USING SPINAL FLEXIBILITY TO PREDICT THE INITIAL IN-ORTHOSIS CORRECTION ON THE PATIENTS WITH ADOLESCENT IDIOPATHIC SCOLIOSIS

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Using Spinal Flexibility to Predict the Initial In-orthosis Correction on the Patients with Adolescent Idiopathic Scoliosis

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ABSTRACT

Adolescent idiopathic scoliosis (AIS) is characterized as a three-dimensional spinal deformity with lateral curvature over 10° in adolescence without known causes. The incidence of AIS was reported as 1 - 3%. Orthotic treatment is generally prescribed for the patients with moderate AIS and surgical treatment will be considered if the deformity becomes severe. The response of the scoliotic spine to the initial orthosis application (initial in-orthosis correction) is essential for clinical decision because it determines the long-term treatment effectiveness.

Spinal flexibility has been used to predict the initial in-orthosis correction on the patients with AIS, as more flexible spines are estimated to experience better correction by spinal orthosis. However, various methods are proposed to assess the spinal flexibility and which method is more effective for this prediction is unknown. A comparison among different spinal flexibilities is needed, but the high ironizing radiation of radiographic imaging technique increases the risk of breast cancer on adolescent thus making this comparison less feasible. Ultrasound imaging technique can be an alternative option since it is radiation-free and reliable for scoliosis assessment. Therefore, this study aimed to investigate an effective assessment method of spinal flexibility to predict the initial in-orthosis correction using ultrasound imaging technique.

Before orthosis fitting, the spinal flexibility was assessed by an ultrasound system in standing and other four positions (supine, prone, sitting with lateral bending and prone with lateral bending) on the patients with moderate scoliosis (n=35). The pre-orthosis spinal curvature was also routinely assessed by a radiographic system in standing and supine position. After orthosis fitting, the initial in-orthosis correction was assessed by both ultrasound and radiographic system in standing position. Comparison and correlation analyses were performed between the ultrasound and radiographic measurements. Comparison and correlation analyses were also performed between the four spinal flexibilities and the initial in-orthosis correction.

The results showed that the ultrasound measurements were highly correlated with the X-ray measurements in standing, supine and in-orthosis position (R = 0.77, 0.82 and 0.84 respectively), which indicated that ultrasound imaging technique could be regarded as a valid technique for the assessment of spinal flexibility. This novel clinical application of ultrasound imaging technique quantifies essential parameters to assist orthosis design, modification and evaluation from the fitting process to the end of orthotic treatment.

Besides, spinal flexibility in the prone position was found not significantly different from ($P > 0.05$) and showed the highest correlation to the initial in-orthosis correction ($R = 0.87$) among the four studied positions. Therefore, the prone position test could be an effective method to predict the initial effect of orthotic treatment for the patients with AIS. This finding provides useful data basis to formulate an individualized guideline in orthosis design and contribute to an evidence-based treatment planning, thus potentially improving the effectiveness of conservative treatment and reducing the chances of surgery intervention.

PUBLICATONS ARISING FROM THE THESIS

Peer-Reviewed Journal Papers (published or accepted)

1. **Chen HE** and Man-Sang WONG. Spinal Flexibility Assessment on the Patients with Adolescent Idiopathic Scoliosis: A Literature Review. *Spine* 2017;43(4): E250-8.
2. **Chen HE**, Kai-Tsun TO, Pui Yin CHEUNG, Man-Chee CHEUNG, Chi-Kwan CHAN, Wei-Wei JIANG, Guang-Quan ZHOU, Kelly Ka-Lee LAI, Yong-Ping ZHENG, Man-Sang WONG. An Effective Assessment Method of Spinal Flexibility to Predict the Initial In-orthosis Correction on the Patients with Adolescent Idiopathic Scoliosis (AIS). *Plos One* 2017;12: e0190141.

Peer-Reviewed Journal Papers (submitted)

3. **Chen HE**, Kai-Tsun TO, Chi-Kwan CHAN, Man-Sang WONG. Significance of Recumbent Curvature in Prediction of In-Orthosis Correction for Adolescent Idiopathic Scoliosis. Under review.

Conference proceedings

4. **Chen HE** and Man-Sang WONG. Using Spinal Flexibility to Predict the Initial In-orthosis Correction on Patients with Adolescent Idiopathic Scoliosis. Prosthetics & Orthotics Scientific Meeting, 23 Sep 2017, Hong Kong.

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30 July - 2 August 2017, Hong Kong.

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Book chapters

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LIST OF ABBREVIATIONS

3-D	Three-dimension
3-D US	Three-dimensional ultrasound
AIS	Adolescent idiopathic scoliosis
ATI	Apical trunk inclination
AVR	Apical vertebra rotation
BMI	Body mass index
CT	Computed tomography
FSU	Functional spinal unit
L	Lumbar
MRI	Magnetic resonance imaging
MAD	Mean absolute difference
n	Number of subjects
P	Probability
PA	Postero-anterior
R	Pearson correlation coefficients
SPA	Spinous process angle
ST	Surface topography
T	Thoracic
TL	Thoracolumbar
TLSO	Thoraco-lumbo-sacral orthosis
UGA	Under general anesthesia
US	Ultrasound

CHAPTER 1 INTRODUCTION

In the beginning of this dissertation, the motivation and objectives of this study is introduced.

1.1 Background

Adolescent idiopathic scoliosis (AIS) is a structural lateral curvature of spine with vertebrae rotation that arises in adolescents, which affects 1–3% of children aged 10–16 years (Weinstein et al. 2008). It is generally diagnosed with posterior-anterior and lateral radiographies using the Cobb angle (angle between the two most tilted vertebrae of a spine segment) (Cobb 1948). Currently, the intervention for patients with AIS include: observation, for patients with mild curves or skeletal maturity; orthotic treatment, for those with moderate curves and skeletal immaturity; and surgical correction, for those with severe curves (Asher and Burton 2006). Until now, orthotic treatment has been proved largely successful in halting curve progression and preventing surgical intervention (Bullmann et al. 2004, Zaborowska-Sapeta et al. 2011, Giorgi et al. 2013, Weinstein et al. 2013), therefore it has been served as a vital non-surgical treatment for immature patients with moderate AIS.

The response of the scoliotic spine to the initial orthosis application (initial in-orthosis correction) is essential to determine the long-term treatment effectiveness (Upadhyay et al. 1995). In current practice, some clinicians estimate the in-orthosis effectiveness by clinical experience in the pre-orthosis stage and use it to guide the orthosis design. While this empirical practice is not a scientific and evidence-based treatment maneuver, which would affect the effectiveness of orthosis consequently.

Some clinicians aim to achieve 40-50% correction of the initial curvature (Carr et al. 1980, Katz et al. 1997, Knott et al. 2013) and use this general accepted standard to assist orthosis design. However, the in-orthosis corrections among patients are usually different due to individualized spinal condition, using a general standard for all patients makes the tailor-made orthosis less personalized and patient-specific. To optimize the current practice, scientific and individualized prediction of initial in-orthosis correction before orthosis fitting is necessary.

Spinal flexibility (correctability) has been used to predict the initial effect of orthotic treatment as more flexible spines are expected to experience better correction. Spinal flexibility describes the correctability of the spinal deformity, comparing the curve angles in standing position and that in a different position with correction effect. Some used the curve correction in supine position (supine flexibility) to predict curve correction obtained by spinal orthosis, because the Cobb angle during lying down position was reported to be close to the Cobb angle within orthosis (Wong et al. 1994, Vidyadhara and Mak 2008). But the detailed statistical results were not provided in their studies. Kuroki et al. (2012) proposed standing with traction method for the estimation of spinal flexibility and prediction of in-orthosis correction, but its correlation with the in-orthosis Cobb angle was diverse because of the influence of patients' maturity status in their study (at 9-18 years with Risser 0-5). Other methods, such as supine with lateral bending and fulcrum bending, predict surgical correction (Cheung and Luk 1997, Hamzaoglu et al. 2005) but may not be applicable for orthotic treatment. At present, the method of spinal flexibility assessment that offers an effective prediction of the initial in-orthosis correction is still unknown and a comparison among these methods are deserved.

Comparison among assessment methods of spinal flexibility may not be feasible in the past because it requires X-ray taking at different body positions, which exposes the patients to high radiation that increase the risk of breast cancer (Hoffman et al. 1989). Radiation-free ultrasound imaging technique can be an option for this comparison, considering the reliability and validity of ultrasound (US) technique in assessing scoliosis had been approved in recent years (Wang et al. 2015, Wang et al. 2016, Zheng et al. 2016). Therefore, this study aimed to investigate an effective assessment method of spinal flexibility to predict the initial in-orthosis correction using ultrasound imaging technique.

1.2 Objectives

1) To assess the feasibility and validity of ultrasound imaging technique in estimation of the spinal flexibility.
2) To investigate an effective method of spinal flexibility assessment to predict the initial effect of orthotic treatment.

1.3 Thesis outline

The main content is divided into 6 chapters.

CHAPTER 1 INTRODUCTION: this chapter introduces the motivation and objectives of this study.

CHAPTER 2 LITERATURE REVIEW: this chapter provides the background information of adolescent idiopathic scoliosis. Previous literatures on initial in-orthosis correction and spinal flexibility are also reviewed.

CHAPTER 3 METHODOLOGY: this chapter demonstrates the procedure of the clinical experiment (pre-orthosis assessment and in-orthosis assessment).

CHAPTER 4 RESULTS: this chapter presents the results of assessment on spinal flexibility and initial in-orthosis correction. Their comparison and correlation analyses are also demonstrated.

CHAPTER 5 DISCUSSION: this chapter discusses the comparison and correlation between spinal flexibilities and initial in-orthosis correction. Possible explanation is given. Limitations of this study are pointed out.

CHAPTER 6 CONCLUSIONS: this chapter summarizes the major findings of this study and suggests future studies.

CHAPTER 2 LITERATURE REVIEW

In this chapter, basic knowledge of adolescent idiopathic scoliosis (AIS) is introduced. Previous literatures studying the effectiveness of orthotic treatment were reviewed, which indicated a necessity of predicting the initial in-orthosis effectiveness. Further review suggested that spinal flexibility can predict the initial in-orthosis correction, while which assessment method of spinal flexibility is more effective is unknown. This investigation can be realized via radiation-free ultrasound imaging technique. Therefore, an effective assessment method of spinal flexibility to predict the initial effect of orthosis treatment should be explored with the assistance of ultrasound imaging technique.

2.1 Spine

Spine is an important musculoskeletal structure for human body. Its functions include surrounding and protecting the spinal cord, keeping upright posture, transmitting load through body, and permitting movement and locomotion in multidimensional space (White and Panjabi 1990). A normal spine has a straight alignment when viewed from coronal plane, has natural curves in the sagittal plane where cervical and lumber spines are convex forward and thoracic and sacral spines are convex backward (Figure 2.1). The natural curves of spine assist spinal stability, increase spinal flexibility and augment shock absorbing capacity.

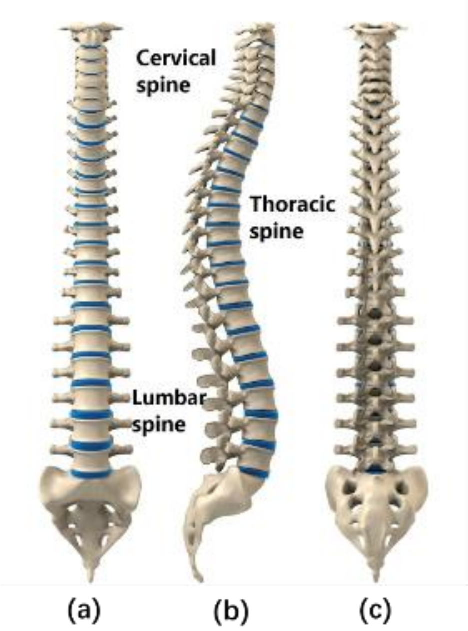

Figure 2.1 Vertebrae column
(a) anterior view (b) lateral view (c) posterior view
[http://anatomy4fitness.blogspot.hk/2013/04/stay-centered-your-guide-to-healthy.html]

Spine is composed of a series of irregular shaped vertebrae which are bounded together by ligaments and separated by intervertebral discs. 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) (Herkowitz et al. 1999).

2.1.1 Anatomy

A normal vertebra (Figure 2.2-a) has a round vertebral body in front. A pair of pedicles are extended to the back from vertebral body and connected by a flat sheet of bone called lamina. A space is formed in the middle allowing spinal cord to pass through. Lamina continues to grow backwards and downward to form spinous process which can be felt as a bony prominence on the back. Transverse process is projected sideways from each pedicle. These bony extensions shaped the major features of vertebral arch at the back of a vertebra. All vertebrae are linked by intervertebral discs, muscles and ligaments. The bony projections on the vertebral arch provided sites for ligaments and muscles attachments. The intervertebral discs lie between two vertebral bodies and occupy one-third of the height of spine. It consists of a thick outer ring of fibrous cartilage termed the annulus fibrosis and a more gelatinous core known as the nucleus pulposus (Figure 2.2-b). The intervertebral discs constantly transmit loads arising from body weight and muscle activities through the spinal column, and provide flexibility to allow spinal movement (Raj 2008). Besides the disc, there are seven ligaments that connect one vertebra to the next (Figure 2.2-c). Contribution to the spine stability by an individual ligament is dependent upon its cross-section, its distance from the instantaneous axis of rotation, and its orientation in space (White and Panjabi 1990).

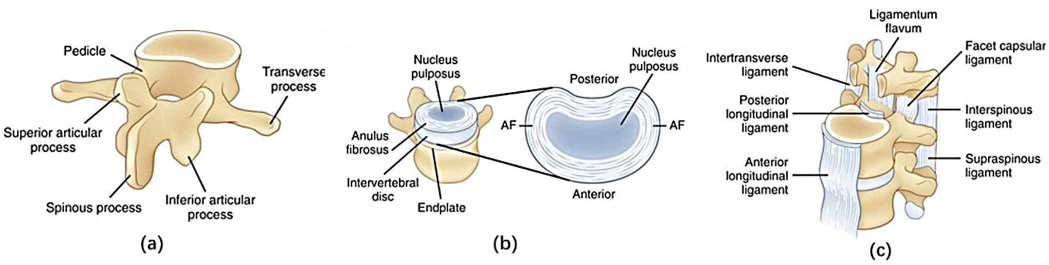

Figure 2.2 Anatomy of vertebrae

[From Bogduk N: Clinical Anatomy of the Lumbar Spine and Sacrum, 4th ed. Edinburgh, Churchill Livingstone, 2005]

2.1.2 Movement

Direction of body movement is defined relative to a coordinate: coronal plane, sagittal plane and transverse plane (Figure 2.3). Flexion and extension are typically described in the sagittal plane, lateral bending occurs in the coronal plane, and rotation occurs along the horizontal plane. Most activities of spine are combinations of movements in these planes.

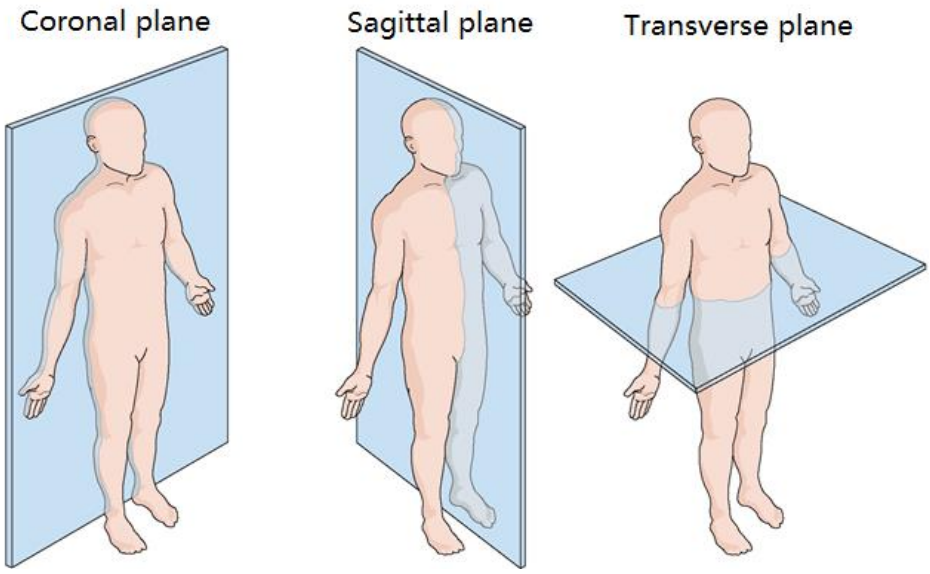

Figure 2.3 Coordinates of human body
[https://www.youtube.com/watch?v=g-yOhVulhZA]

A vertebrae unit has six degrees of freedom, translation along and rotation about each of three axes (Figure 2.4). One degree of freedom is the motion in which a rigid body may translate back and forth along a straight line or may rotate back and forth about the axis. The curved arrows in this figure show the direction in which moments act around a spinal segment. A forward bending moment can be defined around the X-axis resulting in a movement in the sagittal plane, or it can be defined around the Y-axis indicating a lateral bending moment, or it can be defined around the Z-axis indicating torsion moment (rotation) (Bogduk 2005).

