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Development of 3-D Ultrasound System for Assessment of Adolescent Idiopathic Scoliosis (AIS): and System Validation

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***Abstract*—Adolescent idiopathic scoliosis (AIS) is a common spinal disease and the prevalence of AIS is 2 to 4 % of the youngsters in the United States. Radiograph based Cobb's method is regarded as the gold standard. AIS patients normally have to undergo regular X-ray assessment every 4 to 6 months until skeletal maturity is reached. Because of radiation hazard, X-ray images cannot be taken frequently, and thus it is difficult to perform close monitoring for the disease progression and treatment outcomes. In this study, a free-hand 3D ultrasound imaging system has been successfully developed for the radiation-free assessment of AIS. A series of B-mode ultrasound images with their spatial information were exploited to form a spine model for measuring the spine curvature. Sixteen spine phantoms with different simulated deformity were scanned by both conventional X-ray imaging and the 3D ultrasound system. The results showed that there was a strong correlation (R^2 = 0.759) between the Cobb's angles obtained by the two methods. The results also demonstrated a very good intra- and inter-observer reproducibility with ICC of 0.99 and 0.89, repectively. The findings suggest that it is feasible to use 3D ultrasound imaging for the assessment of scoliosis and deserves further clinical tests on patients with spine deformity.**

I. Introduction

Scoliosis is a medical condition of persons with lateral curvature in their spines, and it is often associated with the abnormality in the sagittal plane profile and the axial rotational deformities. In the United States, approximately 20 million people are suffered from scoliosis, and the prevalence of AIS in general population is 2% to 4% [1]. The prevalence of AIS is about 3% in Hong Kong [2]. The most prevalent form of scoliosis among the youngsters (10 to 16 years old) is adolescent idiopathic scoliosis (AIS). By definition, AIS describes those patients with the lateral curvature of the spine more than 10 degrees in the coronal plane, as measured using Cobb's method, which is currently the gold standard for assessing scoliosis, on X-ray radiograph [3]. According to the Scoliosis Research Society, the Cobb's angle is defined as the angle between of the two most tilted end-plates of the vertebral bodies in a standing radiograph.

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To identify the type of spine structure problem, clinical examinations are normally used to screen and evaluate the spine deformity before X-ray imaging. During the examinations, information such as gender, age, height, weight, leg length, onset of menarche, family history, and diseases are collected for determining a tentative prognosis; physical and spinal examination including forward bend test, neurological examination, spine side-to-side symmetry, shoulder height, iliac crest symmetry, and lateral examination are exploited to evaluate suspected AIS [4]. When the hump's angle of truck rotation (ATR) is greater than 7 degrees measured by inclinometer under forward bend test, the patient is recommended for undergoing the standard radiographic evaluation for suspected scoliosis [5]. Evaluating the scoliosis is undertaken by measurement of the Cobb angle. AIS's patients with a Cobb angle of 20 degrees or less, clinical observation is recommended. The patients with immature skeletal and a Cobb's angle of between 20 to 40 degrees are warranted for brace treatment. For those patients with Cobb's angle greater than 40 degrees and immature skeletal or Cobb's angle greater than 50 degrees and mature skeletal are warranted for surgical management [6]. Skeletally immature patients at risk for curve progression can be followed up with posteroanterior radiographs every 6 to 12 months [7]. As Reamy and Slakey [8] reported, there are about 10% of those patients with curve progression warrant intervention. This finding indicates that 90% of the patients are subject to unnecessary radiation.

Regardless the radiation nature of Cobb's method, intrinsic errors exist in radiograph measurement. It is sometimes difficult to identify the oblique projections of the twisting spine in X-ray images, and there is also a considerable variation in the Cobb's angle between the images obtained with different projection angles of the X-ray beam. Intra-observer variation 3- 5° and inter-observer variation 6-9° have been reported in the measurement of the Cobb angle [9][10][11]. The vertebral rotation of spine is also important for predicting prognosis and monitoring the progression; however, no rotation information can be directly acquired by a standard chest radiograph, the accurate measurement of degree of rotation cannot be undertaken [12]. Two radiographs stitched together to produce whole spine view for assessment are occasionally exploited [13], aggravating risk of radiation exposure. Therefore, it is very necessary to provide a system that can accurately measure spine deformity for AIS mass screening and longitudinal follow-up during treatments without any hazard of radiation.

