curvature in spinal deformities: the reliability and**
2 **feasibility of 3D ultrasound imaging**

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3

4 **ABSTRACT**

5 The objective of this study is to test the reliability of sagittal spinal curvature measurements
6 using three-dimensional (3D) ultrasound in adolescent idiopathic scoliosis (AIS) patients.
7 Ultrasound spinous process angle (USSPA) and ultrasound laminae angle (USLA) were measured
8 on sagittal ultrasound images, while Cobb angle (XCA) was measured on sagittal X-ray images.
9 Intraclass correlation coefficients (ICC) for the intra- and inter-observer variability, linear
10 regression analysis and Bland-Altman method including mean absolute difference (MAD) were
11 investigated to evaluate the reliability and validity of the two ultrasound angles as compared to
12 XCA. Excellent measurement reliabilities were demonstrated for both ultrasound angles
13 ($ICC \geq 0.91$). Moderate to good and significant linear correlations and good agreement were
14 demonstrated between the ultrasound methods and XCA (Thoracic ($R^2 \geq 0.574$) / Lumbar
15 ($R^2 \geq 0.635$)). No significant differences were found from the **MADs** between both corrected
16 ultrasound angles and XCA. Sagittal ultrasound angles demonstrated to be reliable for assessing
17 sagittal curvature using spinous processes and laminae, and have good and significant correlations
18 with Cobb angles. Since it is non-ionizing and relatively low cost, this opens the possibility to
19 provide frequent curve monitoring and evaluation, and screening for AIS patients, particularly
20 based on sagittal profiles.

21

22 Keywords: 3D ultrasound; Scoliosis; Sagittal; Spinous processes

23

1 **INTRODUCTION**

2 Idiopathic scoliosis is a three-dimensional (3D) deformity characterized by lateral
3 deviation, sagittal misalignment and transverse axial rotation of the spine (Pope et al. 1984).
4 Among all paediatric spine deformities, adolescent idiopathic scoliosis (AIS) is most prevalent
5 (Cheng et al. 2015; Fong et al. 2015; Tambe et al. 2018). Whereas in the past, the coronal plane
6 deformity has received most attention, it has become clear that the sagittal plane in AIS is at least
7 as important, both in analyzing the overall deformity, as in establishing treatment goals (Cheng et
8 al. 2015; Post et al. 2019). In clinical practice, the traditional standard for evaluating the sagittal
9 profile is by the sagittal Cobb angle (Cobb 1948). However, due to the effect of coupling in
10 different planes, the pattern of deformity in the sagittal plane may be highly influenced and
11 distorted by changes in the other two planes (Hayashi et al. 2009, Sullivan et al. 2017). Different
12 coronal curve patterns are characterized by differences in sagittal profile, and these also differ from
13 normal spines (Schlösser et al. 2014). Quantifying spinal curvatures in different planes is useful
14 for preoperative planning, postoperative evaluation and monitoring curve progression (Cheung et
15 al. 2013; de Bodman et al. 2017, Vrtovec et al. 2009, Post et al 2019) but there are significant
16 limitations with using only two-dimensional posteroanterior and lateral radiographs for evaluating
17 scoliosis.

18 Free-hand 3D ultrasound, combining conventional B-mode ultrasound images with spatial
19 sensing (Huang et al. 2005), is relatively cheap and becoming more popular. Different from X-ray,
20 the gold standard imaging modality for evaluating AIS patients, ultrasound is radiation-free. In
21 addition, in some countries physiotherapists were not authorized to request X-ray examination (de
22 Oliveira et al. 2012). 3D ultrasound was first explored on AIS patients by Suzuki et al. (1989), by
23 combining the transducer with an attached inclinometer to measure coronal Cobb angle and

1 vertebrae rotation. Later on, ultrasound has been demonstrated to be feasible to examine posterior
2 vertebrae morphology (Chin et al. 2011; Darrieutort-Laffite et al. 2014; Salman et al. 2011). Li et
3 al. (2012) investigated the effectiveness of orthotic treatment for patients with AIS using 3D
4 ultrasound in terms of spinous process angle in order to enhance the effectiveness of orthotic
5 treatment. The results showed that the ultrasound-assisted fitting method of spinal orthosis was
6 effective and beneficial to 62 % of the patients. Other than spinous process angle, center of lamina
7 method had also been used for ultrasound to evaluate coronal curvature. This method also showed
8 high intra- and inter-rater reliability and moderate correlation with X-ray Cobb (Young et al. 2015).
9 Wang et al. (2015) further investigated the reliability and validity of this method in clinical setting
10 by comparing to the corresponding MRI measurement on 16 patients with AIS, and similarly high
11 intra- and inter-rater reliability were demonstrated and no significant difference were observed
12 between the ultrasound results and MRI Cobb. Furthermore, tracked ultrasound had been utilized
13 to localize vertebral transverse processes to measure curvature angles on spine phantoms, and close
14 correlation was found between the tracked ultrasound transverse process angle and the
15 radiographic Cobb measurements with small inter-operator differences (Ungi et al. 2014).

16 A 3D ultrasound imaging method was developed and preliminary tests were conducted on
17 flexible spinal column phantoms (Cheung et al. 2013) and human subjects (Cheung et al. 2015).
18 Ultrasound measurements were performed were found to have good linear correlation with X-ray
19 and Bland-Altman showed good agreement between ultrasound and X-ray in both studies. The
20 ultrasound system was further modified and improved, and eventually became the 3D ultrasound
21 imaging system used in this study. It was demonstrated to provide results excellent intra- and inter-
22 rater and operator reliability, and moderate to strong correlation with Cobb's angle in previous
23 study (Zheng et al. 2016), where the results correlated better than Quantec system ($R^2 = 0.66$)

1 (Goldberg et al. 2001) and the Orthoscan system ($R^2 = 0.42$) (Knott et al. 2006). The reliability
2 and validity of different coronal spinal ultrasound angle measurements were further investigated
3 using the same ultrasound system, excellent correlations were found between ultrasound and Cobb
4 measurement and no differences in reliability and validity were observed between the ultrasound
5 angles based on the spinous processes and transverse processes (Brink et al. 2018). The 3D
6 ultrasound system were also demonstrated to provide reliable information of spinal flexibility and
7 in-orthosis correction of patients with AIS in the prone position (He et al. 2017) and the patterns
8 of alternation of coronal curve changes of patients with AIS during forward bending (Jiang et al.
9 2018). In a previous study, ultrasound was shown to be able to provide reliable sagittal
10 measurement of spinal phantoms and a few human subjects (Lee et al. 2019), however the sample
11 size of the human subjects was too small and relatively long period was required for data
12 acquisition. In addition, laminae were observed to be more obvious than spinous processes in
13 ultrasound images for providing reliable landmarks for measurement. As such, the aim of this
14 study is to investigate the utility of 3D ultrasound for measuring the sagittal curvatures with a
15 larger number of AIS subjects, using spinous processes and laminae as landmarks for measurement,
16 respectively.

17

18

19 **METHODS**

20 *Subjects*

21 Patients diagnosed with AIS were recruited from a tertiary scoliosis referral center to
22 participate in this study. Patients were requested to receive both ultrasound scanning and X-ray
23 imaging on the same day. This study was approved by the local institutional review board. Signed

1 informed consents were obtained from all subjects and their parents/guardians. Patients with Cobb
2 angle larger than 50 degrees, metallic implants and body mass index (BMI) greater than 25.0
3 kg/m² were excluded, as metallic implants would affect the spatial sensing accuracy of the
4 ultrasound probe and high BMI would likely lead to poor image quality in the lumbar region.
5 Patients who were wearing a brace during x-rays or allergic to ultrasound gel were excluded.