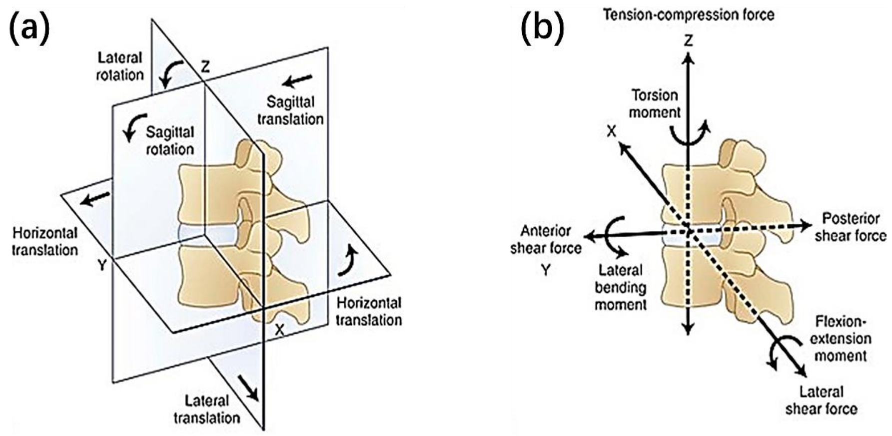

Figure 2.4 Coordinates of vertebrae

(a) Biomechanical coordinate (b) Motions and forces relative to coordinate.
[From Bogduk N: Clinical Anatomy of the Lumbar Spine and Sacrum, 4th ed. Edinburgh, Churchill Livingstone, 2005]

The movement of spine has coupling motion, which refers to the motion in which rotation or translation of a body about one axis is consistently associated with simultaneous rotation or translation about another axis (White and Panjabi 1976). For instance, the spine can bend laterally with spontaneous vertebrae rotation, or bend forward with rotation at the same time. This coupling effect of spinal movement could result from the geometric arrangement of the vertebrae (Veldhuizen and Scholten 1987).

The movement of thoracic and lumbar spine demonstrates different features because of different anatomical structures. The spinous processes are directed downwards obliquely in the upper thoracic region, become longer and almost vertical in the middle thoracic region, horizontal in the lower thoracic and lumbar regions (Masharawi et al. 2007). Besides, a thoracic vertebra has a flat-surface superior and inferior articular facet, the inferior articular facet lies over the superior articular facet like shingles on a roof. This structure allows the inferior articular facet to rotate-slide over the superior articular facet, and this rotary-slide movement of multiple thoracic vertebrae produces the movement of upper torso rotation (Ebraheim et al. 1997). A lumbar vertebra has a cup-shaped superior articular facet with elevated bony side-ridges on side and a dome-shaped inferior articular facet. It allows the inferior articular facet to move in a sagittal plane within the cup-shaped confines of the superior articular facet (Masharawi et al. 2007). This structure allows lumbar spine flexion but resists rotation. Therefore, the articular facet difference makes the thoracic spine has larger range of rotational movement, but lumbar spine has larger range of flexion movement.

2.2 Scoliosis

Scoliosis is defined as a lateral curvature of a spine with torsion of spine and chest as well as a disturbance of sagittal profile (Figure 2.5) (Weiss et al. 2006). A structural curvature with unknown underlying cause is referred to idiopathic scoliosis (Reamy and Slakey 2001).

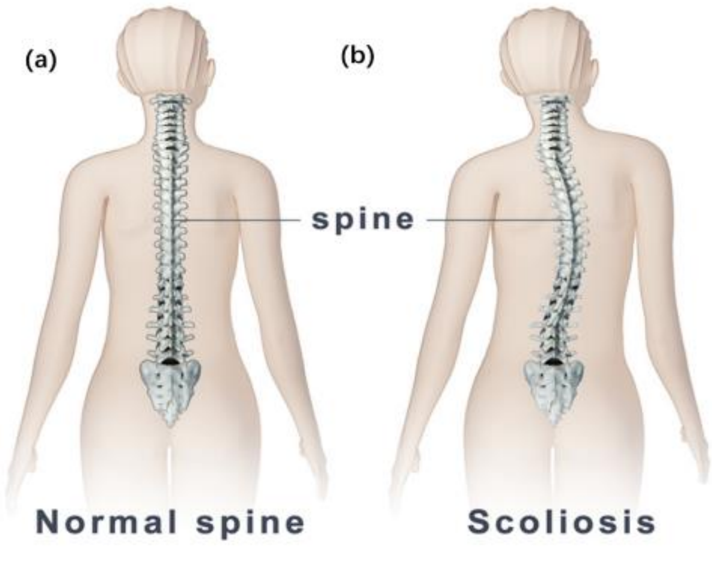

Figure 2.5 Spine in coronal plane
(a) normal spine (b) scoliotic spine [http://www.pedroruizsite.com/]

Idiopathic scoliosis can develop in healthy children at any stage of growth, which classified by age of onset: infantile (birth to 3 years), juvenile (3 - 9 years old), and adolescent (10 - 18 years old). The adolescent idiopathic scoliosis (AIS) is found most common and represents about 80% of scoliosis patients.

AIS is characterized to be a 3-D deformity in the spine with lateral curvature combined with or without vertebral rotation and presents not only in the coronal plane but also in the sagittal and transverse plane (Villemure et al. 2001). This lateral curvature affects the rib cage, presents trunk deformities and may progress throughout the rapid growth period of adolescent (Rogala et al. 1978, Weinstein et al. 2008). The incidence of AIS has been reported as 2-4% in Hong Kong and this incidence 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 (Li 2012).

2.3 Orthotic treatment

Treatment for AIS should be determined with careful evaluation of severity of deformity, skeletal maturity and progression risk etc. (Weiss et al. 2006). The severity of scoliosis is graded by the magnitude of Cobb angle, the skeletal maturity is graded by the ossification stage of the iliac apophysis with Risser sign in standing radiograph (Hacquebord and Leopold 2012). Progression is defined as at least 6° of Cobb angle increase between two consecutive check-ups, therefore continuous monitor at every 6 to 12 months until skeletal maturity is usually prescribed for the patients (Peterson and Nachemson 1995, Weiss et al. 2006). After analyses of the complex set of variables, observation or exercise might be prescribed for the patients with mild curvature or skeletal maturity; orthotic treatment for those with moderate curvature and skeletal immaturity; and surgical correction for those with severe curvature (Asher and Burton 2006). Until now, orthotic treatment has served as a vital non-surgical treatment for immature patients with moderate scoliosis.

Spinal orthosis for scoliosis can be classified as full-time orthosis (e.g. Milwaukee orthosis) and nighttime orthosis (e.g. Providence orthosis); or rigid orthosis (e.g. thoracolumbosacral orthosis) and flexible orthosis (e.g. SpineCor®); or symmetric (e.g. Boston orthosis) and asymmetric orthosis (e.g. Cheneau orthosis), etc. During orthosis treatment, constant supervision is conducted for necessary adjustments with the growth of patient and compliance is encouraged to foster a better long-term treatment outcomes (Brox et al. 2012).

The spinal orthosis is designed with several general accepted principles according to Moe and Lonstein (Moe and Lonstein 1995): 1) Localized and direct pressure on bony prominences should be avoided as local ischemia and pressure sores may occur. 2) Distractive forces could be more effective biomechanically for larger curves and lateral forces for smaller curves. 3) Lateral forces are transmitted via the ribs going to the vertebra below the apex for thoracic curves and via the paraspinal muscles overlying the transverse processes for lumbar curves. 4) Force applied on the apex of the deformity should accompany with counterforce points on the opposite side to create three-point pressure system. 5) Passive correction is exerted and active correction aimed to be stimulated. 6) Lumbar lordosis should be designed to control the spine moving forward and further to achieve contact of the corrective force with the lumbar transverse processes. 7) Correcting pad applied to the ribs should control the curvature without restricting respiration and pulmonary function. Compression against chest, breasts and mandibula should be prevented to avoid any secondary deformities.

2.4 Initial in-orthosis correction

Along the orthotic treatment period, a serious of radiographs with or without orthosis will be taken to monitor the change of curvature. The initial in-orthosis radiograph is usually taken after adaption period (2-4 weeks for a patient to get used to the orthosis) to check the correction effect of initial orthosis application.

The initial in-orthosis correction is crucial for the long-term treatment outcomes (Emans et al. 1986, Peltonen et al. 1988, Upadhyay et al. 1995). Carr et al. (1980) followed 74 patients with idiopathic scoliosis until orthosis weaning and found that the final treatment outcomes were highly dependent on the in-orthosis correction, especially the in-orthosis correction during the first year of treatment. Quantitatively, over 50% initial in-orthosis correction indicated a good chance of obtaining significant long-term correction. In addition, ≥40% initial in-orthosis correction by Boston orthosis could predict significant higher chance of a successful outcome than that of <40%. Similarly, ≥80% initial in-orthosis correction in Charleston orthosis had significantly higher likelihood of a successful outcome than that of <80% (Katz et al. 1997). It also deserves to be mentioned that these findings cannot be interpreted as higher in-orthosis correction leads to better treatment outcomes, because the practice should aim at the best in-orthosis correction and at the same time the best possible comfort for the patient to foster compliance (Borysov et al. 2013).

A general standard of 40-50% of initial in-orthosis correction is usually regarded acceptable in the current clinical practice (Carr et al. 1980, Emans et al. 1986, Katz et al. 1997, Landauer et al. 2003, Knott et al. 2013). Carr et al. (1980) reported over 50% initial in-orthosis correction indicate a good chance of obtaining significant long-term correction in their long-term follow-up study. Emans et al. (1986) retrospectively reviewed 295 scoliosis patients with Boston orthosis until orthosis weaning for at least 1 year. They found the mean initial in-orthosis correction of all 295 patients is higher than that of the 33 patients who ended up with surgery (50% versus 36%). Hence, they proposed that 50% initial correction was needed to achieve curve control and more than 50% initial correction could expect long-term curve correction rather than only preventing progression. A more recent SOSORT guideline was in agreement with this standard and regarded at least 50% initial in-orthosis correction as "effective" bracing (Knott et al. 2013). Landauer et al. (2003) studied the influence of initial in-orthosis correction and compliance to the final treatment outcomes, they reported that girls with ≥40% early in-orthosis correction and a good compliance achieved 7° mean correction until the final follow-up, girls with＜40% early in-orthosis correction and a good compliance can barely maintain the Cobb angle as measured before orthotic treatment despite of their efforts of orthosis wearing. Therefore, more than 40% of initial in-orthosis correction should be aimed at to achieve a potential successful outcome , otherwise the limitation of quality of life while orthosis wearing may not be worthwhile (Weiss and Rigo 2011). Castro (2003) followed 41 patients with TLSO treatment until skeletal maturity and found that patients with progression revealed less than 34% initial in-orthosis correction, and patients with more than 15° progression exhibited 20% or less in-orthosis correction. Therefore, they suggested orthotic treatment not be prescribed to the patient whose in-orthosis correction was less than 20% as they may not benefit from the orthotic treatment.

However, using a general standard of initial in-orthosis correction for all the patients is not a patient-specific maneuver, given that the initial in-orthosis corrections are usually diverse among patients due to different spinal conditions (Steffan and Heinen 2014). For example, a patient with a curvature of 38°can be corrected to -14° while another patient with curvature of 40° can only be corrected to 38°, as demonstrated in previous studies (Weiss et al. 2007, Weiss and Rigo 2011).Therefore, a personalized initial in-orthosis correction according to individual condition should be aimed at.

In addition, most clinicians estimate the in-orthosis effectiveness by their personal experience and use it to guide the orthosis design in the current practice. While this empirical practice is not a scientific and evidence-based treatment maneuver, which would affect the effectiveness of orthosis consequently. A quantitative prediction of in-orthosis effect at pre-orthosis stage could also assist differentiating the patients who are unlikely to benefit from orthotic treatment (such as a patient with an expectation of less than 20% in-orthosis correction (Castro 2003) thus preventing unnecessary orthosis fabrication and application. To improve the current practice, scientific prediction of initial in-orthosis correction according to individual patient’s condition prior to orthotic application is necessary.

Prediction of the in-orthosis correction have been tried in vitro method. Through simulation of the orthosis on personalized biomechanical models on three patients with scoliosis, Clin et al. (2010) found that the initial in-orthosis correction is highly correlated with the bending moments acting on the apical vertebra (R^2 =0.88). Clin and his colleagues also successfully simulated orthoses with 12,288 kinds of designs on patient-specific finite element models (FEM). They found that the initial in-orthosis correction varied among orthoses of different designs. More specifically, the five most influential design factors were the position of the orthosis opening (posterior or anterior), the strap tension, the trochanter extension side, the lordosis design and the rigid shell shape (Clin et al. 2010). All these attempts contribute to a better visualization of the response of scoliotic spine to the orthotic installation. Nevertheless, the in-orthosis correction still cannot be directly predicted by the biomechanical models due to some limitations: the effect of muscle forces and other soft tissues which are important in orthosis biomechanics in the clinical setting could not be well simulated (Lebel et al. 2013), high technical skills and long computational time are needed to manipulate the FEM. Another tool based on a biomechanical model and a graphical interface - ‘‘Spine Surgery Simulator’’- was developed, while it was limited to assist the preoperative planning of instrumentation strategies and predict surgical correction (Aubin et al. 2008). Currently, the biomechanical models still need further improvement and validation before applying in clinic practice to predict the orthotic correction in a large scale.

Vivo methods have been tried for the prediction of initial in-orthosis correction as well. Flexible spines are expected to experience a better correction effect by orthotic treatment than rigid spines. Therefore, spinal flexibility has been used to predict the initial in-orthosis correction clinically. Some studies used the Cobb angle in the supine position to predict the magnitude of correction obtained by spinal orthosis (Wong et al. 1994, Vidyadhara and Mak 2008). However, detailed statistical data was not provided in those studies. Li et al.'s pilot study observed that the correction in supine position did not correlate with the correction achieved by an orthosis, while their observations were inconclusive due to the small sample size (n=9) (Li et al. 2014). Chekryzhev et al. (2009) reported that the curve angle in convex bending position was correlated with the Cobb angle after 3-month bracing (correlation coefficient=0.68), however, the reliability of their measurements in the lateral bending position was unclear due to the uncertain reliability of using "Spinal Mouse" to measure the curvature in the coronal plane.

Kuroki et al. (2012) proposed to use standing with traction position to estimate the in-orthosis correction, however the accuracy of this prediction was affected by the diverse maturity status of their subjects (at 9-18 years with Risser 0-5). They reported that the curve angle in standing with traction position was larger than that of in in-orthosis position in immature patients, while smaller than that in in-orthosis position in mature patients. A recent study reported that the curve angle in the supine with lateral bending position were the same as the initial in-orthosis correction with a mean difference of 0.28° (Ohrt-Nissen et al. 2016), whereas this finding may only be applicable to the Providence orthosis used in their study. The other methods, such as the supine with traction or fulcrum bending, predicted surgical correction but may not be applicable for the orthotic treatment. Thus, it is still unknown which method of spinal flexibility assessment is more effective to predict the initial in-orthosis correction. This question led to a comprehensive review on the spinal flexibility in the following section.

2.5 Spinal flexibility

2.5.1 Definition

Biomechanical definition

Flexibility refers to the ability of the structure to deform under application of a load. Stiffness is the property of a structure by which resistance is offered to an imposed displacement (Panjabi and White 1990). Flexibility coefficient (the ratio of the displacement produced to the load applied) instead of stiffness coefficient (the ratio of the resistance offered to the displacement imposed) was often used to quantitate the structural quality of spine because it is closer to the clinical concepts of spinal instability and range of motion (Panjabi and White 1990).

However, flexibility of human spine cannot be well represented by a single number calculated from loading and corresponding displacement, because the spine exhibits a complex, coupled three-dimensional rotatory and translational response to forces. Firstly, the spine has non-linear, elastic behavior. That is, the behavior of spine is biphasic: at small loads, the spine easily deforms with little resistance; as the load increases, the resistance also increases but at increasing rate. Secondly, the spine demonstrates the viscoelastic behavior, implies that the mechanical behavior of the spine varies with the speed of loading. Thirdly, if the spine is loaded for several times at the same direction, the behavior of the spine will be different every time (Panjabi and White 1990).