A number of radiation-free systems have been developed for scoliosis screening, and among them, optical and surface topography techniques are most commonly used. Quantec spinal image system (Quantec Image Processing, Warrington,

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Chesshire, UK) is using Moire topography for producing a three dimension surface of fringe pattern representing patient's torso, which is exploited to obtain a Q angle that denotes the quantitative measurement of the asymmetry reflected in a coronal plane from the patient's images. [14]. However, this system has been reported with low accuracy of measurement [15]. Radiation-free spatial sensing technique has also been developed for scoliosis screening. In Ortelius system, patient's back is prudently palpated by the examiner in order to search for the tip of spinous process of each vertebra during screening [16]. The relative spatial positions of the tips of spinous processes are marked by utilizing a 3D spatial sensor attached to the examiner's finger. After all tips pinpointed, the data are exploited to reconstruct a spine model for measuring the spinal deformation indices. The spinal column rotation, however, cannot be obtained using. In addition, the positions of spinous processes are manually palpated and determined through the examiner's finger based on body surface, which is subjective.

It has been reported that the spinal deformity indices, such as vertebra rotation can be derived by ultrasound B-mode image [17]. Despite of simplicity of the approach, the Cobb's angle could not be accurately measured. Although it is possible to obtain high quality volumetric images of spine using MRI without the hazard of radiation; high cost and low accessibility hamper the application. Most importantly, it has been shown that the Cobb's angle derived from the supine posture required by MRI scanning is significantly and spontaneously corrected from the standing posture [12]. Recently, freehand 3D systems have been developed by various groups [18][19][20] for different clinical applications. However, few studies have been reported to use 3D ultrasound systems for scoliosis assessment. Accordingly, the objectives of this study were to develop a 3D ultrasound imaging system for the assessment of AIS and to perform a validation using spine phantoms for this new method.

II. Methods

A. Equipments

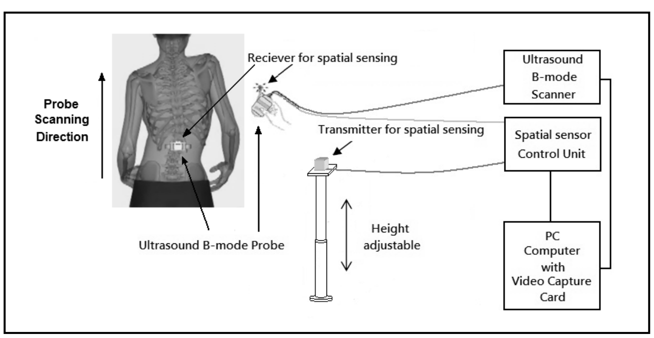

Figure 1. Equipment setup and system block diagram

The 3D ultrasound imaging system was comprised of an ultrasound scanner (EUB-8500, Hitachi Ltd., Japan) together with a 92mm in width and frequency range of 5-10MHz linear probe (L53L/10-5), a frame structure, an electromagnetic spatial sensing device (MiniBird, Ascension Technology Corporation, Burlington, VT, USA), 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++ for imaging and data collection, processing, visualization, analysis, and assessment (Figure 1). The spatial sensor was mounted onto the ultrasound probe for collecting the spatial information and calibrated using a cross wire method. Four flexible spinal column phantoms featured with soft intervertebral discs allowing deformation (VB84, 3B Scientific, Germany) were employed in this study. Each phantom was deformed into four different curvatures to simulate scoliosis; totally 16 conditions were tested.

