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COULD CLINICAL ULTRASOUND IMPROVE THE FITTING OF SPINAL ORTHOSIS FOR PATIENTS WITH AIS?

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M.Phil

The Hong Kong Polytechnic University

2012

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LI MENG

A thesis submitted in partial fulfillment of the requirements for

the degree of Master of Philosophy

February 2011

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Peer-reviewed journal papers (published or accepted)

LI M, CHENG J, YING M, NG B, ZHENG YP, LAM TP, WONG WY, WONG MS. Application of 3-D ultrasound in assisting the fitting procedure of spinal orthosis to patients with adolescent idiopathic scoliosis. Studies in Health Technology and Informatics 2010;158:34-37.

WONG MS, LI M, NG B, LAM TP, YING M, WONG A, CHENG J. The effect of pressure pad location of spinal orthosis on the treatment of adolescent idiopathic scoliosis (AIS). Studies in Health Technology and Informatics 2012;176:375-378.

LI M, CHENG J, YING M, NG B, ZHENG YP, LAM TP, WONG WY, WONG MS. Could clinical ultrasound improve the fitting of spinal orthosis for the patients with AIS? DOI: 10.1007/s00586-012-2273-4. Accepted by European Spine Journal on 10 March 2012.

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Peer-reviewed conference papers

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WONG MS, LI M, NG B, LAM TP, YING M, WONG A, CHENG J.

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ABSTRACT

Adolescent idiopathic scoliosis (AIS) is described as a structural, lateral, rotated deformity of the spine that arises in children during puberty with unknown causes. Spinal orthosis is generally applied onto the patients with AIS to mechanically support the scoliotic spine and prevent further deterioration. The outcome of orthotic intervention for AIS is considered being associated with accurate orthosis fitting and patients' treatment compliance. In current practice, pre-brace X-ray images are used as references for clinicians to design orthotic intervention, however, the optimum location of pressure pads for maximum deformity control may not be determined because the referred X-ray is not a real-time presentation of the spinal curvature (once forces are applied, the spinal deformities could change three dimensionally).

The most commonly used method to assess scoliotic curvature in radiography is the Cobb's method. Besides, spinous process angle (SPA) was proposed to be an alternative method to assess spinal curvature. A correlation study was conducted using X-ray images from 43 patients with AIS, including 37 major curves at the pre-brace stage, and 21 major curves at the in-brace stage. A new method was developed to study the correlation between Cobb's angle and SPA. Intra-rater and Inter-rater reliabilities of this method were found to be high (ICCs>0.9, $p<0.05$). The results of this study indicated that there was a significant correlation ($r=0.80$ for the pre-brace stage and $r=0.87$ for the in-brace stage, $p<0.05$) between Cobb's angle and SPA for patients with AIS. The findings contribute strong evidence to support this new method for assessing scoliosis.

With the advancement of clinical ultrasound, tracing spinal processes along a scoliotic spine becomes possible, which means SPA can be obtained from ultrasound images. This study aimed to apply 3-dimensional ultrasound (3-D US) technique to monitor the fitting method of spinal orthoses for patients with AIS. By means of ultrasound assessments, SPA could be examined and used as the parameter to evaluate the optimal location for pressure pad. Angle calculation software was developed to measure SPA in this study. Ultrasound-assisted fitting method was conducted on 21 patients as a test group, while conventional fitting method was conducted on 60 patients as a control group. Within these 21 patients in test group, there were 13 patients who were required to adjust the location of pressure pad to achieve better curvature correction. The mean immediate correction (Cobb's angle measured from radiographs) of test group (mean thoracic curve correction: 11.5°, mean lumbar curve correction: 11.0°) was found significantly higher than that of control group (mean thoracic curve correction: 5.6°, mean lumbar curve correction: 6.0°) for both thoracic and lumbar curvature ($p<0.005$), which indicated that ultrasound-assisted fitting method of spinal orthosis was effective and helpful to 61.9% patients in this study. According to these findings, 3-D US can be further developed to assess spinal curvature especially for determining the optimal location for pressure pad. In summary, 3-D US is proposed to be a non-invasive, effective and real-time approach to assess scoliotic spine in routine clinical visit and helpful to improve the effectiveness of orthotic treatment for scoliosis.

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"Deep as the Peach Blossom Lake may be,

it is not so deep as the song you sing for me."

- LI Bai (Poet of Tang Dynasty)

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LIST OF ABBREVIATIONS

Abbreviation	**Full Spelling**
AIS	Adolescent Idiopathic Scoliosis
AP	Antero-posterior
CAT	Computerized Axial Tomography
CT	Computed Tomography
CTLSO	Cervico-thoraco-lumbo-sacral Orthosis
EDS	Epidural Space
ICC	Intraclass Correlation Coefficient
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
n	Number of Subjects
p	Probability
PA	Postero-anterior
r	Pearson’s Correlation Coefficients
SPA	Spinous Process Angle
TLSO	Thoraco-lumbo-sacral Orthosis
3-D	Three-dimensional
3-D US	Three-dimensional Ultrasound

CHAPTER 1 INTRODUCTION

1.1 Background

Scoliosis is widely considered to be a three-dimensional (3-D) spinal deformity with lateral curvature and vertebral rotation (Wong and Liu, 2003; Cruickshank et al., 1989; Deacon et al., 1987; Deacon and Dickson, 1987; Perdriolle and Vidal, 1987 & 1985; Dickson et al., 1984). Most cases have an unknown cause and are found in adolescence. This deformity is termed adolescent idiopathic scoliosis (AIS).

In clinical practice, Cobb's method is considered to be the gold standard in assessing AIS and in monitoring the orthotic treatment. In 1990, Herzenberg et al. reported a potential intermediate parameter to assess spinal curvature, spinous process angle (SPA), which is measured by accumulating the angles formed by every two lines joining three neighboring spinous processes. With reference to Herzenberg's finding, there is a high correlation between Cobb's angle and SPA (coefficient of determination = 0.903), and a conversion formula has been developed ($y = -1.0404 + 0.74813x$, where y = SPA, and x = Cobb's angle). However, his findings only limited to the pre-brace stage not extended to the in-brace stage. Moreover, the methodology was not clearly elaborated.

In routine clinical practice, the spinal orthosis treatments prescribed to patients with AIS are usually based on Cobb's angle and bone maturity. Nevertheless, few clinicians or researchers have paid enough attention to some other parameters that can offer a full description of this 3-D spinal deformity, for example, apical vertebral rotation, trunk listing and rib hump (Wong and Liu, 2003). In current practice, pre-brace postero-anterior (PA) standing X-ray images are used as references for clinicians to design a blueprint for orthotic intervention. However, the optimum location of the pads for maximum deformity control cannot be determined.

1.2 Objectives

The objectives of the current study are:

- To verify the correlation between SPA and Cobb's angle both measured from radiographs.
- To investigate the feasibility of tracing the spinous processes of a scoliotic spine using three-dimensional ultrasound (3-D US).
- To evaluate the correlation between Cobb's angle measured from X-ray and that estimated from 3-D US images.
- To compare the clinical outcome of the conventional fitting method with that of the 3-D US assisted fitting method.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction to the Structure of Spine

The vertebral column, which is like a pillar of the human body, is situated centrally and extends from the base of the skull to the pelvis. Its functions include surrounding and protecting the spinal cord, supporting the human in an upright posture, and allowing movement and locomotion. It is composed of a series of irregular shaped vertebrae which are bounded together by ligaments and separated by intervertebral discs between their bodies. The vertebral column is divided into 5 regions and each region has different numbers of vertebrae, including cervical (7 vertebrae: C1-C7), thoracic (12 vertebrae: T1-T12), lumbar (5 vertebrae: L1-L5), sacral (5 vertebrae which have typically fused to form 1 sacrum in adulthood) and coccygeal regions (4 vertebrae which sometimes have fused to form 1 coccyx in adulthood) (Figure 2.1) (Kirchner et al., 2009; Hutchinson et al., 2001; Herkowitz et al., 1999).

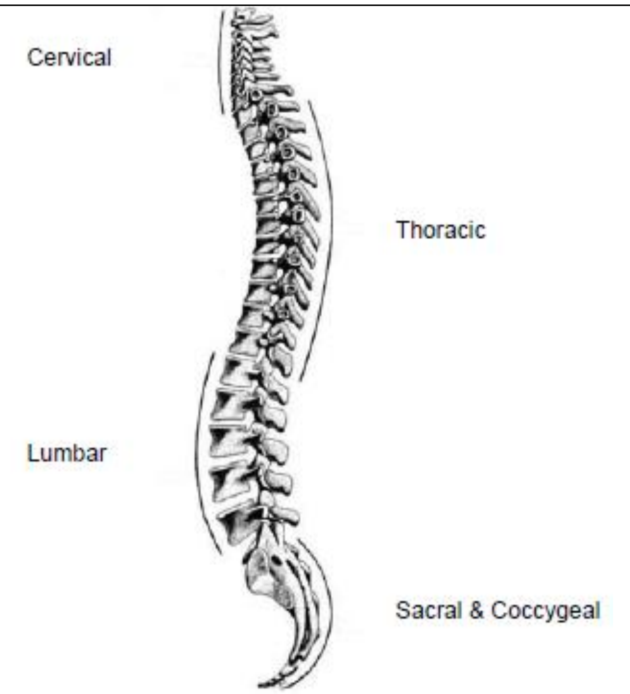

Figure 2. 1. Vertebral Column (Hutchinson et al., 2001)

2.2 Curvatures of the Vertebral Column

Four natural curvatures can be detected in the sagittal plane by observing an ordinary healthy spine, while in the coronal plane minor lateral curvature may be found at thoracic region (Kirchner et al., 2009; Hutchinson et al., 2001; Herkowitz et al., 1999).

Curvatures in the sagittal plane

The curvatures of the vertebral column in the sagittal plane keep changing throughout the entire life development of an individual (Hutchinson et al., 2001). In the fetal period, the embryonic body appears flexed and has primary thoracic and pelvic curves (convex dorsally). After birth, an infant can raise its head within 3 to 4 months, sit upright at about 9 months, and begin to stand and commence walking after the end of the first year. These functional changes influence the development of the secondary curvatures in the vertebral column, cervical and lumbar curvatures in posterior concavity (Hutchinson et al., 2001). The secondary cervical curvature becomes posterior concavity for rising up the head. The development of a secondary lumbar curvature is important for maintaining the center of gravity of the trunk when standing upright and walking. In adults, the curvatures of normal vertebral column can be well regionalized in the sagittal plane, including cervical (posterior concavity), thoracic (posterior convexity), lumbar (posterior concavity), and sacral and coccygeal (posterior convexity). While in the elderly, loss of height and a gradual return of the curvatures to continuous posterior convexity are usually found due to age-related changes in the structures of bones and intervertebral discs (Kirchner et al., 2009; Hutchinson et al., 2001; Herkowitz et al., 1999).

Curvature in the coronal plane

Normally, no lateral curvature could be found in the coronal plane in the vertebral column. Other than in the upper thoracic region, a minor lateral curvature (less than 10 degrees) may be found (Ballinger and Frank, 2003). This is normal and usually as a result of predominant use of upper limb, convex to the right in right-handed person, and to the left in the left-handed.

2.3 Adolescent Idiopathic Scoliosis

Spinal deformity with Cobb's angle greater than 10 degrees will be diagnosed as scoliosis (Miller, 1999; Roach, 1999). Scoliosis is characterized to be a 3-D deformity in the spine with lateral curvature (see Figure 2.2) combined with or without vertebral rotation of spine and presents not only in the coronal plane but also in the sagittal and transverse planes (Carpineta and Labelle, 2003; Villemure et al., 2001). This lateral curvature also affects the rib cage and presents as deformities of the trunk (Raso et al., 1998). The Scoliosis Research Society (2000) reported that more than 80% of the cases are with unknown cause and termed as idiopathic. Idiopathic scoliosis can develop in healthy children at any stage of growth, which classified by age of onset, are infantile (birth to age 3), juvenile (greater than 3 years of age to 9 years of age), and adolescent (from 10 to 18 years of age). The adolescent type is the most common and represents about 80% of this type of scoliosis. Idiopathic scoliosis might progress throughout the rapid growth period of adolescent (Rogala et al., 1978).

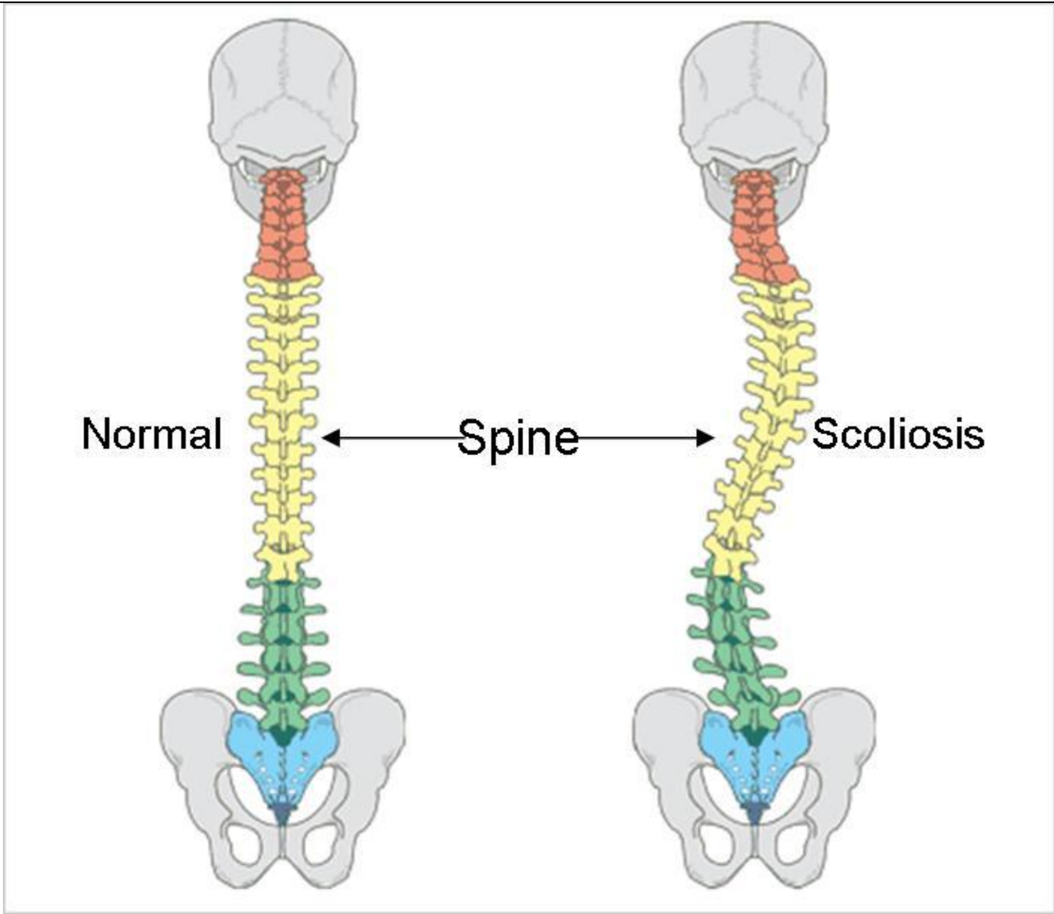

Figure 2. 2. Coronal View of Spine (Newton, 2004)
Left: Normal Spine Right: Scoliotic Spine

2.3.1 Prevalence of AIS

The incidence of AIS has been reported from 2-4% and the figure in Hong Kong is relatively high according to unpublished data from the Department of Health, the Hong Kong Special Administrative Region Government, which conducted a screening program for 520,000 students from 1996 to 2000. A large study was conducted to investigate the school scoliosis screening in Hong Kong (Luk et al., 2010; Fong et al., 2010). A total of 157,444 students were eligible for biennial scoliosis screening in Hong Kong and 115,190 students were screened in their retrospective cohort study. They found that around 2.5% students (3.59% for girls and 1.34% for boys) were confirmed with a Cobb's angle larger than 20°. Approximately 1-3% of teenagers have AIS (Weinstein et al., 2008; Goldberg et al., 1995; Emans, 1984; Leaver et al., 1982). Girls are in higher risk of having AIS of larger curvatures and progression than boys (Berg et al., 2002; Miller, 1999; Roach, 1999; Emans, 1984).

2.3.2 Assessments of AIS

Various assessment methods for AIS have been reported, including radiographic and non-radiographic approaches. This section introduces some examples of these.

Radiographic Methods

Clinical assessment of spinal disorders for planning treatment protocol and evaluating outcome of treatments, generally have been based on radiographic methods, such as repeated radiographs and computed tomography (CT) scans. Geometry of the vertebral column can be measured directly with these methods.

Single Plane Radiographs

Single plane radiographs can be used to measure curvatures of the vertebral column and intervertebral movements from either PA view to give angles in lateral bending and in axial rotation, or lateral view to give angles in flexion and extension. The quantifying method of spinal curvatures in PA view and lateral view is the Cobb's method (Cobb, 1948), the Ferguson's method (Ferguson, 1945) or the Diab's method (Diab et al., 1995). Furthermore, the quantifying methods of vertebral axial rotation are known as Nash and Moe's method (Nash and Moe, 1969), Perdriolle's method (Richards, 1992) and Raimondi's method (Weiss, 1995).

Spinal Curvature Measurement

The Cobb's method is widely used in clinical assessment in both PA and lateral radiographs. The American Scoliosis Research Society has selected the Cobb's method as the standard method of spinal curvature measurement. The angle in Cobb's method is defined as the angle between two lines which parallel to the superior surface of the proximal end vertebra and the inferior surface of the distal end vertebra of a curve. The angle can be measured between perpendiculars of these lines if the magnitude of the curve is small and these two lines do not meet easily according to the Cobb's method (Cobb, 1948) (Figure 2.3a). The end vertebrae are defined as in which superior surface (proximal end vertebra) or interior surface (distal end vertebra) tilts maximally to the concavity of the curve. McAlister and Shackelford (1975) suggested that the curvature of the vertebral column in lateral radiographs can be measured with a similar method. However, the Cobb's angle measures the relative tilt of the end vertebrae of the curve rather than measures either of lateral deviation or curvature. Errors of the Cobb's measurements result from variability in selecting the end vertebrae of the curve and in drawing and measuring the line for indicating the angulations of the vertebral endplates (Stokes et al., 1993).

In Ferguson's method, the angle is defined based on the center of the extreme end vertebrae and the apical vertebra of a curve rather than only the superior and inferior surface of the end vertebrae of the curve (see Figure 2.3 c). The center of the vertebra is determined by the intersection of two diagonal lines from the superior corner of one side of the vertebra to the inferior corner of the opposite side according to Ferguson's method (Ferguson, 1945) (see Figure 2.3d). The Ferguson angle is formed by drawing lines from the center of the apical vertebra to the centers of the end vertebrae. Therefore, the Ferguson's angle is more geometrically describable because it is a measurement of alignment of the curved spine and independent of the angulations of the end vertebrae with respect to the horizontal. In Ferguson's measurements, errors were apparently due to difficulties in positioning the center of the apex vertebra of the larger curves with poor radiography quality, and also variability in selecting the end vertebrae for measurement (Stokes et al., 1993).

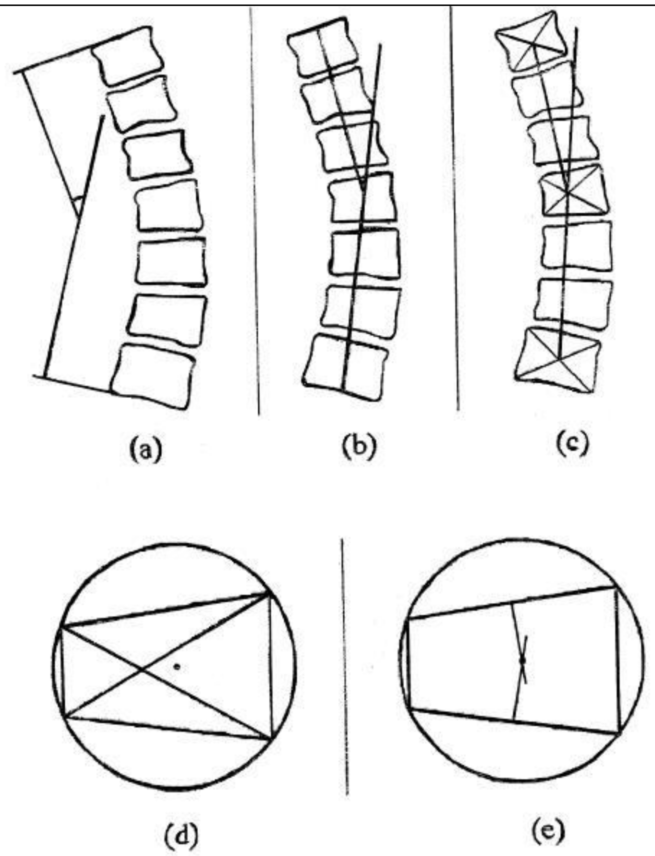

Figure 2. 3. Measurement of a Curve with (a) Cobb's Method (Cobb, 1948) (b) Diab's Method (Diab et al., 1995) (c) Ferguson's Method (Ferguson, 1945). The Principles for Identifying the Center Point of the Vertebral Body for (d) Ferguson's Method (e) Diab's Method.

Stokes et al. (1993) compared measurements of radiographs of patients with idiopathic scoliosis which were measured using Cobb's and Ferguson's methods by means of their magnitude and precision. By observing measurements of 77 untreated patients, there was a high correlation between the Cobb's and Ferguson's measurements of each curve (coefficient of determination = 0.98), with Cobb's measurements averaging 1.35 times greater than Ferguson's measurements. The reproducibility of measurements was studied in the radiographs of 12 patients by three repeated measurements of both methods with three observers. The precision of the Cobb's method was slightly better, and the Cobb's measure was shown to be less sensitive to intentional changes in the selection of the end vertebra. This report concluded that both Cobb's and Ferguson's methods can be useful for spinal curvature measurements and also suggested that Ferguson method could be used as an alternative with multiplying the measurement by 1.35 when Cobb's method is technically difficult or invalid (Stokes et al., 1993).

Diab et al. (1995) presented another method for the measurement of scoliotic curves in PA radiographs (Figure 2.3b). The centers of vertebral bodies of the apical and two end vertebrae of the curvature are represented by the intersection of the lines which are perpendicular drawn from the midpoint of the lines on the upper and lower endplates of the three vertebrae (Figure 2.3e). The center of vertebral body is defined on the basis of geometric principles in this method and is not influenced by changes in the shape of the vertebral body as compared with the Ferguson's method.

In summary, Cobb's method is more preferred for clinical assessment of spinal curvature in PA radiographs than Ferguson's and Diab's methods, because Cobb's method is more convenient and simpler due to the poor radiography quality.

Vertebral Rotation Measurement

Nash and Moe (1969) examined and compared the techniques for evaluation of vertebral rotation based on either spinous process or pedicle-shadow offset position. The Cobb's method was subject to a normal variation in the configuration of spinous processes. The pedicle technique also had similar problem as well but to a less extent because the pedicles are closer to the center of rotation and its configuration has relative constant relationship to the vertebral body throughout the spine. The Pedicle Offset Shadow technique (Figure 2.4) was suggested to be used for evaluation of vertebral rotation in the scoliotic spine rather than using the Cobb's spinous process method (Nash and Moe, 1969).

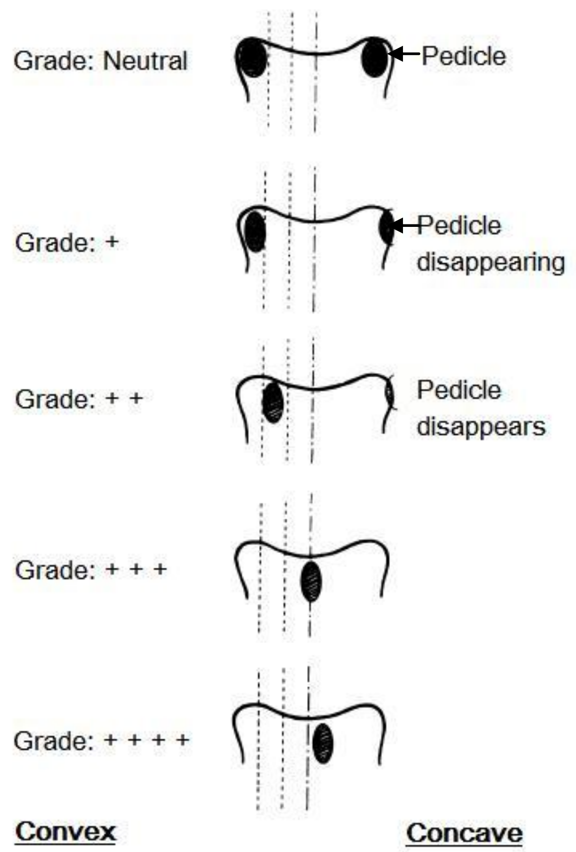

Figure 2. 4. Pedicle Method of Determining Vertebral Rotation (Nash and Moe, 1969)

Another practical method of the measuring vertebral rotation from a single frontal plane radiograph is use of a torsion meter which was developed by Rene Perdriolle in 1979 (Richards, 1992) (see Figure 2.5). The angle of vertebral rotation is measured by determining the middle point of each vertical border on selected vertebra (A and A’) and selecting the middle point of the pedicle on the convexity of the curve, and then superimposing the Torsiometer over points the middle point of each vertical border on the selected vertebra. The measured angle is noted with the convex pedicle at point B (see Figure2.5). The measurements using this instrument should only be made at 5 °increments.