Clinical definition

Duval-Beaupere et al. (1985) defined the flexibility as collapse and reducibility of the spinal curvature, namely, the spinal curvature decreased with gravity reduction and lateral correction force respectively. Büchler et al. (2014) regarded the flexibility as the curvature change with the traction force. However, the force applied on the spine was difficult to be quantitatively and accurately assessed, which made these definitions less applicable in the clinical situation. To demonstrate the flexibility property of scoliosis spine, most clinical assessed the difference between the curve angle in standing position and the curve angle in a different position with correction effect (e.g. lateral bending flexibility).

Spinal flexibility is governed by the biomechanical properties of vertebrae, intervertebral disc, ligaments, capsules of the facet joints and rib cage. Analysis of preoperative flexibility in AIS is essential to classify the curves, to determine structural or nonstructural deformity, and to select the fusion levels for preoperative planning (Torell et al. 1985). The spinal curvature is regarded as structural if a curve cannot be reduced to 25° or less in a lateral bending position in Lenke classification, and the operative correction would only include the major curve and structural minor curves (Lenke et al. 2001). Preoperative flexibility radiographs was also used to aid the classification of curves into specific categories (curve type 1– 6) in order to select the optimal region(s) that need to be fused (King et al. 1983, Mccall and Bronson 1992). Shufflebarger and Clark (1990) advocated fusion to the vertebra above the disc space that neutralized on lateral bending radiographs.

2.5.2 Assessment methods

Vitro assessment on cadavers have been used to assess the spinal flexibility. Experiments on function spinal unit (FSU, the smallest motion segment that consists of two adjacent vertebrae and connecting ligament tissues) showed that the FSUs are more flexible in tension than in compression, and more flexible in flexion than extension, with lateral bending flexibility between flexion than extension (Panjabi and White 1990). These biomechanical tests are vital in deepening the understanding of spinal flexibility, however, vitro methods are not clinically applicable because the pediatric scoliotic cadaver spines are not always available, do not include the rib cage and muscle activity, and a real patient's biomechanics in need of a tailored therapeutic approach cannot be reflected (Hasler et al. 2010).

Vitro assessment to compare the curve angle in standing position and in a different position with correction force on the spine is the primary method to assess spinal flexibility in the current practice. Various attempts have been made to detect the response of the scoliotic spine to the forces application, and five categories of assessment method have been introduced in the past (He and Wong 2018)：(1) lateral bending method (supine / standing with lateral bending, fulcrum bending); (2) recumbent method; (3) manual correction method (supine / prone with manual correction); (4) traction method (standing / supine traction, supine traction under general anesthesia(UGA)); (5) traction and manual correction method (with / without anesthesia). The comparisons among different methods are summarized in Table 2.1 (He and Wong 2018).

Table 2.1 Comparison of spinal flexibilities in different assessment methods

Assessment methods		Correction force	Reproducibility	Radiation	Applicability	Easy operation	Flexibility	Others
Lateral Bending Method	Supine / stand with lateral bending	*	*	*	*	#	≈surgery (traditional instruments) < surgery (modern instruments)	most commonly used
	Fulcrum bending	*	#	*	*	#	> SLB ≈surgery	less applicable to upper thoracic curves
Recumbent Method	Supine	*	#	#	#	#	< SLB < surgery	far less than operative correction
Manual Correction Method	Prone with manual correction	*	*	*	#	#	< SLB < surgery	can provide information of LIV and spinal balance
	Supine with manual correction	*	*	*	#	#	≈SLB < surgery	
Traction Method	Standing traction (Suspension)	#	*	#	#	*	< SLB	applicable for EOS
	Supine traction	*	#	#	#	#	< SLB (Cobb<50°) > SLB (Cobb>50°)	can provide information of LIV and spinal balance
	Supine traction UGA	*	#	#	#	*	> SLB ≈ surgery	cannot give preoperative planning due to anesthesia
Traction and Manual Correction Method	Supine traction and manual correction	*	#	*	#	*	> SLB ≈ surgery	time consuming for setup
	Supine traction and manual correction UGA	*	*	*	#	*	> SLB ≈ surgery	cannot give preoperative planning due to anesthesia

SLB: supine with lateral bending UGA: under general anesthesia LIV: last instrumented vertebrae
Correction Force: # relatively standardized * less standardized
Reproducibility: # relatively high * relatively low
Radiation: # relatively low (one capture can demonstrate both right and left side curves in the radiograph)
* relatively high (two captures are required for demonstrating right and left side curves, or examiners may be exposed to radiation)
Applicability: # can be applied to less collaborative patients * not applicable to less collaborative patients
Convenience: # relatively simple implementation * relatively complicated implementation

Lateral bending method

Supine with lateral bending method is commonly used for spinal flexibility assessment. It is performed with a patient actively bending the trunk to the lateral side when lying down on an examination couch (Figure 2.6). Supine position reduces axial loading, self-lateral bending generates lateral correction force, and supporting surface exerts abdominal directed force to the spine, the combination effect of the three-dimensional force could result in deformity correction.

Approximately 50-60% of curvature correction was reported in supine with lateral bending position on the patients with severe scoliosis (Cheung and Luk 1997, Vedantam et al. 2000, Beuerlein et al. 2003). Transfeldt and Winter (1992) found an average of 88% correction of the lumbar curves and an average of 51% correction of the thoracic curves. Higher flexibility of the lumbar curves than the thoracic curves on lateral bending radiographs was also reported by another study (Lenke et al. 1992). The lower flexibility of thoracic curve may be due to the restriction of rib cage and sternum, as proved by a computer-simulated mathematical analysis of the thoracic spine that the rib cage enhances the stability of the normal thoracic spine during lateral bending (Andriacchi et al. 1974, Lenke et al. 1992).

Vertebrae rotation of the spine during supine with lateral bending was also reported previously. Aronsson et al. (1996) reported 12-36% decrease of apical vertebra rotation (AVR) in lateral bending position on the patients with severe scoliosis, while no significant improvement of axial rotation was observed by Beuerlein et al. (2003). Theoretically, lateral curvature and axial rotation are coupled and they change in tandem in response to lateral bending (Veldhuizen and Scholten 1987).

But whether this change can be accurately detected is still unknown since vertebrae rotation is usually small in magnitude and the rotational changes are even smaller compared with measurement variation.

Postoperative correction was commonly predicted by the supine with lateral bending method in past few decades. Takahashi et al. (1997) reported that the correlation of the Cobb angle in supine with lateral bending and postoperative radiograph are 0.81 and 0.41 in thoracic and lumbar curves respectively. King et al. (1983) and Lenke et al. (1992) also reported good predictability of supine with lateral bending method to postoperative correction, but the specific correlation could not be traced. Even though supine with lateral bending was widely used to predict the surgical correction using traditional instruments such as Harrington instrumentation, its predictability to the correction using modern instruments began to be questioned as the improved correction by up-to-date instruments. Aronsson et al. (1996) demonstrated the inaccurate prediction of supine with lateral bending method as lateral bending (22° correction); Harrington instrumentation (23° correction); Wisconsin wires (29° correction) and Texas Scottish Rite Hospital instrumentation (36° correction). Its inability to predict the correction of pedicle screws and Cotrel-Dubousset system was reported as well (Gotfryd et al. 2011).Greater postoperative correction than that revealed on the supine lateral-bending radiograph was observed in other studies (Aronsson et al. 1996, Cheung and Luk 1997). For better predicting postoperative correction and avoiding unnecessary fusion, more and more new methods were proposed and investigated in recent years.

There are several advantages and limitations of supine with lateral bending method. Lateral bending method can not only provide information of spinal flexibility, but also assist to determine structural or nonstructural curves and select the fusion levels for preoperative planning (Torell et al. 1985). The spinal curvature is regarded as structural if the curve cannot be reduced to 25° or less in a lateral bending position (Lenke et al. 2001). Shufflebarger and Clark (1990) suggested fusion to the vertebra which located above the disc space that was neutralized on lateral bending radiographs. Besides, lateral bending method allows surgeons to observe the respond of curve to a lateral force that is similar to surgical correction force.

Figure 2.6 Supine with lateral bending test
(Gotfryd et al. 2011)

However, the reproducibility of voluntary lateral bending is unclear considering active cooperation of the patients are required (Watanabe et al. 2007). Self-correction method is less applicable to the patients who are mentally retarded or have neurological / muscular disorders (Cheung and Luk 1997). In addition, younger patients (<15 years) may lack the internal power required for lateral bending due to immature development of skeletal muscle, which would in turn affect the correction effect (Watanabe et al. 2007).

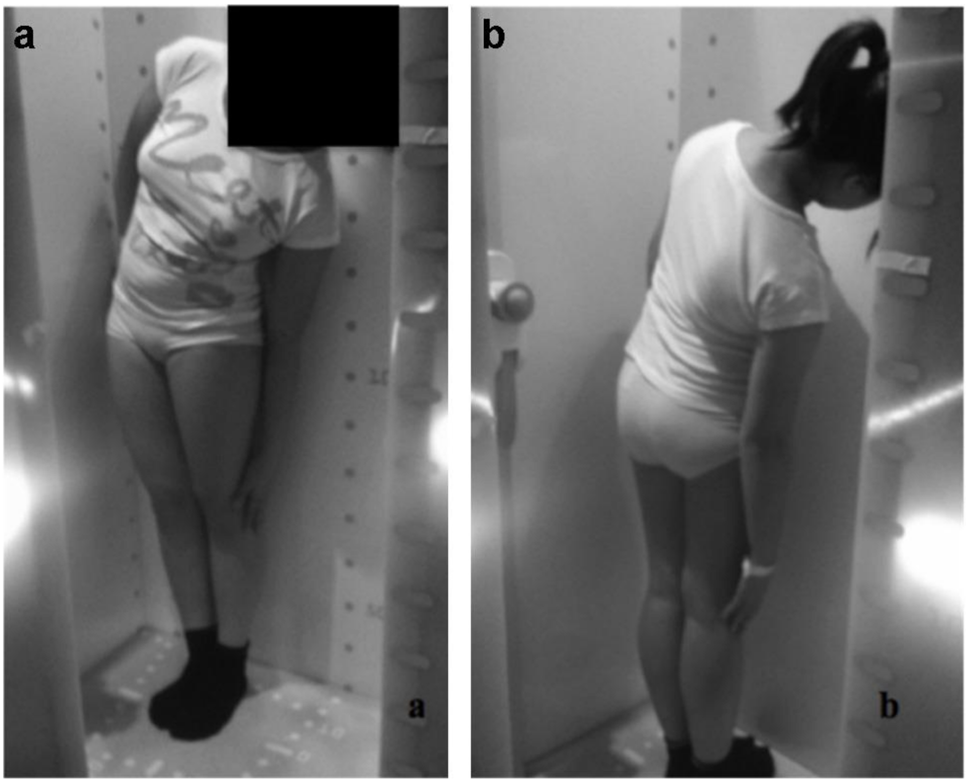

Figure 2.7 Standing with lateral bending test
(Hirsch et al. 2016)

Standing with lateral bending was also proposed for spinal flexibility assessemnt (Figure 2.7). Two studies presented at the Scoliosis Research Society meeting in 1992 showed that supine bend films were better in demonstrating spinal flexibility and predicting postoperative correction than standing bending film (Shufflebarger

1992, Transfeldt and Winter 1992). Transfeldt and Winter (1992) demonstrated higher spinal flexibility of supine than that of standing with lateral bending with average thoracic curve angle of 47° (standing), 32° (standing with bending), 23° (supine with bending) and average lumbar curve angle of 34° (standing), 12° (standing with bending) and 4° (supine with bending). Shufflebarger (1992) further found higher predictability of supine with lateral bending flexibility to the postoperative correction with average thoracic curve angle of 43° (standing), 28° (standing with bending), 22° (supine with bending), 15° (post-operation) and average lumbar curve angle of 35° (standing), 16° (standing with bending), 8° (supine with bending), 10° (post-operation). However, a recent study by Hirsch et al. (2016) found no significant difference between the spinal flexibility in supine and standing with lateral bending with average thoracic curve angle of 53° (standing), 23° (standing with bending), 24° (supine with bending) and average lumbar curve angle of 38° (standing), 5.5° (standing with bending) and 8° (supine with lateral bending). The discrepancy may be due to the difference in subjects and assessment techniques: Transfeldt and Winter (1992) and Shufflebarger (1992) conducted a study on around 20 subjects using traditional X-ray system while Hirsch et al.'s study assessed the spinal flexibility of 50 subjects using contemporary EOS system.

Fulcrum bending method was firstly applied to assess the spinal flexibility by Cheung and Luk (1997). It is performed with the patient lying on his or her side over a bolster (a radiolucent plastic cylinder), which is placed under the apex of a lumbar curve or the rib corresponding to the apex of a thoracic curve. The shoulder and the pelvis are perpendicular to the x-ray beam, with either being lifted off the table to allow a maximum passive bending force to be applied (Figure 2.8). More recently, they modified the bolster to a triangular prism–shaped foam with rounded and padded edges for clinical convenience (Cheung et al. 2014). The fulcrum bending test was claimed reproducible and especially useful for stiffer curve, therefore it has replaced the lateral bending test in the routine preoperative assessment in some institutions (Cheung and Luk 1997).

Figure 2.8 Fulcrum bending test
(Li et al. 2013)

Higher spinal flexibility in fulcrum bending method than supine with lateral bending method has been reported (Cheung and Luk 1997, Luk et al. 1998, Hamzaoglu et al. 2005). In Cheung's study, the mean coronal Cobb angles were 58°, 31°, 24° in the standing, supine with lateral bending and fulcrum bending radiographs, which demonstrated significant higher flexibility of fulcrum bending (59%) than that of supine with lateral bending (47%) (Cheung and Luk 1997). Hamzaoglu et al. (2005) only found a higher fulcrum bending flexibility than supine with lateral bending in thoracic curves (74% versus 66%) but similar spinal flexibility in lumbar curves (83% versus 81%), which was in agreement with findings in the study by Klepps et al. (2001). The possible reason is that thoracic correction force is generated from the bolster in the fulcrum bending test and ribs facilitate the force transformation to the vertebrae, while the correction force is generated from active muscle contraction in the supine with lateral bending test and the correction could be restricted by the ribs. In the lumbar region, the fulcrum bending no longer apply force through ribs but through soft tissues and internal organs, therefore the correction effect could probably be overtaken by the supine with lateral bending.

Postoperative correction has been predicted by the fulcrum bending method. Cheung and Luk (1997) reported that the mean Cobb angle in fulcrum bending radiograph and postoperative radiograph were almost identical (24° and 25° respectively), while that in supine with lateral bending radiograph and postoperative radiograph were different (31° and 25°). They stated that the fulcrum bending radiograph was more predictive to the surgical correction than the supine with lateral bending radiographs, and especially useful for stiffer curves (> 40° on the lateral bending radiograph) since unnecessary anterior release might be avoided. Klepps et al. (2001) reported higher surgical correction than fulcrum bending correction and supine with lateral bending correction in thoracic curves (60%, 50%, 42% respectively, $P < 0.05$), no significant difference of surgical correction, fulcrum bending correction and supine with lateral bending correction in upper thoracic and thoracolumbar / lumbar curves (69%, 64%, 54%, respectively, $P > 0.05$). In addition, Luk et al. (2011) reported the AVR correction approximated a mean 82.7% of postoperative apical vertebral derotation in fulcrum bending position, therefore this method could predict the amount of apical vertebral derotation by posterior spinal fusion.

Some new parameters were introduced with the development of fulcrum bending method, such as fulcrum bending correction index (FBCI) (Luk et al. 1998), fulcrum segmental flexibility. FBCI refers to the ratio between postoperative correction and fulcrum flexibility. A FBCI close to 100% suggests that the surgery has taken up all the flexibility revealed by the fulcrum bending radiograph. It is considered superior to describe the correction effect as it accounts for spinal flexibility (Luk et al. 1998, Yang et al. 2015). Segmental flexibility refers to the segmental responses of scoliotic curves to load (Hasler et al. 2010), as shown in Figure 2.9. Spinal flexibility was not uniform throughout the curve and different segments exhibit greater flexibility / correctability than others. Therefore, Yao et al. (2017) suggested the spinal flexibility in segmental level to be assessed in the clinical decision-making strategy.