6

7 *3D ultrasound system*

8 The spine scanning was achieved using the 3D ultrasound imaging system (Figure 1a),
9 Scolioscan®, (Scolioscan, Model SCN801, Telefield Medical Imaging Ltd, Hong Kong) and
10 EOS® system (EOS® imaging, Paris, France) which is a bi-planar X-ray imaging system that
11 generates upright images of the spine with less radiation and allows 3D spine modeling (Deschênes
12 et al. 2010; Glaser et al. 2012). The specification of the 3D ultrasound system and the testing
13 protocol on human subjects had been reported in a previous study (Zheng et al. 2016). Linear
14 ultrasound probe (frequency of 7.5 MHz, width of 7.5 cm) was used for freehand ultrasound
15 scanning of the spine, with a spatial sensor attached to detect the position and orientation of the
16 probe. Supporters on the chest and hip boards of the ultrasound system, which were adjusted to a
17 patient specific height and length, were positioned to align with clavicle anterior concavities
18 bilateral anterior superior iliac spines respectively to stabilize the patients during the scanning
19 process in a natural standing position (Figure 1b). In addition, patients were asked to keep their
20 eye level horizontal at the level of the eye-spot shown on the patient screen and to focus on the
21 spot throughout the scanning process. Warmed aqueous ultrasound gel was applied to the patient's
22 back by the operators to fill the spinal furrow and to cover the extent of where the probe would
23 sweep. Pre-scanning was performed along L5 and T1, and corresponding adjustment of time gain

1 constant and brightness for B-mode image was conducted to achieve an overall good image quality
2 for the scanning region. After setting the scanning range, the scanning of the spine was conducted
3 by controlling the probe manually, and started approximately from the L5 level and continued to
4 go upward along the spine to the C7 level. The scanning procedure takes approximately 30 seconds.
5 After scanning, the collected B-mode image together with the corresponding orientation and
6 position recorded were used for 3D ultrasound volume reconstruction, and the volumes were then
7 transferred to a customized software for post-processing and generating sagittal ultrasound images
8 for measuring the sagittal curvature. Coronal ultrasound images were automatically formed by
9 obtaining an averaged intensity of all voxels of the ultrasound volume within a selected depth of
10 approximately 10 mm along the anteroposterior direction and using a non-planar re-slicing
11 technique using the skin surface as a reference for selecting the required voxels. The coronal
12 ultrasound angle(s) were measured by manually drawing the lines on the most tilted part of the
13 mid-line on the coronal image, which represents the shadow of the spinous processes (Figure 2),
14 and has been demonstrated to be reliable and repeatable (Brink et al. 2018, Zheng et al. 2016).
15 Since surface references were not available for generating sagittal ultrasound images, they were
16 formed by transferring the ultrasound volume to a customized software and manually selecting the
17 suitable slices along the medial-lateral direction, where the spinous processes and bilateral laminae
18 could be visualized.

19

20 *Data collection*

21 Two operators and three raters were involved to conduct US scanning and angle
22 measurements respectively Rater 1 and Rater 2 were responsible to conduct ultrasonic
23 measurements, who were novice researchers with more than 2 years of experience in studying the

1 human spine using 3D ultrasound. Rater 3 was a spine surgeon responsible for radiographic Cobb
2 angle measurements.

3 For ultrasound, thoracic kyphosis and lumbar lordosis were measured by the spinous
4 process angle (USSPA) and the laminae angle (USLA). To compute USSPA and USLA, three
5 sagittal ultrasound images visualizing the spinous processes (Figure 3a) and bilateral laminae
6 (Figure 3b) were first manually obtained by Rater 1 using a customized 3D ultrasound software.
7 This procedure had been repeated twice to generate two sets of images for each subject by Rater
8 1. The centre of spinous processes and laminae were considered as the landmarks for measuring
9 USSPA and USLA. Thoracic USSPA was defined by the intersection angle between the line
10 joining T3 and T4 spinous processes and the line joining T11 and T12 spinous processes, whereas
11 lumbar USSPA was defined by the intersection angle between the line joining T12 and L1 spinous
12 processes and the line joining L4 and L5 spinous processes (Figure 4a). USLA was defined by the
13 average of the angle values obtained from the left and right laminae. Thoracic USLA was defined
14 by the averaged intersection angle between the line joining T3 and T4 (left/right) laminae and the
15 line joining T11 and T12 (left/right) laminae, whereas lumbar USLA was defined by the
16 intersection angle between the line joining T12 and L1 (left/right) laminae and the line joining L4
17 and L5 (left/right) laminae (Figure 4b). Both measurements were performed using RadiAnt
18 DICOM Viewer software (Medixant, Poland). Approximate levels of T3, T12 and L5 were
19 indicated by Rater 2 on the sagittal ultrasound image to avoid line misplacement on specific
20 vertebral landmarks.

21 Thoracic XCA was defined by the angle formed by the upper endplate of T4 vertebra and
22 the lower endplate of the T12 vertebra, whereas lumbar XCA was defined by the angle formed by
23 the upper endplate of L1 vertebra and the lower endplate of the L5 vertebra from the standing

1 posteroanterior X-ray images by Rater 3 (Figure 4c) (Boseker et al. 2000). All raters performed
2 the measurement independently and were blinded to the patients' details.

3

4 *Statistical Analysis*

5 Statistical analysis was conducted using SPSS Version 20.0 (IBM, SPSS Inc.,
6 USA) software. Intra-class coefficient (ICC) was calculated to evaluate the reliability between the
7 measurements of the raters. For the intra-rater reliability, two measurements acquired from the
8 same sagittal image were compared individually by each rater (Shrout and Fleiss 1979). For the
9 inter-rater reliability, the first measurement results of the two raters were compared (Shrout and
10 Fleiss 1979). In order to test the reliability of the generating procedure of the sagittal image, two
11 sets of sagittal ultrasound angles, measured by Rater 1, each from different ultrasound sagittal
12 images generated using the customized 3D software from the same scan, were compared. The
13 Currier criteria for evaluating ICC values were adopted: very reliable (0.80–1.0), moderately
14 reliable (0.60–0.79), and questioned reliable (≤ 0.60) (Currier 1984). Ultrasound measurements
15 were compared with XCA respectively using linear correlation for thoracic curves and lumbar
16 curves. Linear regression equations with intersections were analyzed with correlation coefficients
17 0.25 to 0.50 indicating poor correlation, 0.50 to 0.75 indicating moderate to good correlation, and
18 0.75 to 1.00 indicating very good to excellent correlation (Dawson and Trapp 2004). Adjusted
19 ultrasound angles were then computed by substituting the ultrasound angles into the regression
20 equation obtained. Bland-Altman method was used to test the agreement between XCA and the
21 adjusted ultrasound angles, based on the results obtained by Rater 1. Mean absolute differences
22 (MAD) between XCA and the adjusted ultrasound angles were calculated and were compared
23 using paired t-tests. The significance level was set at 0.05.