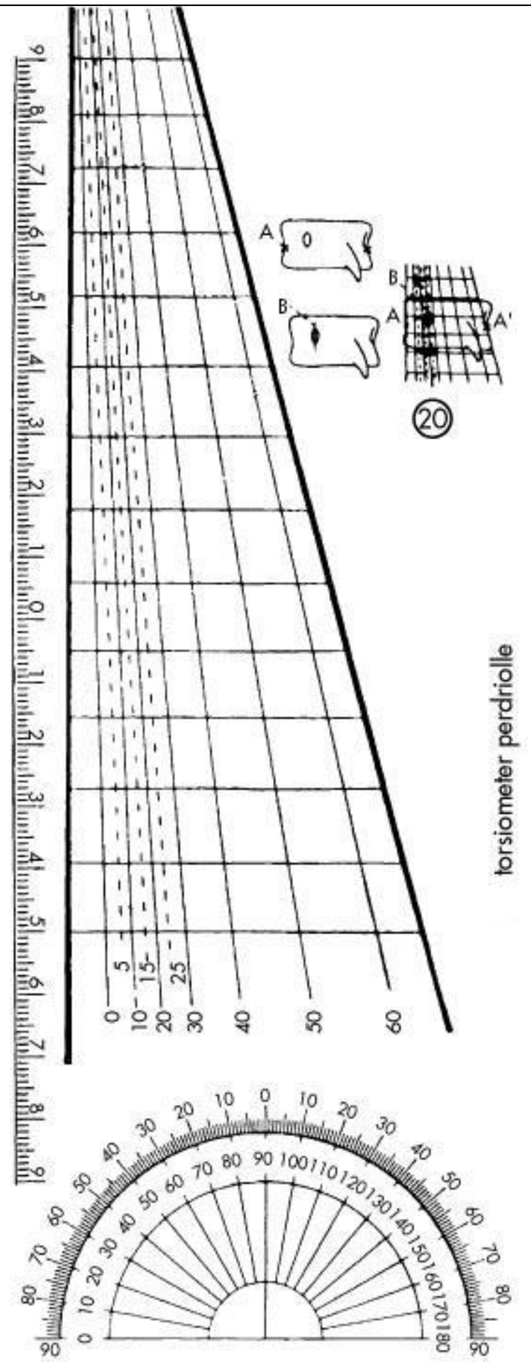

Figure 2. 5. Torsiometer Perdriolle (Richards, 1992)

In Raimondi's method, the vertebral rotation is measured by using the projection of the vertebral pedicles and taking the width of the vertebra as a reference. The largest axis of the pedicle is demarcated and measured on the curve convex side, and the distance of the longitudinal line from the pedicle to the border of the vertebra on the convex side is measured as well. These two values are transported to the ruler, and the rotation of vertebra is obtained (see Figure 2.6).

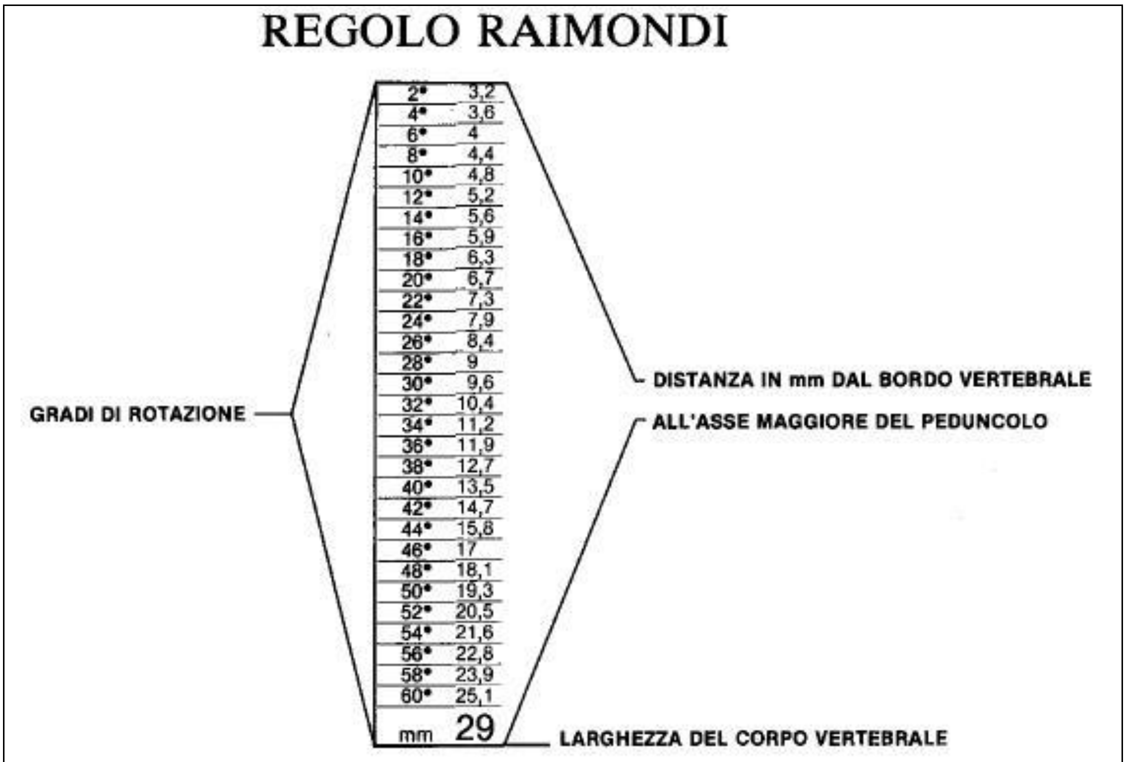

Figure 2. 6. Ruler Used in Raimondi's Method (Weiss, 1995)

Weiss (1995) conducted a study to determine the technical error of both Perdriolle's method and Raimondi's method. His study reviewed the apex vertebra of 40 curves on 20 AP radiographs and the vertebral rotation was measured by using the Perdriolle torsion meter and the Regolo Raimondi. The intra-rater reliability was found ICC(1,3) = 0.99 (Perdriolle) and ICC(1,3) = 0.99 (Raimondi), which means that both methods are useful tools for the follow-up of vertebral rotation as projected on two-dimensional X-rays for the experienced clinicians.

Three-dimensional Technique in Radiography

A spinal CT scan uses X-ray to produce detailed images of the spine. CT scans are also called as computerized axial tomography (CAT) scans, in which a computer is used to construct the image into cross sections of the spine and repeated at multiple different intervals, which can provide more detailed evaluation of an area in additional sections. The CT technique allows a reconstruction of two-dimensional image slices into a 3-D structures, and direct measurement of rotation of the spine and internal deformity of the vertebrae. The CT technique is commonly used for assessment of spinal injury such as fractures, with excellent bony detail (Brendel et al., 2002).

The 3-D reconstruction could be helpful for surgical planning and treatment procedures and also in curve assessment (Raso, 1999). Goh et al. (1999; 2000) compared three methods, including traditional Cobb's method, computer-assisted methods for deriving radius of curvature and an alternative Cobb's method, for measuring thoracic kyphosis in lateral spine radiographs and sagittal computed tomography thoracic scans. It is indicated that computer aided methods appear more appropriate for examination of thoracic kyphosis in cases exhibiting irregularities in vertebral end-plate orientation (Goh et al., 2000).

Non-radiographic Methods

The potential hazards of the repeated radiographic examinations should be prevented for clinical and research applications. This limitation of radiographic method motivates many researchers to develop non-invasive assessment methods that can provide reliable quantitative information in assessment of spinal deformity, for example, skin-surface device (e.g. SpineScan, Spinal Mouse, Ortelius800 system), optical image scanning system and ultrasound technique.

SpineScan

SpineScan (OrthoScan Technologies Ltd., USA, see Figure 2.7) is reported to be an assessment device of spinal deformities, postural disorders and range of motion. SpineScan is a kind of inclination measuring device, which includes an inclination tracking device configured to pass over the object, having a plurality of elements, whose angle of inclination can be mapped by a sensor probe. The sensor probe is configured to sense the position of each of the plurality of elements and to transmit the signals to the inclination tracking device. This inclination measuring device can be used to measure scoliosis (angle of trunk inclination measurements) and kyphosis (sagittal curve measurements). However, the reliability and accuracy of this device required further verifications and a longer training time as reported (Rigo and Villagrasa, 2007).

Figure 2. 7. SpineScan (Rigo and Villagrasa, 2007)

Spinal Mouse

Spinal Mouse (Idiag, Switzerland, see Figure 2.8), which is a computer-assisted electromechanical device, is a skin-surface measurement device for back posture via recording the contours of the back. In the measurements, two rolling wheels follow the contour of the spine with reference to the skin surface palpation. The distance and angle measures are communicated from the device to a base station which is interfaced to a personal computer. Some researchers (Kellis et al., 2008; Mannion et al., 2004) had examined the reliability of spinal extension and flexion measurements by using this Spinal Mouse. The intra-rater ICCs were reported from 0.61 to 0.96 and the inter-rater ICCs were found from 0.70 to 0.93. This showed that Spinal Mouse varied from fair to high reliability in measuring spinal motion.

Figure 2. 8. Spinal Mouse (Kellis et al., 2008)

Ortelius800 System

Ovadia et al. (2007) reported a radiation-free quantitative assessment of scoliosis by using the Ortelius800 system (OrthoScan Technologies Ltd., USA, see Figure 2.9). They conducted a prospective study to investigate the clinical value of Ortelius800 that provides a radiation-free method for scoliosis assessment in three planes (coronal, sagittal, apical). Correlation between Cobb's angle measured manually on standard PA radiographs and those calculated by Ortelius800 showed the difference between these two measurements to be significantly less than 5° for coronal plane and significantly less than 6° for sagittal plane. However, the posture of patients may change during the examination procedure, and the accuracy of this device depends on the experience of the operator when identifying the tips of spinous process through skin palpation. Moreover, when confirming the location of the tips of spinous process the force from the fingertip sensor may cause shift of the patient's body. All these limitations could cause error in assessing scoliosis.

Figure 2. 9. Ortelius800 System and Procedure. Palpation of Spinous Process with the Fingertip Sensor during the Examination Procedure (Ovadia et al., 2007)

Optical Image Scanning System

There have been various optical image scanning techniques for measuring the surface topography of the back developed and proposed (e.g. Integrated Shape Image System, Quantec Spinal Image System and Moire topography). These optical image scanning techniques make use of projection of structured light on the back surface of the subject to record spatial information of 3-D shape of the back and assess the spinal deformities.

Integrated Shape Image System (ISIS)

Horizontal beams of light are projected on the patients' back to provide a raster image of the back and numerical values of parameters for analysis of back surface asymmetry and spinal deformity. Then the ISIS uses an electric light source, a video camera and a computer to record the static surface of the back with several parameters (e.g. lateral asymmetry, volumetric asymmetry and hump severity) (Liu et al., 2001; Thometz et al., 2000; Goldberg et al., 1994).

Quantec Spinal Image System (QSIS)

Different from the ISIS, QSIS focuses on describing spinal angles, rib and loin humps, trunk balance as well as asymmetry of scoliotic spine, though the components and mechanisms of these two systems are the same as the ISIS. Thometz et al. (2000) found that the measurements of the scoliotic curves generated from the QSIS were comparable to Cobb's angle when Cobb's angel was less than 21° and axial surface rotation measured by the QSIS was less than 6°. They suggested that the QSIS could be used as an alternative method for monitoring scoliotic curvatures in mild to moderate thoraco-lumbar curves to reduce radiation exposure.

Moire Topography

Moire topography is developed for analysis of spatial information of 3-D contoured surface. Takasaki proposed to apply this method to body surface shape in 1970. With this method, the contour map of the back to indicate asymmetry of the back surface could be outlined (el-Sayyad et al., 1986). Their team found high correction ($r > 0.93$) between Moire topography and Cobb's method in assessing scoliotic curvature. Therefore, Moire topography could be used as a non-invasive method for scoliosis screening.

The optical image scanning techniques were shown to be capable to provide quantitative information of the surface deformities resulting from scoliosis and predict the site of a scoliotic curve (Liu et al., 2001; Thometz et la., 2000; Goldberg et al., 1994; Drerup and Hierholzer, 1992). However, there are several potential sources of errors when using the optical image scanning techniques, including changes in the subject's positioning, obesity of the subject, and inter-rater and intra-rater reliability of the measurements.

Ultrasound Technique

Ultrasound is high frequncy sound wave which ranges from 20KHz to 50MHz. Ultrasonography is an ultrasound based diagnostic imaging technique which has been applied to many medical areas, for instance to visualize tendons, muscles, joints, vessels and internal organs. However, ultrasound has become popular to image bone to reduce the excessive radiation exposure especially in growing children. Ultrasound waves travel into an object, hit the boundaries of differing densities of the underlying structures and bounce back to the receiver. A portion of the waves will reflect or echo back to the receiver at each boundary and some will continue to travel further through the body until they hit the next boundary. The echoes that return to the receiver are converted into electrical signals. A two-dimensional image of the object being scanned can be formed based on the time of return and strength of the echoes.

Suzuki et al. (1989) used ultrasound to detect the spinous processes and the laminae so as to assess the axial spinal rotation. Harrison et al. (1992) diagnosed abnormal spinal curvature in the fetus with the use of ultrasound. Furness et al. (2002) identified the lumbar intervertebral level with ultrasound imaging and found that the correct identification was obtained up to 71% of cases. Burwell et al. (2002) evaluated a new real-time ultrasound to measure the differences between axial spinal and rib rotation at the apex of the spinal curvature. Lam et al. (2004) established a normal ultrasound assessment of the lumbo-sacral spine in children and concluded that ultrasound is a useful tool for diagnosis of suspected tethering of the spinal cord. McLeod et al. (2005) studied the effectiveness of ultrasonography to facilitate the insertion of epidural space in scoliosis patients.

Ultrasound measurement of the vertebral rotation in idiopathic scoliosis was proposed by Suzuki et al. (1989) and they found a strong linear relationship between the Cobb's angle and the rotation of the apical vertebra in untreated patients, which could not be found in patients who had had brace treatment. The spinous processes and the lamina could be outlined by using ultrasound, so the axial rotation could be measured too. Vertebral rotation could be measured by ultrasound. Therefore, this investigation was suggested to be used at routine follow-up examination of patients with AIS, because it is harmless and fairly rapid. For the ultrasonic examinations they used an ultrasound unit with a 5.0 MHz probe based on a linear electronic scanning method. The patient was laid prone on a firm couch, with the shoulder girdle and the pelvis parallel to each other and the ground. The spinous processes were marked and lines were drawn parallel to the inclination of the vertebrae as seen on an AP radiograph of the spine. The transducer with an attached inclinometer was placed on the spinous process in line. The transverse processes and the lamina were displayed on the screen and the transducer was then inclined until the image of the lamina become horizontal on the screen (Figure 2.10). The inclination of the transducer was then the rotation of the lamina. In each case it was determined from T2 spinous process to the sacrum. It is very important that the shoulder girdle and the pelvis parallel to the ground when patients lay on a firm surface with both. The rotation of the whole spinal column can be measured in a short time with ultrasound by their method. Ultrasound is harmless and can give a clear image of the outline of the lamina, allowing rotation to be measured directly from the inclination of the transducer.

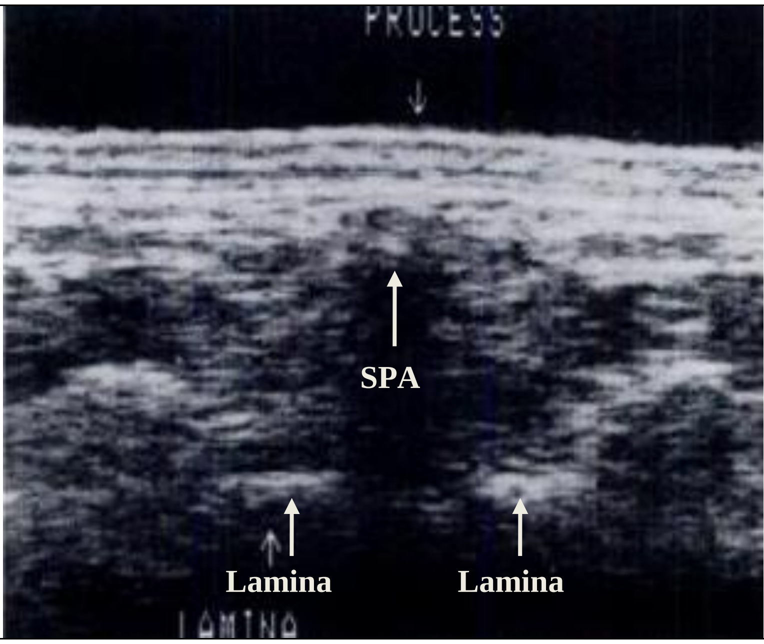

Figure 2. 10. Ultrasound Image of the T2 Spinous Process (Suzuki et al., 1989)

Furness et al. (2002) carried out an evaluation of ultrasound imaging for identification of lumbar intervertebral level. The patient was set in the lateral position and asked to flex her knees and hips. One of three anaesthetists examined the lumbar spine and scored the difficulty in feeling lumbar spinal and iliac crest anatomy (easy, moderately difficult or very difficult). The L2/3, L3/4 and L4/5 interspaces were marked by the anaesthetist's attempt, using a marker only visible under ultraviolet light. Then the ultrasound examination was taken in the patients and after the examination, the patients were placed again in the lateral position with their knees and hips flexed. An ATL 3500 ultrasound machine was applied in their study, and a 3.5-MHz curved array probe was placed in the sagittal plane over the sacral area. The buttock crease was used as a starting position, then the probe was moved in a cephalad direction to identify the sacrum and then the spinous processes of the lower lumbar vertebrae. The individual hyperechoic (white) areas with posterior attenuation (black) were the spinous processes as showed in the images, whereas the sacrum was seen as a more continuous hyperechoic band. Echoes from the deeper structures (i.e. ligamentum flavum) may be seen in the L5/S1 intervertebral space between the lowest lumbar spinous process and the sacrum. The lateral X-ray was used to assess the accuracy of the clinical and ultrasound methods. Ultrasound was more accurately than palpation ($p < 0.001$) in predicting the correct level significantly for all levels. The ultrasound technique had been shown a usable and rapid in performing method by anaesthetists at bedside. To use the technique would need a basic training on the use of the ultrasound equipment, and time to familiarize oneself with the images produced of the lumbosacral spine, because ultrasound images quality can vary markedly between patients. Although it is easy to identify the interspace between the spinous process of L5 and the sacrum by using ultrasound imaging, the L4/L5 space may be misinterpreted as being the L5/S1 space if the L5/S1 disc space is narrowed or the spine is very lordotic.

Lam et al. (2004) studied the ultrasound measurement of lumbosacral spine in children. The aim of their study was to establish normal ultrasound measurements of lumbosacral spine in children as a screening assessment of tethered cord or postoperative retethering of cord. Ultrasonography had been proved to be a well-established method for investigating the spinal cord, spinal canal, and meningeal coverings in infants. Their study aimed to determine ultrasound measurements of lumbosacral spine in normal children as a reference for non-invasive investigation of spinal cord anomalies, such as tethered cord syndrome or postoperative retethering of filum terminale, before embarking on more expensive investigation such as MRI.

Mcleod et al. (2005) investigated the application of ultrasound in assisting epidural insertion in scoliosis patients with a case study. A portable ultrasound system with a 38-mm linear probe in two-dimensional B mode was applied to examine the spine. The echo signals from the lamina became level on the screen at the angulation of the probe head (measured using an inclinometer held in alignment with its long axis), and the angulation of the probe head was taken to correspond to the degree of vertebral rotation. First of all, the least rotated (most neutral) vertebral interspace was located, and a supervised anesthesiology trainee used a loss-of-resistance technique to perform epidural catheter insertion. They concluded that ultrasonography may have a potential role to facilitate insertion of epidural catheters in patients with scoliosis. The depth and location of the epidural space could be estimated by ultrasound technique. It was investigated in the case series that whether this same technique could be used before epidural catheter insertion, and help successfully in placement. Describing the use of ultrasound in epidural cannulation of the more difficult thoracic region was first done in this study, in patients with significant axial rotation of their vertebrae due to severe scoliosis requiring surgical correction. The possibility of this novel technique increasing the success rate of epidural cathether placement as well as improving postoperative analgesia was assessed by this large randomized controlled trial. Their study has not attempted to make a controlled comparison to establish whether this technique improves the success or speed of epidural insertion and also did not attempt to corroborate the ultrasound assessments with radiological measurements, nor perform CT scans of the patients.

Comparison between MRI and Ultrasonography

MRI is a diagnostic standard for the examination of the vertebral column. It provided an excellent anatomical overview in all vertebrae. Phase-contrast MR was found to be useful in detecting diminished motion of the cervical spinal cord in patients with cord tethering (Grau et al., 2001). The steadiness and the size of the image and the high resolution of MRI were the most obvious advantages over US. But MRI is still a costly and time-consuming procedure. The ultrasonic approach of the EDS is complicated by the surrounding vertebral bone structures, especially in the thoracic levels (Grau et al., 2001). And obviously, US provided a smaller image than MRI. Ultrasonography, on the other hand, is widely available, as they are among the most basic diagnostic tools. They are mobile and the handling is comparatively fast.

Schmitz et al. (2005) used an MR animation, which was carried out in a standard supine position, to visualize the spine in order to study the effect of the spinal orthosis and discovered that the orthosis could straighten the thoracic spine, though their project only studied the supine position and could not reveal the effect of spinal orthosis in erect posture under the gravitational pull.

Grau et al. (2002) conducted a study to establish ultrasonography for the prepuncture demonstration of the anatomic structures surrounding the thoracic epidural space (EDS) and to evaluate its precision and imaging quality. There were 20 volunteers examined in his study. There were two imaging techniques used in each participant to identify the extra dural space and the neighboring anatomic landmarks in the intervertebral space T5-6, including magnetic resonance imaging (MRI) and ultrasonography (Figure 2.11). They compared correspondingly regarding distance measurements and the visibility of anatomic landmarks. The ultrasound imaging was limited in depicting the thoracic EDS, as show in Figure 2.11. MR images were proved easier to interpret, due to the better overview, while ultrasound imaging was proved to be of better value than MRI in the depiction of the dura mater. It was found that the overall correlation was satisfying for all important landmarks for the puncture of the thoracic EDS that could be identified with both techniques. Besides, the precision of US was acceptable in depicting the different structures of the thoracic EDS. When compared with the standard imaging technique for the depiction of the spine MRI, US showed good correlation.

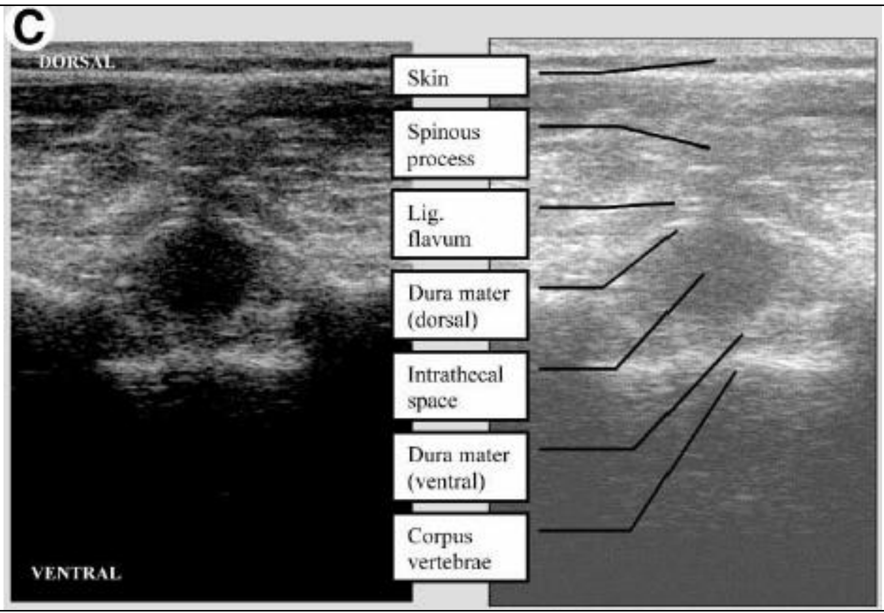

Figure 2. 11. Comparison between MRI and Ultrasonography (Grau et al., 2001)
Left: MRI; Right: Ultrasonography

Comparison between the CT and Ultrasound Method

Computed Topmography (CT) provides a three dimensional image superior in quality to X-rays but CT scans expose the patient to much more radiation than X-rays. Thus, the hazards of exposure to radiation and the high cost make CT not applicable for routine follow-up of spinal deformities.

Brendel et al. (2002) conducted a study to compare the registration of 3-D CT and ultrasound datasets of spine using bone structures. The 3-D US data were acquired with a 3.5-MHz curved array. The direction for the movement of the transducer was craniocaudal with a transverse imaging plane (roughly equivalent to the planned scanning path extracted from a CT dataset of bone surface). B-scans were acquired at a craniocaudal distance of 1-mm. The slice thickness and in-plane resolution are anisotropic and depth dependent with ultrasound imaging. The whole lumbar spine was recorded. The main limitation of intra-operative ultrasound is its low imaging quality, and it is very noisy in the acquired data due to speckle. In addition, only a small part of the bone surface could be showed in ultrasound images, due to the reflection properties of an ultrasound beam at the tissue-bone interface. Because of the total reflection, the tissue-bone interface is imaged as a bright curve with ultrasound. As shown in Figure 2.12, there are two main consequences of these reflection properties. Almost the entire ultrasound wave is reflected at the interface because of the great difference in the acoustic impedances of tissue and bone, so no imaging is possible beyond it (shown in the left one). Furthermore, interfaces that are not orthogonal to the direction of sound propagation deliver a weak image or no image at all (shown in the right one), because the reflection is almost completely specular. Only a small part of the bone surfaces can be visualized with ultrasound for these two reasons. Their study showed an example of a lumbar vertebra to illustrate that in Figure 2.13a. The direction of ultrasound propagation is expected to be from posterior to anterior. The transverse processes (TP, see Figure 2.13b), the lamina (L, see Figure 2.13b), the inferior articular facets, and the posterior edge of the spinous process (SP, see Figure 2.13b) are the structures accessible for ultrasound image acquisition. Covered by elements of the vertebra in the posterior direction, the vertebral body, the pedicles and the superior articular facets cannot be imaged. A typical ultrasound image of a lumbar vertebra is shown in Figure 2.13b.