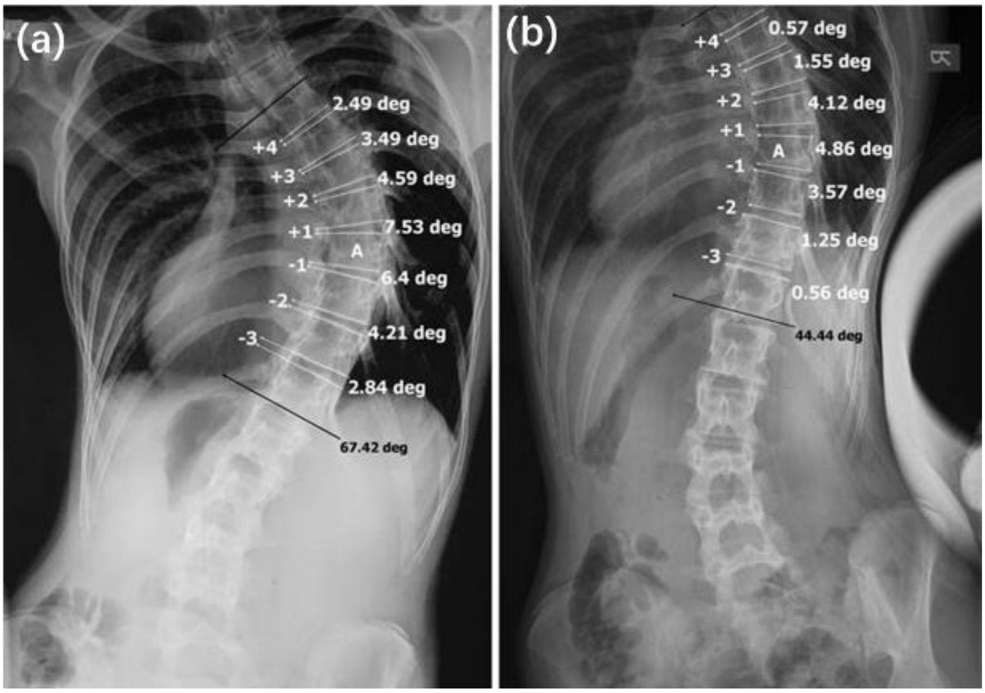

Figure 2.9 Segmental flexibility

Spinal flexibility assessed from the angle of disc wedging in (a) standing position (b)fulcrum bending position (Hasler et al. 2010)

Recumbent method

The spinal flexibility (curve correction) in supine position (Figure 2.10) was demonstrated in biomechanical models. Haderspeck and Schultz added axial load (gravity) to a biomechanical model of spine to mimic postural change from supine to standing, and a significant increase of the scoliosis curve was detected (Haderspeck and Schultz 1981). Supine position provided an approximate "zero load" configuration for the spine, which could act as a starting point for numerical simulations of biomechanical modeling of scoliosis (Adams and Dolan 2005).

An average of 8°-17° reduction of coronal Cobb angle from standing to supine position was reported in previews literatures (Torell et al. 1985, Yazici et al. 2001, Park et al. 2003, Hwang et al. 2008). Zetterberg et al. (1983) reported the correction of 19% and 31% for thoracic and lumbar curves respectively. An average of 6° reduction in apical vertebral rotation between standing and supine position was also detected in the study by Yazici et al. (2001), which indicates the similar improvements comparing with coronal correction (24 % versus 30%). The rotational decrease (6%) in supine position was also reported in Hwang's study but lower than Yazici et al.'s findings (Hwang et al. 2008). The observed rotational correction in recumbent position may because that the body supporting surface pushes the deformed ribs and facilitate rib hump symmetry, hence vertebrae body derotation occurs along with the shape change of the ribcage. In addition , a high correlation between the curve angle in supine position and that in lateral bending position suggested that the supine radiograph may supplant lateral bending radiograph to determine structural or nonstructural curve (Cheh et al. 2007). While attention should be paid to the change of end-vertebrae along with the postural change on the radiographs (Hwang et al. 2008).

Prone position is not commonly adopted for spinal flexibility assessment on the coronal plane but for vertebrae rotation assessment on the transverse plane, because prone is the primary position for Computed tomography (CT) scanning which could accurately reveal the transverse plane deformity (vertebral rotation and ribcage shape) (Krismer et al. 1996). Abul-Kasim et al. (2010) measured the AVR of patients with severe scoliosis on CT image retrospectively and reported 15% spontaneous correction comparing to standing position.

Figure 2.10 Supine test

Prone position has been used to assist preoperative planning (Figure 2.11). Liu et al. (2010) reported that the intraoperative prone radiograph revealed higher spinal flexibility than supine radiograph and less than the supine traction radiograph. Prone position provides the measurement of vertebral rotation in a body position identical to that the surgeons usually faced with on the operating table, thus can be used to assist screw insertion (Abul-Kasim et al. 2010). Besides, prone position was claimed advantageous in less positioning variation and greater patient comfort, particularly in the immediate post-operative period (Scutt et al. 1996). Nevertheless, prone position may not be advocated for the early detection of scoliosis because it produces lower apical trunk inclination (ATI) readings than standing or sitting forward bending position (Burwell et al. 2001).

Figure 2.11 Prone test

Traction Method

Supine traction radiograph can be obtained by applying traction force through a cervical halter from the top and counter-traction force through pelvis halter from the bottom (Figure 2.12). In order to reveal higher inherent flexibility, the supine traction could also be performed under general anesthesia (UGA) intraoperatively.

Figure 2.12 Supine with traction test
(Hirsch et al. 2015)

Supine traction showed lower flexibility than supine with lateral bending for curves less than 60°, whereas higher flexibility for curves over 60° (Vaughan et al. 1996, Büchler et al. 2014). These findings validated that higher correction could be achieved with axial loading for severe curves and with transverse loading for moderate curves (White and Panjabi 1990, Polly and Sturm 1998). When supine traction was performed UGA, the flexibility increased to be higher than that of supine with lateral bending regardless of curve magnitude (Davis et al. 2004). This indicated that patient's muscle spasm could strongly affect curve correction during the flexibility assessment. It should be noted that the number of involved vertebrae in a curvature may influence the superiority of traction to side-bending in revealing the spinal flexibility (Watanabe et al. 2007). Watanabe use a biomechanical model (Figure 2.13) to explain the influence of curve magnitude and number of involved vertebrae on lateral bending and traction method. They supported that better correction can be obtained using lateral bending as the number of involved vertebrae increase, the traction would relatively superior to lateral bending as the curve magnitude increases.

For the prediction of postoperative correction, the supine traction and supine with lateral bending method was reported with equivalent ability (Takahashi et al. 1997). In comparison, supine traction method was superior in imaging the entire spine to evaluate the spinal balance (Moe and Lonstein 1995, Hamzaoglu et al. 2005), supine with lateral bending method was advantageous in evaluating the mobility of each disc space in the lumbar region (Bradford 1988). Davis et al. (2004) and Hamzaoglu et al. (2005)reported that the supine traction UGA reveal higher spinal flexibility and better predict postoperative correction than supine with lateral bending method, which may be owing to the increased correction achieved by anesthesia. Anesthesia reduced the influence of soft tissue such as the interspinous ligaments, facet joint capsules and intervertebral discs thus revealing higher spinal flexibility, especially for thoracic or higher lumbar curves which gradually become stiffer as a result of facet degeneration and arthritic changes (Hamzaoglu et al. 2005). In addition, supine traction UGA is applicable to the patients with neuromuscular disorders and/or mental retardation as self-effort and patient's cooperation is not required. However, the limitation is that surgical plan cannot be finalized until traction UGA radiograph is taken right before the surgery.

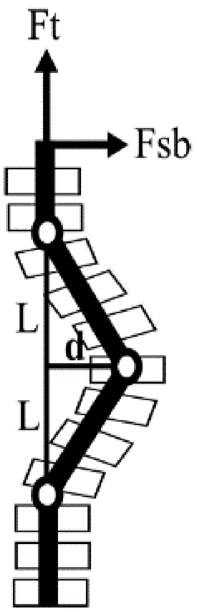

Figure 2.13 Model of comparison between lateral bending and traction test

It is assumed that the curve is comprised of 2 arms connected with 1 joint. The number of involved vertebrae is expressed as "2 × L" and the curve magnitude is expressed as "d". Thus, the moment (Nsb) induced from the side bending force (Fsb) is expressed as "Nsb = L × Fsb", which indicates that the moment (Nsb) will increase as the number of involved vertebrae (L) increases. The moment (Nt) induced from the traction force (Ft) is expressed as "Nt = d × Ft", which indicates that the moment (Nt) will increase as the curve magnitude (d) increases(Watanabe et al. 2007)

Standing with traction (suspension) method is a relative new method proposed for spinal flexibility assessment in recent years (Figure 2.14). It is performed with some variation among studies: patients could be hanged onto a bar with toes touching floor (Kuroki et al. 2012), or raised patients by Sayre collar with the tip of toes on the floor (Büchler et al. 2014, Hirsch et al. 2015), or lifted patients by a axillary harness with feet leaving floor , or suspend patients with cervical traction head halter with 30% body weight force applied (Lamarre et al. 2009).

Comparing standing with traction and supine with traction method, Hirsch et al. (2015) found the two methods revealed similar flexibility for main curves (42% versus 45%), while lower flexibility of standing with traction method for distal curves (43% versus 54%). This may be because a direct traction force is applied on the hip during the supine with traction test whereas the load is only applied to the cervical spine during the standing with traction. Comparing standing with traction and supine with lateral bending method, the standing with traction test induced similar curvature reduction as supine with lateral bending (39% versus 37%) (Lamarre et al. 2009). The ability of the suspension method to predict postoperative correction has not been reported and deserved further investigations.

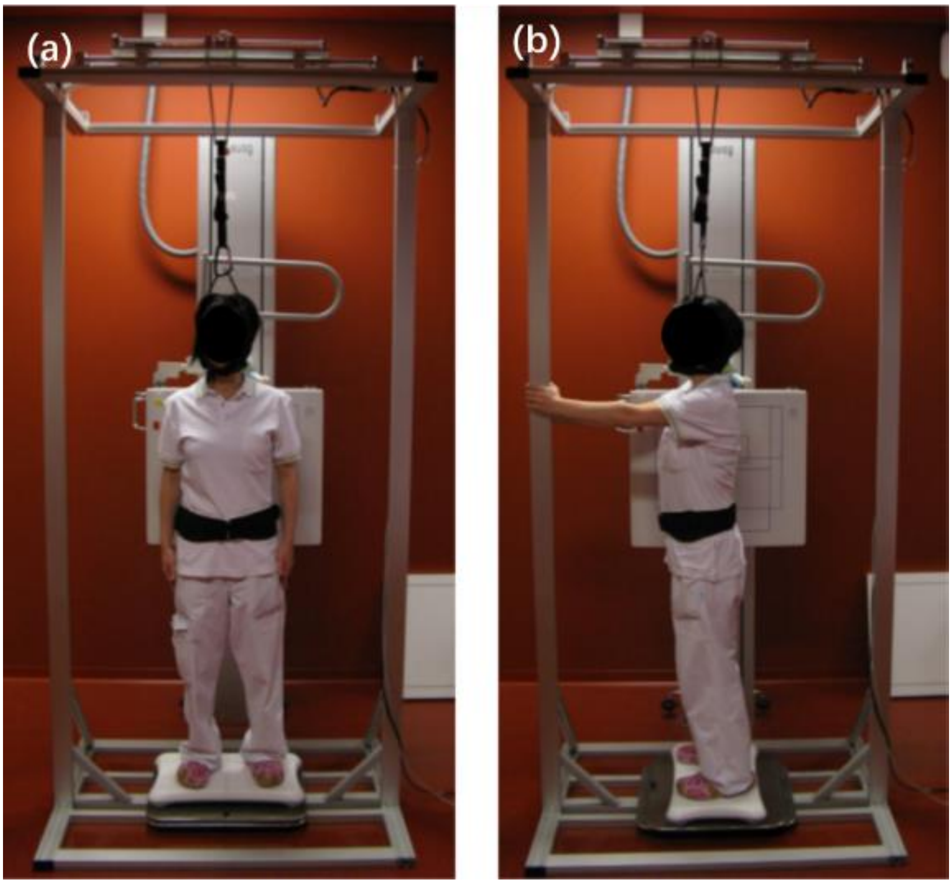

Figure 2.14 Standing with traction test
(a) coronal view (b) lateral view (Büchler et al. 2014)

Correction of vertebra rotation was demonstrated during standing with traction test, while the rotational correction was related to the coronal curve magnitude (Matsumoto et al. 1997). They reported that curves with Cobb angle < 40° showed decreased vertebrae rotation in association with decreased coronal Cobb angles in response to axial traction. In contrast, more severe curves with Cobb>40° showed no improvement in vertebral rotation despite improvement in coronal Cobb angle. The factors that inhibited rotational correction could be wedged vertebrae body, deviated vertebrae disc or muscle contracture on the concave side (Toyama 1988). In addition, more correction of AVR in lumbar region than in thoracic region (11.9%

versus 1.8%) suggested that the ribcage may assist correction of rotational deformity (Matsumoto et al. 1997).

The standing with traction method is advantageous in applying quantitative force (mainly depends on the patient's body weight) which enables the measurement of the biomechanical flexibility rather than curve reducibility (Petit et al. 2004, Watanabe et al. 2007, Kuroki et al. 2012). Büchler et al. (2014) quantifield the overall biomechanical flexibility of patients in their study as ranging from 0.3 °/Nm for stiffer curves to 2 °/Nm for less rigid curve, using the standing with traction method. A linear correlation was also found between the biomechanical flexibility and the Cobb angle reduction. Lamarre et al. (2009) reported the average flexibility as 1.65°/Nm (range: 0.85 –2.91) and no correlation was demonstrated (R^2=0.241) between the biomechanical flexibility and the Cobb angle reduction, but their observations were inconclusive due to the small sample size (n=5). Although standing with traction method is promising in assessing qualitative spinal flexibility, the patient's acceptance and comfort are still a concern which needs to be improved.

Manual correction method

Manual correction method is usually performed with examiners applying translational correction forces on the trunk when the patient is lying in prone or supine position (Figure 2.15). A medial translational force is applied to the torso that corresponds to the apex of the primary curve, and counter forces are applied to the opposite side of the trunk at the axilla and the pelvis region thereby creating three-point correction force on the spine (Vedantam et al. 2000).

Prone with manual correction test was reported with lower flexibility than supine with lateral bending and less accuracy to predict the postoperative correction because the Cobb angle on prone with manual correction radiograph was larger than that on supine with lateral bending and postoperative radiograph (Vedantam et al. 2000), but the corrected Cobb angle was reported of no difference with the corrected angle by surgery in another study (Kleinman et al. 1982). The diverse measurement parameters and surgical instrumentations in different studies made it difficult to draw a solid conclusion. The clinical value of prone with manual correction has been highlighted previously: it better predicts the translational correction and rotation of the last instrumented vertebra (LIV) than supine with lateral bending (Vedantam et al. 2000), assesses spinal balance via demonstrating the correction effect of primary curve on the upper and lower curves (Klepps et al. 2001), and exposes patients to less radiation via showing structural and compensatory curve correction on the same radiograph.

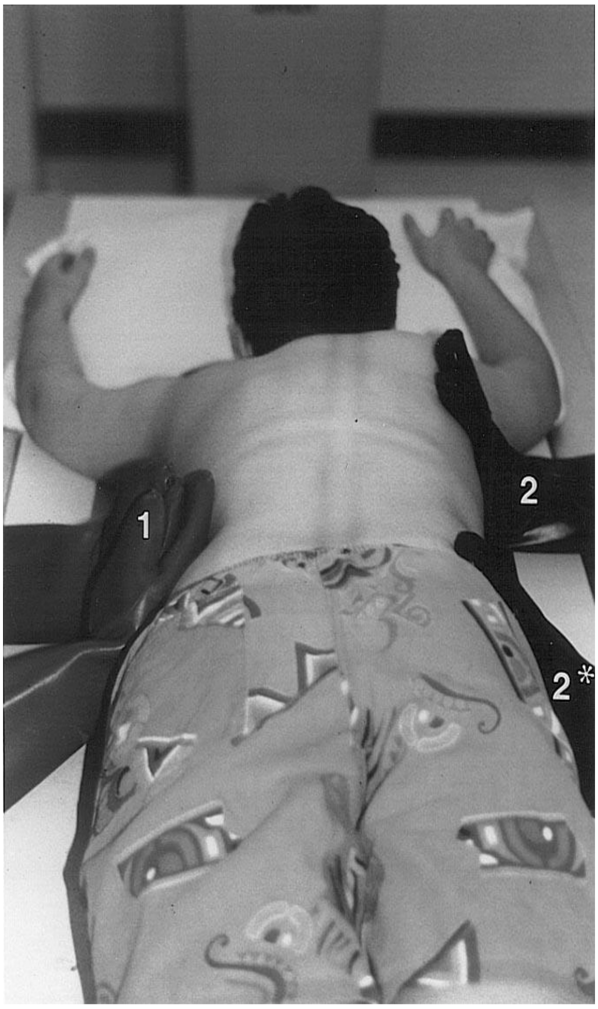

Figure 2.15 Prone with manual correction test
(Vedantam et al. 2000)

Supine with manual correction demonstrated similar spinal flexibility with supine with lateral bending method, but both methods showed less curve correction than postoperative correction (Rodrigues et al. 2014). High reproducibility of manual correlation than self-lateral bending was also claimed in Rodrigues et al.'s study which may because that the force applied by examiners could be better controlled and less affected by the patient's effort or curve patterns.