B. Experimental Protocol

A rigid framework made of acylic plates and nylon screws were exploited to mount the deformed phantom to avoid the change of its shape during transportation and scanning. Each of these spine phantoms underwent X-ray chest radiographies in posterior anterior position and lateral position. The X-ray images were digitized and stored in DICOM format for further processing. The mounted phantoms were then submerged into a water tank until all vertebras covering from T1 to L5 under water. Before data acquisition, the observer needed to submerge the probe at the level of L5. During acquisition, the observer drove the probe slowly and steadily uprising from L5 to T1 vertebra. While the probe was being moved upward, the probe's middle line position was being continuously adjusted to ensure that the traverse processes were included in the collected ultrasound images. The scanning time was approximately 2 minutes for the probe uprising from L5 to T1 vertebra. During each scan, 500 to 700 frames of B-mode image were captured. To test intra-observer repeatability, each deformed phantom was scanned for three times. After that, the phantom was raised up above the water level and then submerged it again for a new scanning to test the repositioning effect. This process was repeated twice. Therefore, totally 9 scans were undertaken for each phantom under the same deformity level. The ultrasound images together with their spatial data were recorded and processed later.

C. Data Processing and Analysis

The collected ultrasound images were viewed in 3D with corresponding spatial information. The images with spinous, traverse articular process, and/or superior process were chosen. The process's tip was manually assigned with a spherical marker in these images by clicking the tip using the PC program, allowing process's spatial information to be found; a virtual 3D model of spine was formed after all processes marked. A series of lines were manually assigned to articulate the spinous, superior articular and traverse processes from the same vertebra to further enhance the spine model. For the sake of comparing with X-ray Cobb's method, the 3D model of spine was projected into a 2D plane to form an image analog to the posterior-anterior X-ray. The X-ray images could be displayed together with the 3D model of spine and its projection. The selected ultrasound images with bony landmarks could also be displayed together with the 3D model of spine and the X-ray image to facilitate the visualization effect. The program also provided a function to project the 3D model into three orthogonal planes (Figure 2). The Cobb's angle was measured according to the most titled pairs of vertebrae in the posterior-anterior X-ray image (Figure 3). The measurement was performed twice by the same operator and the mean value was used for comparing with the result of ultrasound method. This pairs of selected vertebra were identified in the 3D model of spine for the corresponding measurement. A line was drawn along the markers of traverse and superior articular processes for each selected vertebrae. In the projection plane, the angle between these two lines was measured to represent the Cobb's angle (Figure 3).