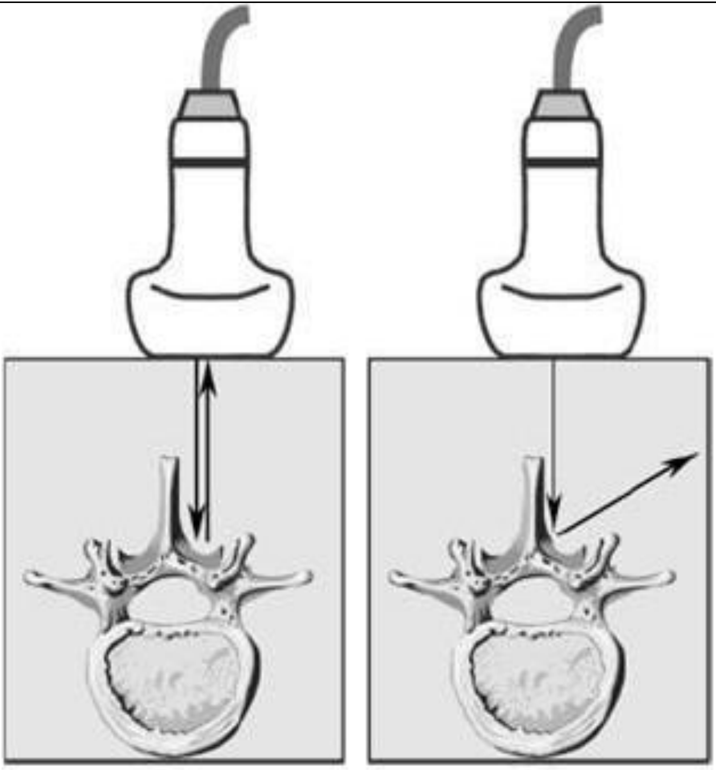

Figure 2. 12. Reflection Region of Ultrasound Wave
Left: Total Reflection of the Ultrasound Wave at the Tissue-bone Interface Inhibits Imaging of the Vertebral Body, because it is Covered by the Posterior Elements of the Vertebra.
Right: Specular Reflection of the Ultrasound Wave at the Tissue-bone Interface Inhibits Imaging of the Right Surface of the Spinous Process, because the Ultrasound Wave is not Reflected towards the Transducer.
(Brendel et al., 2002)

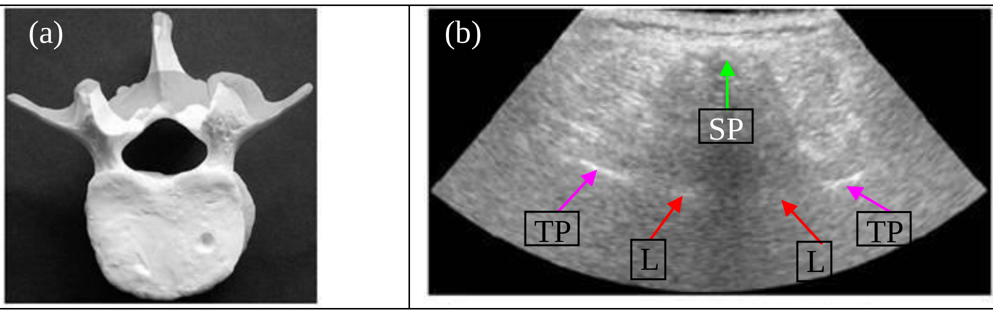

Figure 2. 13. Region of the Lumbar Vertebra Shown in Ultrasound Images
(a) Model of Lumbar Vertebra. The Surfaces of the Bone that can be Visualized with Ultrasound are Marked in Gray.
(b) Typical Ultrasound Images of a Lumbar Vertebra (Cranial View) Recorded with a 3.5-MHz Curved Array. In Plane, only Spinous Process (SP), Transverse Process (TP) and Lamina (L) are Visible.
(Brendel et al., 2002)

2.3.3 Treatments for AIS

Once a patient has been diagnosed to have scoliosis, there are several factors to be considered in choosing an appropriate treatment (e.g. observation, orthotic treatment and surgical treatment) for AIS. For example, skeletal maturity, degree of spinal curvature, age of the patient, potential for progression, location of the curvature (Wong et al., 2003). According to the analyses for this complex set of variables, if the patient is still growing and the degree of the curve is between 25 to 40 degrees, the orthotic treatment will usually be prescribed to the patient (Wong et al., 2003; Roach, 1999; Wright, 1997; Nachemason and Peterson, 1995; Lonstein and Winter, 1994). The particular aspects of the orthosis (e.g. force magnitude, location and direction of pressure pad) should be individually designed according to the diagnosis of the spinal deformity.

Two types of rigid spinal orthoses have been used for intervention of scoliosis, namely cervico-thoraco-lumbo-sacral orthosis (CTLSO) and thoraco-lumbo-sacral orthosis (TLSO). Both of these two rigid orthoses are symmetric in design and for full-time wearing. The components of these orthoses should be prescribed based on the feature of the spinal deformity at the findings of the radiographic examination. The CTLSO for treatment of AIS is represented by the Milwaukee brace (see Figure 2.14) first introduced by Blount and Schmidt at the Academy of Orthopaedic Surgeons in 1946. The components of Milwaukee brace include a pelvic girdle, an anterior metal upright, two posterior metal uprights, a lumbar pad, an outrigger, a thoracic pad, an axilla sling and a neck ring. Scoliotic curvatures with an apex at T8 or above usually requires the CTLSO rather than a lower profile TLSO (Herkowitz et al., 1999).

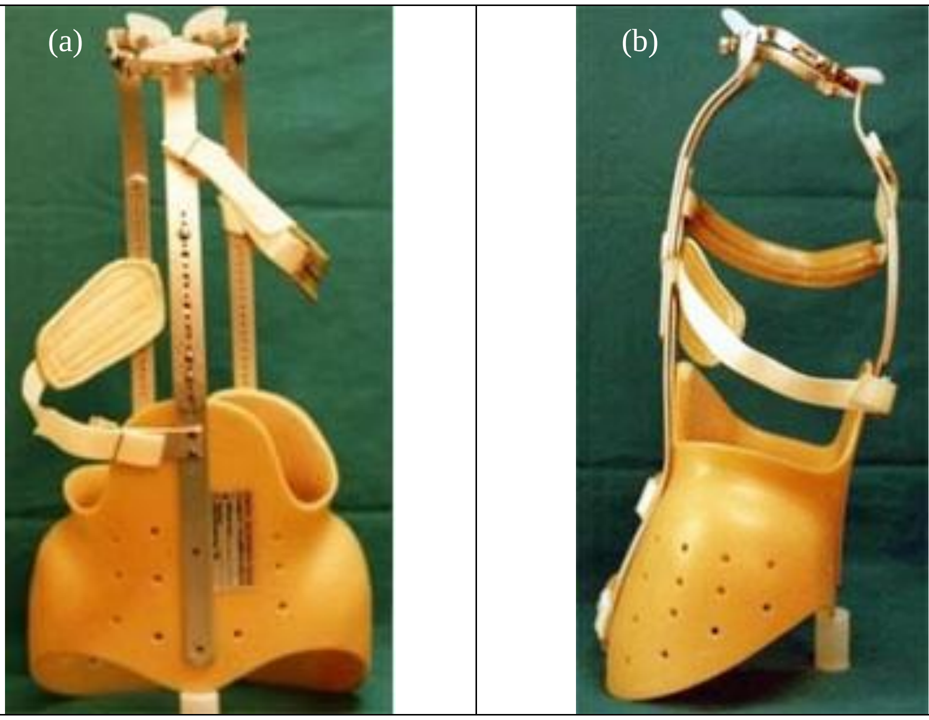

Figure 2. 14. CTLSO (Milwaukee Brace) (a) Anterior View (b) Lateral View

There are varieties of thoraco-lumbo-sacral orthosis (TLSO) used for treatment of AIS with an apex below T8 (Herkowitz et al., 1999). The common components of the TLSO are a pelvic girdle, a built-in lumbar pad and a built-in thoracic pad. The main differences among different types of TLSO are their trim-lines, materials used and locations of opening. The type of TLSO commonly used in Hong Kong named Hong Kong brace is shown in Figure 2.15. The Hong Kong brace is designed with built-in thoracic and lumbar pressure pad, posterior opening and three traps for maintaining orthosis tightness. No matter which type of orthoses was chosen, the aims of orthoses treatment are to prevent further curve progression and to achieve maximum curve correction.

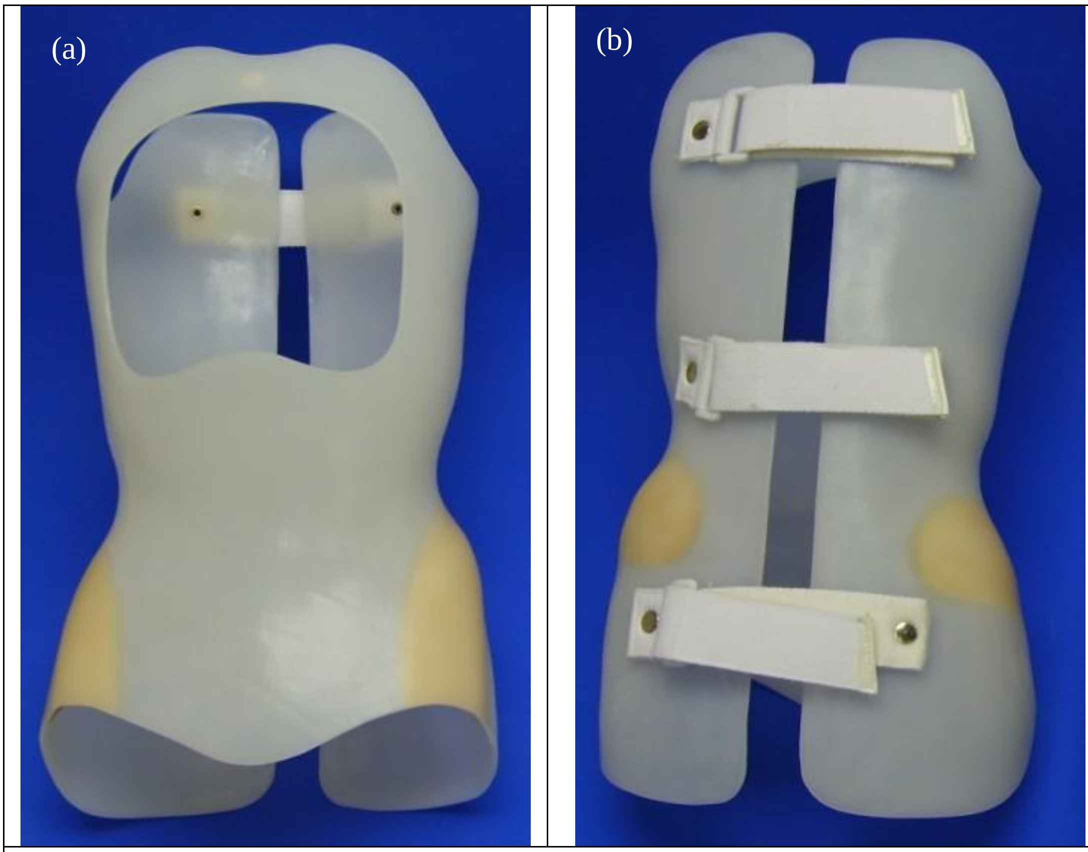

Figure 2. 15. TLSO (Hong Kong Brace) (a) Anterior View (b) Posterior View

Besides rigid spinal orthosis, Coillard et al. (2003) investigated the application of a dynamic soft orthosis named “SpineCor” and tried to improve the patients’ acceptance of the brace, which resembles a non-rigid harness and was developed at Sainte-Justine Hospital between 1992 and 1993. It consists of a plastic pelvic base, which is a belt that includes 3 pieces of soft thermo-deformable plastic stabilized by 2 thigh bands and 2 crotch bands, a bolero made of cotton and four corrective elastic bands of variable size (see Figure 2.16). They use the Corrective Movement principle to control scoliotic deformities via the SpineCor system on the patient and the system must be worn 20 hours a day for a minimum of 18 months (Coillard et al., 2008b). Coillard’s research team conducted prospective observational studies on patients with idiopathic scoliosis with the SpineCor system and concluded that it was effective for treatment of AIS with more than 90% of patients stabilized or corrected their end of brace Cobb's angle up to 2 years after brace (Coillard et al., 2008b; Coillard et al., 2007; Coillard et al., 2003). Weiss's group (2005), and Wong's group (2008a) compared the clinical efficacy of the SpineCor system with rigid spinal orthoses which were Cheneau brace (Weiss and Weiss, 2005) and conventional rigid spinal orthosis (Wong et al., 2008a), respectively. The survival rate of the SpineCor was 68% for Wong's group and 8% for Weiss's group. Their findings are very different from those of the SpineCor developing team (Coillard et al., 2008b; Coillard et al., 2007; Coillard et al., 2003). The SpineCor is a relatively new method for AIS and its efficacy should be further investigated.

Figure 2. 16. SpineCor (Wong et al., 2008a)
Left: Anterior View Right: Posterior View

2.4 Investigation on Effectiveness and Biomechanics of Spinal Orthosis

Since spinal orthosis is usually prescribed to the patients with AIS, it is very important and meaningful to investigate the effectiveness and biomechanics of spinal orthosis.

Effectiveness of Spinal Orthosis

Rigid spinal orthoses have been demonstrated to be effective for the majority of moderate AIS patients, providing that treatment begins early enough and the orthoses is worn compliantly (Yrjonen et al., 2007; Wong et al., 2000; Nachemson and Peterson, 1995; Lonstein and Winter, 1994; Emans et al., 1986; Winter et al., 1986; Carr et al., 1980; Blount et al., 1957).

Wong et al. (2000 & 2003) have found that rigid spinal orthoses demonstrated effectiveness in controlling curve deterioration in moderate AIS. Wong et al. (2005a) conducted a study of the CAD-CAM method and conventional manual method in the design and fabrication of spinal orthoses. It was found that the total delivery time could be shortened by 66% in the CAD-CAM method. Wong et al. (2005b) carried out a clinical study comparing the effectiveness of CAD-CAM method and the conventional manual method, and found that both methods are equally effective in controlling spinal curvature. Chu et al. (2006) conducted a pilot cross-sectional study on the effectiveness of spinal orthoses in the correction of spinal curvature of 14 patients with moderate AIS at the positions of supine, prone, right and left decubitus using magnetic resonance (MR) imaging and multi-planar reconstruction technique. Evaluation of the scoliotic spine in the coronal, sagittal and axial planes and the effect of spinal orthosis on AIS at different recumbent positions were studied. There was significant reduction of coronal Cobb's angle ($p < 0.05$) with orthoses at all four recumbent positions and the maximal reduction was found in the prone position (17% reduction). The sagittal Cobb's angle was only significantly reduced at the supine position, while the axial rotation did not change significantly in all positions.

Many studies (Carr et al., 1980; Emans et al., 1986; Noonan, 1996; Katz, 1997; Goldberg et al., 1993) showed that the long-term follow-up Cobb's angle is close to the pre-brace Cobb's angle which means that no additional correction was caused by spinal orthoses. These studies argued that spinal orthosis was effective in preventing the curve progression but no additional correction. One thousand and twenty patients, who had been diagnosed as AIS and were treated by Milwaukee brace between January 1954 and December 1979, were reviewed in a study (Lonstein and Winter, 1994). Their study indicated that the factors affecting the progression of the curve include the pattern and magnitude of the curve, the age of the patient at the presentation, the Risser's sign, and the menarche status for girls.

Biomechanics of Spinal Orthosis

Even though the effectiveness of spinal orthoses is debatable, many studies have focused on the working mechanism. The amount of support and corrective action provided by an orthosis depends on the location, magnitude and direction of the pressure exerted upon the spine (Patwardhan et al., 1986; Emans et al., 1986). From the biomechanical point of view, the combined effects of end support, transverse loading and curve correction have improved in relative stability of a broad scoliotic spine. Researchers and clinicians (Jiang et al., 1992; Houghton et al., 1986; Havey et al., 2002; Lou et al., 2004a & 2004b) believe that successful orthotic treatment requires accurate orthosis fitting and also requires patients to wear orthoses as prescribed, including securing of the straps so as to provide adequate pressure on the convexity of the curve. All these studies indicate that knowledge of the biomechanics of spinal orthosis is very important.

Location of Pressure Pad

Chan et al. (2006) designed a new spinal orthosis for the high thoracic curve and found that the new design could provide improved control of trunk listing. They also tested the feasibility of placing tinfoil strip around the pressure pad edge in order to locate the pad in X-ray images. It was found that the position of the pad can be outlined but with an average displacement of 1 cm from the desired location. To better control the curvature for patients with AIS, a non-invasive and fast assessment should be developed.

Direction of Pressure

The actual working mechanism of spinal orthosis is rather complicated because it involves the force transmission from soft tissues and rib cage to the spine, so the biomechanics of spinal orthosis are still not fully understood (Beausejour et al., 2002).

The direct acting corrective force is considered to be one of the working mechanisms of spinal orthosis. It is indicated that the amount of correction of the scoliotic deformity can be influenced by the variations in the corrective force, though little evidence has been found to prove such a correlation in a study (Van den Hout et al., 2002). However, significant alterations in the exerted forces are believed to cause some changes in body posture. Van den Hout et al. (2002) also indicates that in all positions the mean corrective force through the lumbar brace pad is larger than the mean corrective force over the thoracic brace pad.

Strap Tension

Strap tension is strongly believed to affect the interface pressure of spinal orthosis. Wong et al. (1998 & 2000) developed a tension transducer to measure strap tension and used a Dynamic Pressure Monitor to measure the interfacial pressure between the body and pressure pad. They found a high correlation between the strap tension and pad pressure (correlation coefficient = 0.91, $p < 0.05$). In addition, the standing Cobb's angle is considered to be highly correlated with the pressure applied by the pad (correlation coefficient = 0.93, $p < 0.05$). Mac-Thiong et al. (2003) had maintained similar findings when studying the relationship between the strap tension and optimal brace interface forces by applying the Boston brace onto the patients with AIS. Nevertheless, there was no objective method of measuring the instant change of spinal curvature during the fitting of spinal orthosis in their studies.

Cheng et al. (2006) used the IntelliBRACE system to measure patients' interfacial pressure between the body and spinal orthosis for tracking their compliance. The results showed that the mean orthosis wearing hours were 15.9 hours (69% of the prescribed time) in which 10.5 hours (46% of the prescribed time) were at 80-120% of the prescribed tightness. An orthosis tightness study was also conducted and 3 experienced clinicians were invited to individually prescribe the amount of interfacial pressure needed for the 30 subjects in fitting of spinal orthosis. A mean force of 1.56N was found but significant differences ($p < 0.05$) were found among the 3 clinicians in prescribing the controlling pressure. Therefore, a scientific approach should be explored for an effective prescription of orthosis tightness.

Therefore, it is hypothesized that the clinical outcome of orthotic treatment for AIS is associated with accurate orthosis fitting and subsequent patient's compliance. Nevertheless, there is a lack of technical information such as "What is the optimum location for pressure pad placement? How tight should patients wear the orthoses? How long should they wear the orthoses? Whether all these are really important and necessary and related to the clinical efficacy?" This study aims to investigate the optimum location for pressure pad placement.

2.5 Summary of Literature Review

Though there are many different methods to assess scoliosis (radiographic methods or non-radiographic methods), yet the most commonly used parameter to assess scoliosis is the Cobb's angle which can only be obtained via X-ray imaging at the pre-brace stage and in regular clinical follow-up with a 4-month interval but not at the fitting stage of spinal orthosis in consideration of the X-ray dosage. The only physical mean, trunk listing, is generally used as an indicator to check whether the orthosis is alleviating or worsening the deformity in the fitting process. However, there is no evidence for a direct relationship between the trunk listing and the spinal curvature. Moreover, to what extent the deformities can be controlled during the orthosis fitting is far from known with the existing arrangements and practice.

In current clinical practice, pre-brace PA standing X-rays are used as reference for clinicians to design a blueprint for orthotic intervention. In principle, the pressure pad, such as a thoracic pad, is located on the postero-lateral aspect of the trunk at a level corresponding to the rib of the curve apex (Wong et al., 1998). However, the optimum location and pressure magnitude of the pad for providing maximum deformity reduction cannot be determined in current practice. This is because once a pressure pad acts on the scoliotic spine, the geometry of the whole spine will alter and the original pre-brace X-ray can no longer be taken as reference.

Compared with the CT or MRI systems on examining and localizing spine, 3-D US is potential to be further developed as for assessing scoliotic spine. With the development of 3-D US technique, tracing spinal processes along a scoliotic curve has become possible. Using 3-D US, it could help to trace SPA not only at the pre-brace stage but also at the in-brace stage. Therefore, US can be applied to monitor the fitting method of orthotic treatment for patients with AIS. Furthermore, it is well known that bracing may cause a reduction of thoracic kyphosis or even thoracic lordosis. Using 3-D US as a fast and non-invasive assessment tool, optimum pressure pad location could be confirmed for best lateral curvature control without hypo-kyphosis/ lordosis.

This study aims to apply 3-D US to assess scoliosis in a 3-D approach and to monitor the fitting method of spinal orthosis. The ultimate goal of current study is to improve the effectiveness of orthotic treatment with an advanced 3-D US-assisted fitting method via determining the optimal location of pressure pad.

CHAPTER 3 METHODOLOGY

This study aimed to develop a non-invasive, fast and effective method to assess scoliosis and enhance the fitting of spinal orthosis and treatment of scoliosis. This project mainly consisted of two parts. The first part was a correlation study, which examined the correlation between the SPA and Cobb's angle from X-ray images. The main portion of the study was its second part, the ultrasound study. In the ultrasound study, feasibility of using 3-D US to trace the spinous processes was first tested and then the correlation between SPA measured from X-ray images and that measured from 3-D US images was investigated. Moreover, the correlation between Cobb's angle estimated from ultrasound images and that measured from X-ray images was examined. Based on the correlation between these two parameters, 3-D US was then applied to assist the fitting of spinal orthosis to patients with AIS.

3.1 Correlation Study

The Cobb's method measures lines drawn parallel to the upper end plate of the vertebral bodies at the beginning and the lower end plate of the curve and the angle between these two lines is equal to the Cobb's angle that reveals more the anterior deformity of the spine. Spinous process angle, which reveals more the posterior deformity of the spine, is measured by accumulating the angles formed by every two lines joining three neighboring spinous processes. The correlation between the Cobb's angle and the SPA measured from the X-ray images was examined in this study. The relationship between the SPA and Cobb's angle suggests new parameter to evaluate scoliosis, offering more approaches to assess this deformity.

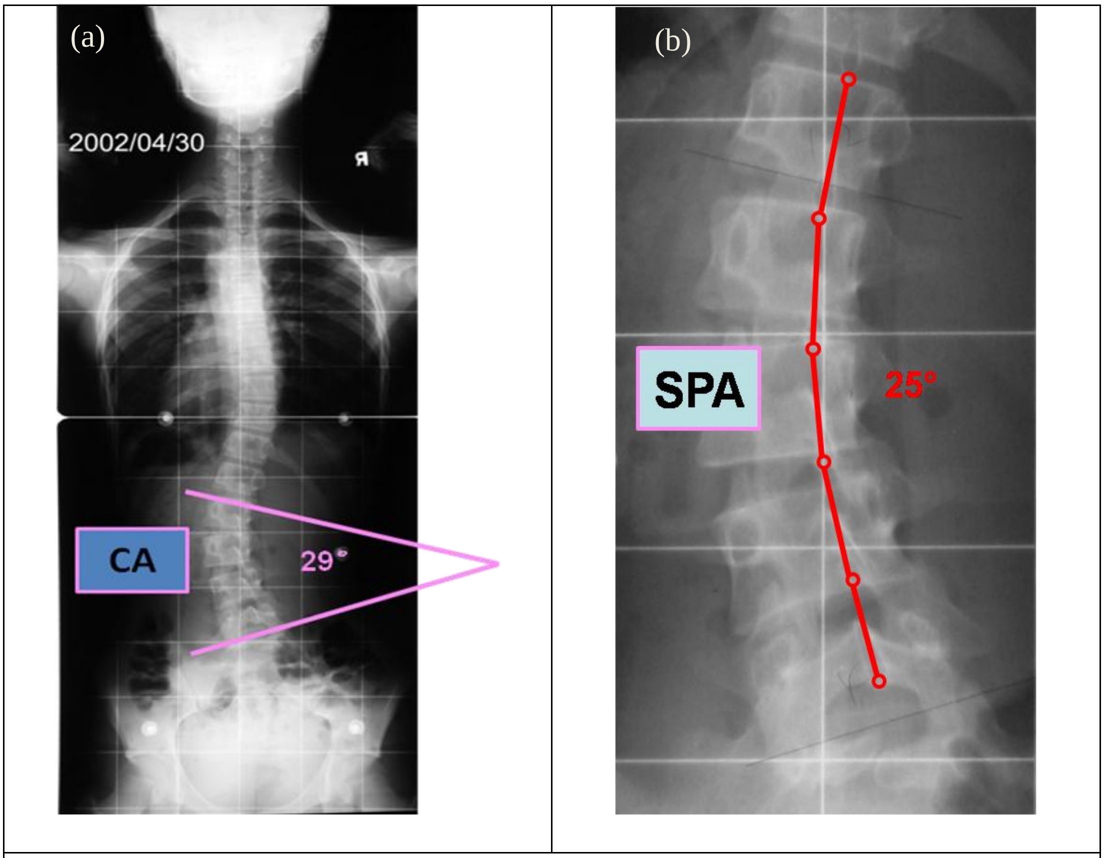

Figure 3. 1. Angle Measurements (a) Cobb's Angle (CA) (b) SPA

3.1.1 Subjects

The subject selection criteria are as follows: 1) female patients with AIS; 2) Cobb's angle: 20°- 40°; 3) curve pattern: double right thoracic and left lumbar (RTLL); 4) age: 9-14; 5) Risser's sign: ≤ 2.