Traction and manual correction method

Traction and manual correction is performed by applying traction force under axillae and ankles, meanwhile applying translational force at the apex of the convexity of the curve (Figure 2.16). The traction and manual correction force could also be applied automatically by an electric correction bed as described in the study by Chen et al. (2011).

Supine traction and manual correction without anesthesia revealed higher flexibility on main thoracic curves, equivalent flexibility on thoracolumbar / lumbar curves comparing with supine with lateral bending (Chen et al. 2011). When this method was performed with anesthesia, greater flexibility than supine with lateral bending was observed regardless of curve location (Rodrigues et al. 2014), greater flexibility than fulcrum bending was also demonstrated (Ibrahim et al. 2008). This indicates that muscle spasm may greatly restrict the correctability of scoliotic curve in the flexibility test.

Figure 2.16 Traction and manual correction test under general anesthesia (Ibrahim et al. 2008)

Comparing supine traction and manual correction method to supine with lateral bending, standing with traction and fulcrum bending method, the traction and manual correction method showed the highest flexibility and the closest correction value with the postoperative correction (Chen et al. 2011). The high correction achieved could be explained by the dual effect of lateral and axial correction force to the scoliotic spine. When the traction and manual correction was performed UGA, even higher flexibility and high correlation with postoperative correction was also demonstrated (Rodrigues et al. 2014). Currently, this method is still not widely used considering the standardization of implementation and the feasibility of intraoperative arrangement.

Summary

The previous literatures on assessment methods for spinal flexibility was reviewed aiming to understand a more effective method for the in-orthosis correction prediction. However, the proposed methods in previous literatures were mainly for the prediction of surgical correction. Only three methods (supine, standing with traction, supine with lateral bending) were used to predict the orthotic correction, among which limited statistical data was provided and controversial findings were reported. The focus of current researches of spinal flexibility were mainly on surgical patients, because spinal flexibility was a routine assessment to define structure / non-structure curve, select treated segment, identify neutral vertebrae and predict postoperative correction in current practice. The spinal flexibility was seldom routinely assessed on the patients with orthotic treatment since the parameters such as fusion level were not required for orthotic intervention. In a summary, the literatures on utilizing the spinal flexibility for surgical correction prediction had been established, while the knowledge of using spinal flexibility to predict orthotic correction was lacking.

A more comprehensive review on previous work led to some knowledge gaps and possible solutions. Firstly, which assessment method of spinal flexibility was more predictive for surgical correction is still unknown. The variations on studied subjects, surgical technique / instruments, assessment procedure / protocols of different studies made it difficult to establish a formidable database for comprehensive and homogeneous comparison. Besides, experts' opinions varied on the optimal assessment method of spinal flexibility for the prediction of surgical correction. The AOSpine Knowledge Forum Deformity performed a modified Delphi survey on 48 experts from 29 countries to gather their opinions of the optimal assessment method of spinal flexibility (De Kleuver et al. 2014). The percentage of agreement among experts were fulcrum bending (10 %), traction (20 %), supine side bending (5 %), both fulcrum bending and supine with lateral bending (65 %) for the patients with curvature 40° - 70°. The percentage of agreement were fulcrum bending (33 %), traction (38 %) and supine side bending (29 %) for the patients with curvature 70° - 90°. Secondly, recumbent and lateral bending methods demonstrated higher potential to predict the in-orthosis correction than other methods. Among the five categories of flexibility assessment methods introduced previously (lateral bending methods, recumbent methods, traction methods, manual correction methods, traction and manual correction methods), the latter 3 categories showed less potential: severe scoliotic spine was more responsive to axial forces (traction methods), manual correction methods were relatively complex in implementation and less standardized in correction force, traction and manual correction would reveal excessive curve correction to render the correction by conventional treatment. The former 2 categories could be relatively applicable and feasible for the prediction of in0orthosis correction, considering recumbent method revealed the response of spine to longitudinal gravity reduction and lateral bending methods involved self-bending force that is potentially suitable for moderate curves. Basing on the previous literatures, potential methods out of the lateral bending methods category and recumbent methods category deserved further exploration to study an effective assessment method of spinal flexibility for the prediction of initial in-orthosis correction.

However, comparison among spinal flexibilities may not be feasible because it required X-ray taking in different body positions that exposed patients to high radiation. An alternative imaging technique which could assess the spinal flexibility with less or even no radiation should be sought for. With this purpose, the possible imaging techniques for spinal curvature assessment was reviewed in the following section.

2.5.3 Assessment techniques

X-ray radiography

The posteroanterior full length standing spine radiograph with curvature measurement using Cobb method has been most commonly used to diagnose and monitor scoliosis (Klos et al. 2007). When a primary beam passes through human body, some x-rays energy is absorbed and the remaining is captured by a detector. Basing on the information collected from the detector, a superimposed 2D image with internal structures was displayed. The good contrast power of X-rays in differentiating bone and soft tissue (Chan et al. 2013) enables determining the severity of deformity as well as apical vertebrae, vertebrae rotation, spinal balance, Risser sign , etc. (Yazici et al. 2001, Chan et al. 2013). While the inherent limitation of the ironizing radiation of X-ray radiography relates to a higher incidence of breast cancer. Doody et al. (2000) reported that nearly 15% of patients undergone more than 50 radiographic examinations, and approximately 17% received an estimated cumulative radiation dose of more than 20 cGy.

Cobb method is the most common method to measure the coronal curvature on radiograph. The Cobb angle was defined as the angle between the superior endplate of the most tilted superior affected vertebra and the inferior endplate of the most tilted inferior affected vertebra. Cobb measurement is the mainstay of diagnosis, epidemiological analysis, monitoring and therapeutic intervention in scoliosis. Ferguson method is another approach for coronal curvature measurement. The scoliotic curvature is determined by the intersection angle of 2 lines: one connects the center of the apical vertebra and the center of the superior end vertebra, another connects the center of the apical vertebra and the center of the inferior end vertebra (Diab et al. 1995, He et al. 2009). As a part of assessment, radiographs in the lateral review are usually taken during the first clinical consultation to acquire additional information (e.g. sagittal deformity and balance) to assist treatment planning (Schmitz et al. 2001).

Confounding factors such as measurement errors, standardization of image acquisition, positioning of a patient as well as postural and diurnal variations may affect the accuracy of radiographic measurement (Pruijs et al. 1994, Rigo 2011). The inter- and intra-observer variability of Cobb angle measurement was 3° ~ 8° (Morrissy et al. 1990, Shea et al. 1998). Diurnal variation can result in 5°

measurement difference (Beauchamp et al. 1993). As the wide usage of computer-aided software which minimizes the subjective factors such as end-vertebrae selection, the measurement variability and error have been reduced in recent years (Chockalingam et al. 2002, Stokes and Aronsson 2006, Zhang et al. 2009, Chen et al. 2013).

For spinal flexibility assessment, radiography was regarded superior than the other imaging techniques as it allows positioning patients in various postures, while CT and MRI are usually conducted in recumbent positions and EOS mainly allows for the upright position. In terms of feasibility and practicality, X-ray based radiography is the primary technique adopted for spinal flexibility assessment in the current practice.

Computerized tomography

Computerized tomography (CT) could acquire detailed morphological structures of vertebrae in three dimensions and generate 3-D spine model of scoliosis (Ding et al. 2009, Heo et al. 2010), as shown in Figure 2.17. It uses multiple views sampled at angular spacing to produce tomographic images, in which the spinal deformity in transverse plane can be captured in high resolution. Hence vertebrae rotation can be accurately measured on CT images, with the commonly used Aaro-Dahlborn and Ho's method (Aaro and Dahlborn 1981, Ho et al. 1993).

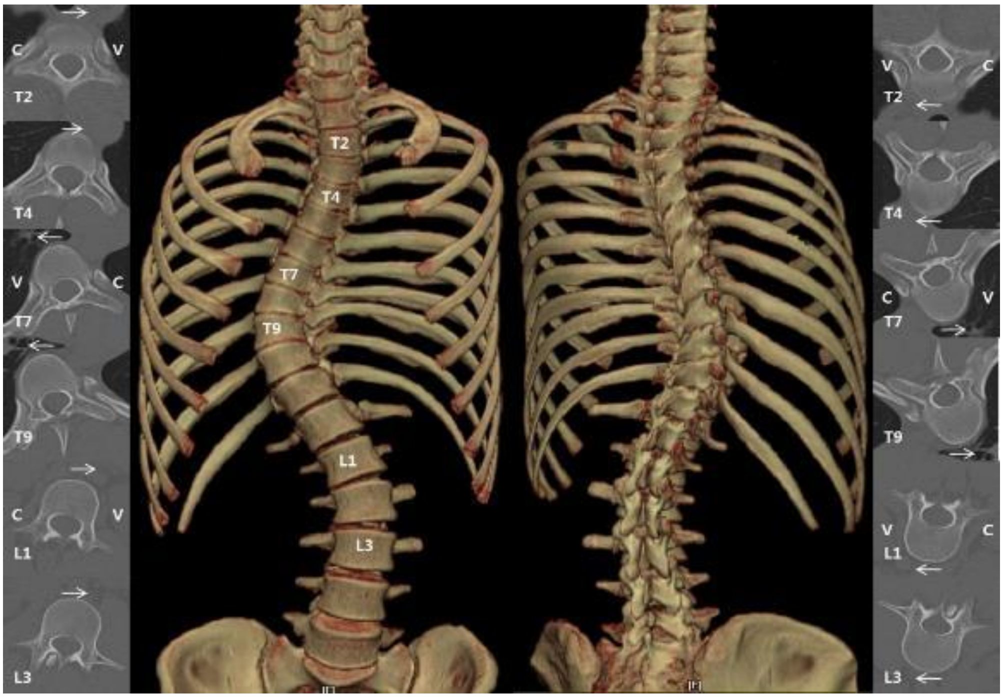

Figure 2.17 CT image of scoliotic spine
(Hong et al. 2013)

However, CT scan is not routinely taken for all patients with scoliosis and primarily used to assess a section of spine to identify the underlying causes or assess post-operative complications (Imagama et al. 2011). The reason could be that non-weight-bearing recumbent position is adopted in CT scanning which may underestimate the deformity (Zetterberg et al. 1983). Furthermore, the location accuracy of trunk axis is affected by the deformed ribcage on the CT image (Matsumoto et al. 1997). Most importantly, CT scanners emit much more ionizing radiation than conventional radiography (Aaro and Dahlborn 1981), which is an important consideration for adolescents due to the greater radiation sensitivity and higher risk of developing fatal cancer .

To reduce radiation exposure in the patients with scoliosis, new imaging technologies, such as stereo-radiography (EOS), magnetic resonance imaging

(MRI), ultrasound (US) and surface topography, are exploring to visualize the characteristics of scoliotic spine.

EOS

The EOS imaging system scans patients with coronal and lateral X-ray sources and provides simultaneous radiographs of the two planes. Then the details (simultaneity and orthogonality) of several landmarks digitized on both radiographs are combined and a priori statistical knowledge is utilized to reconstruct a 3-D envelope of the spine (Figure 2.18). The radiation dose of EOS decreases 6–9 times and image quality improve over computed radiography (Deschênes et al. 2010, Mckenna et al. 2012). The accuracy of EOS reconstruction was claimed as similar as CT technique (Glaser et al. 2012). However, it is still not widely used due to its high acquisition, maintenance costs as well as the long time required for 3-D reconstruction.

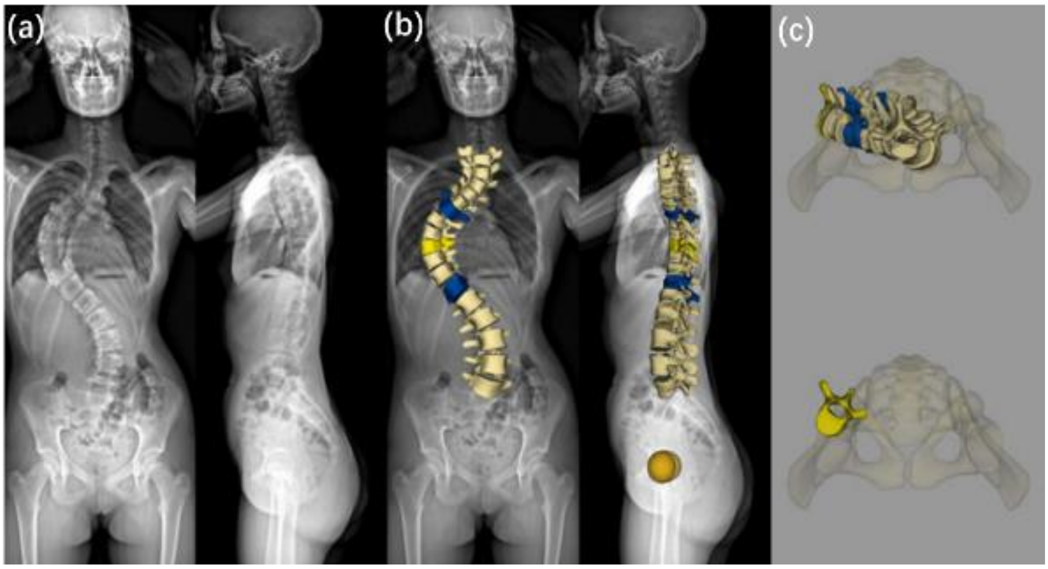

Figure 2.18 EOS image of scoliotic spine

(a) 2D image in coronal and sagittal plane (b) 3-D image in coronal and sagittal plane (c) 3-D image in transverse plane (Illés and Somoskeöy 2012)

Recently, EOS system has been used for the spinal flexibility assessment in AIS. Hirsch et al. (2015) compared the standing with traction radiograph obtained from EOS system and supine with traction radiograph from traditional radiographic system. EOS revealed lower spinal flexibility for distal curves (43% versus 54%) while similar spinal flexibility for main curves (42% versus 45%) comparing with traditional radiography. 3-D parameters such as AVR, AVR flexibility, thoracic kyphosis and thoracic kyphosis flexibility were also provided by the EOS system, which contribute to a global vision of the spinal flexibility. One year later, Hirsch et al. (2016) compared the standing with lateral bending radiograph from EOS system and supine with lateral bending radiograph from traditional X-ray system. They reported no significant difference between the lateral bending angle assessed by EOS system and that assessed by traditional X-ray system regardless of main thoracic curves (23.5° versus 22.7°) or lumbar curves (8° versus 5°). However, 3-D parameters could not be obtained by EOS in the lateral bending position. The patients are positioned off center in the EOS booth to leave enough room for lateral bending, therefore two simultaneous orthogonal acquisitions required for 3-D reconstruction are not feasible to be performed. After their attempts in validation of the EOS system in spinal flexibility assessment, they claimed that EOS system is a promising technique to assess spinal flexibility in scoliosis with seven times less radiation exposure. Further studies on other assessment positions are still needed as EOS system is mainly applicable for upright positions currently.

Magnetic resonance imaging

Magnetic resonance imaging (MRI) makes use of the property of nuclear magnetic resonance to image nuclei of atoms inside the body to visualize internal structures.

MRI is a radiation-free technique which demonstrates detailed internal structures (especially tissues with much hydrogen and little density contrast such as brain, muscle), shows good contrast between soft tissues and bone structures and allows for multi-planar reconstruction to generate high-quality 3-D image (Chu et al. 2006), as shown in Figure 2.19. High reliability and reproducibility of scoliosis assessment in coronal, sagittal and transverse plane on MRI images has been reported previously (Birchall et al. 1997, Schmitz et al. 2001, Schmitz et al. 2005). However, MRI is still not a common choice for scoliosis assessment because it is relatively expensive, time-consuming and needs for multiple acquisitions of axial sequences to cover the region of interest (Abul-Kasim et al. 2010).

Figure 2.19 MRI image of scoliotic spine
(Day et al. 2008)

MR technique was used to determine the effect of spinal orthosis on the scoliotic spine in the study of Schmitz et al. (2005). They visualized and compared the scoliotic spine with and without orthosis in 9 vertical planes (rotate coronal plane according to body axis from -90° to 90°) on the MR images, found that orthoses applied laterodorsal force to the spine which push the spine forward and lead to back straightening in the sagittal plane.

