Analysis of Sagittal Profile of Spine Using 3D Ultrasound Imaging: A Phantom Study and Preliminary Subject Test

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Abstract

Radiographic Cobb's angle is the gold standard for evaluation of spinal curvature, however X-ray is ionizing. In contrast, ultrasound is non-ionizing and inexpensive, thus more accessible. However, no study has reported the reliability and accuracy of ultrasound on sagittal curvature analysis. Ultrasound and X-ray scanning were conducted on 16 sets of spine phantoms with different deformities. Intra-rater and inter-rater reliability, correlations, mean absolute differences (MAD) and linear regression of Ultrasound spinous process angles (USSPA), X-ray spinous process angles (XSPA) and X-ray Cobb's angles (XCA) together with the intra-operator reliability of USSPA were investigated. In addition, USSPA and XCA of five AIS subjects were scanned using the ultrasound system. In the phantom study, excellent intra-rater and inter-rater reproducibility for the three angles and excellent intra-operator reproducibility for USSPA were demonstrated. Good to moderate correlations were obtained between lumbar XCA and XSPA and between lumbar XCA and USSPA, whereas excellent correlations were observed between the other angles. All three angles indicated positive linear relationships, with MAD of 5.8°, 3.0° and 6.0° for XSPA against XCA, USSPA against XSPA and USSPA against XCA, respectively. The results of the preliminary study demonstrated a high intra-reliability for the ultrasound measurements. The measured difference between the USSPA and XCA methods was 6.3° ± 5.4°. It should be noted that ultrasound and X-ray measurements were based on different structures of the vertebrae. The results showed that ultrasound is feasible for measuring sagittal curvature and has the potential for monitoring the curve progression and evaluating sagittal spinal profiles.

Keywords: Spine, sagittal balance, Cobb's angle, 3D ultrasound imaging, spinous process

Introduction

Human spine composes of five regions: cervical, thoracic, lumbar, sacrum and coccyx. Thoracic kyphosis and lumbar lordosis are two common sagittal parameters when analyzing sagittal profile. For normal individuals, acceptable ranges for kyphosis and lordosis are between 20 to 50 degrees and 31 to 79 degrees, respectively (Boseker et al. 2000, Bridwell and Bernhardt 1989). It is essential to maintain a balanced sagittal spinal profile because an optimal degree of kyphosis and lordosis is necessary to maintain spine motor control with minimum energy expenditure, enhance the load tolerance of the spine and increase spinal muscle efficiency (Kim et al. 2006). From clinical point of view, a better understanding of the sagittal spinal profile helps to evaluate patients with spinal pathology, assist surgical planning and minimize complications such as spinal deformity issues like sagittal imbalance (Cho et al. 2014).

For young individuals, such as schoolchildren, one of the potential threats that could alter their sagittal profile is carriage of overloaded backpack, which is common among schoolchildren in different regions (Goodgold et al. 2002, Cottalorda et al. 2004). The overloaded backpack has been found to cause back pain and spinal deformities (Moore et al. 2007, Hong et al. 2011, Talbott et al. 2009). Different other factors have also been reported to cause deformity in spinal sagittal profile, such as improper practice of elongation exercises (Drzał-Grabiec et al. 2014), hereditary factors (Janssen et al. 2013), patients with idiopathic scoliosis (Roussouly et al. 2013, Yong et al. 2012, Janssen et al. 2011, Hu et al. 2016, Hong et al. 2016), intervertebral disc degeneration (Barrey et al. 2007, Cil et al. 2005), Parkinson's disease (Baik et al. 2009, Schwab et al. 2012), gender effect (Chaléat-Valayer et al. 2011, Abelin-Genevois et al. 2014, Takács et al. 2015), and age (Hammerberg and Wood 2003, Gelb et al. 1995, Tang et al. 2012, Li and Hong 2004). Therefore, an accurate and convenient assessment method for spinal sagittal deformity is very much demanded.