Based on subject selection criteria and the available data obtained from the Scoliosis Clinic of the Prince of Wales Hospital, a retrospective correlation study was conducted using X-ray images from 43 patients (aged 10-14 years) with AIS which included 37 major curves (6 were excluded for the poor image quality) from pre-brace X-ray images, 21 major curves from in-brace X-ray images and 22 major curves at the in-SpineCor stage (Wong et al., 2008). All major curves were studied that their spinous processes could be clearly identified.

3.1.2 Experiment Design

Every X-ray image was measured three times to obtain the spinous process angles and Cobb's angle. Then the correlation between Cobb's angle and SPA was studied and the reliability of the method for this measurement was examined.

3.1.3 Experiment Procedure

The quality of the original digital radiographs was not adequate for distinguishing all the spinous processes. As a result, Photoshop (Adobe Photoshop CS2 version, Adobe, USA) was used to process all the radiographs, including adjustment of color gradation, contrast, size, and format. Contrast was the main factor that affected the quality of radiographs. The guideline for improving the image quality was to change the contrast until all the spinous processes along the scoliotic spine could be correctly identified. After processing the images, the spinous processes which could be identified clearly were marked with same size (9 pixels) dots right at the center of the end point (see Figure 3.1 & Figure 3.2). This procedure for processing images and identifying the spinous processes was conducted three times for each image. After these procedures, the processed and marked images were saved as a BMP (Bitmap Image) file format of the same pixel size [768(H)*306(W)].

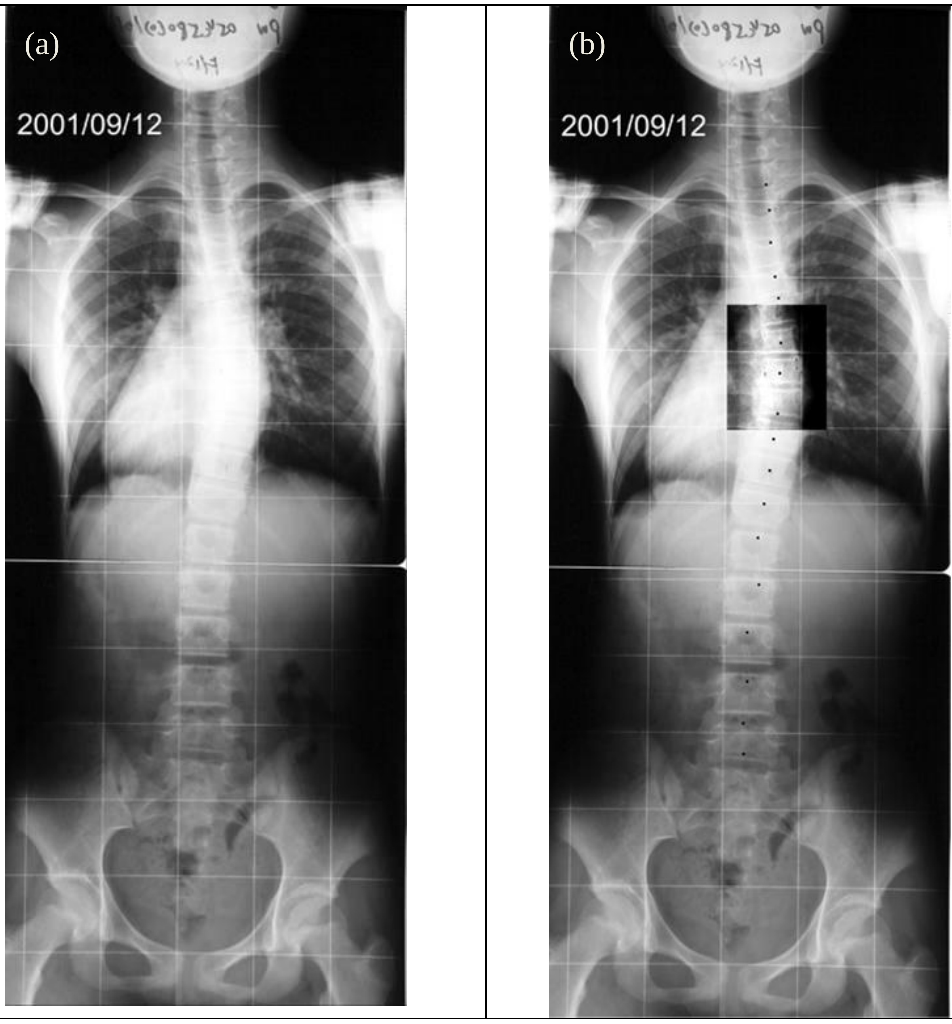

Figure 3. 2. Images Processing
(a) Original X-ray Image (b) Processed X-ray Image

Then, the spinous process angles were measured by using the Spinous Process Angle Calculator (see Figure 3.3), which is a software program developed in this study with Visual Basic Programming Language for processing bitmap pictures of the spine and calculating the spinous process angles. Visual Basic Programming Language is the third-generation event-driven programming language and integrated development environment from Microsoft for its component object model programming model. Because of its graphical development features and basic heritage, Visual Basic Programming Language is considered to be relatively easy to learn and use for this study. This angle calculating software has an easy-to-use interface and simply limited functions, practical enough to serve the purpose of this study. When all the tips of spinous processes were marked, the angle between any upper point and lower point could be calculated as shown in the red circle in Figure 3.3.

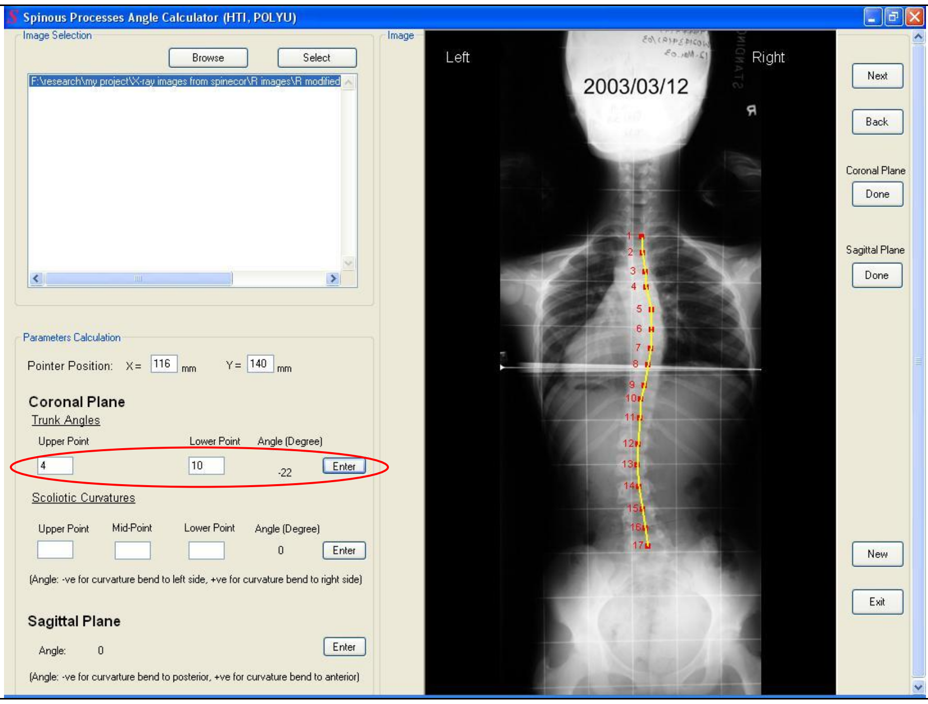

Figure 3. 3. Spinous Process Angle Calculator for Measurements of SPA

The method for measuring the SPA is quite different from the Cobb's method, because the trend of the spinous processes is not easy to predict. The involved levels of the spinous processes were not always matched with the upper body and the end body of the Cobb's angle. To improve the intra and inter reliability of the Spinous Process Angle Calculator, a new method was developed to define the levels of different curves for the SPA, a two-point measurement (start point and end point). Using this measurement, the spinous process angles were assessed with apical spinous process indentified first, which is the most displaced and rotated process in the trend line of all spinous processes. The starting spinous process and the end spinous process are then identified through the curve above and below. The starting/end spinous process are the most superior and inferior spinous processes which are least displaced and rotated in the trend line of all spinous processes. Using this two-point measurement, the spinous process angles were measured by accumulating the angles formed by every two lines joining three neighboring spinous processes between the starting point and the end point.

The signs of spinous process angles as shown in the Spinous Process Angle Calculator are defined to indicate the direction of the curve. When the apical spinous process located on the right side of the line drawn by the upper and lower neighboring spinous processes, this curve is defined as an angle with a “-ve” sign (right side curvature). On the other hand, when the apical spinous process located on the left side of the line drawn by the upper and lower neighboring spinous processes, this curve is defined as an angle with a “+ve” sign (left side curvature).

Every image was measured three times to obtain the spinous process angles. Then the correlation between Cobb’s angles and spinous process angles was studied and the reliability of the method for this measurement was examined too.

3.2 Ultrasound Study

In ultrasound study, the feasibility by using 3-D US to detect spinous process and to measure SPA was investigated. The correlation between SPA measured from X-ray and that measured from 3-D ultrasound was examined. Then 3-D US was applied to assist the fitting method to improve the effectives of orthotic treatment. Ultimately, the correlation between the Cobb’s angle measured from radiographs and the SPA measured from 3-D ultrasound images were verified.

3.2.1 Subjects

The subject selection criteria are as follows: 1) Female patients with AIS; 2) Cobb's angle: 20° - 40°; 3) Curve pattern: right thoracic (RT) or double right thoracic and left lumbar (RTLL); 4) Age: 9-14; 5) Risser's sign: ≤2; 6) Newly prescribed with spinal orthosis.

In testing trials, 12 patients were recruited according to the selection criteria for taking pre-brace X-ray and 3-D ultrasound scanning to study the correlation between SPA measured from X-ray and that measured from 3-D ultrasound. The 12 selected patients were all female and had double right thoracic curve and left lumbar curves with Cobb's angles ranging from 10° to 28°.

Eighty-one subjects were selected from the scoliosis clinic of the Prince of Wales Hospital, Hong Kong. Two groups of patients were selected according to the subject selection criteria. One group were fitted with orthoses using the conventional method (control group, 60 subjects) while the other group were managed under the ultrasound-assisted fitting method (test group, 21 subjects). The control group was a retrospective group selected from the database (from 2006 to 2009) of the Prince of Wales Hospital, Hong Kong. The test group was recruited group from new cases of the same hospital from July 2009 to July 2010. All subjects and their parents were required to give written consent. Human ethical approval was granted from the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University and the Prince of Wales Hospital.

3.2.2 Equipment

All ultrasound examinations were performed with an Esaote Technos MPX ultrasound unit (Esaote China Ltd., China, see Figure 3.4a, on the left side) with a 7.5 MHz linear transducer, and in conjunction with a 3-D add-on system (Tom Tec 3-D Sono-Scan Pro, Germany, see Figure 3.4a, on the right side).

Figure 3. 4. 3-D Ultrasound System
(a) Ultrasound Unit and 3-D Add-on System (b) Probe of Ultrasound Unit with a Silicone Sleeve (c) The Probe in Ultrasound Scanning Procedure

A silicone sleeve was designed and attached to the ultrasound probe to ensure a good surface contact between patients' skin and the probe (see Figure 3.4b). The silicone sleeve was produced by mixing additional silicone materials and 150% plant oil. Additional silicone melted with temperature set at 80 ℃ in a container, and then 150% plane oil was added to the melted additional silicone. An air ejector machine was used to extract the bubble inside the mixed material for 5 minutes. Then liquid mixed material was poured into a made model to finalize the design of the silicone sleeve according to the shape of the US probe. This silicone sleeve could fill up the gap between the probe of ultrasound and the scoliotic spine (see Figure 3.4c).

Personnel

The Orthotist involved in this study has more than ten years experience in treating patients with AIS. He was responsible for measurements, design, fabrication, and fitting of the spinal orthosis. The author with intensive training in the 3-D US system was responsible for scanning the scoliotic spine of the subjects and analyzing the collected data. All the radiographs were examined by the author as well as a blinded rater.

Clinical Treatment Procedure

The clinical assessments, measurements and CAD/CAM fabrication of spinal orthosis were the same for both subject groups. In the control group, 60 subjects were selected retrospectively (from 2006 to 2009) according to the same criteria as those in the test group and these subjects were treated with routine fitting method. In the treatment process, the pre-brace PA standing X-ray images were used as references by the Orthotist to design a blueprint for orthotic intervention. The Orthotist then made strategic adjustments such as changing the location of the pressure pad or strap tension for trying to obtain the optimum improvement of the deformity through his own clinical experience. The subjects were then instructed to wear the orthosis 23 hours a day for 2 weeks. After this two-week adaptation period, the patients would come back for further adjustments if necessary and then they would be referred to the X-ray department for taking in-brace PA standing X-ray for deformity assessment.

In the test group, the procedure was the same as the control group until the fitting process. During the fitting method, the subjects were first scanned by the ultrasound system in standing position to obtain the spinous process images for estimation of pre-brace spinal process curvature. Then they were fitted with spinal orthoses and ultrasound imaging was performed at the posterior opening of the orthosis for tracing the spinal processes. It was designed to alter the location and pressure magnitude of the pads that may render different biomechanical effects on the spinal process curvature. Starting with the pre-set pad location (refer to pre-brace X-ray images) and prescribed strap tension by the experienced Orthotist as references, the Orthotist then made strategic adjustments - changing the location of the pressure pad (five positions: prescribed position referring to the pre-brace X-ray image; 1 cm and 2 cm above and below the prescribed position) so as to obtain the optimum improvement of the spinous process curvature. Once the lowest Cobb's angle (estimated from 3-D US) was obtained after the deliberate changes, the optimum pad location was confirmed and recorded. The resting procedures were the same as for the control group.

3.2.3 3-D Ultrasound Scanning Procedure

Before data acquisition, a position sensor was fixed onto the transducer and an electromagnetic field transmitter was placed on a wooden scanning stool [Tom Tec FOB (Flock of Bird) Freehand Scanning Unit, Germany]. With the 3-D system activated, the region of interest was scanned through a single sweep, the reconstructed 3-D images were reviewed, and the spinous processes were identified in the images.

<u>Pre-brace Scanning Procedure</u>

Firstly, the subject was asked to bend forward for identifying C7 as the starting point to scan the involved vertebrae. Then the general trend of the spine was marked on the skin by a water soluble marker according to skin palpation. In the pre-brace-stage, the subject was positioned in standing with feet at shoulder width and eyes looking at a horizontal steadfast object (set by a tripod). With the 3-D system activated, the region of scoliotic spine was scanned through a single sweep and three successful trials of data were captured (see Figure 3.5). One trial of a single sweep for acquiring the ultrasound images required around 40 seconds.

Figure 3. 5. Pre-brace Ultrasound Scanning Procedure

To identify the spinous processes, the reconstructed 3-D images were reviewed. The bright reflection at the tip of spinous process (in red circle) and the reflection on the origin of laminae (in green circle) in the images were the major indicators for confirming the identification procedure (see Figure 3.8). After identifying all the spinous processes, the SPA Calculator developed in this study was used in which lines were drawn through the tips of spinous processes, the angles between the lines were accumulated, and the sum angle was the SPA of the measured curve. One trial of identifying all spinous processes (from T1 to T12 and from L1 to L5) along the scoliotic spine required around four minutes. And one trial of computing the SPA required 30 seconds. Thus, the 3-D US assisted fitting method required around 15 minutes for the pre-brace stage.

In-brace Scanning Procedure

In the current project, the location of pressure pad and the tightness of straps were firstly prescribed and marked by the experienced Orthotist according to the assessment from the pre-brace X-ray images. With the design of the experienced Orthotist, the width of the posterior opening of brace was set to 6.5 cm to ensure the probe could get through the opening during 3-D US assisted fitting method (the width of ultrasound probe is 6.2 centimeters). The width of the posterior opening was also used as the indicator to check the tightness of straps. In general, 77 minutes are required for the in-brace stage (testing for 5 pad locations and 3 times for each pad location).

The Locations for Pressure Pad

According to the study conducted by Chan et al. (2006), there could be 1 centimeter deviation in locating the thoracic pressure pad since the design of spinal orthosis according to the pre-brace X-ray which could not provide real-time assessment and once a controlling force is applied via the pressure pad, there are 3-D changes in the spine. Therefore, during the fitting method, the pad was located to the five designated levels (see Figure 3.6) in order to test the corresponding effect of the scoliotic spine.

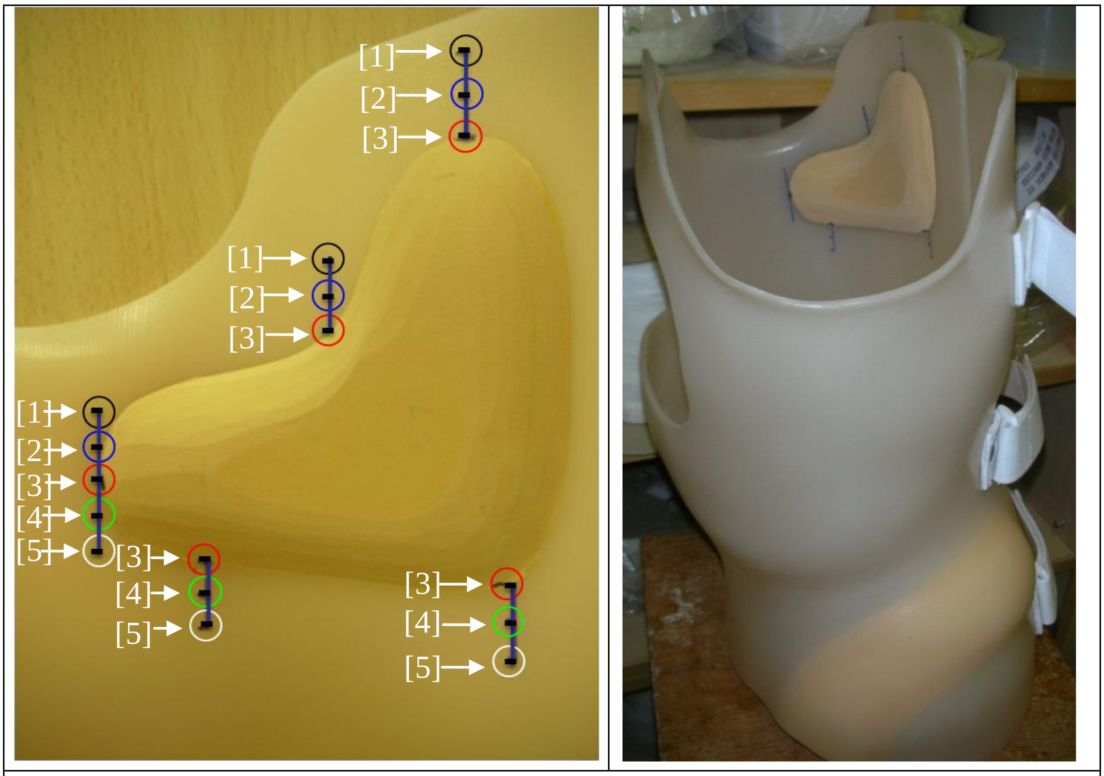

Figure 3. 6. Five Locations for Pressure Pad
([1] Dark Circle: +2 cm; [2] Blue Circle: +1 cm; [3] Red Circle: Original location; [4] Green Circle: -1 cm; [5] White Circle: -2 cm)

Then 3-D US was applied to assist the fitting method to confirm the optimal location for pressure pad. Before unfastening the straps, a fast-grip setting was used to ensure the same orthosis tightness - using the width of the posterior opening as reference (see Figure 3.7). After unfastening all the straps and exposing the posterior opening of the orthosis, the region of scoliotic spine was scanned through a single sweep (see Figure 3.7). Then, the location of the pressure pad was adjusted and three trials of ultrasound scanning were conducted to have three successful trials for each location of pressure pad.

With the image analysis similar to the pre-brace stage, the scoliotic angles in the coronal plane, and kyphosis/lordosis angles in the sagittal plane from all trials were studied. The SPA of the coronal plane was used to determine the correction rendered by the brace. The location of pressure pad was confirmed by comparing the SPA which could offer optimal curve control to the scoliotic spine.

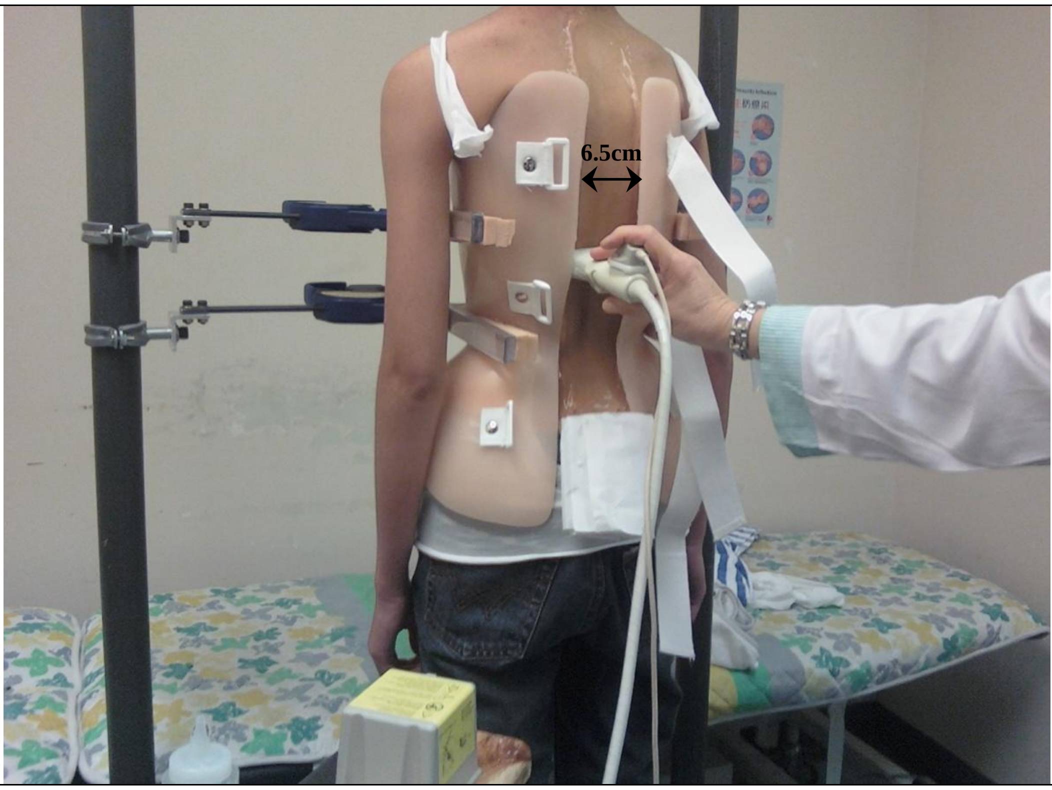

Figure 3. 7. In-brace Ultrasound Scanning Procedure

3.2.4 Experience of Using 3-D US to Identify the Tips of Spinous Process

Transverse planes of 3-D US images of a vertebra dummy from superior to inferior are shown in Figure 3.8. Images (c) captured from ultrasound scanning system show the transverse level of the most prominent region of the spinous process. There is a bright reflection (green circles) at the tip of the spinous process in those images. In the same images, the reflection on the origin of the laminae can be observed (red circles). The reflections are the major indicators for confirming the identification of the spinous processes with the 3-D US. An example showing the software of the TomTec machine is displayed in Figure 3.8 (a). The lower right window represents the 3-D image which was reconstructed by TomTec system. The upper left window represents the transverse plane of the spine. The lower left window shows the coronal plane and the upper right corner shows the sagittal plane. With ultrasound images revealing 3-D planes of scoliotic spine, it is feasible to assess this 3-D deformity rather than limit the assessment by using only 2-D radiography.

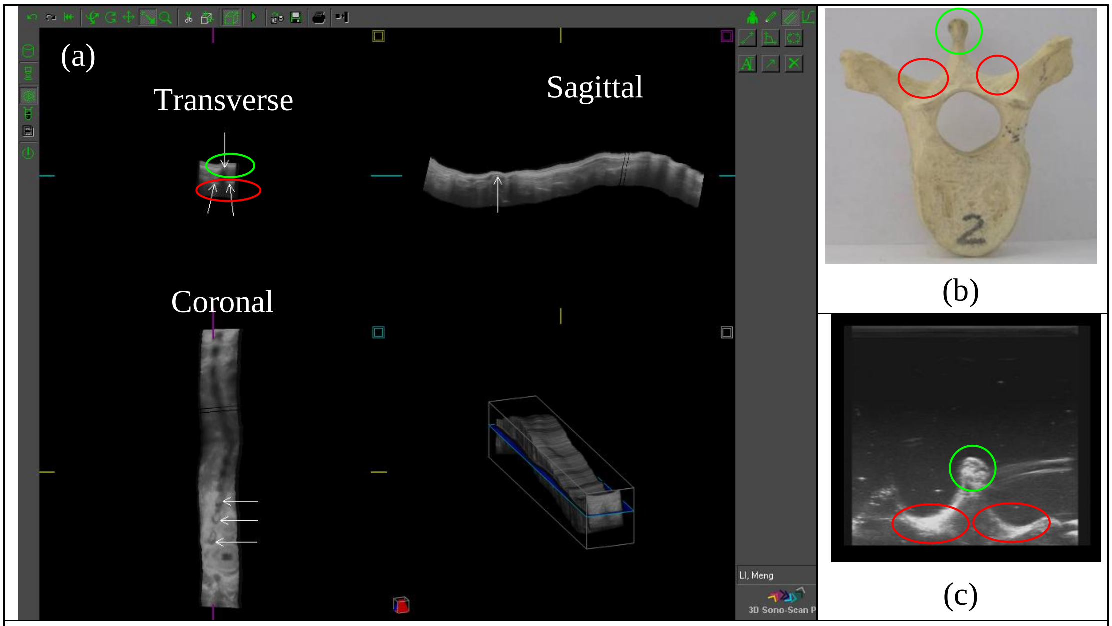

Figure 3. 8. (a) 3D CUS Reconstructed Images of a Spine by the Tom Tec System (b) Vertebral Phantom (c) Transverse US Image of Vertebral Phantom

For the identification of spinous processes, the window of the transverse plane is focused on. As mentioned above, the spinous processes can be identified by the reflections. After the slice of the transverse plane including the spinous process is identified, the slice is moved to locate the tips of the spinous process on the middle of the window. Then once one of the window's slices is moved, and the other two window's slices are moved to the corresponding position automatically. If the tip of spinous process is in the middle of the transverse plane's window, it would also be in the middle of other planes' windows. Then it is possible to trace and mark the reflection of the tip on the windows of the other planes. The three white arrows on the lower left window indicate the location of reflection.