1 **RESULTS**

2 A total of 21 patients (14 females) with mean age of 15.7 ± 1.3 years (range 12-18 years)
3 were included in this study. 2 patients had to be excluded since USSPA could not be measured due
4 to insufficient imaging quality caused by poor contact surface of the skin of skinny subjects. The
5 mean coronal Cobb angle was $24.5 \pm 9.0^\circ$ (range $11.1 - 41.9^\circ$), which was evaluated by the angle
6 formed between lines drawn on the most tilted upper vertebral endplate and lower vertebral
7 endplate of coronal curves. Thoracic and lumbar sagittal XCAs were on average $22.7 \pm 14.0^\circ$
8 (range $0.7 - 44.6^\circ$) and $38.0 \pm 12.6^\circ$ (range $14.7 - 60.0^\circ$) respectively. Thoracic and lumbar sagittal
9 ultrasound angles were on average $28.1 \pm 10.4^\circ$ and $18.5 \pm 9.2^\circ$ (USSPA) and $34.6 \pm 10.5^\circ$ and
10 $26.5 \pm 12.0^\circ$ (USLA).

11 Excellent reliabilities were obtained for both ultrasound angles in both thoracic and lumbar
12 regions from the same set (Table 1) and different set of images (Table 2). Both USSPA (Figure 5a)
13 and USLA (Figure 5b) showed moderate to good linear correlations with XCA. Thoracic USLA
14 was found to have the lowest R^2 value (0.574), while lumbar USLA was found to have the highest
15 R^2 value (0.701). The Bland-Altman plot showed a good agreement between the ultrasound angles
16 adjusted with the linear equations and the XCA (Figure 6a and 6b). No significant difference was
17 found between both adjusted ultrasound angles (MAD: USSPA $6.4 \pm 4.8^\circ / 6.1 \pm 4.4^\circ$; USLA 7.5
18 $\pm 4.9^\circ / 5.3 \pm 4.2^\circ$; $p \geq 0.326$ for thoracic / lumbar curves respectively).

19

20

21 **DISCUSSION**

22 The importance of the sagittal plane of the spine has become well recognized. Traditionally,
23 sagittal curvature of spine is evaluated by radiographic Cobb angle, which necessitates ionizing

1 radiation to form the images. Alternative imaging modalities have been suggested to minimize or
2 avoid the radiation issue. Bi-planar stereoradiography utilizes lower dosage of radiation, but it is
3 expensive and not readily available to most medical practitioners. Ultrasound imaging is non-
4 ionizing and relatively cheap, and has the potential of wide spread use and screening purposes.
5 During ultrasound scanning, subjects are maintained in the upright posture, same as that adopted
6 during traditional radiographic examination, thereby providing a real alternative to erect X-ray
7 images. But since ultrasound scanning is conducted on the back of the subjects, only posterior
8 structures of the vertebrae can be seen from the ultrasound images, thus landmarks like spinous
9 processes and bilateral laminae were used for sagittal spine measurement instead of vertebral
10 endplates in this study. Previous study has demonstrated the possibility of ultrasound to assess the
11 sagittal spinal curvature on spinal phantoms (Lee et al. 2019), and this paper further validates the
12 reliability and validity of studying the sagittal plane, using different sagittal angle measurement
13 methods using ultrasound. Excellent intra- and inter-rater reliabilities were demonstrated for
14 ultrasound sagittal angle measurement, and good to moderate linear correlations were
15 demonstrated between the ultrasound angles and radiographic Cobb angles. The average MAD of
16 the corrected ultrasound measurements was about 6.3° , without significant difference between the
17 different ultrasound measurements. Since the maximum measurement error on X-ray images was
18 found to be 6 degrees (Prujis et al. 1994), the ultrasound results obtained in this study were
19 sufficient for clinical use. The MADs were higher in the thoracic region for both ultrasound
20 methods and were probably due to the instability of the patients to maintain the posture during
21 scanning, since scanning initiated from the lumbar to the thoracic region and longer time was
22 needed to scan the thoracic region.

1 There is a difference between the US and X-Ray measurements. The sagittal ultrasound
2 angles obtained were larger in the thoracic curves and smaller in the lumbar curves as compared
3 to their corresponding sagittal radiographic Cobb angles. There were several possible reasons for
4 the discrepancies: 1) The ultrasound measurements were based on spinous processes and bilateral
5 laminae, which are structures located more posteriorly than the vertebral body, which is where
6 Cobb angle is by definition measured (Brink et al. 2018). Differences in structures used for
7 measurements thus will possibly lead to a different projection of the 3D deformity (Herzenberg et
8 al. 1990). In addition, it has been found that measurements based on posterior vertebral structures
9 would cause the angular value differences (Appendix B) (Chernukha et al. 1998); 2) Different
10 positions of arms were adopted for different imaging modalities. Patients were in a relaxed
11 standing posture with arms at the sides for ultrasound, whereas arms were bent with fists overlying
12 ipsilateral clavicles was the adopted position for X-ray scanning respectively (Pasha et al. 2016).
13 Decrease in kyphosis and increase in lordosis were observed when patients adopted the fists
14 overlying ipsilateral clavicles position compared to relaxed standing (Marks et al. 2009); 3)
15 Different levels of vertebrae were involved for X-ray and ultrasound assessments due to different
16 measurement techniques. To conduct sagittal measurements, lines were drawn on upper or lower
17 endplates and adjacent spinous processes and laminae on X-ray images and ultrasound images
18 respectively, hence an extra level was involved for every line drawn on ultrasound images. To
19 achieve consistency on the level selection, the spinous process or laminae of the superior vertebrae
20 were involved during sagittal measurement on ultrasound images. Thus T3 and T4 were involved
21 for constructing the superior line for thoracic curvature measurement in ultrasound images, which
22 possibly lead to a larger value of the thoracic ultrasound angle (Appendix B). Usually, on standard
23 X-Ray, it is difficult to obtain a clear image of any vertebra higher than T4 due to over-projection

1 of the shoulders, which is not a problem in ultrasound. We should bear in mind that using
2 traditional Cobb angles alone is not sufficient to comprehensively study the complex 3D deformity
3 of scoliosis. In addition, sagittal ultrasound images formed in this study are based on the projection
4 of the spinous process or bilateral laminae selected in the 3D ultrasound volume. This reflects a
5 real sagittal profile of that segment of the scoliotic spine, rather than the projection of a twisted
6 structure on a lateral radiograph, which is influenced by vertebral rotation and magnitude of
7 deformity.

8 It has been known that radiographic evaluation requires the use ionizing radiation, which
9 was especially harmful to children during puberty (Cheung et al. 2016). Repeated radiation
10 exposure may increase the risk of breast and endometrial cancer in female AIS patients (Doody et
11 al. 2000, Ronckers et al. 2010, Simony et al. 2016) and contribute to leukaemia and prostate cancer
12 in adolescents (Schmitz-Feuerhake et al. 2011). Though bi-planar stereoradiography provides
13 coronal and sagittal X-ray images with reduced radiation dosage and can be used to reconstruct
14 the 3D spine deformity with customized reconstruction software (Al-Aubaidi et al. 2013), biplanar
15 x-ray is not readily available for all healthcare providers due to its high cost and requiring a large
16 area for installation (McKenna et al. 2012). In addition, relatively large difference in accuracy was
17 found between the anterior and the posterior vertebral regions, since several anatomical landmarks
18 on the posterior arch such as the transverse and/or spinous processes may be barely visible on the
19 X-ray images, which caused reconstruction error leading to discrepancies (Mitulescu et al. 2002).
20 In addition, the time needed to reconstruct a detailed 3D spine model was an average of 20 to 30
21 minutes, and cases with a severe scoliotic curve would definitely require a significantly longer
22 time (Somoskeöy et al. 2012), which was not feasible under routine clinical circumstances.
23 Magnetic resonance imaging (MRI) and computed tomography (CT) are also common for

1 investigating scoliotic spine in the clinical and research fields. However, both MRI and CT are
2 costly and less accessible (Diefenbach et al. 2013). In addition, MRI requires expertise to operate
3 with long acquisition time, whereas CT requires a higher amount of radiation dosage than
4 traditional radiograph. Most importantly, patients are required to be assessed in supine position.
5 Different anthropometric tools have been used to evaluate sagittal spinal curvature such as stereo
6 camera (Goldberg et al. 2001), 3D digitizer (Salem et al. 2015), reflective skin markers (Schmid
7 et al. 2015), inclinometers (Lewis et al. 2010), adapted arcometer (Chaise et al. 2011), spinal
8 mouse (Mannion et al. 2004). However, these methods were either not precise enough or requires
9 a long period for palpation. Moreover, the above methods only consider the back topography, but
10 not the actual spinal anatomy.