It has been reported that modification of spinal sagittal profile has a strong correlation with musculoskeletal problems development in the spine (Betsch et al. 2015, Nam et al. 2014). For instance, reduction of lumbar lordosis and sacrum inclination reduced the natural curvature of the lumbar spine (Makhsous et al. 2013, Alexander et al. 2007, Drzał-Grabiec et al. 2015). In addition, it was demonstrated that alternation of sagittal spinal curvature caused viscoelastic deformation of spinal tissues (Solomonow et al. 2003), higher intra-discal pressure (Wilke et al. 1999) and spine overloading and degeneration (Makhsous et al. 2013, Alexander et al. 2007, Drzał-Grabiec et al. 2015, Beach et al. 2005). Moreover, flattening of the thoracic kyphosis was found to be a risk factor for scoliosis (Roussouly et al. 2013) and reportedly cause diminution of the lung function in patients with scoliosis (Winter et al. 1975). Furthermore, shear loads experienced by vertebrae were altered once the sagittal spinal profile was disturbed, hence facet joints in the posterior portion of the posterior inclined vertebra were unlocked, inducing rotational instability to the spinal column and causing further progression in spinal deformity (Janssen et al. 2011, Schlösser et al. 2014, Castelein et al. 2005, Kouwenhoven et al. 2007).

Spinal sagittal imbalance also affects the quality of life of an individual. Previous studies reported that alternation of the lumbar lordosis led to the occurrence of lower back pain (Jackson et al. 2011, Bernard et al. al. 2008, de Jonge et al. 2002), headaches, fatigue and cervical pain (Chow et al. 2007). In some severe cases, social interaction of the patients was affected due to deficient forward gaze (Roussouly and Nnadi 2010). Thus, it is essential to monitor the sagittal spinal profile, especially for young individuals who are at their puberty age.

X-ray and magnetic resonance imaging (MRI) are the two commonly used imaging modalities for evaluating sagittal spinal curvature, where using Cobb's method on radiograph is the gold standard at present (Cobb 1948, Vrtovec et al. 2009, Harrison et al. 2001). The major drawback of radiograph evaluation is that patients are exposed to radiation. Patients with spinal deformity generally receive repeated exposure of radiation due to regular and repetitive monitoring for the deformity progression. Although the recent developments, such as EOS machine, a system which uses slot-scanning technology to provide bi-planar X-ray image and is compatible to a 3D reconstruction software for 3D analysis of the deformed spine, have reduced the radiation exposure to patients (Deschênes et al. 2010), ionizing radiation remains an issue for patients who require repetitive scanning, on top of the high cost and installation complexity. MRI has been used for spinal deformity evaluation because of its high resolution. However, it is costly and less accessible (Diefenbach et al. 2013). Moreover, patients are required to be imaged in supine position, where the spinal curvature is spontaneously corrected when compared with that in weight-bearing position, hence the natural spinal curvature cannot be acquired (Yazici et al. 2011). Furthermore, different tools have been used to evaluate sagittal spinal curvature such as inclinometers (Lewis and Valentine 2010), adapted arcometer (Chaise et al. 2011), spinal mouse (Mannion et al. 2004, Ripani et al. 2008), flexicurve (de Oliveira et al. 2012), motion analysis system with reflective markers (Schmid et al. 2015), and Zebris US-based motion analysis system (Zsidai and Kocsis 2006, Takács et al. 2015). However, these methods could just evaluate the spinal curvature based on the back topography of the patient, instead of measuring the actual curvature of the spine.

Free-hand 3D ultrasound imaging, which combines a conventional B-mode imaging system with a position sensor, has been developed over two decades and recently become more popular due to its features of radiation-free, wider accessibility and lower cost in comparison with other 3D imaging modalities (Huang et al. 2005, Huang and Zeng 2017, Mozaffari et al. 2017). Ultrasound evaluation of coronal curvature and vertebral rotation was reported by Suzuki et al. (1989) back to 1980's. Later, a number of 3D ultrasound imaging systems for the coronal plane assessment of scoliosis have been reported by different groups have been reported (Cheung and Zheng 2010, Li et al. 2010, Prunama et al. 2010, Chen et al. 2013, Ungi et al. 2014). Cheung et al. (2013, 2015) reported preliminary tests on spinal column phantoms and human subjects based on spinous process angle, and later the same system was used for testing a larger number of subjects, demonstrating high intra- and inter-rater and operator reliability, and good correlation with Cobb's angle (Zheng et al. 2016, Brink et al. 2018). Spinous process angle was also used to investigate the effectiveness of orthotic treatment for patients with AIS (Li et al. (2012). A study utilized tracked ultrasound to localize vertebral transverse processes as landmarks along the spine to measure curvature angles on spine phantoms, where close correlation was found between the tracked ultrasound transverse process angle and the radiographic Cobb measurements (Ungi et al. 2014). Huang et al. (2018) further developed this method by continuously monitoring image spatial information to form an continuous curved plane for scoliosis assessment. Centre of laminae methods had been used for both coronal curvature and vertebral rotation assessment. Coronal measurement on cadaver spine phantom (Chen et al. 2013) and patients (Young et al. 2015) of the laminae method showed high intra- and inter-reliability and were comparable with those obtained from X-ray. Axial vertebral rotation obtained using the laminae method also showed high intra- and inter- reliability (Chen et al. 2016), and good agreement was found between the laminae ultrasound results with those obtained by the Aaro-Dahlborn method in the magnetic resonance images (Wang et al. 2016). Though there were various studies using ultrasound on the evaluation of vertebrae features, coronal spinal curvature and vertebrae rotation, no study has been reported on the reliability of 3D ultrasound imaging for evaluating the sagittal spinal curvature.