3.2.5 Measurements of SPA (Coronal and Sagittal Planes)

Reconstructed images of the spine in the coronal and sagittal planes from the 3-D US system were captured and the Spinous Process Angle Calculator was used to compute the Scoliotic Curvatures (spinous process angles, see Figure 3.9) in the coronal plane, kyphosis angle and lordosis angle (see Figure 3.10) in the sagittal plane. Using the measurement software, lines were drawn through the tips of spinous processes, and the angle between the lines could be measured as mentioned in correlation study. With these facilities, the spinal process curvature of a scoliotic spine could thereby be evaluated. Therefore, the spinous process curvature (angle) was proposed to act as an objective indicator for checking the effectiveness of spinal orthosis during the fitting method.

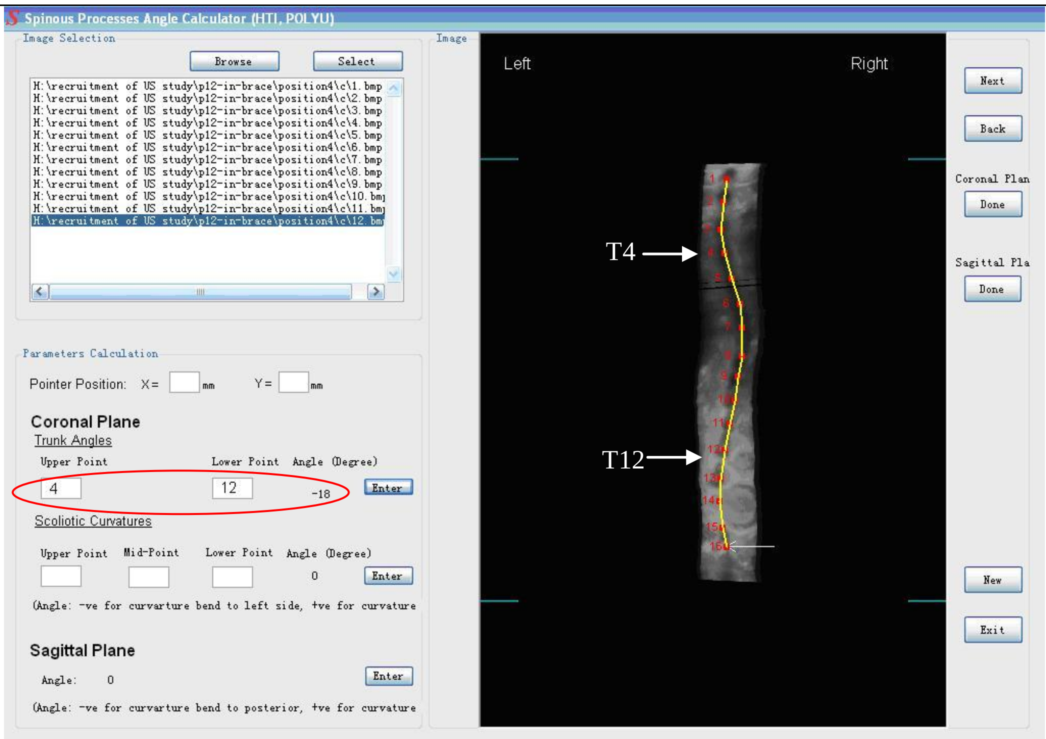

Figure 3. 9. Spinous Process Angle Calculator for Measurements of SPA (Coronal Plane)

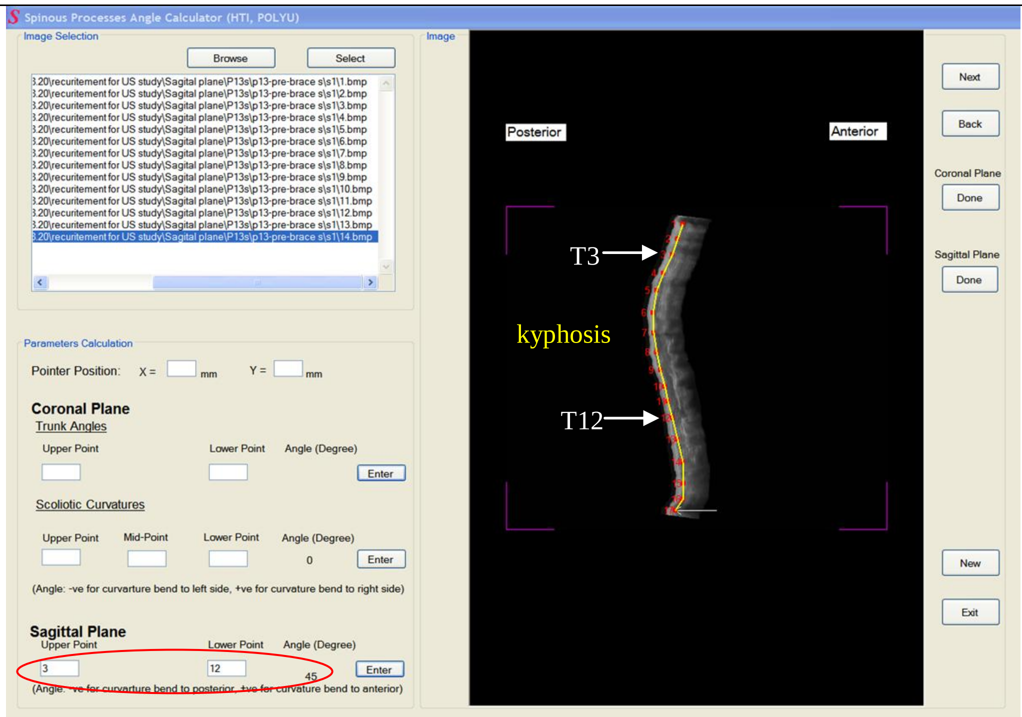

Figure 3. 10. Spinous Process Angle Calculator for Measurements of Kyphosis and Lordosis (Sagittal Plane)

With all the 3-D ultrasound images analyzed, the spinous process angles assessed under the five locations of pressure pad as designed were compared. The location of pressure pad that offered optimal immediate curve correction was confirmed as the best location among the five. Same method for confirming the optimal pressure pad location was applied onto all the 21 recruited subjects of test group to help improve the accuracy of fitting method. After the 3-D US assisted fitting method, the patients were required to wear the prescribed brace (with a confirmed pressure pad location) 23 hours per day. In this study, the patients of both control group and test group were assumed to have similar compliance with the prescribed treatment. A regular clinical follow-up was conducted after having one-month treatment and X-ray images of the in-brace stage were taken for each subject. Cobb's angle measured from the radiographic method is considered as the gold standard for evaluating the treatment effect of different fitting methods.

3.3 Data Analyses

The data were analyzed using the Statistical Package for Social Sciences (SPSS Statistics 17.0, Inc., USA). The confidence interval was set at 95% ($p < 0.05$). In the coronal plane, the Pearson product-moment correlation tests were used to determine the correlation between the Cobb's angle (from radiographs) and the SPA (from radiographs) measured at the pre-brace and in-brace stages, the correlation between the SPA (from radiographs) and the SPA (from US images) at the pre-brace stage and the correlation between the Cobb's angle measured from radiographs and that estimated from US images both at the pre-brace and in-brace stages. The paired student t-tests were applied to compare the mean differences and the levels of significance for the studied clinical parameters (in the coronal plane) between the pre-brace stage and the immediate in-brace stage for the control group (with regard to Cobb's angle) as well as the test group (with regard to Cobb's angle and SPA). In addition, the independent samples t-tests were applied to compare the mean differences for curvature correction (in the coronal plane) with reference to the control group and test group. The one-way repeated measures ANOVA was applied to compare the mean difference for the SPA (in the sagittal plane, from ultrasound images) among the five different pressure pad locations.

CHAPTER 4 RESULTS

According to a series of analyses, both the correlation study and ultrasound study have achieved some preliminary results. In the correlation study, formulas were drawn for representing the correlation between Cobb's angle and SPA measured from radiographs of patients with AIS for both the pre-brace and in-brace stages. In ultrasound study, the correlation between SPA measured from radiographs and that from ultrasound images was verified, and then the feasibility of using ultrasound technique to monitor and improve the accuracy of fitting method of spinal orthosis was reported in this study.

Parameters

Cobb's angle, SPA, and trunk listing were measured from the pre-brace and immediate in-brace PA radiographs for the evaluation of clinical efficacy of the two fitting methods. The Cobb's angle and the spinal process curvature measured from the radiographs were compared, to verify the formula ($y = - 1.0404 + 0.74813\,x$, where y = SPA and x = Cobb's angle) as stated above. The spinal process curvature traced by the 3-D US system was compared with the Cobb's angle and the spinal process curvature measured from the radiographs. Moreover, Cobb's angle estimated from ultrasound images was compared with that measured from radiographs.

To examine whether there are any significant decreases found between the pre-brace and immediate in-brace visits for both methods, the X-ray was used to evaluate the immediate in-brace visits. To determine whether the test method is effective or not, the immediate response of the conventional method and test method were compared. When comparing the effectiveness of the control group and the test group, Cobb's angle and SPA were measured for both the pre-brace stage and the in-brace stage from radiographs which is considered to be the gold standard for assessing scoliosis.

4.1 Correlation Study

In the correlation study, the 43 selected patients were all female and had both right thoracic curve and left lumbar curves with Cobb's angle ranging from 11 ° to 30 °. The mean SPA was 17.5 ° for the pre-treatment stage, 16.0 ° for the in-brace stage and 17.5 ° for the in-SpineCor stage, compared with the mean Cobb's angle of 21.5 ° for pre-treatment stage, 18.9 ° for the in-brace stage and 21.0 ° for the in-SpineCor stage (see Table 4.1). Within the pool of pre-treatment X-ray images of the recruited subjects, only 37 of them could be measured because 6 of them were with poor image quality.

Table 4. 1. Cobb's Angle and SPA (from X-ray Images)

Parameter	Stage	Curvature Mean (SD; Range)	Sample Size (n)
Cobb's Angle	Pre-treatment	21.5 ° (±5.1 °; 11 °- 30 °)	37
	In-brace	18.9 ° (±3.6 °; 15 °- 26 °)	21
	In-SpineCor	21.0 ° (±3.5 °; 15 °- 27 °)	22
SPA	Pre-treatment	17.5 ° (±4.2 °; 7 °- 23 °)	37
	In-brace	16.0 ° (±3.4 °; 10 °- 23 °)	21
	In-SpineCor	17.5 ° (±4.0 °; 9 °- 25 °)	22

According to a series of investigations, some promising preliminary results have been achieved in the correlation study. The intra-rater [ICC (3,3)] and inter-rater

[ICC (2,3)] reliability for the measurements of calculating spinous process angles were more than 0.9 (see Table 4.2), which meant the measuring method is highly repeatable. The Pearson's correlation coefficients (r) of Cobb's angle and SPA for the pre-treatment group, the in-brace group and the in-SpineCor group were 0.80, 0.87 and 0.80 respectively (see Table 4.3). The Pearson's correlation coefficient (r) of the in-brace group was higher than those of the pre-treatment group and the in-SpineCor group. The graphic representation of these data suggested that three formulas could be derived to convert SPA values into Cobb's angle values (see Figure 4.1 for the pre-treatment set of data, Figure 4.2 for the in-brace set of data and Figure 4.3 for the in-SpineCor set of data).The three derived formulas for converting these two parameters were $y = 0.6577x + 3.6389$, $y = 0.8238x + 0.3926$ and $y = 0.9322x – 2.0553$ (where y = SPA and x = Cobb's angle) for the pre-treatment group, the in-brace group and the in-SpineCor group respectively.

Table 4. 2. Reliability Test Results of Measurements of SPA (n=37)

Intra-rater reliability of using the SPA calculator ICC (3,3)	Rater 1	0.92
	Rater 2	0.97
Inter-rater reliability test (average of 3 trials) ICC (2,3)	Rater 1 VS Rater 2	0.90

Table 4. 3. Correlation Coefficients (r) of Cobb's Angle and SPA

Group	Pearson's correlation coefficients (r)	Sample no. (Curves)
Pre-treatment	0.80	37
In-brace	0.87	21
In-SpineCor	0.80	22

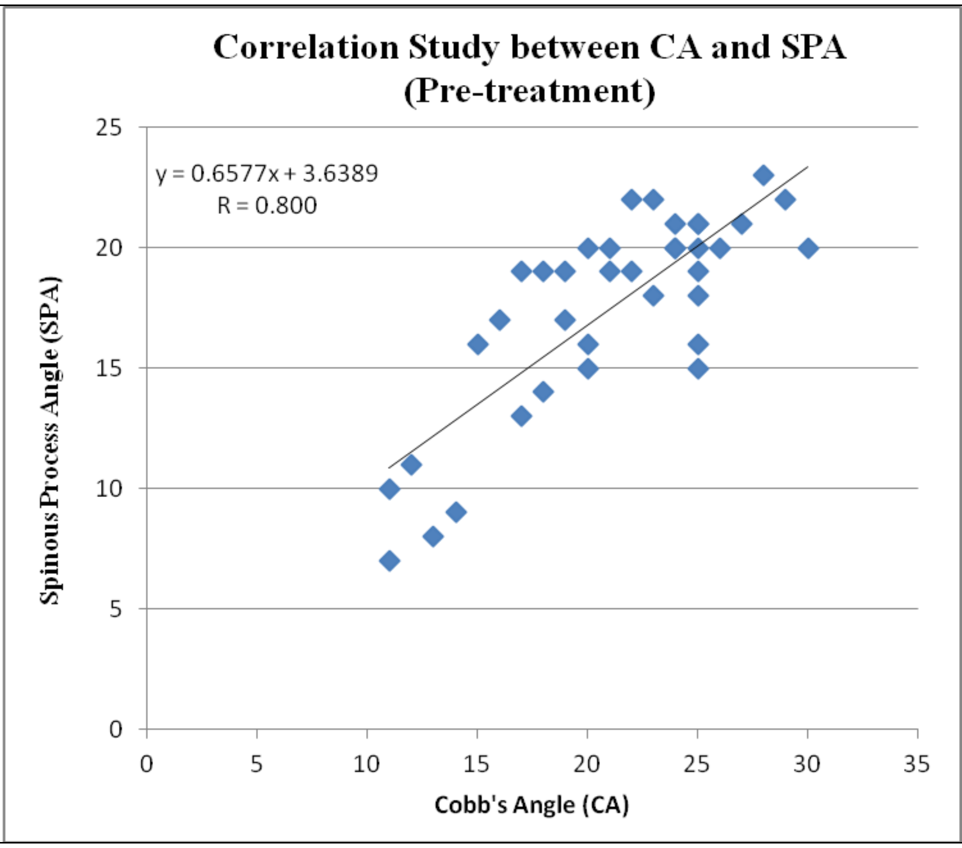

Figure 4. 1. Correlation Study between Cobb's Angle and SPA (Pre-treatment)

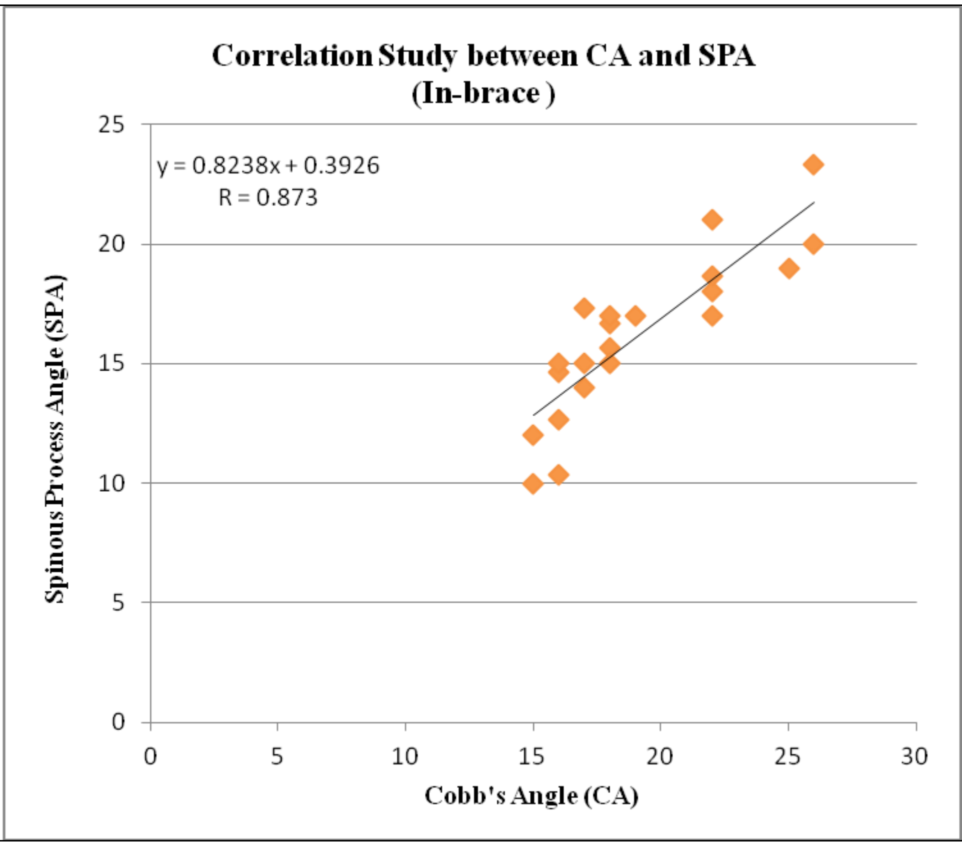

Figure 4. 2. Correlation Study between Cobb's Angle and SPA (In-brace)

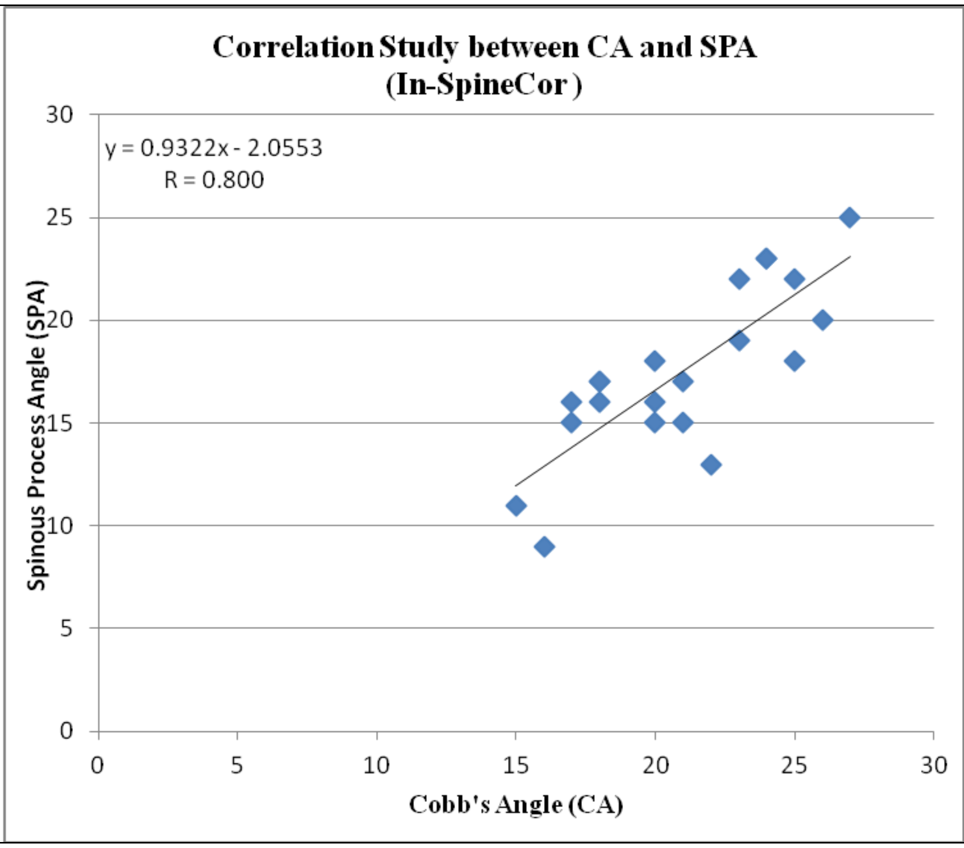

Figure 4. 3. Correlation Study between Cobb's Angle and SPA (In-SpineCor)

4.2 Ultrasound Study

Ultrasound study was conducted on two parts, the first part was test trial with 12 AIS patients and the second part was clinical trial with 21 AIS patients. The 3-D reconstructed ultrasound images were used to assess scoliotic spine in three dimensions (transverse, coronal and sagittal planes) and to investigate the application of 3-D US in assisting the fitting method of spinal orthosis.

4.2.1 Ultrasound Images of Lumbar Region

In the test trial, the feasibility of using 3-D US to detect the spinous processes of a right curve in the lumbar region was verified. As shown in the coronal plane of ultrasound images, the tips of spinous process present as a hyper echo dot (a bright reflection dot). The ultrasound images are clear adequate for identifying all the lumbar spinous processes from L1 to L5 (see Figure 4.4).

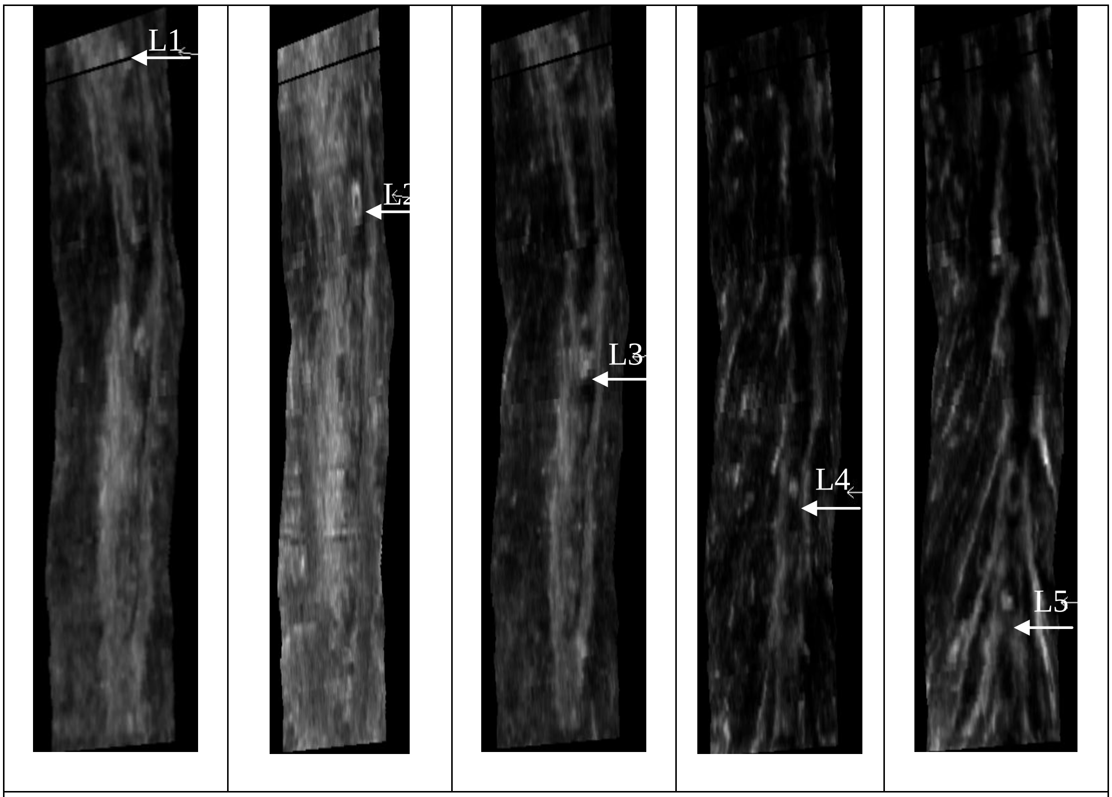

Figure 4. 4. Ultrasound Images of Lumbar Region (Coronal Plane, from L1 to L5)

4.2.2 Ultrasound Images of Thoracic Region

Since the spinous processes of the thoracic spine are quite small, so the ultrasound images of the thoracic spine are not as clear as the lumbar spine. Up till now, few studies have examined the method of detecting the thoracic spine by using ultrasound. In this study, ultrasound scanning trials have been conducted to investigate the feasibility of using ultrasound to detect the thoracic spine by using ultrasound, even though this needs a skillful operation with more experience of using the ultrasound system. The spinous processes of the thoracic spine are difficult to identify as the reflection area is smaller than that of lumbar spine (see Figure 4.5 & Figure 4.6).