11 We observed that sagittal curvature analysis using ultrasound requires a higher demand on
12 scanning and image quality control than that of coronal curvature analysis, because sagittal
13 measurements were required to be conducted directly on vertebrae structures, instead of just
14 measuring the spinous process shadow for coronal curvatures measurement. In addition, patients
15 with high BMI were not included in the study as the ultrasound frequency used has been mostly
16 attenuated and could not reach the vertebrae structure. Hence additional attention should be paid
17 in the future during scanning, such as using lower frequencies ultrasound probes, especially for
18 patients with a lumbar curves in order to capture the vertebral structures since they are deeper from
19 the skin surface. In addition, sagittal images were needed to be generated manually using the
20 customized software. Such process required a certain degree of expertise in viewing ultrasound
21 and spine anatomy, thus the inter-rater reliability of sagittal image generation could not be tested
22 in this study. Age and BMI might be confounding factors that possibly affect the sagittal
23 parameters, however we think that it may not be necessary to adjust the angle measurements for

1 such factors in this study as no significant correlation has been observed between these factors and
2 the sagittal angles. In addition, the patients included in this study has similar ages (small standard
3 deviation) and BMI < 25, thus we think our results are suitable enough to reflect the real situation,
4 though the effect of BMI on the quality of the ultrasound images requires to be explored in future
5 study. Patients with Cobb angles larger than 50 degrees were excluded in this study since spinal
6 sagittal measurement can be prone to measurement error due to the presence of severe rotation
7 (Bao et al. 2018). 2 subjects had been further excluded in this study because the appearance of the
8 spinous processes in the ultrasound images of some patients would somehow be affected for very
9 skinny patients, due to the protruded scanning trajectories when their backs were being scanned.
10 This problem could be tackled by applying a large ultrasound gel pack at the back of these patients
11 in future studies. However, the laminae would not be affected due to the above issue, thus USLA
12 measurement is more preferable when these patients are being assessed in future study. Since the
13 MADs of the two ultrasound angles were not significantly different, the USLA should be used to
14 overcome this issue for future study. Nevertheless, this study showed that for this scoliotic
15 population, sagittal curvature of the spine can be evaluated using the 3D ultrasound system, either
16 using spinous processes or bilateral laminae. Future studies with larger number of both scoliotic
17 and non-scoliotic subjects are worthwhile to be conducted to further verify the correlation between
18 the results of ultrasound and X-ray measurements.

19

20 **CONCLUSIONS**

21 This is the first study to report the feasibility of using ultrasound to assess the sagittal
22 curvature of human scoliotic spines, based on images obtained by the spinous processes and
23 laminae. In this study, we found moderate to good correlations between the ultrasound and Cobb

1 angles, and similar results of reliability and validity were found between the two ultrasound angles.
2 The differences in angle values can be explained by the different structures used for measurement,
3 and by the fact that ultrasound offers the possibility to assess in the true sagittal plane of the studied
4 spinal segment using the 3D ultrasound software. AIS is a 3D deformity and thus the true sagittal
5 profile is not well delineated by a simple 2D X-ray due to the coupling that occurs between the
6 deformations in the three planes. In this study, three-dimensional ultrasound is suggested as a new,
7 non-ionizing technique to provide the real sagittal and coronal profile in an upright, unforced
8 position.

9

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11 Dr. Zheng reports grants and other from Telefield Medical Imaging Limited, outside the
12 submitted work. In addition, Dr. Zheng has patents "A three-dimensional (3D) ultrasound imaging
13 system for assessing scoliosis. Patent issued: US 8,900,146 B2; China 201080040696.0; Japan
14 5849048. Pending in Canada, Australia, and EU. Filled in Jul 2009"; "Method and device for 3D
15 ultrasound imaging. Chinese patent. No. 200810094381.9. Filed in Apr 2008"; "Rapid 3D
16 ultrasound measurement. Chinese patent issued. No. ZL 200510127193.8. Mar 18 2009". with
17 royalties paid to The Hong Kong Polytechnic University by Telefield Medical Imaging Limited.
18 In addition, Dr. Zheng has following patent pending: "Imaging method and device.
19 PCT/CN2016/080261; Filed in Apr 2016", "Method and device for measuring spinal column
20 curvature. PCT/CN2016/080159. Filed in Apr 2016. "Medical imaging system with mechanical
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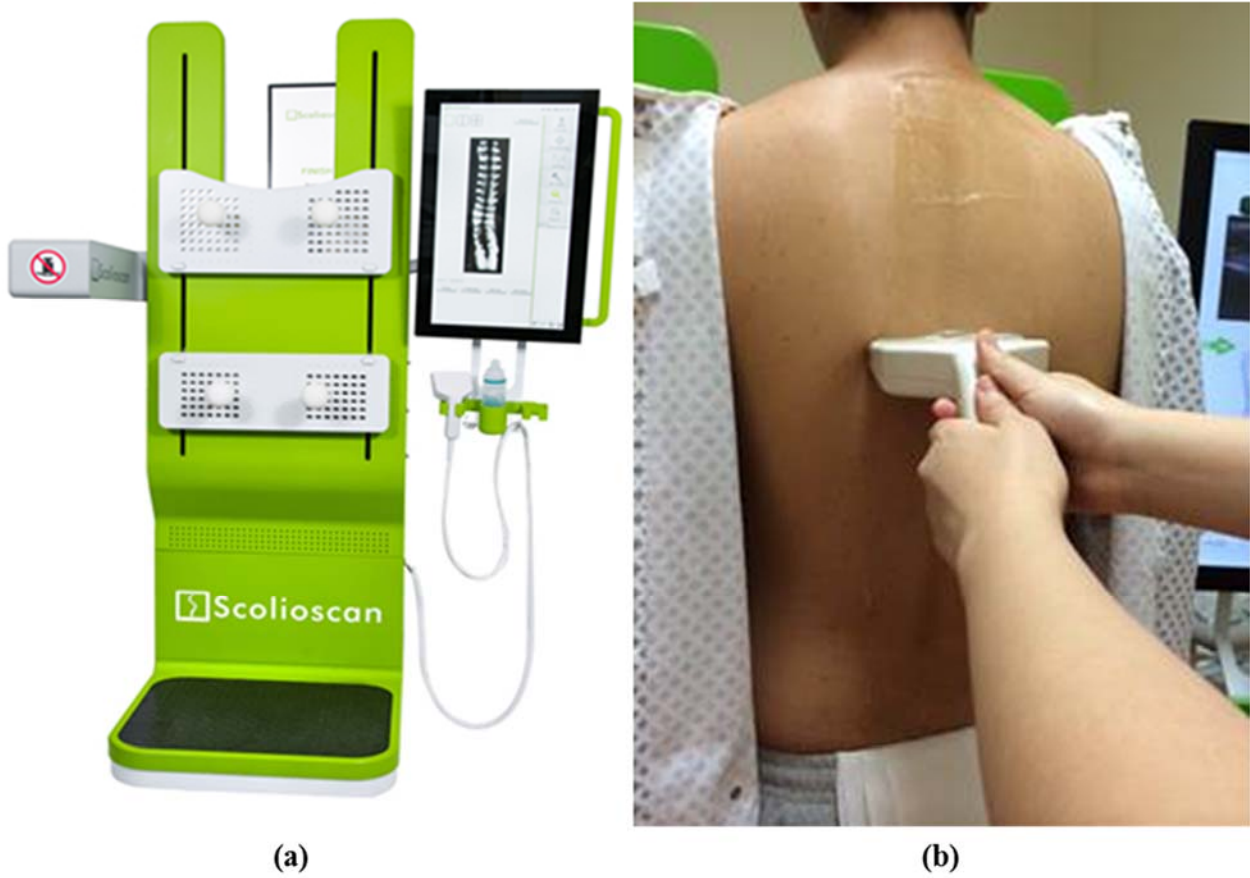
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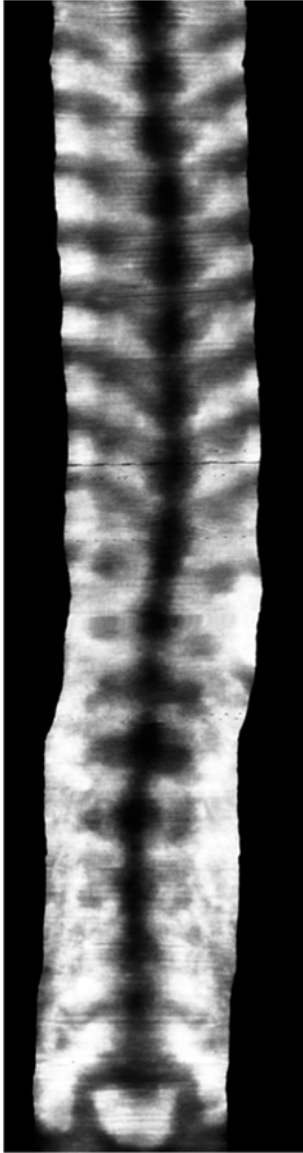
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1 **FIGURE CAPTION LIST**