The aim of this study is to investigate the reliability of a 3D ultrasound imaging system for the measurement of sagittal curvature of a spine phantom. Sagittal angles were represented in terms of 1) spinous process angle obtained from 3D ultrasound imaging, 2) spinous process angle obtained from sagittal X-ray images, and 3) traditional sagittal Cobb's angle. The intra-operator scanning reliability to obtain ultrasound results was tested. In addition, the intra-rater and inter-rater reliabilities of all the three parameters were also studied and compared. Furthermore, the correlations among the three types of angle were investigated. We also performed a pilot study on five adolescent idiopathic scoliosis (AIS) subjects who were scanned using the 3D ultrasound imaging system. Their sagittal curvature measurements from the ultrasound images were compared with the corresponding X-ray Cobb angles. It is believed that the results of this study would provide a good reference for further evaluation on human subjects and clinical applications.

Methods

The 3D ultrasound imaging of spine was achieved using an ultrasound scanner (EUB-8500, Hitachi Medical Corporation, Tokyo, Japan) with a linear probe (L53L/10-5) with frequency of 5-10 MHz, an electromagnetic spatial sensing system (MiniBird Ascension Technology Corporation, Burlington, VT, USA) with its mounted on the probe surface, a desktop PC installed with a video capture card (NIIMAQ PCI/PXI-1411, National Instruments

Corporation, Austin, TX, USA) and a PC program written using Microsoft Visual Studio 6 with Visual C++ data collection, image processing, visualization and analysis (Figure 1) (Cheung, et al. 2015a, Cheung, et al. 2015b). According to the manufacturer, positional accuracy, position resolution, angular accuracy and angular resolution of the electromagnetic spatial sensor in terms of root-mean-square were 1.8 mm, 0.5 mm, 0.5 degrees and 0.1 degrees, respectively. Four flexible spinal column phantoms featured with soft intervertebral discs allowing deformation (VB84, 3B Scientific, Germany) were used in this study (Figure 2). Each spine phantom was scanned using a water-tank scanning approach (Figure 1). Plastic frames made of acrylic plates and nylon screws were fabricated for the four phantoms and spatial sensor transmitter, to avoid any induced motion by the operator during the scanning process and transportation for X-ray imaging. These spine phantoms were 105cm in height without any deformity. Each of the phantoms was deformed to have four different sagittal curvatures in the presence of scoliotic curvature to simulate different scoliotic conditions. Therefore, in total, 16 different sagittal spinal curvature cases were evaluated.

All the four phantoms first underwent X-ray chest radiography in lateral positions. The X-ray images were digitized for sagittal Cobb's angle and sagittal spinous process angle measurement using Sante DICOM Viewer free edition version 4.0.13 (Santesoft Ltd, Athens, Greece). To conduct 3D ultrasound scanning, the mounted phantoms were first submerged into a water tank filled with water, with all T1 to L5 vertebrae submerged under water. Prior to scanning, the scanning range was first determined by submerging the probe to the levels of L5 and T1 to define the starting point and ending point respectively. This procedure was exploited for defining the 3D images stack coordinates. During scanning, the probe was oriented with its imaging plane in horizontal plane, and was driven slowly and steadily upwards from L5 to T1 vertebra. The probe's middle line position was maintained to align with the spinous processes of the phantom to ensure that the processes were imaged in the US images during the scanning process. The average scanning time was approximately 1 minutes with a frame rate of 10 frame per second, hence around 500 to 700 frames of B-mode images were captured during each scan. After the scanning was completed, the collected ultrasound images (Figure 3a) were viewed in 3D with corresponding spatial information (Figure 3b). Spinous processes were then manually selected from the stacked ultrasound images using the PC program (Figure 4a), where the tips of the processes were manually assigned with a spherical marker in these images using the PC program (Figure 4b), and then the spatial information of the processes can be obtained (Cheung et al. 2013, 2015a).