Ultrasound

Ultrasound based diagnostic imaging technique has been commonly used to visualize soft tissues such as tendons, muscles, vessels and internal organs. Ultrasound waves travel into the region of interest of tissues, hit the boundaries of different tissues and bounce back to the receiver. The echoes that return to the receiver are detected and converted into electrical signals. A cross-sectional image (B-mode image) of the tissue could be formed based on the time of return and strength of the echoes (Li 2012).

In recent years, ultrasound imaging has been used to characterize bone tissues (Zheng et al. 2007, Le et al. 2010, Tran et al. 2013) and further came to be applied to visualize the scoliotic spine as the increasing concern of high ionizing radiation of traditional radiography. Previous studies have demonstrated that ultrasound could visualize and locate the posterior arches of the spine, such as spinous process, laminae and transverse processes. These components can be used as landmarks to quantify the lateral curvature or rotational change of a scoliotic spine (Chen et al. 2012, Ungi et al. 2014, Cheung et al. 2015).

US assessment on the scoliosis has been validated in recent years in Japan (Suzuki et al. 1989), Canada (Chen et al. 2011, Chen et al. 2012, Chen et al. 2013), Hong

Kong (Cheung et al. 2013, Li et al. 2015, Wang et al. 2015, Zheng et al. 2016), Australia (Thaler et al. 2008), Netherlands (Purnama et al. 2010) and other places.

Suzuki et al. (1989) firstly applied ultrasound imaging technique to scan the scoliotic spine to measure the AVR three decades ago. Firstly, the vertebrae inclination was determined on the radiograph, lines parallel to the inclination of the vertebrae were drawn on patients' back basing on the spinous processes that was palpated and marked. Then, the US probe attached with an inclinometer was placed on the spinous process, and gradually adjusted until the laminae was horizontal on the cross-sectional image which displayed on a screen. Afterwards, the AVR was determined by the rotation of the laminae and inclination of the probe. Their attempts showed that US could be used to visualize the spinous process and the laminae, leading to the measurement of the AVR of a scoliotic spine.

Chen et al. demonstrate the feasibility of US to identify bony landmarks for measuring spinal curvature and validated the measurements in a phantom study (Chen et al. 2012, Chen et al. 2013). The curve angle was measured by the angle between two lines going through the center of lamina (COL) of the two most tilted vertebrae of the curve. US assessment was reported with a high intra-rater and inter-rater reliabilities (ICCs > 0.88, $P < 0.05$), and the difference of US measurement and X-ray measurement was small (0.7° ± 0.5°). Wang et al. (2015) conducted a clinical trial on scoliosis patients to evaluate the reliability and validity of US measurement via comparing with magnetic resonance imaging (MRI) measurements. No significant difference was found between the curve angle assessed from US and the Cobb angle measured from MRI ($P < 0.05$). Bland-Altman method demonstrated an agreement between these two methods and

Pearson's correlation coefficient (R) was high (R > 0.9, P < 0.05). These attempts established the reliability and validity of US assessment of scoliosis in coronal plane. The other study by Li et al. (2015) validated the US measurement via comparing with radiographic measurement. They assessed spinous process angle (SPA) on the US image and found a significant correlation between SPA measured from US and that measured from the radiography (R = 0.90, P < 0.01). The findings supported the new parameter (SPA) in the estimation of the Cobb angle of a scoliotic curve in the coronal plan.

Cheung et al. (2015) designed a system with a freehand 3-D US system and an electromagnetic spatial sensing device for a scoliosis assessment. Cheung et al. (2015) compared the spinal curvatures measured on radiographs using Cobb method and that on US images using transverse process and spinous process. Their results showed that the intra-rater and inter-rater reliabilities of US measurement was high (ICC > 0.92) and the US methods had good linear correlation with X-ray Cobb method (R^2 = 0.8, P < 0.01). When the transverse process and superior articular process were used as landmarks for US image measurement, a significant linear correlation with radiographic measurement (R^2 = 0.86, P < 0.01) was reported as well (Cheung et al. 2015). Using the same 3-D US system, Zheng et al. (2016) demonstrated a good intra-rater and intra-operator reliabilities for curve angle measurement (ICCs > 0.88), good inter-rater and inter-operator reliability for the scanning procedure (ICCs > 0.87). Moderate to strong correlations (R^2 > 0.72) were reported between the curve angles and Cobb angles and a regression equation y = 1.1797x (R^2 = 0.76) was produced to translate the curve angle (x) to Cobb angle (y).

Chen et al. (2016) recently demonstrated high reliability of AVR measurement on US image with intra- rater and inter-rater reliability of ICCs > 0.91 and mean absolute difference (MAD) < 1.4° in both vitro and vivo study. Good agreement with the radiographic measurement was shown in vitro study (ICC = 0.84 - 0.85, MAD = 4.5° - 5.0°), while poor agreement was found in the in-vivo study (ICC = 0.49 - 0.54, MAD = 2.7° - 3.5°). Since the findings of this pilot study was not conclusive due to small sample size (n=13), Wang et al. (2016) conducted a larger scale validity study as a supplement. They used the COL method and the Aaro-Dahlborn's method to measure the AVR on the US image and MRI image, respectively. The in-vivo study reported high intra-rater and inter-rater reliabilities (ICC (2, k) > 0.98). In addition, the MAD between the two methods are negligible (0.3°, 0.5°, 1.0° difference for curves with AVR < 5°, 5°-10°, >10°, respectively).

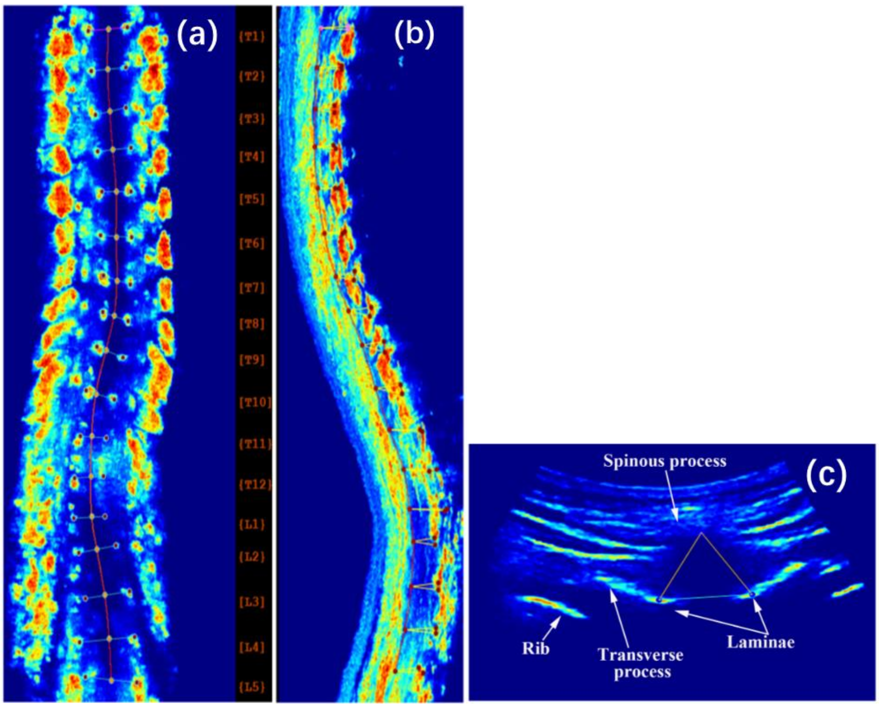

Figure 2.20 Ultrasound image of scoliotic spine.

(a) coronal plane (b) sagittal plane (c) transverse plane (Wang et al. 2015)

In another trend, Young et al. (2015) tried to improve the reliability and accuracy of the US measurement with the aid of radiographs. They laid the US image over the radiograph with laminae on the US image and pedicles on the radiograph lining up, and the last pair of ribs indicating vertebra T12 on the US image. The measurement from the overlaid images showed an increasing agreement between US and radiograph measurements (R^2 = 0.90, MAD = 2.8°) and higher accuracy of the end-vertebrae selection comparing with measuring US images only (improve 43%). Furthermore, Zhou et al. (2016) developed a semi-automatic method to supplement manual method for US images measurement, which improved the measurement accuracyy and efficiency. In addition to the improvement in image measurement, attempts are also made for facilitating the clinical convenience. Jiang et al. (2015) developed a fast projection imaging method recently. This new projection method directly projected the raw images to the coronal plane instead of the volume generation in conventional 3-D rendering method, which reduced the image processing time to one tenth of the previous and therefore largely improved the efficacy of clinical application.

After dedicated validation of US measurement on scoliosis in the past years, US is being applied to optimize the scoliosis treatment procedure and facilitate treatment effectiveness. Li et al. (2012) applied US technique in the orthosis fitting procedure aiming to improve the initial treatment effect of the spinal orthosis. In the ultrasound-assisted fitting group in their study, orthotist adjusted the pressure pad location in five locations, meanwhile US scanning was performed to provide a real-time feedback of the in-orthosis curve angle in the corresponding locations. Once the lowest curve angle was obtained, the optimum pad location was confirmed and recorded. In the conventional fitting group, the pad location was determined by the experience of orthotist without any assistance of US scanning. Their results showed that the ultrasound-assisted fitting of spinal orthosis benefited 62 % of the patients in their study with higher immediate in-orthosis corrections (10.3° versus 4.6° for thoracic curves, 10.1° versus 6.0° for lumbar curves). Hence, they suggested using US as a non-invasive real-time assessment tool to improve the effect of the orthosis treatment.

Lou et al. (2015) applied real-time US to aid orthotists in determining both pad location and pressure level with the aim of achieving an optimal in-orthosis correction. In the ultrasound-assisted fitting protocol, orthotist used a custom standing Providence orthosis design system to apply pressures against patient's torso and a pressure system to record the pressures on the pad. A standing US scan was taken as baseline and follow-up US scan was taken in the patient with an adjustment (necessary or not was determined by orthotist). A real-time US was performed to compare the baseline and the second configuration until achieving the best simulated in-orthosis correction. The results showed an immediate improvement of the in-orthosis correction on 56% of the subjects in their study, and largely reduced requirement of additional orthosis adjustments and in-orthosis radiographs.

Li et al. (2014) used ultrasound imaging technique to investigate the time dependent response of scoliotic curve to spinal orthosis (the time to reach maximum correction after donning spinal orthosis and the time to return to original curvature after doffing spinal orthosis). They assessed the curve angle at an interval of every 30 minutes up to 180 minutes after a patient putting on or taking off the orthosis. Result showed that over 5° curvature change occurred only after 30 minutes and maximum change occurred at or after 120 minutes no matter putting on or taking off the orthosis. A time lag phenomenon between the application of spinal orthosis and its effect on scoliotic curvature was observed in this study, therefore, they suggested radiograph to be obtained within 2 hours of putting on or taking off spinal orthosis to achieve the maximum correction effect. However, this pilot study needs further investigation with larger sample size to confirm the observation and facilitate comprehensive understanding in the mechanism of orthotic intervention to the patients with AIS.

US technique has some limitations for scoliosis assessment. Firstly, vertebral body is difficult to be recognized on the ultrasound images, leading to difficulty in identifying the upper end plate of the superior end vertebra and the bottom end plate of the inferior end vertebra to determine the Cobb angle. Secondly, ultrasound measurement is more applicable to mild and moderate rather than severe scoliosis curves. Ultrasound adopts the posterior components of vertebrae such as center of laminar or spinous processes as landmarks to measure the spinal curvature, which usually show severe rotational change on severe scoliosis curves. Hence, these landmarks will either be far away from the vertebrae body or invisible on the ultrasound image. As a result, the measurement accuracy of severe scoliosis curves will be reduced. Thirdly, identification of landmarks on the ultrasound image needs experience. Quality of ultrasound image affects the measurement accuracy. The majority of incident ultrasound beams are reflected at the interface between soft tissue and bone. However, the blurred interface between two different media makes the landmarks less recognizable. Furtherly, the quality of ultrasound images may be reduced on a patient with thick back muscles due to higher ultrasound attenuation and less reflected ultrasound signals.

Surface topography

Surface topography (ST) is designed to capture the 3-D torso geometry using laser scanners or structured light projections (Figure 2.21). The visible torso asymmetry is often the most troubling aspect for adolescents with scoliosis which driven them to seek for treatment (Chan et al. 2013). Ovadia et al. (2007) conducted a multi-center study to investigate the accuracy of ST to assess scoliosis, and found that the Cobb angles measured from radiograph and that estimated from ST image were highly correlated in both coronal (R = 0.86) and sagittal plane (R = 0.85) in mild to moderate curves. Frerich et al. (2012) also reported a strong correlation between the measurements from the ST and radiography techniques in the coronal plane (R = 0.87, 0.76 for thoracic and lumbar curve respectively). However, the standard deviation between the two measurements (>7°) was relatively high which reduced the prediction accuracy.

ST has been useful in defining torso asymmetry and may be used for monitoring the evolution of the deformity of non-treated patients. However, it is still not readily used for quantitatively diagnosis of scoliosis or treatment outcomes evaluation since the underlying bone structure cannot be visualized (Rigo 2011, Chan et al. 2013).

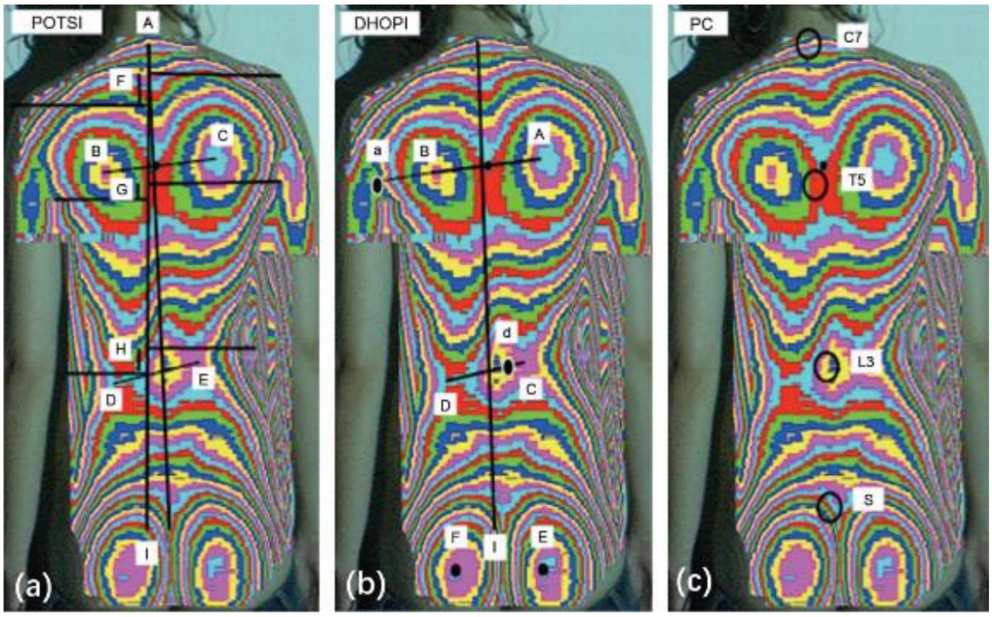

Figure 2.21 Surface topographic image of scoliotic spine
(a) coronal plane asymmetry (b) transverse plane asymmetry (c) profile plane asymmetry (Pino-Almero et al. 2017)

Summary

Currently radiography is the main technique for the evaluation of scoliosis. However, X-ray based technique exposes adolescents to harmful ionizing radiation, years of follow-up monitor of the curve progression accumulates more radiation doses that increase the risk of breast cancer on young patients. Alternative radiation-free technique for scoliosis evaluation have been explored while most are not readily to replace the traditional X-ray imaging technique. The EOS imaging system exposed patients to low-dose radiation, but its wide usage is currently restricted due to the high acquisition and maintenance costs. Surface topography demonstrates torso asymmetry but does not visualize the underlying bone morphology. MRI provide high-quality tomographic image of spine, but it is relatively costly and time consuming for routine assessment.

For the assessment of spinal flexibility, spinal curvature need to be assessed at two body positions (standing position and another position with curvature correction), even more positions are required for the comparison among different spinal flexibilities. Although radiographic examination allows assessment in various positions theoretically, the repetitive radiation exposure induces serious ethical issues on young children. Other imaging techniques may not be readily used for spinal flexibility test because of limited assessment positions: CT and MRI may only be conducted with patients in recumbent positions; EOS imaging and surface topography is mainly conducted in upright position. Ultrasound imaging technique can be a potential technique to assess and spinal flexibility, since it allows reliable and valid assessment of spinal curvature in different body positions without radiation.