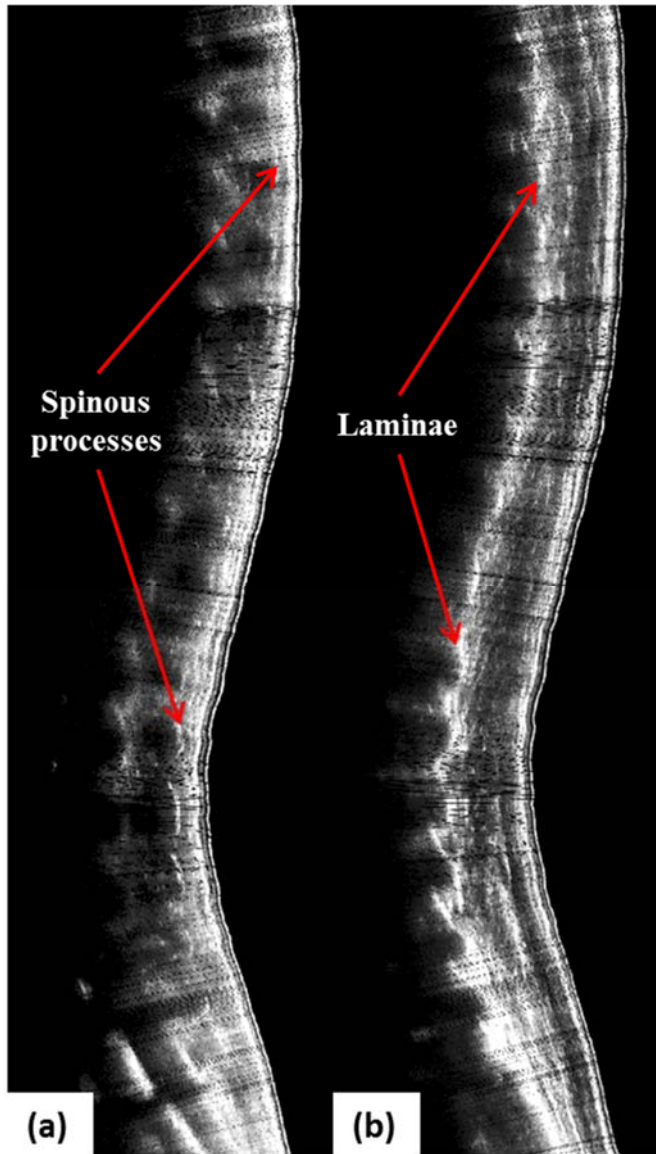
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3 Figure 1 The diagram illustrates the (a) 3D ultrasound device used in this study and (b) subject
4 being scanned using Scolioscan ultrasound system in natural standing posture



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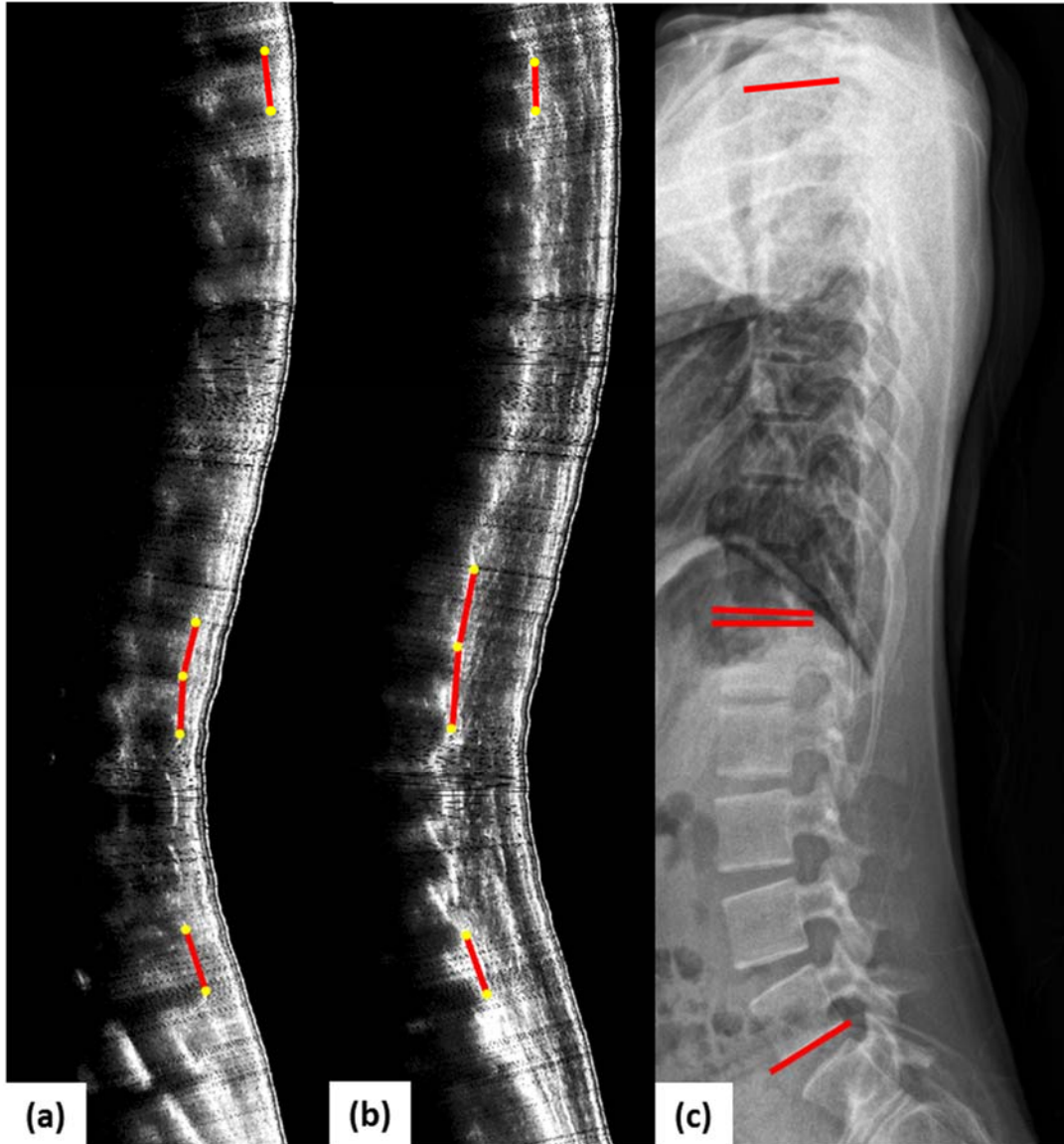
2 Figure 2 The diagram shows the measurement of coronal ultrasound angle(s) on the coronal image