Three sets of data were obtained from the phantom: 1) spinous process angle obtained from 3D ultrasound imaging (USSPA), 2) spinous process angle obtained from sagittal X-ray images (XSPA), and 3) traditional sagittal Cobb's angle (XCA). Both thoracic kyphosis and lumbar lordosis were represented in absolute values for all these angles. The most common radiographic landmarks used in scoliosis measurement are end-plates of vertebrae, because they are clearly visible in radiographs. Endplates are not visible in B-mode ultrasound images because the posterior anatomical structure of the vertebrae hinders them from being detected by the ultrasound beam. Indeed one of the most clearly visible vertebral structures observable by ultrasound is the spinous process. Thus USSPA was evaluated for sagittal spinal curvature using the B-mode images. All the B-mode images were first reviewed manually to identify those images with the echo representing spinous process (Figure 4a). Normally multiple images would contain a specific spinous process, then the one with the sharpest echo, often the one located in the middle of all identified images, was selected to represent the tip of spinous process (Figure 4b and 4c). Once the location of a spinous process in a specific B-mode image was identified, the 3D spatial coordinates of this location were calculated based on the spatial information of the probe captured by the electromagnetic spatial sensor, a matrix to transfer the location of each pixel in a B-mode image to 3D spatial coordinates (Huang et al. 2005). The spatial coordinates of spinous processes of T2-L4 were identified using this method (Figure 4c). Before data analysis, sagittal profile formed by the spinous processes curvature formed by the spinous processes was visually compared with the sagittal shape formed by the spinous processes in the radiograph (Figure 4d). The coordinates of the sagittal spinous process profile were then compiled and used to generate a curve using a 5^{th} order polynomial curve fitting algorithm using a custom-designed Matlab program script (Salem et al. 2015). The corresponding slopes of the tangents of T2, T12 and L4 of the generated curves were then obtained. The slopes of tangents of T2 and T12 were used to calculate the thoracic USSPA and those of T12 and L4 were used to calculate the lumbar USSPA.

For the Cobb's angle measurement of the X-ray images, thoracic XCA was defined by the angle formed by the straight lines drawn from the upper endplate of T2 vertebra and the lower endplate of the T12 vertebra, whereas lumbar XCA was defined by the angle formed by the straight lines drawn from the upper endplate of L1 vertebra and the lower endplate of the L4 vertebra from the X-ray images (Boseker et al. 2000). The lines were drawn using the Sante DICOM Viewer software and the thoracic and lumbar Cobb's angles were measured from the computer screen using a protractor (Figure 5a). For XSPA, image analysis software (Image J ver. 1.49, National Institutes of Health, USA) was used for manually locating the spinous process from T2-L4 in the sagittal radiograph (Figure 5b). Similar to the computation of USSPA, the coordinates representing the sagittal plane of the spinous process markers were used to obtain the slope of tangents of T2, T12 and L4 using 5^{th} order curve fitting process to find out the sagittal thoracic and lumbar XSPA.

An operator, named as Operator A, was responsible to conduct the US scanning for twice. Another investigator in this study, named as Rater B, was responsible to obtain two sets of USSPA, XSPA and XCA images respectively at an interval of one week to investigate the corresponding intra-rater reliability. All the second measurements were performed one week after the first measurements to eliminate bias caused by the effect of memory of Rater B. In addition, Rater B was responsible to acquire a set of USSPA for the two US scans to test the intra-operator reliability for the US scans. Another rater, namely Rater C, took another measurement from the ultrasound images and X-ray images obtained from the first scan of each phantom to test the inter-rater reliability of USSPA, XSPA and XCA respectively. The correlations of USSPA, XSPA and XCA obtained by Rater B were also tested.