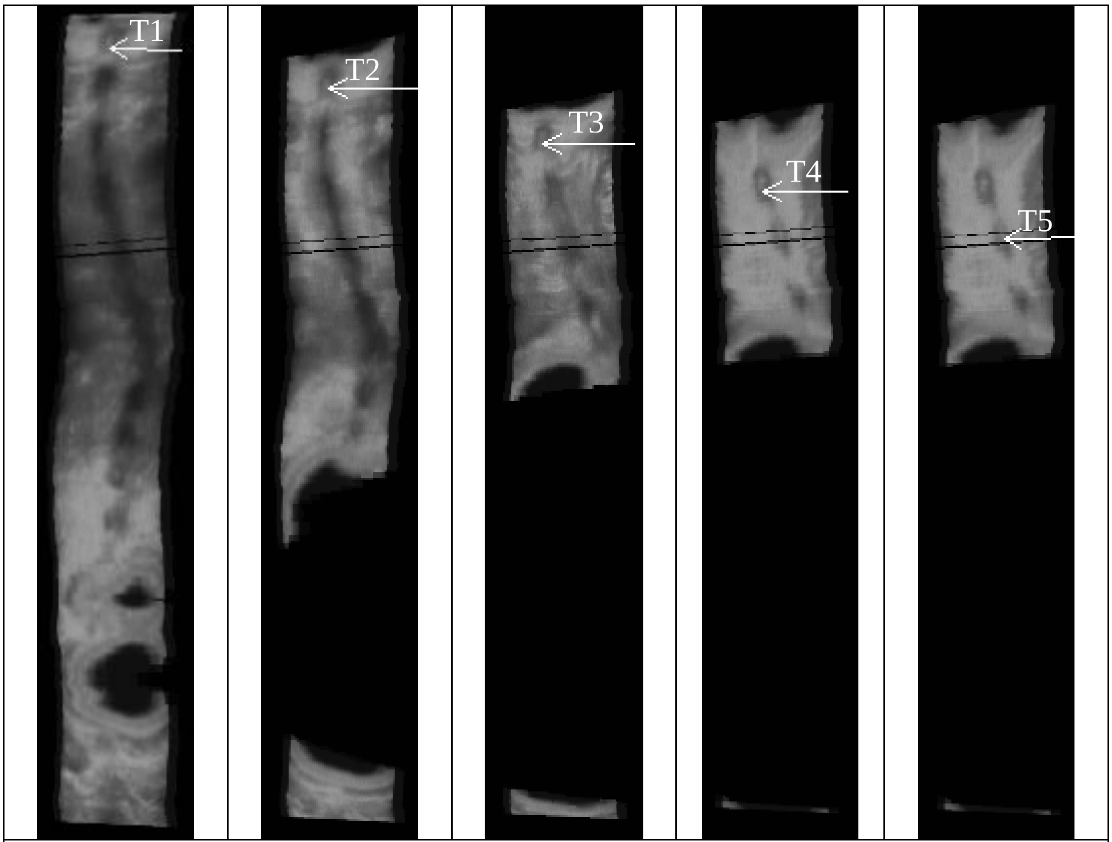

Figure 4. 5. Ultrasound Images of Thoracic Region
(Coronal Plane, from T1 to T5)

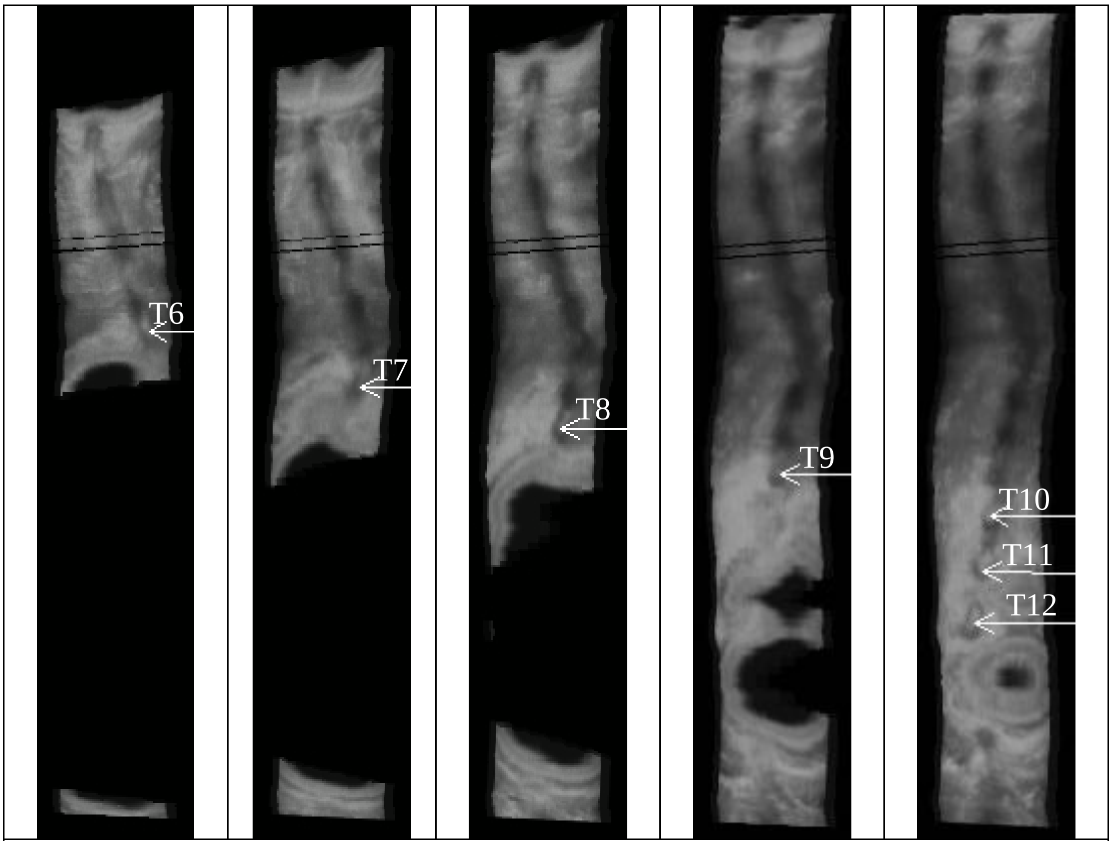

Figure 4. 6. Ultrasound Images of Thoracic Region
(Coronal Plane, from T6 to T12)

In all these images, 3-D US has been proved to be effective in tracing all the spinous processes (From T1 to T12 and from L1 to L5), though these procedures need competent scanning skills. The slices of 3-D US images should be examined and selected carefully until the spinous process showing as a bright white dot surrounded by small dark circle at the thoracic level. To avoid missing the spinous processes at the thoracic level, which usually appear smaller than that of the lumbar level, more attention should be paid when identifying the spinous processes. After identifying all the spinous processes, these 3-D US images were processed by the Spinous Process Angle Calculator to measure the spinous process angles.

4.2.3 Comparison of SPAs to Confirm Optimal Location for Pressure Pad

The SPAs under the five designed locations (2 cm above prescribed, 1 cm above prescribed, prescribed, 1 cm below prescribed and 2 cm below prescribed) of pressure pad was assessed and compared from 3-D US images. The location of pressure pad that offered optimal immediate curve correction was considered as the best location among the five locations. A typical case is shown from Figure 4.7 to Figure 4.11 in red circle, the SPAs (from T9 to L2) are 25 °, 27 °, 26 °, 22 ° and 25 ° at the 5 locations respectively. According to the results, the data indicated the location of pressure pad at 1 cm below the prescribed location offered optimal immediate curvature correction. Then the optimal location for pressure pad was confirmed and fixed at 1 cm below the prescribed location.

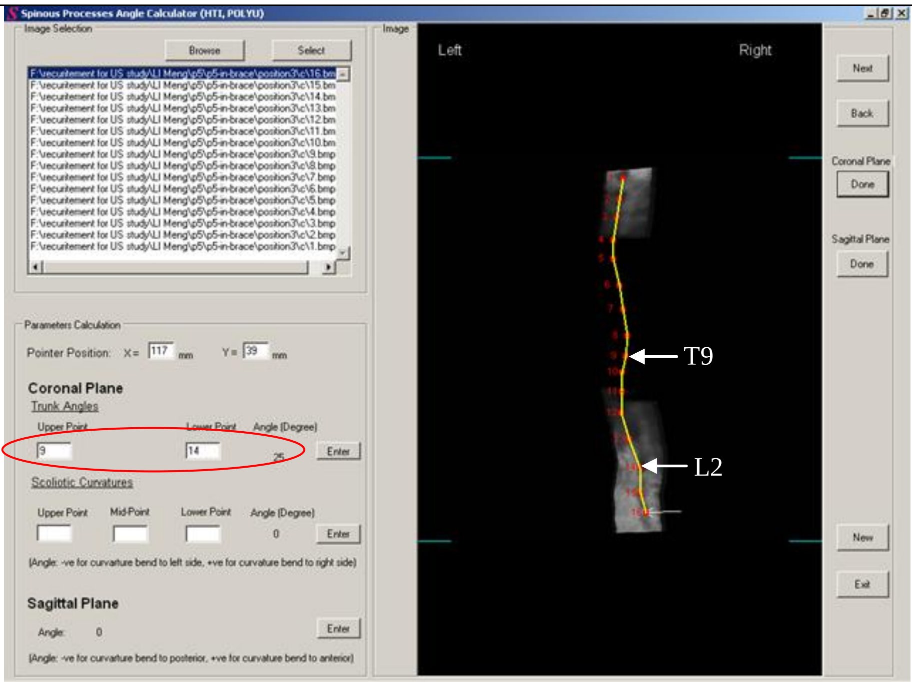

Figure 4. 7. SPA (T9-L2) at 2 cm above Prescribed Pressure Pad Location: 25 °

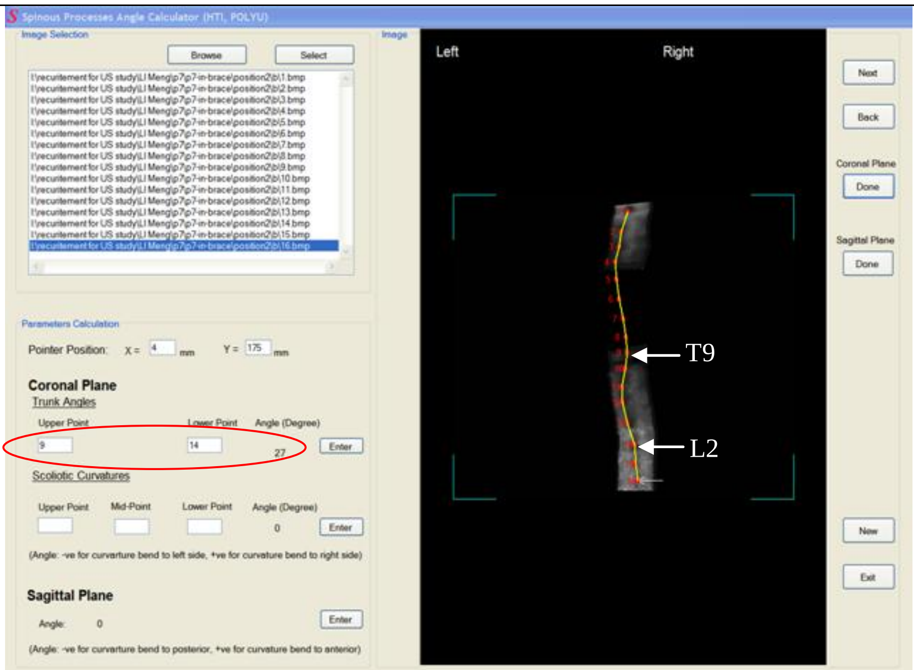

Figure 4. 8. SPA (T9-L2) at 1 cm above Prescribed Pressure Pad Location: 27 °

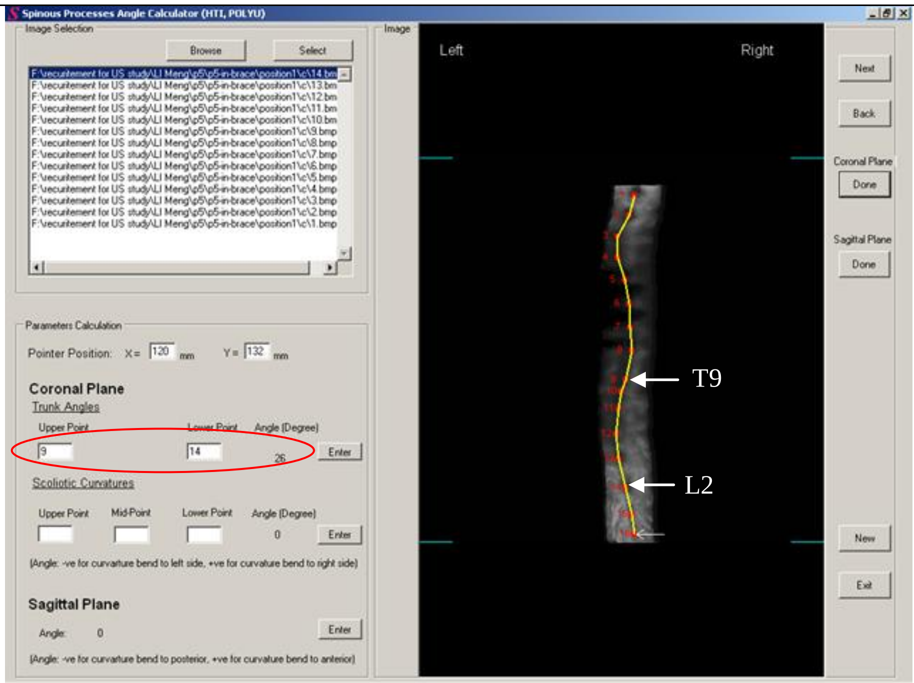

Figure 4. 9. SPA (T9-L2) at Prescribed Pressure Pad Location: 26 °

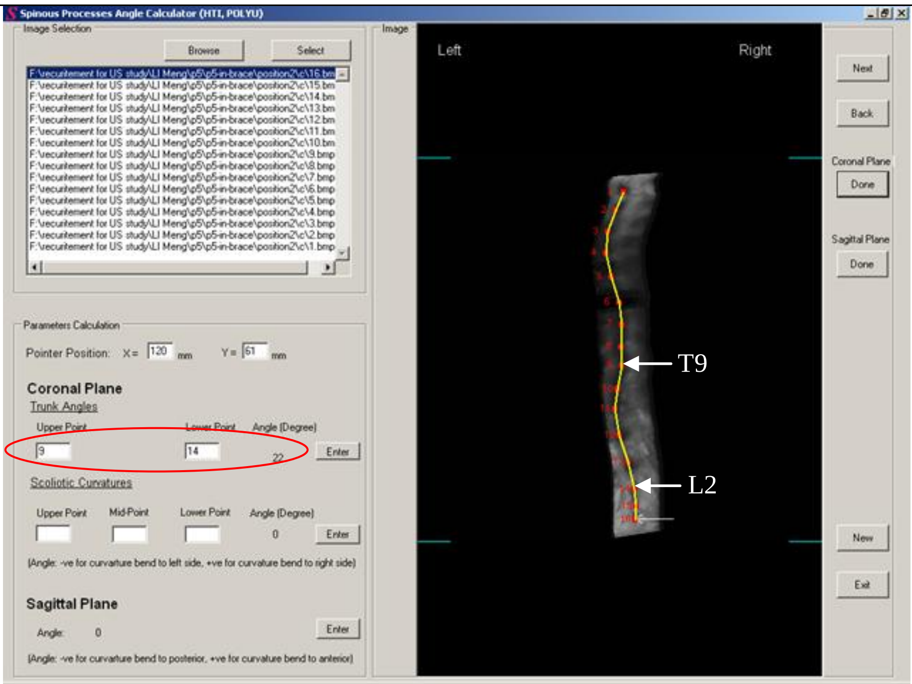

Figure 4. 10. SPA (T9-L2) at 1 cm below Prescribed Pressure Pad Location: 22 °

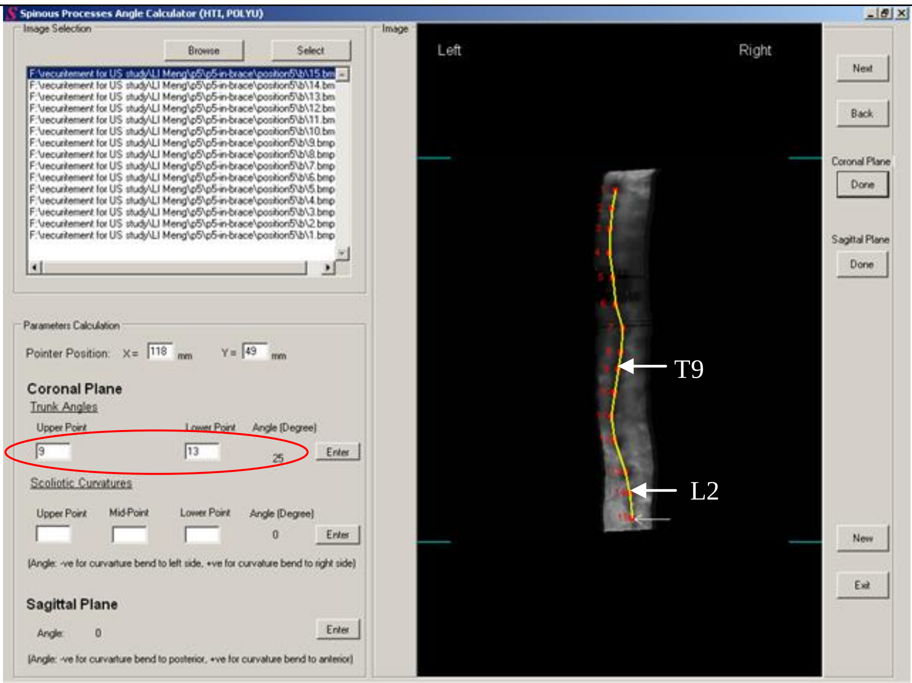

Figure 4. 11. SPA (T9-L2) at 2 cm below Prescribed Pressure Pad Location: 25 °

Same method for confirming the optimal pressure pad location was applied onto all the 21 recruited subjects of test group to help improve the accuracy of fitting method.

4.2.4 Assessments of Scoliotic Spine (Coronal Plane and Sagittal Plane)

In the coronal plane, the mean SPA were 21.6° (range 12°-33°) and 15.9° (range 5°-25°) for the pre-brace stage and in-brace stage with pressure pad at optimal location respectively (see Table 4.4). The intra-rater reliability [ICC (3, 3)] for using ultrasound to measure SPA was > 0.9 ($p < 0.05$).

From the previous correlation study, two formulas were found for converting SPA to Cobb's angle, which are $y = 0.6577x+3.6389$ ($r = 0.80$, $p < 0.05$) for the pre-brace stage and $y = 0.8238x+0.3926$ ($r = 0.87$, $p < 0.05$) for the in-brace stage (y = SPA, x = Cobb's angle). Regarding the 12 patients recruited in the test trials of ultrasound study, high correlation was found between SPA measured from radiographs and that from US images ($r=0.90$, $p < 0.05$) of the pre-brace stage and the formula generated was SPA (X-ray) = 1.0246 * SPA (US) + 0.1893. Moreover, this correlation was further verified in the clinical trial with 21 patients in the pre-brace stage and further extended to the in-brace stage with $r=0.94$ for both stages ($p < 0.01$). Applying these formulas, Cobb's angle could be estimated from the SPA measured by ultrasound images. Furthermore, the correlation between Cobb's angle estimated from the measurement of SPA in 3-D US images and Cobb's angle measured from X-ray was found significant in both the pre-brace stage ($r = 0.81$, $p < 0.05$) and the in-brace stage ($r = 0.89$, $p < 0.05$) (see Table 4.5).

Table 4. 4. SPA Measured from US Images of the Test Group (Coronal Plane)

Subject Code	Curvature Level	Position 1 (+2 cm)	Position 2 (+1 cm)	Position 3 (Prescribed Location)	Position 4 (-1 cm)	Position 5 (-2 cm)
S1	T	*Nil*	19 °	16 °**	21 °	*Nil*
	L	*Nil*	12 °	9 °**	14 °	*Nil*
S2	T	21 °	21 °	21 °	16 °**	26 °
	TL	21 °	29 °	29 °	19 °**	24 °
S3	T	25 °	19 °**	24 °	24 °	20 °
	L	19 °	13 °**	17 °	17 °	18 °
S4	T	27 °	23 °	21 °	20 °**	24 °
	L	23 °	21 °	19 °	15 °**	20 °
S5	T	23 °	20 °	15 °**	22 °	25 °
	TL	20 °	21 °	16 °**	23 °	23 °
S6	T	25 °	23 °**	27 °	25 °	26 °
	L	23 °	23 °**	26 °	23 °	24 °
S7	T	27 °	24 °	24 °	11 °**	26 °
	L	24 °	23 °	25 °	13 °**	26 °
S8	T	23 °	22 °	19 °**	24 °	23 °
	L	23 °	23 °	22 °**	24 °	24 °
S9	T	26 °	25 °**	25 °	28 °	29 °
	L	27 °	24 °**	26 °	24 °	23 °
S10	T	24 °	25 °	26 °	12 °**	24 °
	L	22 °	23 °	22 °	13 °**	23 °
S11	T	22 °	23 °	22 °	22 °**	23 °
	L	25 °	23 °	24 °	17 °**	25 °
S12	T	26 °	25 °	10 °**	27 °	28 °
S13	T	25 °	27 °	24 °	17 °**	27 °
	L	28 °	19 °	25 °	12 °**	23 °
S14	T	26 °	20 °**	26 °	22 °	30 °
S15	T	24 °	23 °	18 °**	26 °	20 °
S16	T	30 °	29 °	17 °**	28 °	25 °
	L	10 °	17 °	6 °**	12 °	18 °
S17	T	27 °	24 °	15 °**	18 °	24 °
	L	24 °	19 °	15 °**	21 °	20 °
S18	T	16 °	8 °**	17 °	12 °	17 °
	TL	17 °	5 °**	15 °	16 °	16 °
S19	T	22 °	22 °	22 °	18 °**	23 °
	TL	20 °	22 °	21 °	15 °**	17 °
S20	T	18 °**	20 °	20 °	19 °	21 °
	L	16 °**	20 °	9 °	17 °	21 °
S21	T	23 °	20 °	15 °**	22 °	25 °
	L	19 °	20 °	14 °**	21 °	21 °

T—Thoracic L—Lumbar TL—Thoraco-Lumbar
**-- The selected location for pressure pad provides optimal curvature correction.
Nil-- Only three positions of pressure pad were tried on S1 for testing the time cost.

Table 4. 5. SPA, Estimated Cobb's Angle from US Images and Cobb's Angle from X-ray of the Test Group (Coronal Plane)

Subject Code	Curvature Level	SPA (from US Images)		Estimated Cobb's Angle		Cobb's Angle (from X-ray)	
		Pre-brace	In-brace	Pre-brace	In-brace	Pre-brace	In-brace
S1	T	20 °	16 °	25 °	19 °	28 °	18 °
	L	17 °	9 °	21 °	11 °	16 °	6 °
S2	T	23 °	16 °	29 °	19 °	26 °	26 °
	TL	25 °	19 °	32 °	23 °	33 °	30 °
S3	T	18 °	19 °	23 °	23 °	26 °	18 °
	L	21 °	13 °	27 °	16 °	20 °	8 °
S4	T	25 °	20 °	32 °	24 °	38 °	22 °
	L	27 °	15 °	34 °	18 °	30 °	15 °
S5	T	19 °	15 °	24 °	18 °	28 °	20 °
	TL	23 °	16 °	29 °	19 °	25 °	12 °
S6	T	33 °	23 °	42 °	27 °	40 °	34 °
	L	20 °	23 °	25 °	27 °	28 °	25 °
S7	T	23 °	11 °	29 °	13 °	29 °	15 °
	L	22 °	13 °	28 °	16 °	25 °	14
S8	T	22 °	19 °	28 °	23 °	25 °	26 °
	L	23 °	22 °	29 °	26 °	30 °	29 °
S9	T	31 °	25 °	40 °	29 °	40 °	37 °
	L	26 °	24 °	33 °	28 °	38 °	35 °
S10	T	20 °	12 °	25 °	14 °	25 °	11 °
	L	24 °	13 °	31 °	16 °	25 °	12 °
S11	T	31 °	22 °	40 °	26 °	36 °	20 °
	L	19 °	17 °	24 °	20 °	29 °	21 °
S12	T	20 °	10 °	25 °	12 °	29 °	6 °
S13	T	24 °	17 °	31 °	20 °	27 °	15 °
	L	21 °	12 °	27 °	14 °	27 °	10 °
S14	T	20 °	20 °	25 °	24 °	30 °	29 °
S15	T	26 °	18 °	33 °	21 °	30 °	16 °
S16	T	23 °	17 °	29 °	20 °	33 °	16 °
	L	20 °	6 °	25 °	7 °	20 °	0 °
S17	T	20 °	15 °	25 °	18 °	30 °	20 °
	L	23 °	15 °	29 °	18 °	24 °	18 °
S18	T	20 °	8 °	25 °	10 °	20 °	11 °
	TL	12 °	5 °	15 °	6 °	12 °	0 °
S19	T	21 °	18 °	27 °	21 °	25 °	23 °
	TL	13 °	15 °	16 °	18 °	20 °	18 °
S20	T	21 °	18 °	27 °	21 °	30 °	20 °
	L	12 °	16 °	15 °	19 °	18 °	12 °
S21	T	21 °	15 °	27 °	18 °	28 °	11 °
	L	15 °	14 °	19 °	17 °	22 °	10 °

Formula for converting SPA (from US images) to Cobb's angle:
Pre-brace: $y = 0.7714x+0.4351$ In-brace: $y = 0.863x+0.453$
(x = Cobb's Angle; y = SPA)

Table 4. 6. Cobb's Angle from X-ray of the Control Group (Coronal Plane)

Subject Code	Curve Level	Cobb's Angle		Subject Code	Curve Level	Cobb's Angle		Subject Code	Curve Level	Cobb's Angle	
		Pre-brace	In-brace			Pre-brace	In-brace			Pre-brace	In-brace
P1	T	30 °	27 °	P21	T	33 °	10 °	P41	T	26 °	19 °
	L	27 °	34 °		L	27 °	20 °		L	21 °	19 °
P2	T	33 °	22 °	P22	T	26 °	28 °	P42	T	25 °	22 °
	L	27 °	16 °		L	26 °	27 °		L	22 °	5 °
P3	T	28 °	25 °	P23	T	38 °	30 °	P43	T	30 °	30 °
	L	35 °	28 °		L	36 °	32 °		L	24 °	24 °
P4	T	30 °	22 °	P24	T	25 °	17 °	P44	T	26 °	10 °
	L	26 °	15 °		L	27 °	13 °		L	21 °	12 °
P5	T	34 °	33 °	P25	T	30 °	44 °	P45	T	32 °	32 °
	L	25 °	28 °		L	33 °	37 °		L	22 °	22 °
P6	T	26 °	18 °	P26	T	32 °	32 °	P46	T	27 °	11 °
	L	28 °	17 °		L	34 °	34 °		L	20 °	5 °
P7	T	30 °	14 °	P27	T	30 °	30 °	P47	T	26 °	20 °
	L	35 °	16 °		L	25 °	25 °		L	24 °	13 °
P8	T	33 °	26 °	P28	T	37 °	37 °	P48	T	25 °	26 °
	L	30 °	33 °		L	30 °	30 °		L	20 °	12 °
P9	T	30 °	25 °	P29	T	25 °	20 °	P49	T	29 °	25 °
	L	27 °	22 °		L	25 °	12 °		L	24 °	13 °
P10	T	26 °	21 °	P30	T	28 °	28 °	P50	T	29 °	21 °
	L	33 °	16 °		L	26 °	26 °		L	21 °	14 °
P11	T	29 °	29 °	P31	T	38 °	38 °	P51	T	25 °	19 °
	L	25 °	25 °		L	12 °	36 °		L	22 °	10 °
P12	T	28 °	28 °	P32	T	28 °	12 °	P52	T	26 °	26 °
	L	19 °	19 °		L	30 °	16 °		L	23 °	16 °
P13	T	35 °	35 °	P33	T	34 °	31 °	P53	T	29 °	29 °
	L	27 °	27 °		L	26 °	14 °		L	24 °	24 °
P14	T	27 °	18 °	P34	T	27 °	14 °	P54	T	26 °	24 °
	L	25 °	15 °		L	20 °	12 °		L	24 °	16 °
P15	T	28 °	28 °	P35	T	29 °	20 °	P55	T	26 °	22 °
	L	36 °	36 °		L	20 °	18 °		L	24 °	24 °
P16	T	31 °	15 °	P36	T	26 °	20 °	P56	T	28 °	25 °
	L	26 °	9 °		L	24 °	16 °		L	24 °	17 °
P17	T	30 °	25 °	P37	T	40 °	33 °	P57	T	25 °	24 °
	L	30 °	16 °		L	22 °	20 °		L	24 °	20 °
P18	T	33 °	32 °	P38	T	26 °	35 °	P58	T	28 °	12 °
	L	26 °	23 °		L	24 °	17 °		L	20 °	4 °
P19	T	36 °	4 °	P39	T	38 °	24 °	P59	T	26 °	18 °
	L	28 °	4 °		L	24 °	23 °		L	20 °	10 °
P20	T	30 °	15 °	P40	T	35 °	25 °	P60	T	32 °	32 °
	L	30 °	23 °		L	22 °	11 °		L	20 °	20 °

Note: T—Thoracic Curvature L—Lumbar Curvature
The medical records of 60 patients with AIS were collected as the control group.