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2 Figure 3. The diagram shows a sagittal ultrasound sagittal image illustrating (a) spinous processes

3 and (b) lateral laminae.

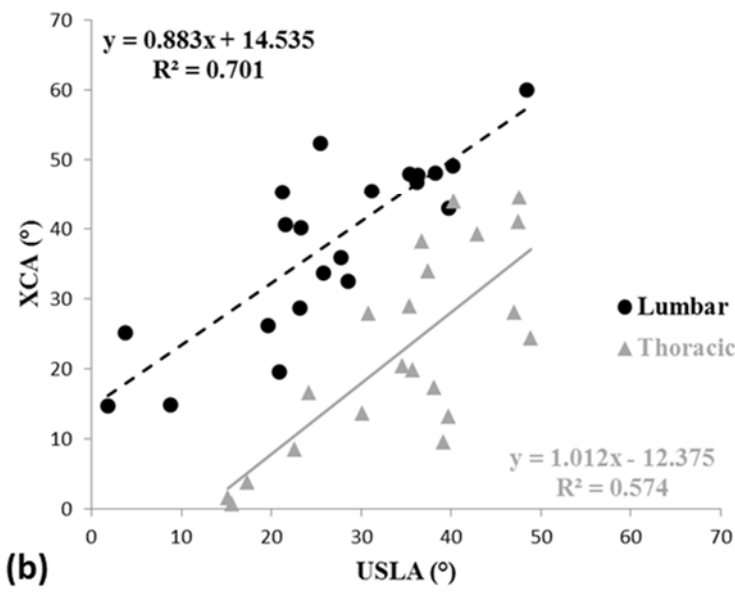
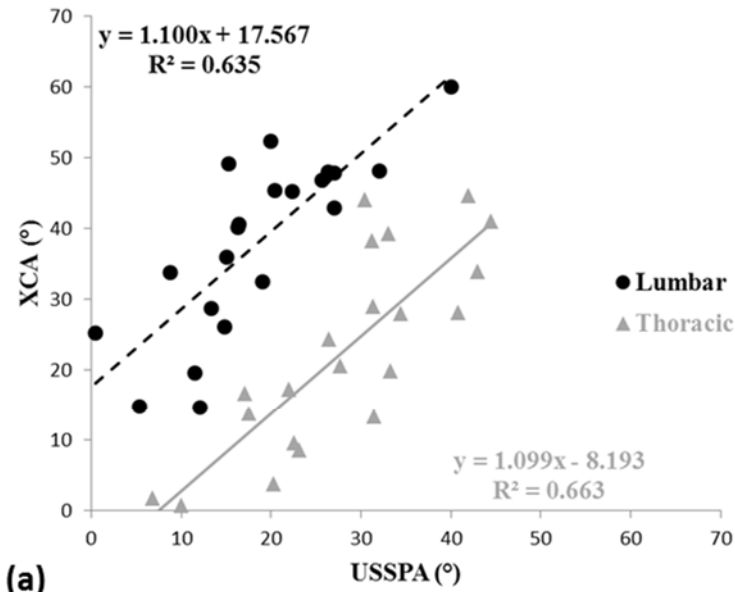


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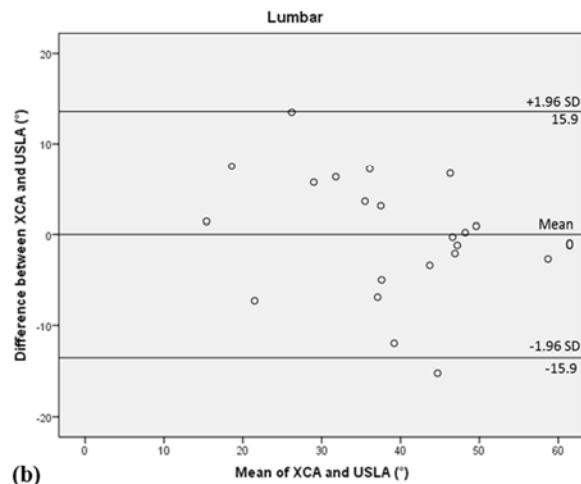
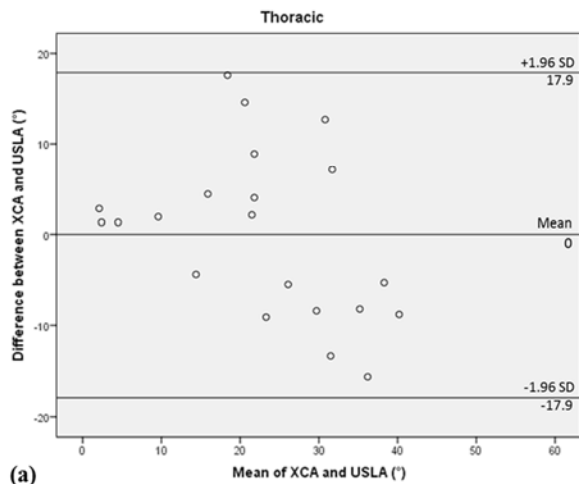
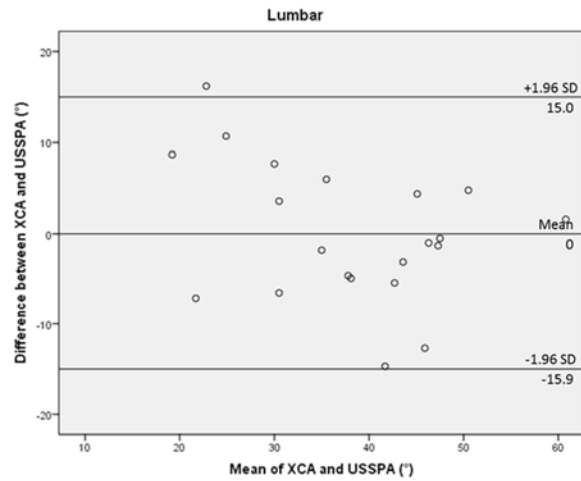
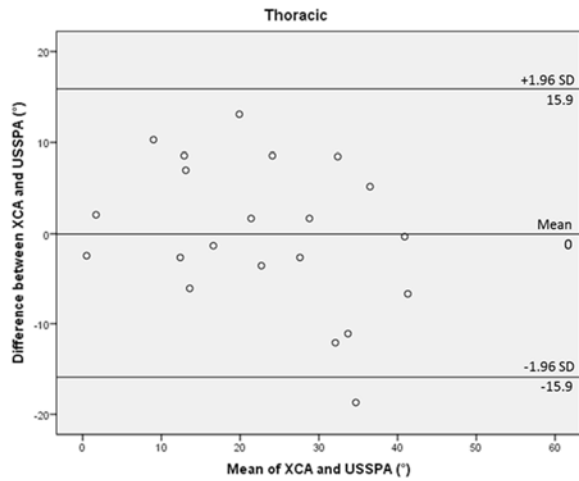
2 Figure 4. The diagram shows the measurement of (a) ultrasound spinous process angle (USSPA),