SPSS Version 20.0 (IBM, SPSS Inc., USA) software was used for statistical analysis. The intra-operator reliability for US scanning was analyzed by comparing the first set of USSPA obtained from the first scan with that obtained from the second scan. To investigate the measurement reliability of Rater B for USSPA, XSPA and XCA measurements, the first set of USSPA (first scan), XSPA and XCA measurements were compared with the second set of the corresponding measurements from the same scan or image. Both the intra-operator and intra-rater reliabilities were analyzed using intra-class correlation coefficient (ICC) (two-way random and consistency) (Shrout and Fleiss 1979). To analyze the inter-rater reliability for USSPA, XSPA and XCA, the first set of measurements obtained by Rater B was compared with that obtained by Rater C from the first US scan and X-ray image respectively. The inter-rater reliabilities for all angles were analyzed using intra-class correlation coefficient (ICC) (two-way random and absolute agreement) (Shrout and Fleiss 1979). The Currier criteria for evaluating ICC values were adopted: very reliable (0.80–1.0), moderately reliable (0.60–

0.79), and questioned reliable (≤0.60). Furthermore, Pearson coefficients were calculated to describe the relationship of the overall sagittal curvature measured (combining thoracic and lumbar angles obtained) for all three angles, with correlation coefficients 0.25 to 0.50 indicating poor correlation, 0.50 to 0.75 indicating moderate to good correlation, and 0.75 to 1.00 indicating very good to excellent correlation (Dawson and Trapp 2004). Mean absolute differences (MAD) and standard deviation (SD) among the three methods were calculated based on the first set of ultrasound measurement to investigate the measurement differences of the methods. Equations describing the line of best-fit through the data of the three methods were also evaluated. The experimental design of this study was illustrated in Figure 6 for better understanding. All the details of the statistical tests and corresponding data sets used were summarized in Table 1.

A preliminary study for AIS subjects was performed after the phantom experiment to further validate the proposed spinous process method for sagittal curvature measurement. The subjects were recruited from a tertiary scoliosis referral center and they were arranged to conduct both 3D ultrasound scanning and their regular X-ray imaging on the same day. This study was approved by the local institutional review board. Signed informed consents were obtained from all subjects and the guardians of the subjects. The inclusion criteria were: (1) diagnosed with AIS but not received surgical treatment, (2) the largest Cobb angle was below 40 degrees, (3) radiographs were taken not in-brace, and (4) without metallic implant as it would affect the spatial sensing accuracy of the ultrasound probe. Five subjects were scanned using the 3D ultrasound imaging system, Scolioscan®, (Scolioscan, Model SCN801, Telefield Medical Imaging Ltd, Hong Kong) and EOS® X-ray system (EOS® imaging, Paris, France). The specification of the 3D ultrasound system and the testing protocol on human subjects had been reported in a previous study (Zheng et al. 2016). This 3D ultrasound imaging system had been demonstrated to provide reliable coronal curvature measurements in AIS patients (Zheng et al. 2016). It used an ultrasound probe with a frequency of 7.5 MHz, which was similar to what used for the phantom study. The scanning of the subject spine was also conducted by controlling the probe manually, and started approximately from the L5 level and continued to go upward along the spine to the C7 level. The image processing and measurement of sagittal curvature were similar to that for spinal phantoms. Rater B performed the measurements using the proposed USSPA twice with a 1-week interval, and XCA once for comparison. Intra-rater measurement was investigated by calculating the MADs and SDs of thoracic and lumbar USSPA between the two trials were evaluated. The MADs and SDs between the first set of thoracic and lumbar USSPA and XCA from the radiographs taken on the same day were also evaluated. XSPA could not be acquired for the subjects because the spinous processes were hindered by the ribs in the X-ray image, thus only USSPA and XCA were obtained and analyzed in the human pilot study.

Result

Though 3D coordinates of the spinous processes and coronal plane of the X-ray images were acquired, only the sagittal curvatures of the spine phantoms were analyzed and compared for USSPA, XSPA and XCA since validation of our proposed ultrasound method on sagittal spinal analysis were the focus of this study. The average sagittal curvatures and ranges of the phantoms measured for the three angles obtained by Rater B were: USSPA: 25.6 ± 12.3 degrees (5.5 to 36.9 degrees), 26.5 ± 9.9 degrees (7.6 to 41.3 degrees); XSPA: 23.9 ± 9.7 degrees (4.0 to 36.9 degrees), 25.7 ± 8.6 degrees (11.1 to 39.5 degrees); and XCA: 30.5 ± 8.9 degrees (19.0 to 46.0 degrees), 28.9 ± 5.0 degrees (21.0 to 36.0 degrees) for the thoracic region and lumbar region, respectively.