Table 4. 7. Thoracic Kyphosis and Lumbar Lordosis (SPA in Sagittal Plane)

Subject Code	Curve Level	Pre-brace Stage	In-brace Stage				
			Position 1 (+2 cm)	Position 2 (+1 cm)	Position 3 (Prescribed Location)	Position 4 (-1 cm)	Position 5 (-2 cm)
S1	kyphosis	30 °	*Nil*	37 °	28 °	29 °	*Nil*
	lordosis	37 °	*Nil*	30 °	32 °	26 °	*Nil*
S2	kyphosis	33 °	29 °	30 °	26 °	27 °	27 °
	lordosis	38 °	36 °	37 °	37 °	26 °	28 °
S3	kyphosis	34 °	26 °	29 °	33 °	37 °	38 °
	lordosis	46 °	36 °	33 °	38 °	37 °	26 °
S4	kyphosis	40 °	33 °	38 °	23 °	24 °	38 °
	lordosis	44 °	33 °	33 °	29 °	32 °	37 °
S5	kyphosis	47 °	29 °	24 °	19 °**	26 °	30 °
	lordosis	35 °	29 °	33 °	31 °	25 °	32 °
S6	kyphosis	34 °	24 °	26 °	26 °	24 °	30 °
	lordosis	52 °	26 °	30 °	29 °	34 °	36 °
S7	kyphosis	36 °	38 °	33 °	32 °	36 °	36 °
	lordosis	47 °	30 °	39 °	31 °	23 °	28 °
S8	kyphosis	45 °	33 °	35 °	36 °	33 °	24 °
	lordosis	38 °	29 °	29 °	28 °	29 °	29 °
S9	kyphosis	49 °	33 °	25 °	32 °	33 °	37 °
	lordosis	36 °	35 °	32 °	33 °	30 °	37 °
S10	kyphosis	35 °	32 °	38 °	28 °	34 °	29 °
	lordosis	33 °	25 °	29 °	22 °	23 °	23 °
S11	kyphosis	37 °	32 °	33 °	34 °	29 °	30 °
	lordosis	42 °	32 °	31 °	33 °	31 °	36 °
S12	kyphosis	41 °	23 °	24 °	32 °	25 °	25 °
	lordosis	47 °	24 °	26 °	33 °	26 °	23 °
S13	kyphosis	45 °	38 °	32 °	30 °	34 °	40 °
	lordosis	43 °	36 °	35 °	33 °	36 °	32 °
S14	kyphosis	43 °	26 °	27 °	28 °	30 °	27 °
	lordosis	32 °	30 °	30 °	26 °	31 °	30 °
S15	kyphosis	48 °	28 °	24 °	33 °	34 °	27 °
	lordosis	45 °	27 °	34 °	37 °	30 °	26 °
S16	kyphosis	42 °	32 °	32 °	29 °	34 °	29 °
	lordosis	43 °	27 °	31 °	35 °	29 °	30 °
S17	kyphosis	33 °	26 °	25 °	24 °	25 °	24 °
	lordosis	43 °	33 °	39 °	34 °	34 °	34 °
S18	kyphosis	41 °	36 °	40 °	38 °	33 °	30 °
	lordosis	47 °	36 °	39 °	44 °	34 °	32 °
S19	kyphosis	40 °	20 °	25 °	29 °	21 °	23 °
	lordosis	48 °	30 °	29 °	32 °	25 °	25 °
S20	kyphosis	38 °	25 °	23 °	27 °	24 °	29 °
	lordosis	42 °	26 °	26 °	27 °	29 °	35 °
S21	kyphosis	37 °	29 °	31 °	30 °	28 °	30 °
	lordosis	39 °	29 °	33 °	31 °	25 °	32 °

**Potential hypo-kyphosis case caused by rigid brace in terms of SPA in the sagittal plane.

The effect of rigid-brace on thoracic kyphosis and lumbar lordosis were investigated with pressure pad at different locations using ultrasound images in the sagittal plane. The kyphosis angles and lordosis angles (SPAs) of the pre-brace stage and in-brace stage are shown in Table 4.7. According to the data analyses, the mean of thoracic kyphosis angle and lumbar lordosis angle in the pre-brace stage were 39.5 ° and 42.0 ° respectively. The mean reduction of thoracic kyphosis angle were 9.6 °, 9.5 °, 10.0 °, 10.3 °, and 9.8 ° with pressure pad at the prescribed location, 1 cm above prescribed location, 2 cm above prescribed location, 1 cm below prescribed location and 2 cm below prescribed location respectively (see Table 4.8). The mean reduction of lumbar lordosis angle were 10.3 °, 9.9 °, 11.6 °, 12.5 °, and 11.7 ° with pressure pad at prescribed location, 1 cm above prescribed location, 2 cm above prescribed location, 1 cm below prescribed location and 2 cm below prescribed location respectively (see Table 4.8).

Table 4. 8. Mean SPA of Kyphosis and Lordosis (Sagittal Plane)

Curve Type	Mean SPA of Pre-brace	Mean SPA of In-brace				
		Position1 (+2 cm)	Position2 (+1 cm)	Position3 (Original)	Position4 (-1 cm)	Position5 (-2 cm)
Thoracic Kyphosis (n=21)	39.5 °	29.5 °	30.0 °	29.9 °	29.6 °	30.1 °
Lumbar Lordosis (n=21)	42.0 °	30.3 °	32.1 °	31.6 °	29.7 °	30.5 °

The one-way repeated measures ANOVA shown that both thoracic kyphosis and lumbar lordosis (with regard to SPA) were significantly decreased by rigid brace at all the five designated locations of pressure pad. However, for the in-brace stage no significant difference was found among the thoracic kyphosis angles and lumbar lordosis angles (SPAs) of the 5 locations of pressure pad.

4.2.5 Effectiveness of 3-D US Assisted Fitting Method on Scoliotic Spine

In the test group, thirteen out of twenty-one patients were required to adjust the location of pressure pad. This indicated that ultrasound assisted in the fitting method of spinal orthosis was effective and helpful to 61.9 % of the patients in this study.

The software named Photoshop (Adobe Photoshop CS2 version, Adobe Systems Inc., USA) was used to improve the image quality of the radiographs. Cobb's angle was measured by two observers (the first author and a blinded observer). The intra-rater [ICC(3,3)] and inter-rater [ICC(2,3)] measurement reliability of the Cobb's angle from radiographs were found 0.99 and 0.96 respectively ($p < 0.01$). The mean pre-brace Cobb's angle of the test group (see Table 4.5) was found no significant difference with that of the control group (see Table 4.6) ($p < 0.01$). The mean pre-brace radiographic thoracic Cobb's angle were 32.9° (±5.3°, range 20° - 40°) and 29.6° (±3.9°, range 25° - 40°) for the test group and the control group respectively. The mean pre-brace radiographic lumbar Cobb's angle were 27.6° (± 6.4°, range 12° - 38°) and 25.4° (± 4.7°, range 12° - 36°) for the test group and control group respectively. The mean immediate correction of test group was 11.5° for the thoracic curvature and 11.0° for the lumbar curvature. The mean immediate correction of the control group was 5.6° for the thoracic curvature and 6.0° for the lumbar curvature. The immediate correction of the test group was found significantly different from that of the control group ($p < 0.005$) for both the thoracic and lumbar curvatures (see Table 4.9).

Table 4. 9. Mean Immediate Correction in the Test Group and the Control Group (Coronal Plane) ($p<0.005$)

Grouping	Curve Level	Pre-brace Cobb's Angle Mean (SD; Range)	In-brace Cobb's Angle Mean (SD; Range)	Mean Immediate Correction (Percentage)
Test Group (n=21)	Thoracic	32.9 ° (±5.3 °; 20 °- 40 °)	21.4 ° (±7.6 °; 6 °- 37 °)	11.5 ° (35.0%)
	Lumbar	27.6 ° (±6.4 °; 12 °- 38 °)	16.6 ° (±9.0 °; 0 °- 35 °)	11.0 ° (39.0%)
Control Group (n=60)	Thoracic	29.6 ° (±3.9 °; 25 °- 40 °)	24.0 ° (±7.9 °; 4 °- 44 °)	5.6 ° (18.9%)
	Lumbar	25.4 ° (±4.7 °; 12 °- 36 °)	19.4 ° (±8.3 °; 4 °- 37 °)	6.0 ° (23.6%)

CHAPTER 5 DISCUSSIONS

The findings from both correlation study and ultrasound study was discussed in this chapter. In the correlation study, the Cobb's angle and SPA was investigated and compared to Herzenberg's findings. In the ultrasound study, the possibility of applying ultrasound technique to assess AIS and to improve the fitting accuracy of spinal orthosis in clinical treatment was examined and discussed. Eventually, the limitations of this study were listed.

5.1 Correlation Study

With reference to the study of Herzenberg's group (1990), there was a high correlation between the Cobb's angle and the SPA (coefficient of determination = 0.90), and a conversion formula had been developed ($y = -1.0404 + 0.74813x$, where y = SPA, and x = Cobb's angle). However, this correlation was only studied without specifying the patients' treatment stage, and no further indications for the correlation in the in-brace stage. The range of the Cobb's angles chosen in their study was from 0° to 70°, while the range for the present study was from 11° to 40° which indicated that the findings in the present study are more relevant and applicable for the patients whom are diagnosed of scoliosis and prescribed with observation or orthotic treatment. Moreover, this correlation is also applicable for the fitting method of the spinal orthosis because the orthotic treatment is usually prescribed to the immature patients with Cobb's angle between 25° to 40° (Lonstein and Winter, 1994; Nachemson and Peterson, 1995; Wong and Liu, 2003). Based on the reliability and reproducibility studies, the correlation of Cobb's angle and SPA (for the pre-brace stage) in the present study was found with $r = 0.80$ ($p < 0.05$). The findings showed that the correlation was well demonstrated in mild and moderate scoliotic curves.

Furthermore, the present study also investigated the Pearson's correlation coefficients between Cobb's angle and SPA in the in-brace stage. The correlation coefficient (r) between Cobb's angle and SPA of the in-brace stage ($r = 0.87$, $p < 0.05$) was close to that of the pre-brace stage (0.80, $p < 0.05$), which revealed SPA was applicable for assessing scoliosis for both pre-brace and in-brace stages. Even though high correlation between Cobb's angle and SPA was found, these two parameters are not exactly the same. Cobb's angle reveals more on the lateral curvature, while SPA reveals not only the lateral curvature but also the vertebral rotation because the vertebral rotation could affect the location of spinous processes. Moreover, Cobb's angle only involves the tilting of the end vertebral bodies, while SPA reveals the deformity of the whole spine. When applying correcting force to a scoliotic spine, the vertebral rotation can be reduced and SPA becomes closer to Cobb's angle. This could be the reason why the correlation coefficient between Cobb's angle and SPA at the in-brace stage is a bit higher than that of the pre-brace stage.

According to these findings, the fitting method of the spinal orthosis is possible to be real-time monitored by 3-D US images. Many studies (Carr et al., 1980; Emans et al., 1986; Goldberg et al., 1993; Katz et al., 1997; Noonan et al., 1996) showed that the long-term follow-up Cobb's angle is close to the pre-brace Cobb's angle. Landauer et al. (2003) conducted a retrospective study to investigate the possibility of predicting the final outcome of bracing for idiopathic scoliosis at a follow-up period of the first 6 months and reported that compliant patients with a high initial correction can be expected with a final correction of around 7 degrees.

For the SpineCor group (Wong et al., 2008), the correlation coefficient (r) between Cobb's angle and SPA was comparable with that of the pre-brace group ($r = 0.80$ for both groups, $p < 0.05$), while the correlation coefficient between these two parameters was slightly higher for in-brace group ($r = 0.87$, $p < 0.05$). The actual working mechanism of these two spinal orthoses (rigid spinal orthoses and SpineCor) is still not fully understood. However the efficacy of SpineCor is still controversial (Wong et al., 2008, Coillard et al., 2008a; Coillard et al., 2008b; Coillard et al., 2007; Coillard et al., 2003), and some researchers demonstrated that rigid spinal orthosis showed a significantly higher treatment efficacy than SpineCor in controlling the progression of spinal curvature (Wong et al., 2008). The results of the current study contribute evidence that the external force created by SpineCor may be not the same as that created by rigid brace.

Spinal orthosis is generally prescribed to the patients with AIS during puberty to mechanically support the spine and prevent further deterioration. The spinal orthosis applied onto the patients causing the force transmission from soft tissues and rib cage to the spine. However, the actual working mechanism of spinal orthosis has not been fully studied. Some over correction might occur when the external force applied onto the scoliotic spine, which means a right thoracic curve may turn into be a left thoracic curve for a small Cobb's angle when remarkable force is applied to the scoliotic spine by fitting the spinal orthosis to the patients with AIS. This situation shows the necessity of distributing the signs to indicate the direction of the curve which may change due to unpredictable and unknown changes of the biomechanics in the spine when there are external forces applied to it (Beausejour et al., 2002). For this reason, the present study developed a new measurement for SPA. The intra-rater and inter-rater reliabilities of this new method were assessed (ICCs > 0.9, $p < 0.05$) and the results showed this method was highly reproducible.

5.2 Ultrasound Study

As Cobb's angle has been one of the standard assessment parameter for AIS, the amount of change in magnitude reflects curve progression or improvement under treatment. In the measurement of Cobb's angle, the end plates of the end vertebra bodies have to be identified. However, the limitations of using Cobb's angle (via radiography assessment) are widely known including multiple radiation exposures and expression of a 3-D deformity in a 2-D plane. It has been shown that a few CT- or MRI-based systems are implemented in localizing the bone, but the major disadvantages of these systems are the cost, the application difficulties, and the radiation exposure (in CT-based systems).

Kadoury's group (Cheriet et al., 2007; Kadoury et al., 2007) developed a 3-D X-ray reconstruction system of the spine and rig cage for 3-D clinical assessment of spinal deformities. This system needs two successive X-ray acquisitions of the spine for the 3-D reconstruction which means it could help to get a 3-D image of spine by involving much less radiation than CT scanning. Labelle et al. (2007) combined this system and a surface topography to assist the adjustment of braces in idiopathic scoliosis. Clin et al. (2010b) applied this element model to compare the biomechanical 3-D efficiency of different brace designs for the treatment of scoliosis. These 3-D reconstruction technologies using bi-planr radiographs now are commercially available (e.g. Biospace's EOS bi-planar low-dose radiographic system) or commonly used (Phan et al., 2011), however, even low-dose still involves radiation. Over a lifetime of having radiographs, a patient with scoliosis can be cumulatively exposed to high doses of ionizing radiation (Parisini et al., 2006). In particular, radiography exposes sensitive breast tissues to ionizing radiation. Females comprise about 80% of cases followed for scoliosis. The breast cancer rate has been reported higher in females who have been followed for scoliosis (Hoffman et al., 1989; Morin et al., 2000). Moreover, these systems are not portable for school screening of AIS. Consequently, more measurement methods and technique may be developed and applied to assess scoliosis in a non-invasive fashion.

To deal with all these short comings, ultrasound could be a solution. And the advantages of ultrasound are fast, non-invasive, inexpensive imaging application and easy data acquisition. The clinical ultrasound could be further developed as a non-invasive real-time assessment for the spinal curvature, because tracing spinal processes along a scoliotic spine becomes possible with the advancement of clinical ultrasound technique. Ultrasonography, however, can display directly the rotatory position of the lamina and the transverse processes. Suzuki et al. (1989) used ultrasound to measure vertebral rotation in patients with AIS.

As a non-invasive and real-time imaging tool, ultrasound has been widely used in clinical for many years. There are still many studies aiming to apply ultrasound technique in many fields, including diagnose the disease, used as an assessment too for many kinds of diseases, and so on. Even thought the images quality of ultrasound is not as good as CT or MR, still it could offer much useful information for clinical use. The popular trend of ultrasound technique development is application in detecting the bone. The great difference in the acoustic impedances of tissue and bone makes not all of the information of bone could be got with ultrasound, but some of the superficial structure of the bone could be obtained with this imaging technique.

Taking the spine as an example, the vertebral body could not be imaged by ultrasound, but the posterior structure of a vertebra (the spinous process) could be traced as a bright curve. On the other hand, the 3-D reconstruction technique has been successfully applied in the ultrasound technique. With these developments, the spine could be reconstructed, and the spinous processes could be indentified from the ultrasound images. Even though these images may not be clear for the noisy signal, still they could contribute much in many fields. For example, this technique could be applied as an assessment tool for screening the children with AIS and helping them achieve appropriate treatment as early as possible, and it could be used in the routine examination for the patients with AIS to monitor the effect of the orthoses.

Ultrasound is considered to be effective in tracing spinous processes (McLeod et al., 2005; Lam et al., 2004; Burwell et al., 2002; Furness et al., 2002; Suzuki et al., 1989). Nonetheless, the contemporary ultrasound technique can track the spinal process of a vertebra but not go deep enough to image the vertebral body without corresponding interferences. The current study proposed a new parameter that could be obtained via 3-D US for assessing scoliosis. Moreover, 3-D US could be well emerged as a potential assessment tool for evaluating AIS. Consequently, ultrasound technique may be further developed and applied to assess scoliosis in a non-invasive and real-time fashion in the future.

The current study evaluated the feasibility of using ultrasound to detect the spinous processes (from T1 to T12 and From L1 to L5) in three dimensions (i.e. transverse plane, coronal plane and sagittal plane). The transverse plane of ultrasound images was mainly used as the indicator to locate and identify the tips of spinous processes.

In the coronal plane, SPA was measured by ultrasound images and taken as an intermediate parameter to get estimated Cobb's angle for assessing the scoliotic spine by 3-D US. The intra-rater reliabilities of this new method was assessed (ICC [3,3] = 0.91, $p < 0.05$) and the results showed that this method is highly relevant and reliable. The SPA measured from the radiographs was found highly correlated with that measured from the ultrasound images ($r = 0.90$, $p < 0.05$). Moreover, it was found that the correlation between Cobb's angle estimated from the measurement of SPA in 3-D US images and Cobb's angle measured from X-ray was found significant in both the pre-brace stage ($r = 0.81$, $p < 0.05$) and the in-brace stage ($r = 0.89$, $p < 0.05$). These promising results gave an evidence to support SPA as a new parameter in assessing scoliosis.

In terms of Cobb's angle, the normal range for thoracic kyphosis angle (from T3 to T12) is from 20° to 45° and normal range for lumbar lordosis angle (from L1 to L5) is from 35° to 55° (Giglio and Volpon, 2007; Herkowitz et al., 1999; Tribus, 1998; Fernand and Fox, 1985). In current study, both thoracic kyphosis and lumbar lordosis angles were evaluated by SPA measuring from 3-D US images in the sagittal plane, instead of Cobb's angle, because the sagittal plane radiographs were not available for the majority of patients (not a routine practice). The results showed that both thoracic kyphosis and lumbar lordosis were significantly decreased by rigid-brace at all the five designed locations of pressure pad in terms of SPA. However, no significant difference was found among different locations for pressure pad. One patient was found to have a small SPA of lumbar lordosis (i.e. 19°) during the in-brace ultrasound scanning, but it is not applicable to confirm a potential hypo-kyphosis because no evidence proves that SPA equals to Cobb's angle when representing lumbar lordosis so far.

It is generally believed that spinal orthosis could possibly induce a reduction in the kyphosis (Clin et al., 2010a&b; Chekryzhev et al., 2009; Weiss et al., 2009; Carlson, 2003; Aubin et al., 1997). Labelle et al. (1996) found the hypokyphosing effects of braces using a 3-D reconstruction method based on 2-D radiographs, though their method was involved radiation. More evidence is still needed to prove that the reduction in kyphosis caused by spinal orthosis could lead to hypo-kyphosis/lordosis. The current study used 3-D ultrasound as a non-invasive and fast assisted technique to monitor the changes of scoliotic spine in both the coronal and sagittal plane during the fitting method of spinal orthoses. With these assessment data, the findings can further support the concern that spinal orthosis would potentially cause hypo-kyphosis/lordosis in the patients with AIS. Since hyper/hypo kyphosis/lordosis would make the structure spine unstable (Herkowitz et al., 1999), it is meaningful to monitor the changes in kyphosis and lordosis during the orthotic treatment. Once the accuracy of using 3-D US to assess thoracic kyphosis and lumbar lordosis is further evaluated, it is possible and practical to monitor the curvature changes in the sagittal plane and avoid the hypokyphosing and hypolordosing effects even under a good correction in the coronal plane by using the 3-D US-assisted fitting method.

The 3-D US assisted fitting method proved to improve the effectiveness of orthotic treatment. There are 13 patients out of the 21 recruited who were required to adjust the location of the pressure pad, which indicated that ultrasound assisted in the fitting method of spinal orthosis was effective and helpful to around 61.9 % patients in this study. The mean immediate correction of the test group was 11.5 ° for the thoracic curvature and 11.0 ° for the lumbar curvature. The mean immediate correction of the control group was 5.6 ° for the thoracic curvature and 6.0 ° for the lumbar curvature. The immediate correction of the test group was found significantly different from that of the control group for both the thoracic and lumbar curvature. In general, the ultrasound-assisted fitting method improves the in-brace correction to nearly double. These results indicated that 3-D US could be further applied in the fitting process to improve the accuracy of determining the optimal location of pressure pad, thus enhancing the treatment effectiveness.

The present study suggested that 3-D US could be used as a low-risk, low-cost method of screening for spinal deformities in school children. Moreover, 3-D US could be a new approach to non-invasive and real-time assessment for scoliosis in routine clinical follow-up, especially for improving the fitting method of spinal orthosis that could improve the treatment effect with determining the accurate position for pressure pad of spinal orthosis. In summary, 3-D US is considered to be a potential radiation-free technique for assessing scoliosis from a 3-D approach especially for improving the accuracy of fitting method of spinal orthosis. This advanced fitting protocol is worthy of further investigation in the future.

5.3 Limitations

Although the present study developed a reliable method for supporting the SPA as an additional parameter to Cobb's angle for evaluating scoliosis, the findings in this study could only represent moderate idiopathic curves instead of wide range of the deformity for the small sample size. This is due to the time limitation (only one year time for recruiting subjects). Based on the risk progression factor calculated from the studies of Lonstein's theory (1994) (70% risk of progression in the selected target group) and Wong et al. (2000) (44% risk of progression with biofeedback intervention), this study requires 50 subjects in each group to detect an effect size of 0.5 (medium level) at pre-determined level of significance of 0.05 and power of 0.8. Thus, the sample size of this study should be increased for representing more general subject group.

The subjects selected for the control group were treated by four certified Orthotists during the past four years (from 2006 to 2009), while the subjects recruited for the test group were treated by one certified Orthotist. Due to the time constraint of the current study, the subjects recruited in this study could not be randomly divided into the control group and test group, and the involved Orthotist who is responsible for the treatment of the test group could not handle more than 40 patients with AIS in a year.

Moreover, the identification procedure of spinous processes (from T1 to T12 and from L1 to L5) required around 4 minutes for each ultrasound image and there were 18 trials of ultrasound images (including the pre-brace stage and the in-brace stage) acquired from each patient. This procedure is relatively time-consuming. Therefore, an image processing system with automatic identification of the spinous processes should be developed to facilitate the measurements.