3 (b) ultrasound laminae angle (USLA) and (c) Cobb's angle (XCA) for evaluating thoracic kyphosis

4 and lumbar lordosis respectively.



1
 2 Figure 5. The graphs show the correlations (R^2) and equations between the X-ray Cobb's angles
 3 (XCA) and the ultrasound angles based on (a) spinous processes (USSPA) and (b) laminae (USLA)
 4 of the thoracic (grey) and lumbar (black) curves.

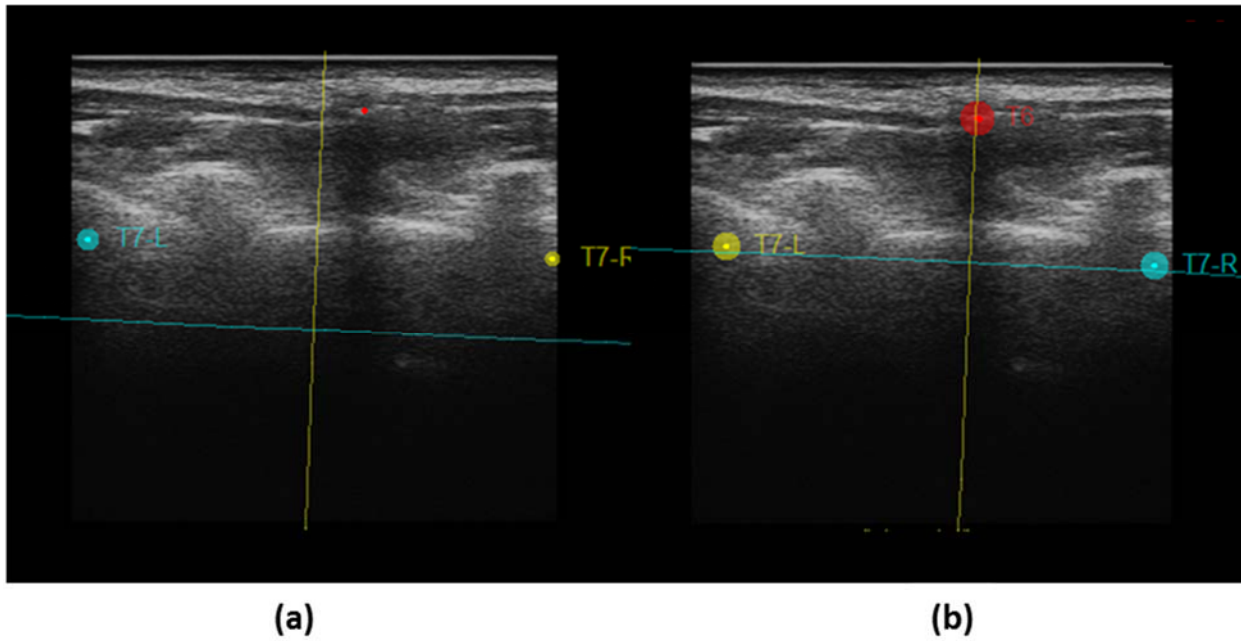


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2 Figure 6. The Bland-Altman plots which shows the differences between X-ray Cobb's angles
 3 (XCA) and the sagittal ultrasound angles (USSPA and USLA respectively) corrected with the
 4 linear regression equations of the (a) thoracic and (b) lumbar regions respectively. SD: standard
 5 deviation.



1
 2 Figure A.1. The diagram which shows the components of the customized 3D software used in this
 3 study to generate optimal sagittal images for sagittal curvature analysis: a) B-mode image window;
 4 b) Coronal plane images window; c) Sagittal image window; and d) Overall ultrasound volume
 5 window with all three planes.



1

2 Figure A.2 The diagram which shows a) the temporary marker attached to the T6 spinous process
3 and b) the corresponding T6 marker in the marker point set was manually dragged to the location
4 of the temporary marker, making the customized cut plane align with the spinous process.



1

2 Figure B.1 The diagram which shows the measurement of centre of posterior tangent Angle (XPTA)
3 for evaluating thoracic kyphosis and lumbar lordosis respectively.

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Table 1. Intra-rater and inter-rater reliability of the sagittal ultrasound angles by Rater 1 and Rater 2.

Angle	Curve	Rater 1	Rater 2	First measurement
		Intra ICC	Intra ICC	Inter ICC
USSPA	Thoracic	0.98 (0.96 – 0.99)	0.93 (0.84 – 0.97)	0.95 (0.87 – 0.98)
	Lumbar	0.96 (0.91 – 0.98)	0.92 (0.81 – 0.97)	0.94 (0.86 – 0.98)
USLA	Thoracic	0.99 (0.96 – 0.99)	0.97 (0.92 – 0.99)	0.95 (0.88 – 0.98)
	Lumbar	0.98 (0.94 – 0.99)	0.97 (0.92 – 0.98)	0.94 (0.40 – 0.98)

**ICC: Intraclass correlation coefficient; USSPA: Ultrasound spinous process angle; USLA: Ultrasound laminae angle; Parentheses represent the 95% confidence interval for the coefficient*

1 **Table 2.** Intra-rater reliability of the sagittal ultrasound angles measured by Rater 1 from different
 2 ultrasound sagittal images generated using the customized 3D software from the same scan

Angle	Curve	Rater 1 Intra ICC
USSPA	Thoracic	0.95 (0.91 – 0.98)
	Lumbar	0.91 (0.84 – 0.96)
USLA	Thoracic	0.96 (0.90 – 0.98)
	Lumbar	0.93 (0.84 – 0.97)

3 **ICC: Intraclass correlation coefficient; USSPA: Ultrasound spinous process angle; USLA:*
 4 *Ultrasound laminae angle; Parentheses represent the 95% confidence interval for the coefficient*