Raters demonstrated excellent intra-rater and inter-rater reproducibility for USSPA, XSPA and XCA. For intra-rater reliability, the ICC ranged from 0.97 to 0.99 for the angle measured in the thoracic region and from 0.91 to 0.99 for the angle measured in the lumbar region among the three angles (Table 2). For inter-rater reliability, the ICC ranged from 0.93 to 0.99 and from 0.86 to 0.98 for the thoracic and lumbar regions, respectively (Table 3). In addition, scanning skill for Operator A was found to be very reliable since the ICC values were greater than 0.9 for the results obtained for both the regions (Table 4).

USSPA, XSPA and XCA were found significantly correlated with each other with $p < 0.05$. The MADs of the thoracic and lumbar angles among the three methods were shown in Table 5. Pearson coefficients for XSPA against XCA, USSPA against XSPA and USSPA against XCA were $r = 0.82$, $r = 0.95$ and $r = 0.84$ for thoracic region and $r = 0.72$, $r = 0.89$ and $r = 0.51$ for lumbar region respectively (Table 5). The extrapolated linear equation of the comparisons of the thoracic and lumbar angles among the three measurement methods indicated a positive linear relationship (Figure 7, 8 and 9).

Five subjects (4 females, 1 male; mean age 15.8 ± 1.1 years; Cobb 27.1 ± 7.7 degrees) participated in this study. Table 6 shows the individual results of the two ultrasound measurements (USSPA1 and USSPA2) and the X-ray measurement (XCA) performed by Rater B. The MAD ± SD between USSPA1 and USSPA2 for the thoracic region and lumbar region were 1.3 ± 0.7 degrees and 2.7 ± 1.6 degrees respectively, whereas the MAD ± SD between USSPA1 and XCA for the thoracic region and lumbar region were 3.8 ± 3.1 degrees and 8.7 ± 6.5 degrees respectively.

Discussion

The reliability of using 3D ultrasound imaging system for the measurement of sagittal spinal curvature was tested and comparisons of the US results with those obtained from traditional X-ray images were made in this study. All the parameters obtained from either X-ray or 3D ultrasound were demonstrated to have excellent reliability.

Both USSPA and XSPA were obtained using the spinous process angle. Though the imaging modality was different, the MAD between them was the smallest and the Pearson correlation was the greatest among the three comparisons of the three angles. The difference could be possibly due to the nature of the selection processes of the lateral radiograph and US stack image. Selection of spinous processes was performed from the 2D X-ray image of the spine phantom in the sagittal plane and from the B-mode images of 3D ultrasound volume stack respectively. Thus the perspective difference was one of the major reasons that explained the discrepancies of the results (Vrtovec et al. 2009, Gstoettner et al. 2007). Indeed, a nearly one-to-one relationship was observed between these two parameters, suggesting that they were very much comparable.

Since USSPA was measured using spinous processes and XCA was measured using superior and inferior endplates of the vertebral bodies, lumbar curvatures formed from the spinous processes were likely to be smaller than those measured from vertebrae because the bulky shape of the processes prohibits the lumbar region of the spine phantom for further progression during deformation, while the soft intervertebral structures between the vertebral plates allow larger degrees of deformation. Hence as expected, lumbar USSPA tended to be underestimated compared with XCA. A study used biplanar radiographs to evaluate the apical thoracic sagittal profile (Hayashi et al. 2009). By comparing the results obtained from the standard lateral projection with those from the "true lateral" view, it was found that the sagittal curvature was significantly greater ($p < 0.001$) in the traditional sagittal view by 10 degrees in average than the "true lateral" view (Hayashi et al. 2009). This suggested that XCA obtained in the study might not be reflecting the 'real' sagittal curvature, but indeed a slightly larger curvature. In addition, the study suggested that the larger the thoracic Cobb's angle in the coronal plane measured, the more kyphotic the thoracic apical profile on the standard lateral radiograph would appear, which would eventually lead to a greater difference in the thoracic apical alignment between the two views (Hayashi et al. 2009). Hence, it is necessary to measure the sagittal spinal curvature using an alternative method instead of using the traditional 2D X-ray projection, and ultrasound could be a potential method for sagittal spinal curvature evaluation.