Furthermore, the current study mainly focused on investigating the location of thoracic pressure pad, while the location of lumbar pad and the tightness of the strap could also contribute to curvature correction. Since more combination of the biomechanical factors of spinal orthosis could result in more time consuming, it is not practical to investigate two factors at a time. The strap tension was maintained by a four-point-fixed fast-grip while the posterior opening of the brace was used as the tightness indicator. It was well recognized that the strap tension could not be 100% consistent, because it would change once the location of pressure pad was changed. Thus, this method was taken because the posterior opening is a simple, direct and more practical reference to maintain the brace tightness. Future studies could be conducted to systematically monitor the magnitude of strap tightness and test the effect of other biomechanical factors on the spinal orthosis.

A silicone sleeve (which is smaller in size, cheaper, replaceable, and US penetrable) was designed and fabricated as a medium to ensure good skin contact during US scanning. Nonetheless, the posterior opening of the spinal orthosis (Hong Kong Brace) was still designed up to 6.5 cm in this study to fit the US probe during the 3-D US scanning. Normally, the width of posterior opening should be around 2.5 cm. This usual width allows the patient to gain some weight during growth. If the brace width gets larger, the brace may need to be renewed in a shorter time. If the size of the probe could be smaller, the width of posterior opening could be reduced to avoid this limitation.

Besides, the 3-D US assisted fitting method is applicable to the orthotic design with posterior opening and fabricated without metal materials. It is because ultrasound could not detect spinous process from anterior aspect of the body and metal materials will affect the accuracy of the Tom Tec 3-D localizing system (because Tom Tec 3-D system is based on using electromagnetic wave to transmit and receive signal).

In addition, the accuracy of using 3-D US to assess kyphosis and lordosis is yet to be further evaluated. It is because not all of the patients would take X-ray in the sagittal plane as clinical routine and this study aims to maintain the radiation dosage in the assessment procedure, then no additional X-ray was required. Future study could be conducted to investigate the correlation between kyphosis/lordosis angle estimated by 3-D US and that measured from X-ray images or other methods. Though the current study attempted to verify this correlation, no significant relationship was found due to lack of enough sagittal plane X-ray images for analysis.

Ultimately, the current study only compares the immediate curvature correction (in-brace correction after having a month of treatment) between treatment with conventional fitting method (control group) and that with 3-D US assisted fitting method (test group). Even though the mean immediate curvature correction of the test group is significantly higher than that of the control group ($p < 0.005$), the long-term effect of orthotic treatment is needed to be further investigated. Moreover, future study should also include monitoring and improving the compliance of the patients during the whole orthotic treatment period (ensuring that the patients follow the prescribed tightness of straps and the wearing time of orthosis when they return home), because optimal fitting should combine with the patients' subsequent compliance in order to have the best treatment effect.

CHAPTER 6 CONCLUSIONS

6.1 Conclusions

It is difficult to determine the optimal location of pressure pad in the conventional fitting method of spinal orthosis. This study aimed to develop a non-invasive, radiation-free and fast method to monitor the fitting of spinal orthosis in order to improve the treatment effectiveness for patients with AIS.

The results found that the correlation study could strongly support SPA to be an intermediate parameter to estimate Cobb's angle for describing the spinal deformity because high correlation between SPA and Cobb's angle was verified both at the pre-brace stage and the in-brace stage. Besides, this study has developed an applicable, non-invasive, fast and reliable method for measuring the SPA by using 3-D ultrasound. According to the investigation on the feasibility of using ultrasound to trace spinous processes in present study, 3-D US has been proved to be a potential radiation-free technique for measuring SPA. Furthermore, Cobb's angle estimated from 3-D ultrasound is significantly correlated to that measured from X-ray images. In the current study, ultrasound has been proved to be an effective tool for the clinical assessment not only to monitor the progression of scoliosis but also to enhance the treatment effectiveness of the spinal orthosis via improving the accuracy of fitting method.

6.2 Future Study

With these findings and rapid development of ultrasound, the present study suggests that ultrasound could be a new approach to fast and non-invasive assessment of scoliosis, especially for improving the fitting method of spinal orthosis and reduction of X-ray exposure in the routine clinical visits.

This study mainly investigated the accuracy of determining optimal location for pressure pad, but not considering the tightness of strap tension, because two more combinations require more time and make the fitting too tedious to the involved patients. The patient should not be involved too long time. Automatic system for identifying and labeling the tips of spinous process and calculating the angles should be developed to reduce the treatment time and to minimize the manual error. Thus, more combinations of biomechanical parameters (e.g. locations of pressure pad, force directions caused by different tilting angles of pressure pad, force magnitudes caused by the tightness of strap tension) in spinal orthosis could be studied. In the future study more intelligent systems could be developed and commercialized, 3-D US could be recommended for the Department of Prosthetics and Orthotics as a regular clinical assessment tool.

Moreover, this study only examined the immediate correction of the 3-D US assisted fitting method of spinal orthoses due to time limitation. In the future study, the patients' compliance to the spinal orthoses should be monitored and the long-term treatment effect (till skeletal maturity) should be studied as well.

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APPENDICES

APPENDIX A -- CONSENT TO PARTICIPATE IN RESEARCH

<u>Project Title: Could clinical ultrasound improve the fitting of spinal orthosis for patients with AIS</u>

I ______________________________ hereby consent to participate in the captioned research study conducted by Dr. Bobby Ng Kin Wah and Dr. M. S. Wong, and assisted by LI Meng.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant: ____.

Signature of participant: ____.

Name of the participant's parent / guardian: __________________________________.

Signature of the participant's parent / guardian: _______________________________.

Name of researcher: ____.

Signature of researcher: ____.

Name of supervisor: ____.

Signature of supervisor: ____.

Date: ____________________

APPENDIX B -- CONSENT TO PARTICIPATE IN RESEARCH

(CHINESE VERSION)

參與研究同意書

計劃名稱: 關於超聲波檢查是否有助於青春期特發性脊柱側彎患者佩戴脊柱矯形器的研究

本人 ______________________________特此同意參加由香港中文大學矯形外科及創傷學系 吳健華 顧問醫生和香港理工大學醫療科技及資訊學系 黃文生 副教授 負責執行及加以說明，並且將由 李夢 來協助執行的研究項目。

我理解此研究所獲得的資料可用於未來的研究和學術交流。然而我有權保護自己的隱私，我的個人資料將不能洩漏。

我對所附資料的有關步驟已經得到充分的解釋。我是自願參加與這項研究。

我理解我有權在研究過程中提出問題，并在任何時候決定退出研究而不會受到任何不正常的待遇或責任追究。

參加者姓名：______________________________
參加者簽名：______________________________

父母姓名或監護人姓名：______________________________
父母或監護人簽名：______________________________

研究人員姓名：______________________________
研究人員簽名：______________________________

導師姓名：______________________________
導師簽名：______________________________

日期：______________________________

APPENDIX C -- INFORMATION SHEET

Project Title: Could clinical ultrasound improve the fitting of spinal orthosis for patients with AIS?

You are invited to participate in a study conducted by Dr. Bobby Ng Kin Wah, Consultant of Orthopaedics and Traumatology Department, The Chinese University of Hong Kong and Dr. M. S. Wong, Associate Professor of the Department of Health and Informatics, The Hong Kong Polytechnic University, and Miss LI Meng, who is a M.Phil student of Dr. M. S. Wong and will be the assistant in this study.

This study aims to apply ultrasound technique in the fitting of spinal orthosis for patients with adolescent idiopathic scoliosis. Subjects will be divided into either the control or the test groups. In the control group, a routine fitting method will be used. In the test group, the procedure is same as the control group till the orthosis fitting process - subjects will be scanned by an ultrasound system and curve control will be estimated. As general clinical instruction, you are required to wear the orthosis 23 hours a day and visit the clinic in a month for follow-up checking. The orthosis should be tightened according to the strap markings made by your Orthotist. The results of this study can contribute in scientific practice of orthotic intervention and form a data base for further developments of orthotic treatment protocol for adolescent idiopathic scoliosis.

The testing should not result in any undue discomfort as spinal orthosis has been prescribed for scoliosis over half of a century. All information related to you will remain confidential, and will be identifiable by codes only known to the researcher.

You have every right to withdraw from the study before or during the measurement without penalty of any kind. The whole investigation will take about two hours.

If you have any complaints about this research study, please do not hesitate to contact Mr Eric Chan, Secretary of the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office of the University).

If you would like more information about this study, please contact Dr. M. S. WONG at 2766-7680.

Thank you for your interest in participating in this study.

Dr. Bobby Ng Kin Wah

Dr. M. S. WONG

Principal Investigators

APPENDIX D -- INFORMATION SHEET (CHINESE VERSION)

相關資料

計劃名稱:關於超聲波檢查是否有助於青春期特發性脊柱側彎患者佩戴脊柱矯形器的研究

誠邀閣下參加由香港中文大學矯形外科及創傷學系 吳健華 顧問醫生和香港理工大學醫療科技及資訊學系 黃文生 副教授負責執行的研究計劃。此項目將由李夢 來協助執行。她是 黃文生 副教授的在讀碩士研究生。

此研究的目標是設法運用超聲波技術來輔助青春期特發性脊柱側彎患者試配脊柱矯形器。參加者將分開成控制組或測試組。慣常的矯形器試配方法將被使用在控制組的參加者的治療程序中。在測試組，參加者的治療程序大至同控制組的一樣，除了在矯形器的試配過程中加設了運用超聲波技術來輔助估計脊柱弧度并且加以控制的程序。閣下需要根據矯形師在繫緊帶上所留下的標號拉緊矯形器。按照臨床的規定，閣下需要每天 23 小時佩帶矯形器和一個月后到訪診所作一次檢查即可。此研究的結果可在矯形器的治療科學運用作出貢獻及能形成一個數據庫以便進一步研發為治療青春期特發性脊柱側彎的矯形器及療程。

在測試過程中將不會令閣下有任何不必要的不適。凡有關閣下的資料均會保密，一切資料的編碼只有研究人員知道。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究，而不會受到任何對閣下不正常的待遇或責任追究。完成整個測試過程將需要大約兩小時。

如果閣下有任何對這項研究的不滿，請隨時與香港理工大學人事倫理委員會秘書親自或寫信聯絡（地址：香港理工大學人力資源辦公室 M1303 室轉交）。

如果 閣下想獲得更多有關這項研究的資料, 請與 黃文生 副教授聯絡，辦公室電話： 2766-7680.

謝謝 閣下參與這項研究。

吳健華 顧問醫生

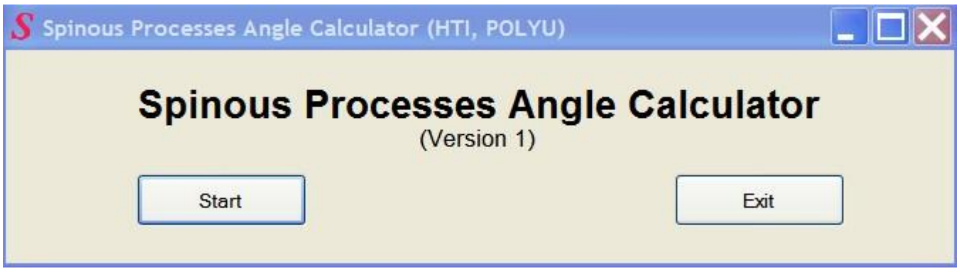
黃文生 副教授

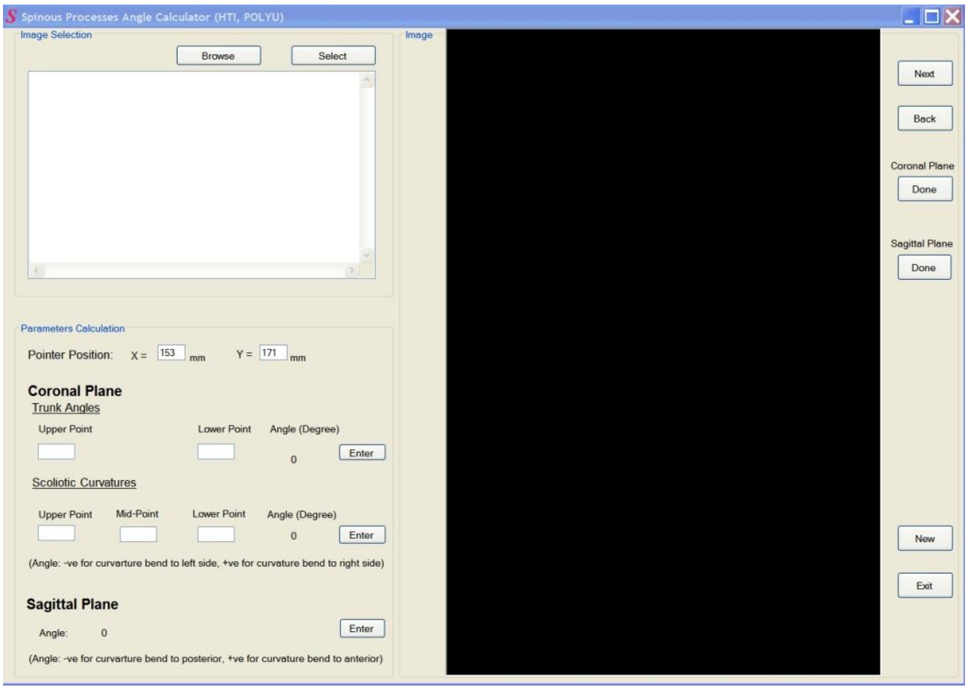
首席調查員

APPENDIX E -- INSTRUCTION FOR SPA CALCULATOR

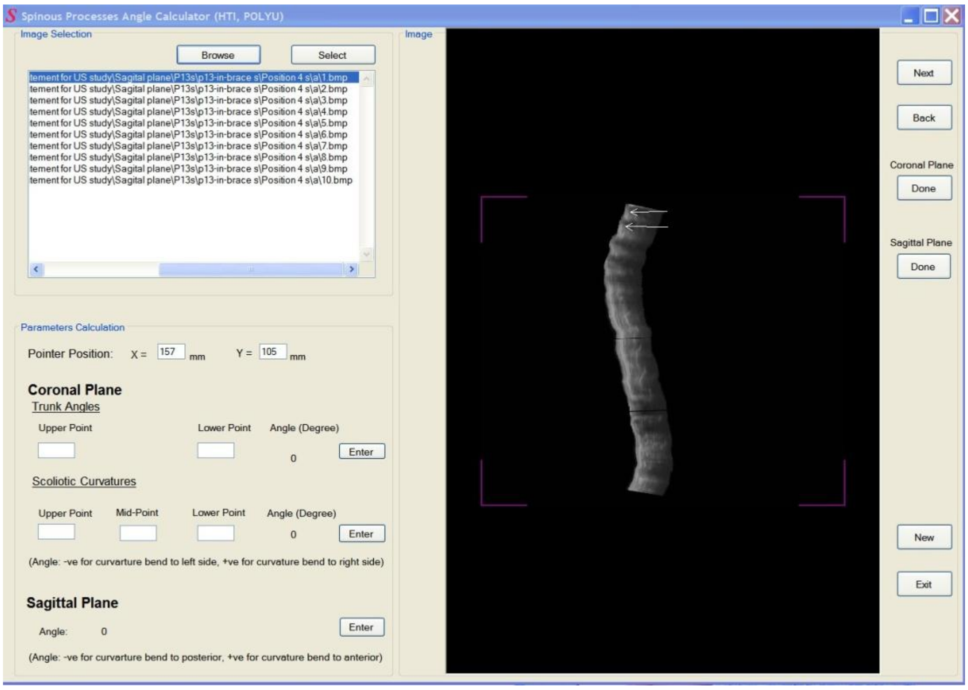
Spinous Processes Angle Calculator is developed for processing the bitmap pictures of the spine which captured from the TomTech ultrasound system and calculating the spinous processes angle.

Once the computer has a copy of the "Spinous Processes Angle Calculator" program, you can use the program to analyze and report the spinous processes angle.

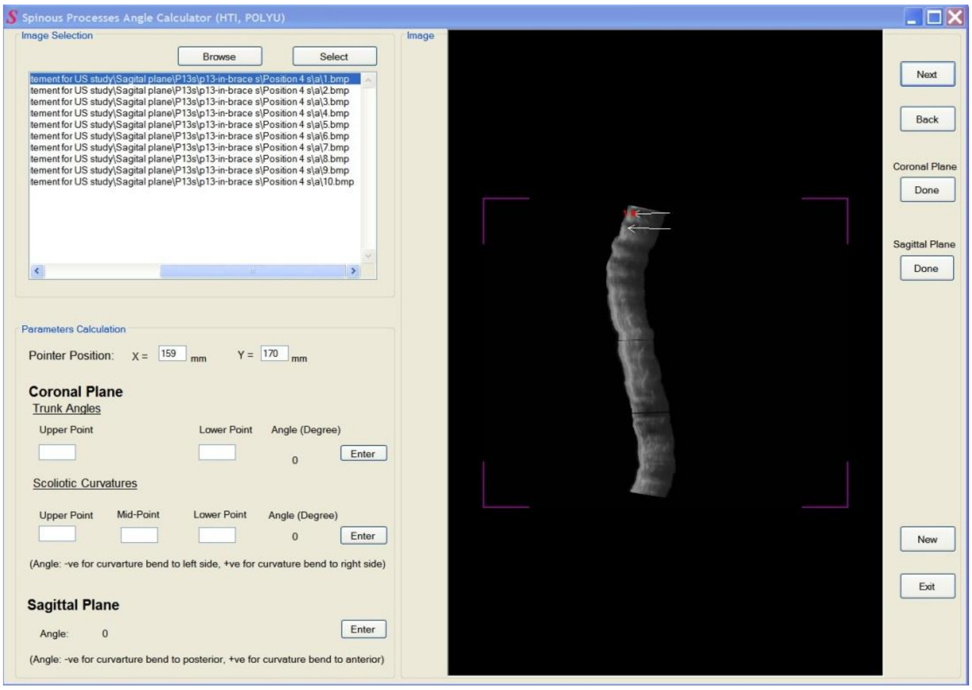




1. Click the "Browse" button to import the image files to the program and click the file name to select the image and then click the "Select" button to display the image on the right hand side of the interface.

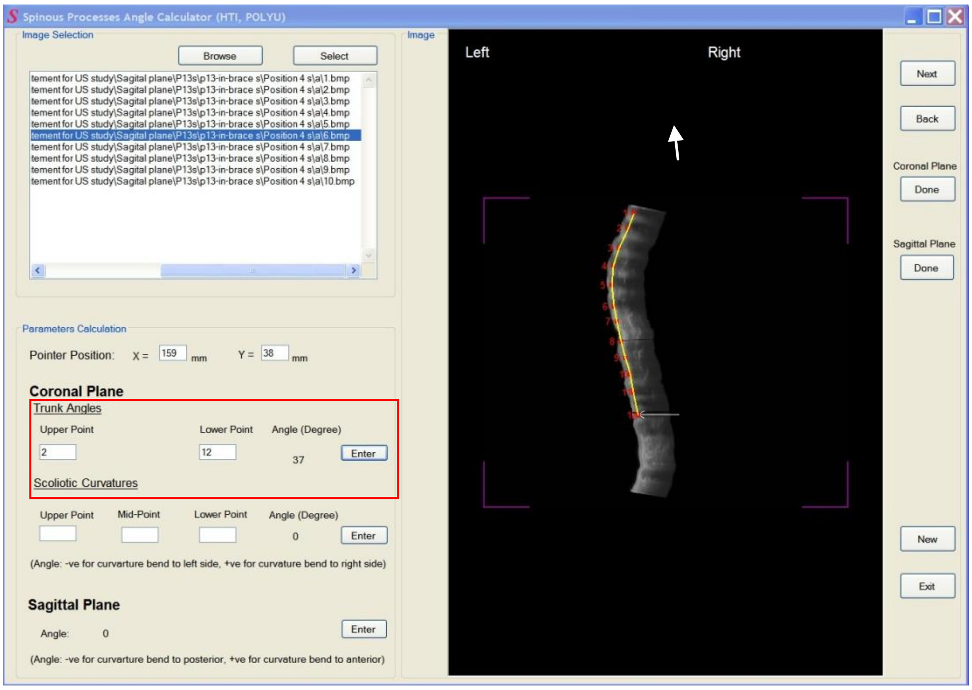


2. Use the pointer to locate the spinous process and left click the mouse button. Then one small red square-shaped point was drawn on the head of the indicating arrow



3. Then, click the "Next" button to confirm the location of the spinous process or the "Back" button to re-locate the spinous process on the image. Click the "Done" to display all the points and curves. Enter the point number of the spinous processes on

the left hand side of the interface and then click the 'Enter' buttons to compute the spinous processes angles.



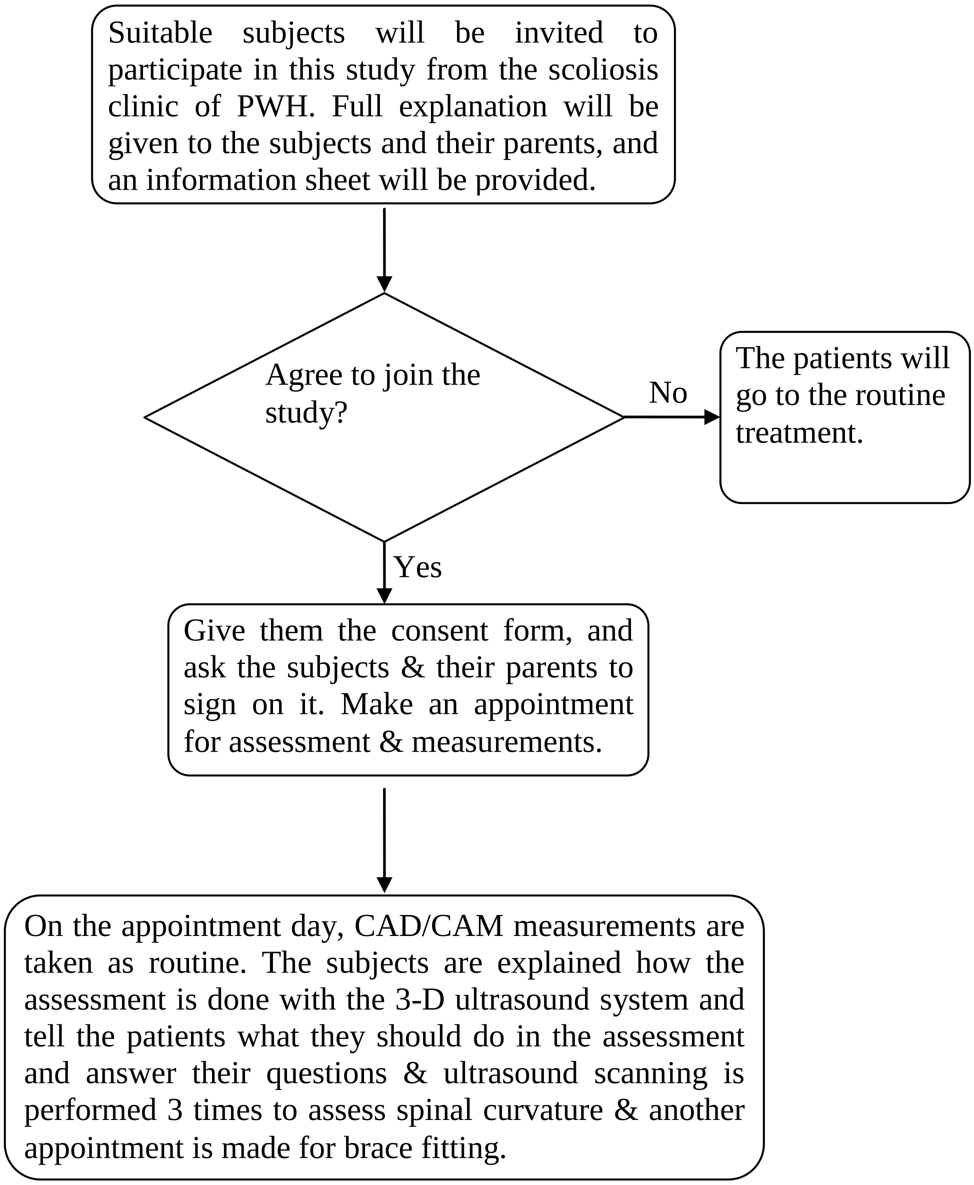
By typing upper point (T2) and lower point (T12) into the related blankets, the degree of the angle appears accordingly. The function under sagittal plane is for measuring the thoracic kyphosis angle and lumbar lordosis angle. The procedures for computing the thoracic kyphosis angle and lumbar lordosis angle are similar to that of computing SPA. The definition for signs of both thoracic kyphosis angle and lumbar lordosis angle is also similar to that of SPA.

4. Click the 'New' button to start the new trial or the 'Exit' button to close the program after finished the trial.

APPENDIX F -- PROJECT PROTOCOL

Project Title:
Could clinical ultrasound improve the fitting of spinal orthosis for patient with AIS?

Part I (Subject Recruitment)



Part II (Brace Fitting & Comparison)

On the appointment day, Orthotist will do the necessary adjustments to the brace in the first fitting as routine.

↓

The subjects are further explained how the assessment is done with the 3-D ultrasound system and tell the patients what they should do in the assessment and answer their questions.

↓

Arrange the patients in a standing position without brace, and scan the thoracic and lumbar spine with the 3-D ultrasound system for 3 times.

↓

When the Orthotist finishes the brace adjustments, the patient is arranged in the same standing position as pre-brace. The brace is worn and the fitting is assessed by scanning with the 3-D ultrasound system. The thoracic pad is located at 5 levels, including the starting position which is set according to the pre-brace X-ray, 1cm and 2cm proximal, 1cm distal and 2cm distal to the starting position and scan the spine for 3 times for each level.

↓

Ask the patient to take a seat and then calculate the Spinous Process angle in order to estimate Cobb's angle in the coronal and sagittal planes at different pad levels. Compare all the angles and determine the level of the pad which offers maximum correction to the scoliotic spine.

↓

Recommend the optimum pad location from the findings and then follow clinical routine as the control group.

↓

Compare the immediate in-brace Cobb's angle (taken from X-ray) between the study group and the control group in order to assess the usefulness of the 3-D ultrasound system.

End