In a summary, this study aimed to explore a method of spinal flexibility assessment that was effective to predict the initial in-orthosis correction via assessing and comparing different spinal flexibilities. Traditional radiography was less feasible for this assessment due to high radiation exposure, radiation-free ultrasound imaging technique showed higher potential to achieve this purpose.

CHAPTER 3 METHODOLOGY

In this chapter, the information of subjects and instrument (ultrasound imaging system) is introduced. The procedure of pre-orthosis and in-orthosis assessment is elaborated. Validity analysis of ultrasound assessment and correlation analyses between spinal flexibility and initial in-orthosis correction are also explained.

3.1 Subjects

Subject inclusive criteria were: AIS patients with (1) Cobb angle: 25° to 45° in major curve; (2) age: 10 to 14 years; (3) Risser sign: 2 or less; (4) no prior treatment and initially fitted with a spinal orthosis. A sample size of 28 subjects was calculated (assuming that effect size (d) = 0.5; statistical power (1-β) = 0.8; level of significance (α) = 0.05 used for 2-tailed T-test). Totally 35 patients (age = 12 ± 2 years, Cobb = 27.5° ± 6.9°, n = 67 curves) with AIS scheduled for orthotic treatment were consecutively recruited.

The human subject ethics was approved by the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University and the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster. Before experiment, the purpose and procedure of this study were fully explained to the subjects and their parents or guardians, written consent were obtained. Only female researchers were involved in the whole procedure of data collection considering most of the subjects were young females. A gown with a narrow opening at the back was used to protect the subjects from embarrassment. Parents or guardians of the patients witnessed the whole procedure and the patient privacy was safeguarded during any procedure of the experiment.

3.2 Equipment

An ultrasound system "Scolioscan" (Model SCN801, Telefield Medical Imaging Ltd, Hong Kong) was used for the assessment of spinal flexibility and initial in-orthosis correction (Figure 3.1). This system was comprised of an ultrasound scanner (EUB-8500, Hitachi Ltd., Japan) together with a 75mm in width and frequency range of 5-10MHz linear probe (L53L/10-5), a 38mm in width and frequency range of 5-10MHz linear probe (L53L/10-5), a frame structure, an electromagnetic spatial sensing device (MiniBird, Ascension Technology Corporation, Burlington, VT, USA), a desktop PC installed with a video capture

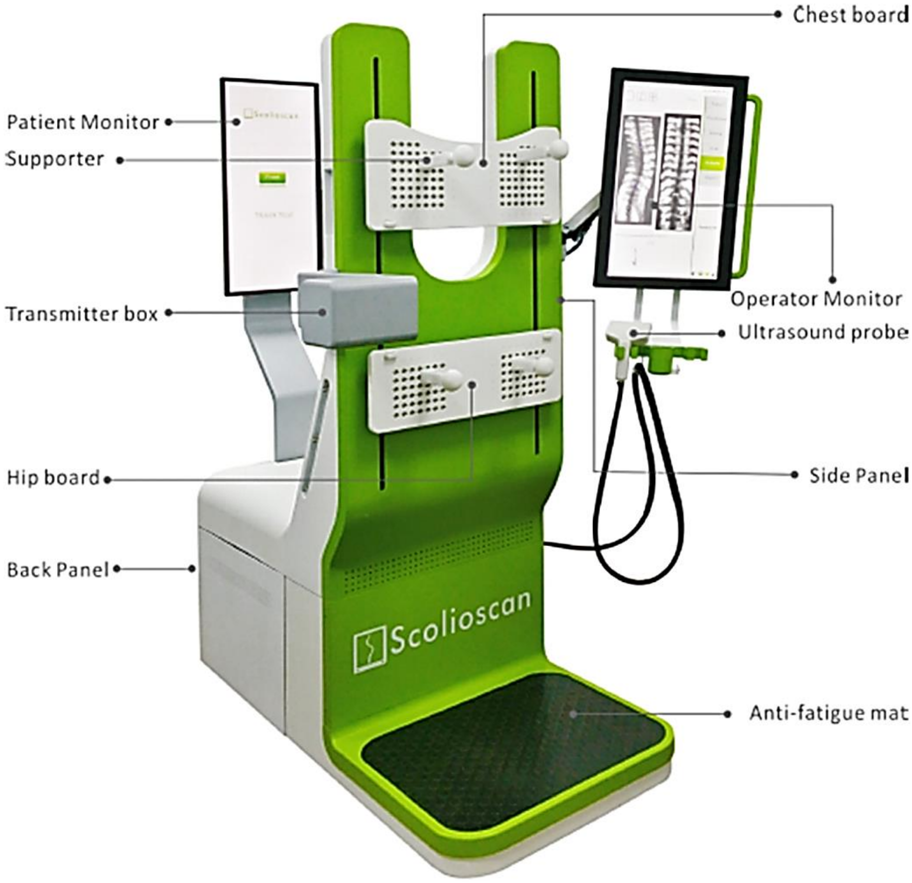

Figure 3.1 Ultrasound system (Scolioscan)
(Zheng et al. 2016)

card (NIIMAQ PCI/PXI-1411, National Instruments Corporation, Austin, TX, USA) and a PC program written using Microsoft Visual Studio 6 with Visual C++ for imaging and data collection, processing, visualization, analysis, and measurement. The spatial sensor was fixed onto the ultrasound probe for collecting the position and orientation information. A crosswire phantom was used to calibrate the spatial offsets between the position sensor and the ultrasound probe.

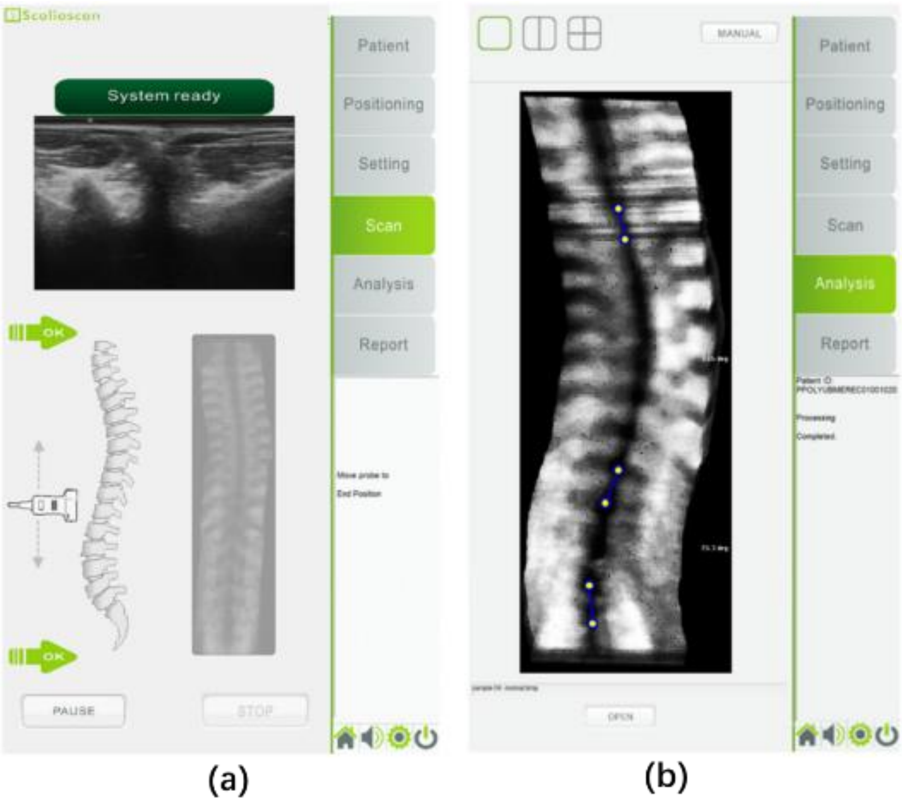

Figure 3.2 Interfaces of ultrasound system
(a) scanning (b) image display (Zheng et al. 2016)

3.3 Clinical procedure

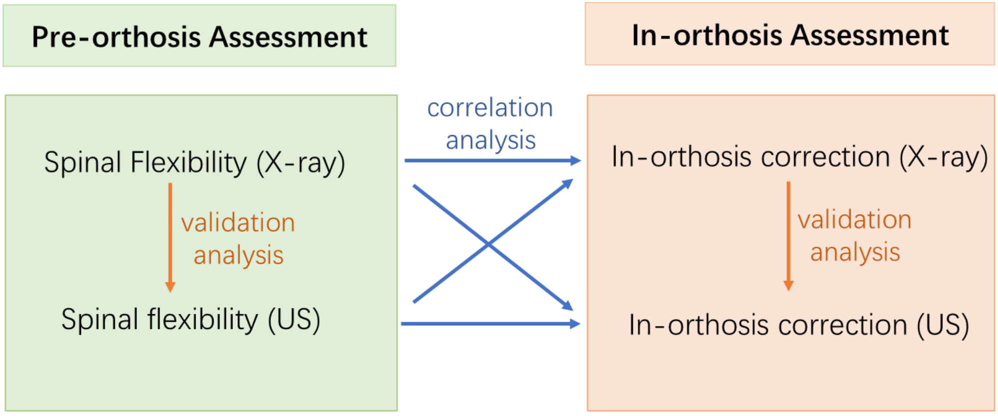

Figure 3.3 Diagram of clinical procedure and data analysis

3.3.1 Pre-orthosis assessment

X-ray evaluation

As routine practice, a patient visits the Department of Prosthetics and Orthotics 3 times with a time interval of 2-3 weeks for completing the initial orthosis fitting in the Duchess of Kent Children's Hospital (DKCH). All patients in this study took the routine standing, supine and in-orthosis radiographs according to a standard protocol. The standing radiograph was taken within 3 months of the first time of hospital visit. The supine radiograph was taken after 2-3 weeks of the first visit (2^{nd} visit) during which the orthosis had been fabricated. The in-orthosis radiograph was taken after 2-3 weeks of the second visit (3^{rd} visit) during which the patient tried to adapt to the orthosis.

The radiographic evaluation was conducted in standing and supine positions before orthosis fitting. Assessment positions were standardized as follows:

- Standing - stand still and keep respiration as shallow as possible with arms folded at 45°.
- Supine - lie facing up on a scanning table with legs straight and arms alongside the trunk.

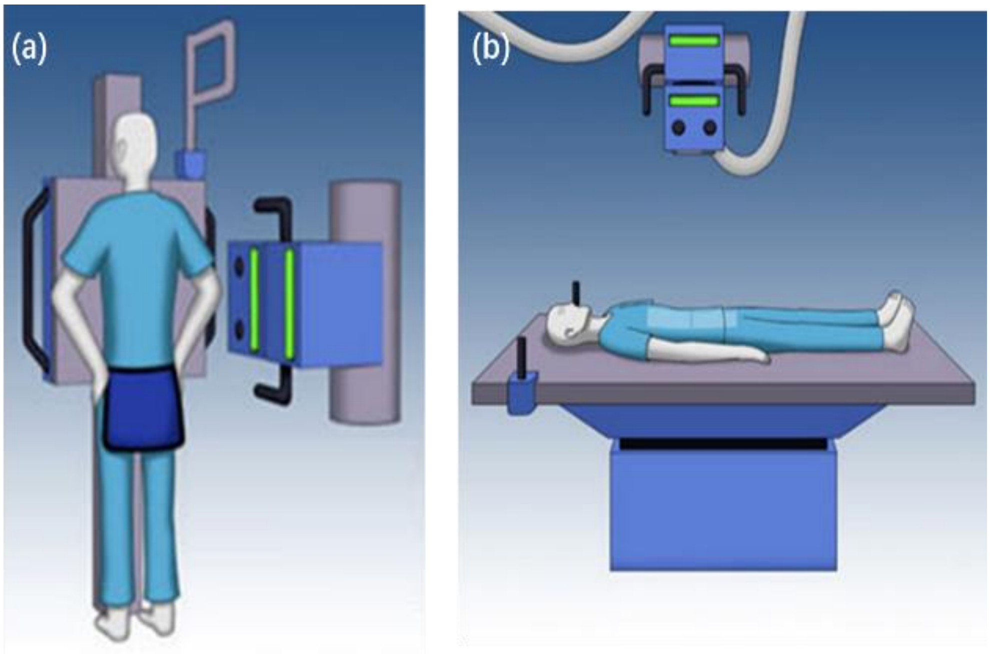

Figure 3.4 Radiographic assessment of spinal flexibility
(a) standing position (b) supine position. Images from [http://www.pted.org/?id=chestradiograph4] [http://oumed.congenital.org/?id=chestradiograph5]

US evaluation

The spinal flexibility was assessed in the 2nd visit (immediately after supine X-ray was taken) and the initial in-orthosis correction was assessed in the 3rd visit (immediately after in-orthosis X-ray was taken), to reduce the influence of time lag in the comparison between radiographic and ultrasound assessment.

A subject was requested to change upper garments with a gown that has an opening on the back (expose the spine for ultrasound scanning). All metallic wears, electronic goods, magnet, and any possible ferromagnetic materials were removed from the subject to avoid interference with US. Pelvis obliquity and leg discrepancy were examined, wood boards were inserted beneath the foot if necessary. Then, the subject was instructed to stand on the platform of the ultrasound machine.

Before ultrasound scanning, four supporters of the machine which located in front of the patient were adjusted to support and record the standing position: two supporters were on the chest board aligning with clavicle anterior concavities and two supporters were on the hip board aligning with bilateral anterior superior iliac spines. Gain and dynamic contrast settings of the ultrasound machine were adjusted by viewing the B-mode image from the positions of T1 to T12. Ultrasound frequency, focus and scanning depth was set at 7.5 Hz, 3.5 cm and 7.1 cm respectively. During ultrasound scanning, aqueous gel was applied on the back of the patient for better conduction between the probe and skin. Then the probe moved uprising from L5 to T1 slowly and steadily with the patient relaxed and breathing naturally. Each scanning took approximately 25 - 40 seconds and 500 - 700 frames of B-mode image was captured. All B-mode images, the corresponding spatial position and orientation data were saved. Then the coronal ultrasound image was reconstructed using the volume projection approach for the assessment of spinal curvature.

The above procedure of ultrasound scaning was conducted in 4 positions (apart from standing): supine, prone, sitting with lateral bending (right and left side for double curves), prone with lateral bending (right and left side for double curves). Assessment positions were standardized as follows (Figure 3.5):

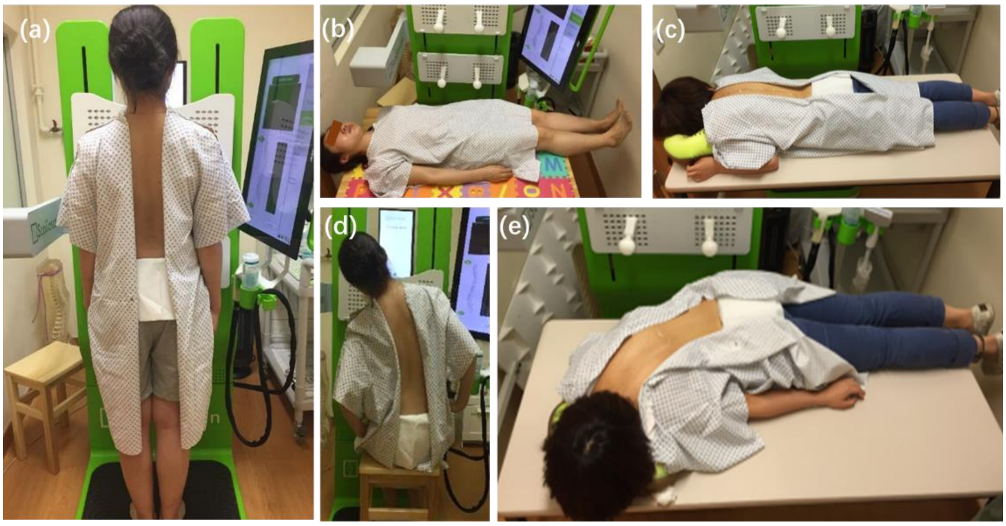

Figure 3.5 Ultrasound assessment positions of spinal flexibility

(a) standing position (b) supine position (c) prone position (d) sitting with lateral bending position (e) prone with lateral bending position

- Standing - stand straight with pelvis level and feet at shoulder-width apart. The position of supporters on the machine was recorded which served as a reference for the follow-up assessment.
- Supine - lie facing up on a scanning couch, with legs straight and arms beside trunk (the couch was purposely designed with a central rectangular slot (size: 12 cm [width] × 60 cm[length]) to allow for scanning under the couch in supine position).
- Prone - lie facing down on a scanning couch, with legs straight and arms beside trunk.
- Siting with lateral bending - start from neutral sitting position, then bend to the curve convex side until the maximum, keeping shoulders in the frontal plane

and pelvis level (monitored by a laser alignment device). Bending to both sides was required for the patients with double curves.