The Pearson correlations obtained from the phantom in this study suggested that ultrasound angles in the thoracic regions were more representative than that in the lumbar regions. The differences between the correlation between the thoracic and lumbar region might be accounted for the level differences involved for these two regions, where thoracic vertebrae levels involved to compute thoracic angle is much more than that for the lumbar angle. Previous studies had compared the mean Cobb values of normal lumbar lordosis obtained from previous studies and found out that lesser the vertebral levels involved would likely result in smaller lordosis angle at (Stagnara et al. 1982, Fernand and Fox. 1985, Saraste et al. 1985). This effect might be emphasized when using spinous processes for sagittal measurement.

A previous study investigated 39 adolescent girls with double-curved idiopathic scoliosis and reported that the linear relationship between XSPA and XCA was XCA = 0.84*XSPA + 9.63

and XCA = 0.66*XSPA + 33.96 for thoracic and lumbar regions (Delorme et al. 1999), whereas the best-fit equations obtained in our study for XCA against XSPA were XCA = 0.75*XSPA + 12.57 and XCA = 0.42*XSPA + 18.10 for the two regions respectively. Since Pearson correlations obtained in the two studies for both thoracic and lumbar regions were similar and the intra-reliabilities of the measurement in our study were excellent, one of the possible reasons which caused the discrepancies of the results could be the difference in the calculation of XSPA used in the two studies. However, the statement could not be confirmed as the calculation details were not described in the previous study (Delorme et al. 1999). In addition, water was used as the tissue mimicking background, which was also one of the limitations of the phantom study. For human subjects, due to the attenuation of the soft tissues and speckle noises, the interface of bone would not be so clear in the ultrasound images. According to what we observed for the 5 AIS subjects tested in this study, we confirmed that the spinous processes could all be successfully detected. Further studies with a larger group of subjects with different conditions, such as high BMI, should be conducted to further investigate the detectability of spinous process as well as to develop methods to enhance the echoes from spinous processes. Moreover, the levels of vertebrae involved for lumbar curvature are different between parameters, where L1-L4 levels were used for XCA while T12-L4 levels were used for XSPA and USSPA. The reason for such a selection is that we noted the spinous process of T12 (instead of L1) is more aligned with the upper plate of L1, and that of L4 is more aligned with the lower plate of L4. However, such alignment may vary from subject to subject, thus future studies are required to investigate the alignment deviations among subjects and its potential effect on the curvature measurement. Furthermore, spine phantom was used in our study while female patients were investigated in that study, the existence of vertebrae and spinous process deformity in their subjects could also affect the XSPA and XCA results obtained, hence causing extra discrepancies.

The results of the preliminary study further demonstrated the feasibility of the proposed method for measuring sagittal curvature using 3D ultrasound imaging. The measurement of 5 subjects demonstrated a small variation in the intra-observer comparison and an observation that MADs of the thoracic angles obtained between ultrasound and X-ray methods were generally smaller, which agreed with the phantom results. The pilot results showed that overall deviation between the two measurement methods was 6.3 ± 5.4 degrees, which was very similar to the phantom results (6.0 ± 5.1 degrees). Various studies also reported that the values of lumbar lordosis evaluated using different topographic tools were consistently underestimated in comparison with that from radiograph, and such deviation was larger for the lumbar lordosis, comparing to thoracic kyphosis (Guermazi et al. 2006, Schmid et al. 2015, Takács et al. 2018). Our study performed direct measurement on the spine based on spinous processes using ultrasound, and a similar phenomenon was observed. Hence, anatomical difference should be the major reason causing a bigger difference in the lumbar curvature measurement, since spinous processes and vertebral endplates were the targeted structures for the ultrasound and X-ray approach, which the former structures are relatively posterior than the latter ones. Although the spinal phantom study together with the pilot study on AIS subjects had demonstrated the feasibility of measuring sagittal curvature of spine using the 3D ultrasound imaging method, we cannot make a conclusive statement from this small sample size. In future studies, more clinical trials should be conducted to further demonstrate the reliability of the proposed ultrasound method. In addition, only a single point was selected to represent the spinous process of all vertebrae from T2 to L4 in ultrasound images in this study. However, spinous process is not a single point, and selection of different locations of the same spinous process may induce variations in curvature measurement. A selection criterion with more spinous process information involved can improve the reliability of measurement in future studies, and measurement using other more bony landmarks can also be explored.