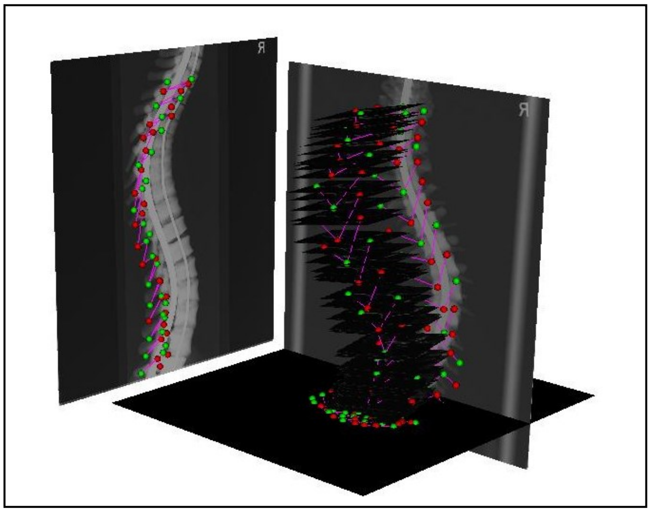

Figure 2. Spine Virtual Model with 3 plane projections

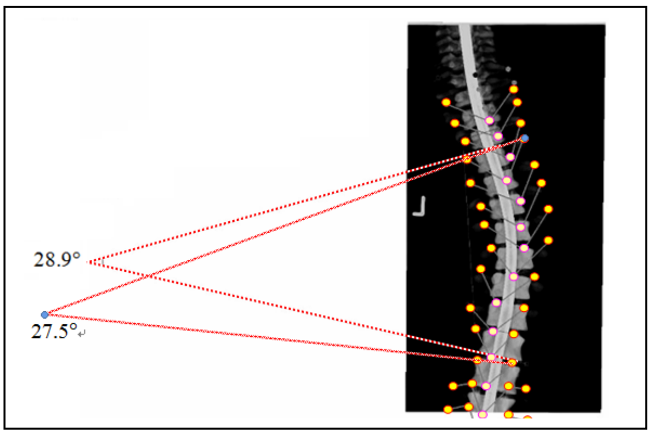

Figure 3. Measurement of curvature using Cobb's method

The intra-observer reproducibility between the results of the repeated sets of 3D ultrasound scanning was tested using intra-class coefficient (ICC) and linear correlation. Linear correlation and Bland-Altman plot were used to test the correlation between the Cobb's angles obtained using the 3D ultrasound and X-ray methods. For this correlation, the mean of two repeated measurements using X-ray images and the mean of the nine repeated measurements using 3D ultrasound imaging were used.

III. RESULTS

The results demonstrated that the 3D ultrasound imaging system could reliably collect images with body landmarks from the spine phantoms. With the help of the program, the virtual spine model was successfully formed for each phantom using the extracted landmarks. The intra- and inter- observer reproducibility test showed that the proposed measurement was highly repeatable with ICC value of 0.99 ($p<0.001$) and 0.89 ($p<0.001$), respectively. It has been achieved to view the deformity of the spine phantom in three orthogonal planes through the projection of the virtual model in different direction. The Cobb's angle of the 16 spine phantoms ranged from 10° to 54°. A very good linear correlation ($R^2 = 0.7586$) was found between the Cobb's angles obtained using the 3D ultrasound and X-ray methods (Figure 4). The Bland-Altman plot showed that there was a good agreement between the results obtained by the two methods with all data points located inside ±1.96 SD from the mean, with a mean difference of -0.55° and 95% confidence interval (between -2.72° and 1.62° (Figure 5).