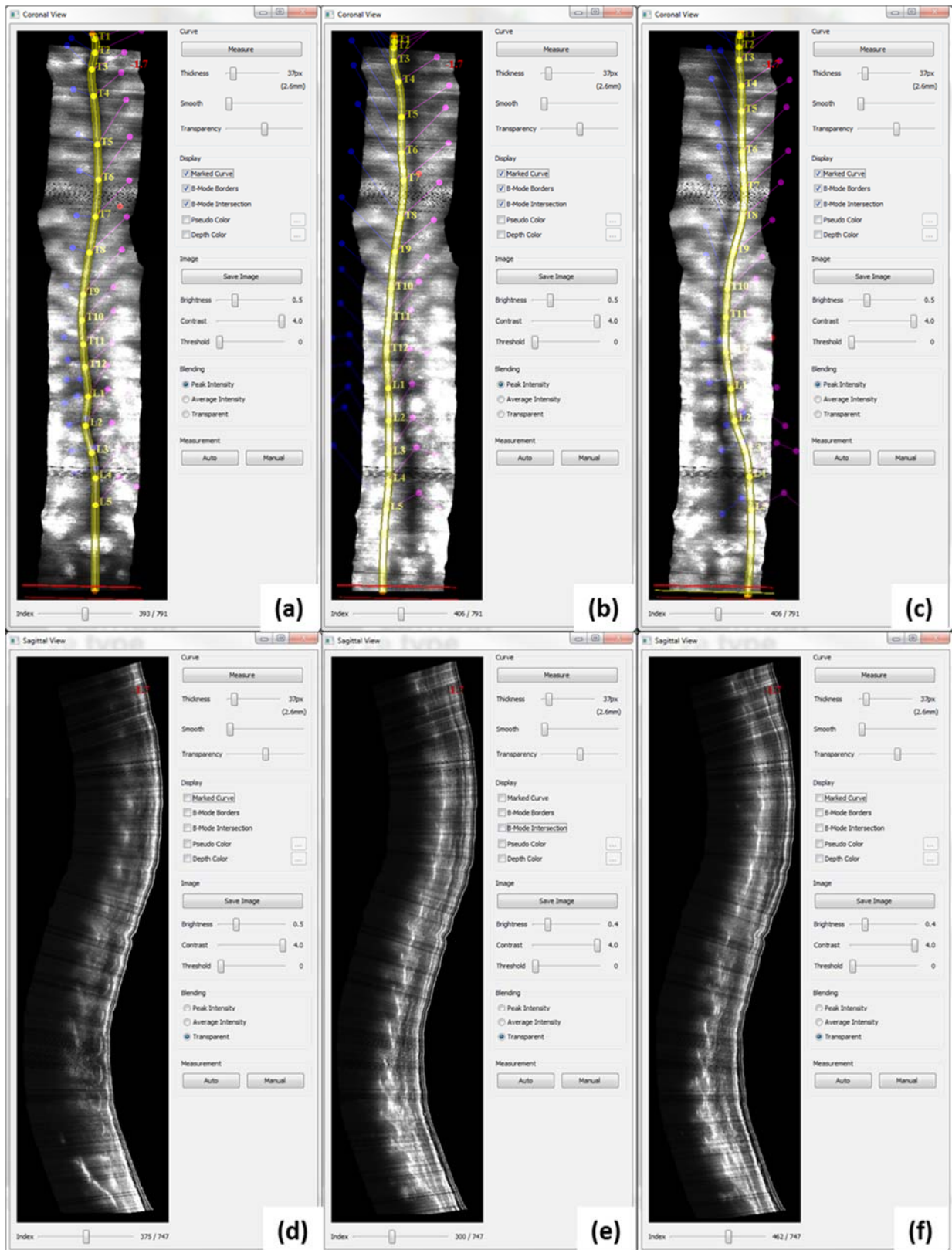
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1 **APPENDIX A**

2 After the 3D ultrasound volume was collected for the patient, it was then transferred to the
3 customized 3D software for further processing. For coronal images, back surfaces of the patients
4 are used as the reference for forming the sagittal cut plane before performing volume projection
5 imaging, to form the coronal images (Zheng et al. 2016). However, the coronal cut planes, which
6 are needed to generate the sagittal images which illustrates the spinous processes (Figure 3a) and
7 bilateral laminae (Figure 3b), required manual formation. The 3D software allows the user to view
8 the B-mode images with marked frame numbers, the coronal and sagittal views of the ultrasound
9 volume and the three planes over the entire volume (Figure A.1). From the coronal and sagittal
10 view windows of the 3D software, a marker set model and an intersection frame also appear in
11 both windows (Yellow and blue in coronal and sagittal view respectively) (Figure A.1b and A.1c).
12 The coronal intersection frame in the coronal window projects the sagittal image in the sagittal
13 window and vice versa. The position of the markers on the marker set model of each window can
14 be manually deformed and the shape of the intersection frame will change simultaneously,
15 eventually the corresponding projected images in both planes.

16 An algorithm developed in previous study (Zhou et al. 2017), which allows auto-detection of the
17 spinous process shadow of the coronal images, was embedded in the 3D software and employed
18 to coarsely form the coronal cut plane illustrating the spinous processes. The shadow of the ribs
19 appeared in the coronal image from the coronal window allow the user to identify the T12 vertebrae.
20 With the view of the coronal and sagittal projected images and the raw B-mode images from the
21 3D software and the knowledge of the posterior anatomy of the thoracic and lumbar vertebrae,
22 individual spinous process and bilateral laminae in each vertebral level could also be identified.
23 After identifying the best frames that illustrate the spinous process and bilateral laminae of each

1 laminae from the B-mode images, the corresponding markers from the marker set model could be
2 dragged to the vertebrae structures (Figure A.2). This dragging procedure is facilitated by a
3 function embedded in the 3D software, where a temporary marker could be set on the B-mode
4 image and could be seen on the coronal and sagittal images. Generally, spinous processes appear
5 under the spinous process shadow and bilateral laminae appear bilaterally next to the spinous
6 process shadow. Hence by repeating the above procedures, the manually defined coronal cut planes
7 which align with the spinous processes (Figure A.3a) and bilateral laminae (Figure A.3b: left
8 laminae and A.3c right laminae) could be formed and the corresponding sagittal images were
9 outputted for analysis (Figure A.3d, A.3e and A.3f).



1

2 **Figure A.3.**

1 **APPENDIX B**

2 An extra set of X-ray measurements, called the Centre of Posterior Tangent Angle (XPTA), was
 3 measured in order to explore and demonstrate the effect of different structures and measurement
 4 techniques on sagittal measurements, which is based on the posterior tangent method by Harrison
 5 et al. (1996). For XPTA, thoracic kyphosis was defined by the angle formed between the line
 6 joining the centre of T3 and T4 posterior border and the line joining the centre of T11 and T12
 7 posterior border, whereas lumbar lordosis was defined by the intersection angle between the line
 8 joining the centre of T12 and L1 posterior border and the line joining the centre of L4 and L5
 9 posterior border (Figure B.1). All the measurements were performed using RadiAnt DICOM
 10 Viewer software (Medixant, Poland) and were shown in Table B.1. It could be observed that there
 11 was a clinically significant difference between the XCA and XPTA, and XPTA obtained had a
 12 smaller angular difference with USLA and USSPA compared to XCA.

13

14 **Table B.1** Mean value of thoracic kyphosis and lumbar lordosis obtained from four different
 15 methods using X-ray and ultrasound respectively.

16

	X-ray		Ultrasound	
	XCA	XPTA	USLA	USSPA
TK (°)	22.7 ± 14.0	30.0 ± 13.1	34.2 ± 10.7	28.1 ± 10.4
LL (°)	38.0 ± 12.6	28.9 ± 11.9	27.1 ± 12.1	18.5 ± 9.2

17 *XCA: X-ray Cobb angle; XPTA: X-ray centre of posterior tangent angle; USLA: Ultrasound*
 18 *laminae angle; USSPA: Ultrasound spinous process angle; TK: Thoracic kyphosis; LL: Lumbar*
 19 *lordosis*

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