3D ultrasound imaging, supported by the current data, is a potential imaging modality for screening and monitoring the development of individual's sagittal spine profile. It should be always be noted that ultrasound and X-ray measurements were based on different structures of the vertebrae, thus it is reasonable that the results between these two modalities do not represent each other. The excellent intra-operator reliability for ultrasound scanning on phantoms as well as excellent intra- and inter-rater reliability for angle measurement shown in this study demonstrated that 3D ultrasound imaging can be used for long-term and repetitive monitoring of sagittal spinal profile, especially for schoolchildren, thanks to its non-radioactive feature. In addition, 3D ultrasound imaging can be used to monitor the progression of the sagittal curvature for patients with sagittal spinal deformity such as sagittal imbalance or spondyolithitis. Regular monitoring provides sufficient time for clinicians or doctors to diagnose whether patients require restoration of their sagittal spinal curvatures, where adequate restoration of sagittal plane alignment is necessary to improve significantly clinical outcome and avoid subsequent pseudoarthrosis (Farcy and Schwab 1997, Booth et al. 1999).

Considering that manual procedure was involved in the measurement preprocess and the complexity of spinal deformity, a future study with much larger number of subjects with different deformity curvatures and patterns should be conducted to study the reliability of measurement for clinical applications. For the phantom tests reported in this study, it was fixed thus had no motion. However, during the real subject tests, the subject may move forward and backward to change the spinal sagittal profile during the ultrasound scanning.

One potential solution for this issue is to stabilize the subject during scanning, as introduced by Zheng et al. (2016) for their coronal curvature study, which used four supporters to stabilize the subject. Such an approach can be considered for coming large-scale clinical study.

Conclusions

In conclusion, this study has demonstrated that 3D ultrasound imaging was feasible for repeated scanning and measurement of sagittal spinal curvature in spine phantoms, and the results were comparable with that by radiograph. 3D ultrasound may also be suitable for monitoring sagittal curvature progression and examining surgical treatment outcomes for patients with spine deformities. Further studies on subjects are required to demonstrate its clinical values. It is also necessary to further investigate its potential of studying the correlation between the 3D deformity parameters.

Abbreviations

3D: Three dimensional

ICC: Intraclass correlation coefficient

USSPA: Ultrasound spinous process angle

XSPA: X-ray spinous process angle

XCA: X-ray Cobb's angle

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Figures Captions

Figure 1. Experimental set-up and system block diagram for the phantom scanning. Experimental set-up and system block diagram for the phantom scanning. The grey lines were illustrating the connections between the devices.

Figure 2. Four flexible spinal column phantoms with different simulated deformity curvatures

Figure 3. a) A typical B-mode image obtained from the phantom, and (b) 3D ultrasound image series collected from the 3D ultrasound imaging system and stacked according to the orientation and location of each image for further spinous process angle measurement. The spinous process of each vertebra was manually selected from the B-mode images.

Figure 4. The two measurement methods of curvature used on radiograph: (a) Cobb's method and (b) spinous process angle by selecting spinous process

Figure 5. Diagram illustrating spinous processes extracted from 3D ultrasound images. (a) A stack of ultrasound images with spinous processes marked in 3D in corresponding B-mode image, where the black region meaning there was an image stacked and white region without B-mode images; (b) A typical B-mode image containing a spinous process and marked accordingly; (c) Spinous process profile projected in sagittal plane; (d) Corresponding sagittal X-ray image and marked spinous processes. Before data analysis, sagittal spinous process curvature obtained from 3D ultrasound was compared with that from radiograph

Figure 6. Diagram showing the experiments conducted and the corresponding statistical tests for reliability in this study

Figure 7. Scatter plot of thoracic and lumbar Cobb's angle against X-ray spinous process angle, with the associated trend line equation. (*XSPA: X-ray spinous process angle; XCA: X-ray Cobb's angle)*

Figure 8. Scatter plot of the thoracic and lumbar ultrasound spinous process angle against X-ray spinous process angle, with the associated trend line equation. (*USSPA: Ultrasound spinous process angle; XSPA: X-ray spinous process angle)*

Figure 9. Scatter plot of the thoracic and lumbar Cobb's angle against ultrasound spinous process angle, with the associated trend line equation. (*USSPA: Ultrasound spinous process angle; XCA: X-ray Cobb's angle)*