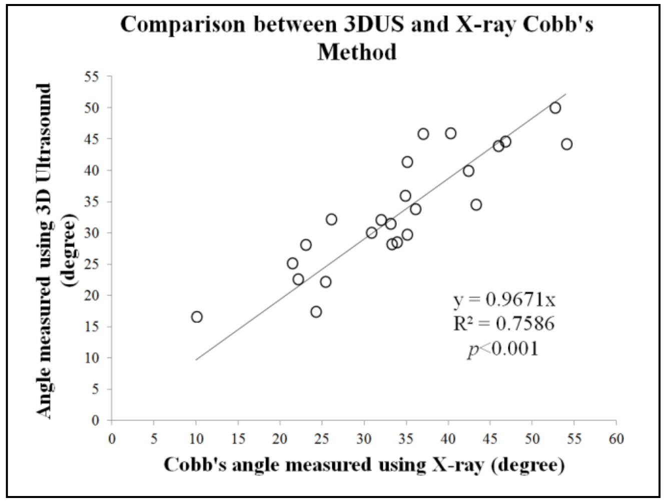

Figure 4. Correlation between 3DUS and X-ray Cobb's method

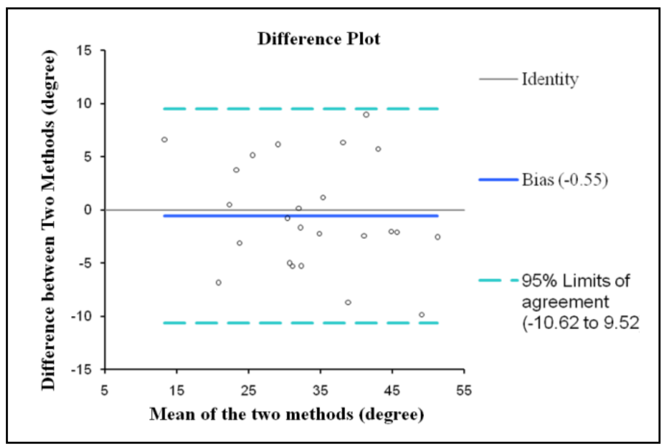

Figure 5. Bland-Altman plot

IV. DISCUSSION

In this study, we have successfully developed a 3D ultrasound imaging method for the radiation-free assessment of scoliosis, and the results of spine phantom tests showed that the new method was reliable and had very good intra- and inter- operator repeatability. Since a virtual 3D model of spine (from L5 to T1) could be formed based on the bony landmarks extracted from ultrasound images, the system provided the deformity of the spine phantom in three orthogonal planes. In this study, we only used the data projected in the coronal plane for comparing with X-ray images. We have also demonstrated that the spine rotation could be obtained; further studies are needed.

The validation of other radiation-free assessment systems for scoliosis has recently been reported. It was reported that the spine curvature measured by the Quantec system (y) has a linear correlation with the X-ray Cobb's angle (x) with $R^2 = 0.66$ and y = 2.91+0.52*x [21]. For Orthoscan800 system, it was reported that the correlation between the results of the Orthoscan measurement and the Cobb's method was poor ($R^2 = 0.42$ for thoracic curvature data, and $R^2 = 0.017$ for lumber curvature data) [22]. In this study, we demonstrated that there was a very good correlation between the Cobb's angles measured based on the 3D ultrasound measurement (y) and X-ray method (x) ($R^2 = 0.759$, Y = 0.967*x). It should be noted that the data reported for the two commercial systems were from human subjects, while the data reported in the current study were obtained from the phantoms. The future clinical study of using the 3D ultrasound method should be conducted. Nevertheless, the results of this study showed that 3D ultrasound method is a promising alternative method for the assessment of scoliosis without the hazard of radiation and low cost; longitudinal study of AIS patient becomes more viable. With portable ultrasound system and movable framework, this system can be mobile, allowing operation in small clinic or school for mass-screening. No restriction of frequency use and period time for monitoring patient's spine is obliged while undergoing observation or treatment.

AIS is increasingly treated as a 3D spine deformity problem. Yazici et al. [12] suggested that AIS should be evaluated on coronal, sagittal, and traverse plane with standing images. Although CT and MRI can provide high resolution images in 3D, they require patients being imaged in supine position; measurement of rotation is disputable. The virtual 3D model of spine in this study revealed that the vertebra rotation and the spinal deformity can be measured in three orthogonal planes. It has been previously reported that there was a correlation between the Cobb's angle and the vertebra rotation according to a relatively simple ultrasound measurement [17]. Therefore, the vertebra rotation information may be an important factor to improve the measurement of Cobb's angle using the 3D ultrasound method. Future studies need to be conducted along this direction.

In spite of the encouraging results demonstrated, we identified some limitations. The manually placing of marker is a timely procedure with accuracy depending on the quality of ultrasound images and the subjective interpretation from the operator. We demonstrated the intra-operator repeatability was very high for the spine phantom measurement, but the image quality might be reduced in human subjects because of obesity and complexity of muscle layering. Ultrasound image enhancement, automatic or semi-automatic tip identification methods have to be developed to alleviate the manual efforts in placing the markers.

In summary, we have developed a 3D ultrasound imaging system for the radiation-free assessment of scoliosis. The results of spine phantom study demonstrated that the Cobb's angle measured using the new system correlated well with the result obtained by X-ray method. It was also demonstrated that the virtual 3D model of spine formed by the bony landmarks extracted from ultrasound images could provide the deformity of spine in different planes as well as the vertebrae rotation information. Clinical trials of using the new system for assessing scoliosis patients are ongoing to further demonstrate its potential for the practical use.

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