- Prone with lateral bending - start from neutral prone position, then bend to the curve convex side until the maximum, keeping shoulders in the frontal plane and pelvis level (monitored by a laser alignment device). Bending to both sides was required for the patients with double curves.

A laser alignment device was used to monitor the alignment of the pelvis and shoulders during the assessment. All patients were requested to practice the positions 3 times to meet the abovementioned requirement before ultrasound scanning. The scanning was repeated for two times with one-minute rest in between in every position and each scanning took approximately 30 seconds, i.e. 10 scans for the patients with single curves and 14 scans for the patients with double curves (roughly 15 minutes).

3.3.2 In-orthosis assessment

Hong Kong orthoses (Figure 3.6) were used in this study, which was a kind of symmetric underarm rigid spinal orthoses constructed of high temperature thermoplastics, polyurethane. Posterior and chest opening were incorporated in orthosis design. Correction pads were attached according to the curve pattern to provide controlling force. The pelvic module was intimate with the pelvis to create a stable foundation. A reduction of lumbar lordosis was designed to achieve contact of the corrective force with the lumbar transverse processes and induce correction of the thoracic deformity.

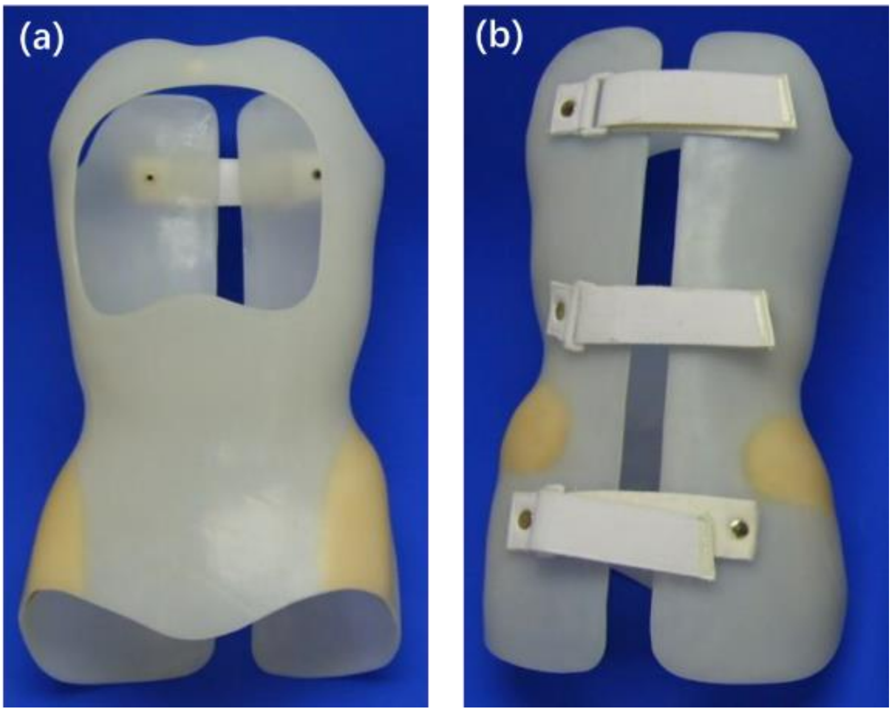

Figure 3.6 Hong Kong Orthosis

(a) anterior view (b) posterior view (Li 2012)

A team of orthotists with more than 5-year clinical experience applied standardized protocol to design, fabricate and fit orthoses on the patients. The pre-orthosis posteroanterior standing and supine X-ray images were used as references for treatment planning and orthosis fabrication. Strategic adjustments, such as changing the pad location/orientation, were made to avoid any intolerable discomfort and obtain the optimum correction through the clinical experience of orthotists. The width of the posterior opening of orthosis was trimmed to 6 cm for allowing the ultrasound probe (width: 5 cm) to go through the spine. The patients were then instructed to wear the orthosis 23 hours a day for 2-3 weeks to adapt to the orthoses. After the adaption period, the patients returned to the orthotist to check the in-orthosis correction and make further adjustments if necessary. Then the tightness of the straps were prescribed and marked by the orthotist, in-orthosis correction was assessed by radiography and US after fitting orthosis for more than two hours to achieve the maximum in-orthosis correction (Li et al. 2014).

X-ray evaluation

During the posteroanterior radiographic assessment, the subject wore the orthosis in standing position with arms folded at 45°, meanwhile respiration was kept as shallow as possible.

US evaluation

Before loosening the orthosis straps for ultrasound scaning, the width of posterior opening was recorded and a purpose-design fixture (Li 2012) was used to anchor the spinal orthosis onto the patient’s trunk. After unfastening the 3 upper straps, width of posterior opening of the orthosis was adjusted to the recorded level (assume the same tightness with straps fastened) through adjusting the fixture. Then in-orthosis ultrasound scanning was conducted (2 times) on the exposed region of scoliotic spine in standing position (Figure 3.7).

Figure 3.7 Ultrasound assessment of initial in-orthosis correction.

The straps are loosened for scanning and orthosis tightness is kept by a purpose-design fixture.

3.3.3 Image measurement

X-ray image measurement

The X-ray images were measured using Cobb's method (Cobb 1948). Firstly, the most tilted vertebrae above and below the apex of the curve (upper and lower end-vertebrae) were identified. Then, two lines perpendicular to the top of end plate of the upper and the bottom of end plate of the lower end-vertebrae were drawn. The angle between the intersecting lines was measured as the Cobb angle. Three times of measurement was conducted, the average value was calculated as the Cobb angle of the spinal curvature.

US image measurement

After ultrasound scanning, a series of B-mode images were collected and used to reconstruct coronal images according to corresponding the spatial information (Figure 3.2-a). Non-planar re-slicing technique was applied to cut the images from the 3-D spine volume using the skin surface as a reference (Cheung et al. 2015). The position of a non-planar cut-plane was defined according to the distance between probe and skin surface in the B-mode image. It was not feasible to measure the angle directly on the curved non-planar plane, the data of non-planar cut-plane was firstly projected in the posterior-anterior view by relocating the voxels from the spine tissue according to their coordinates along the posterior-anterior direction. The voxels of body tissue with the most posterior coordinate was set as the baseline coordinate with the other two spatial coordinates unchanged. As a result, each non-planar cut-plane of the tissue voxels was formed a rectangular plane with its plane normal parallel to the posteroanterior direction, and a set of rectangular planes layers at different depths, which were normal to the posteroanterior direction, were generated. Since these data were not noise-free, projections of fifty non-planar cut-plane data, which covered around one-centimeter thickness of nearby tissue, were exploited for further processing. Then, ten volume projection images were formed which could be used to reveal the spine features at different depth (Figure 3.8).

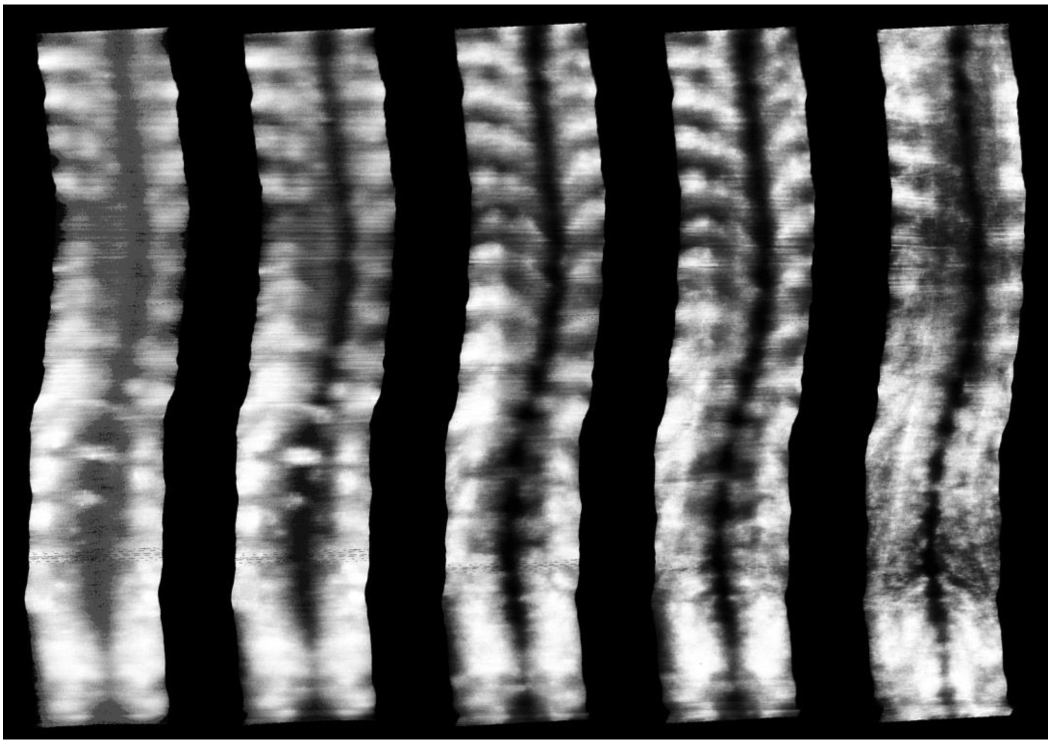

Figure 3.8 Ultrasound images at different depths

The reconstructed ultrasound images in coronal plane were measured using a standardized method as described by Zheng et al. (2016). The spinous processes of each vertebra were marked, and the levels of the upper and lower end-vertebrae were selected according to the standing radiograph, then, a line was drawn to join the spinous process at each level, and the curve angle basing on the selected end-vertebrae was calculated automatically by a purpose-developed software (Figure 3.9).

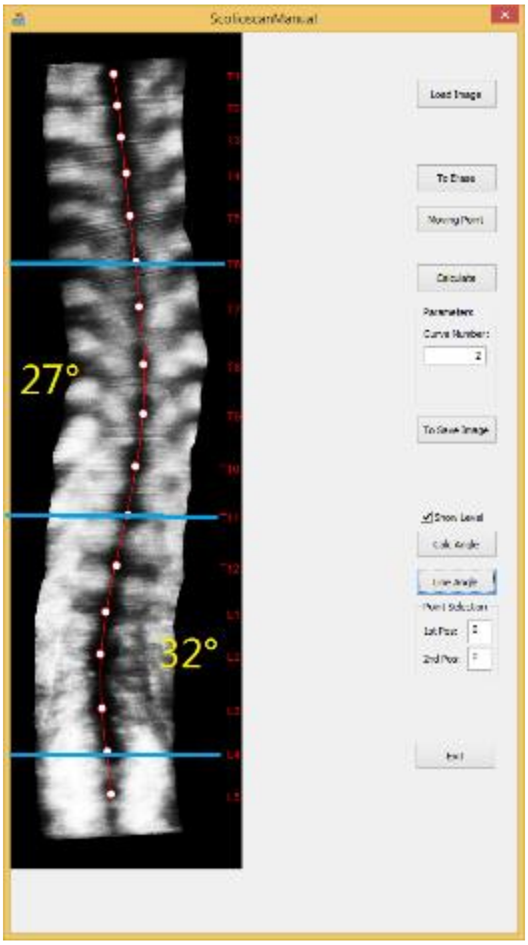

Figure 3.9 Interface of image measurement software

3.4 Data Analysis

Statistical analyses were performed using the IBM SPSS Statistics Version 21 (IBM, Armonk, New York, USA). Descriptive statistics was used to describe the age, height, weight, body mass index, menarche period and risser sign of the participants. All the ultrasound measurements were presented as mean with standard deviation. The curve angle in each position was the average result of the two scans. The curves were divided into mild thoracic curves (< 25°), moderate thoracic curves (25° ~ 45°), mild lumbar curves (< 25°) and moderate lumbar curves (25° ~ 45°) for analyses in order to reduce the effect of curve magnitude and location on the corresponding correlation between spinal flexibility and in-orthosis correction. The spinal flexibility and initial in-orthosis correction was calculated as follows: Spinal flexibility = (Curve angle $_{stand}$ – Curve angle $_{given\ position}$) / Curve angle $_{stand}$ × 100%; Initial in-orthosis correction = (Curve angle $_{stand}$ – Curve angle $_{in\text{-}orthosis}$) / Curve angle $_{stand}$ × 100%.

For the validity analysis, paired T test was used to compare the means. Root-mean-square differences (RMS) difference was calculated to show the agreement between the curve angles assessed by US and X-ray. Pearson product-moment correlation was applied to analyze the correlation between the curve angles measured from US and X-ray images.

For the correlation analysis, one-way repeated ANOVA with least-squared differences (LSD) post-hoc test was performed to compare the curve angles / flexibilities with the initial in-orthosis angle / correction rate. The confidence interval was set at 95% ($P < 0.05$). Then, the Pearson product-moment correlation was used to determine the correlation between curve angles / spinal flexibilities and in-orthosis curve angles / spinal flexibilities, with correlation coefficient 0.00 - 0.25 indicating no correlation , 0.25 to 0.50 indicating low correlation, 0.50 - 0.75 indicating moderate correlation, and 0.75 - 1.00 indicating high correlation (Portney and Watkins 2000).

CHAPTER 4 RESULTS

At the beginning of this chapter, the validity of ultrasound assessment is analyzed through mean comparison and correlation analyses between US and X-ray measurement. Then, the correlation between spinal flexibilities and in-orthosis correction is studied via mean comparison and correlation analyses. The position that shows the closest value to and highest correlation with the initial in-orthosis correction is determined as the effective method for the prediction of initial in-orthosis correction.

4.1 Subjects

A total of 35 patients (mean age: 12 ± 2 years, mean Cobb angle: 27.5° ± 6.9°, Risser sign: 0 - 2) underwent pre-orthosis spinal flexibility assessment. All 35 patients were followed with the radiographic in-orthosis assessment, while only 22 patients (mean age: 12 ± 2 years, mean Cobb angle: 28.1° ± 7.3°, Risser sign: 0 - 2) were followed with the ultrasound in-orthosis assessment and the other 13 patients lost follow-up (mainly due to the change of appointment or tight clinical schedule during the follow-up visit). Hence, the predictability of spinal flexibility to the X-ray in-orthosis correction and the US in-orthosis correction was analyzed respectively. The patient demographic data was shown in Table 4.1. The typical radiographic and ultrasound images of a patient were shown in Figure 4.2 and Figure 4.1.

Table 4.1 Patient demographic data						
Patient ID	Gender	Age	Riser Sign	BMI (kg/m2)	Cobb angle (T)	Cobb angle (TL/L)
01	M	13	2	20.1	30.0°	15.0°
02	F	12	2	15.1	26.5 °	28.5 °
03	F	12	1	21.1	35.8 °	15.5 °
04	F	10	0	20.1	25.0 °	22.8 °
05	F	11	0	16.9	34.8 °	27.1 °
06	F	11	0	14.3	18.4 °	15.8 °
07	F	12	2	19.9	32.8 °	25.6 °
08	F	12	0	13.0	23.6 °	12.0°
09	F	11	0	23.0	29.0 °	26.0°
10	F	13	1	15.6	29.1 °	28.3 °
11	M	13	1	19.2	20.8 °	40.3 °
12	F	11	1	18.6	21.4 °	29.4 °
13	F	13	2	21.4	24.8 °	No L curve
14	F	12	0	20.0	21.3 °	27 °
15	F	14	0	16.6	26.0 °	22.2 °
16	F	11	0	16.4	37.3 °	29.7 °
17	F	13	2	18.7	30.2 °	41.9 °
18	F	13	2	20.3	44.8 °	25.7 °
19	F	11	0	18.7	No T curve	29.0 °
20	F	12	2	21.1	36.4 °	27.5 °
21	F	12	2	19.8	27.9 °	32.9 °
22	F	12	1	16.4	26.0 °	23.1 °
23	F	12	2	18.1	44.1 °	25.0 °
24	F	12	2	19.9	30.3 °	27.8 °
25	F	13	1	17.4	20.0 °	32.0 °
26	F	13	0	19.8	30.0 °	22.0 °
27	F	13	0	15.8	30.0 °	41.9 °
28	F	12	2	20.3	36.3 °	33.4 °
29	F	11	0	22.8	33.8 °	No L curve
30	F	13	0	23.2	26.6 °	17.7 °
31	F	12	2	18.0	27.6 °	16.8 °
32	M	14	1	18.0	22.0 °	31.0 °
33	F	11	1	20.2	26.0 °	28.0 °
34	F	12	2	15.8	21.0 °	24.0 °
35	F	10	0	16.4	27.4 °	22.2 °

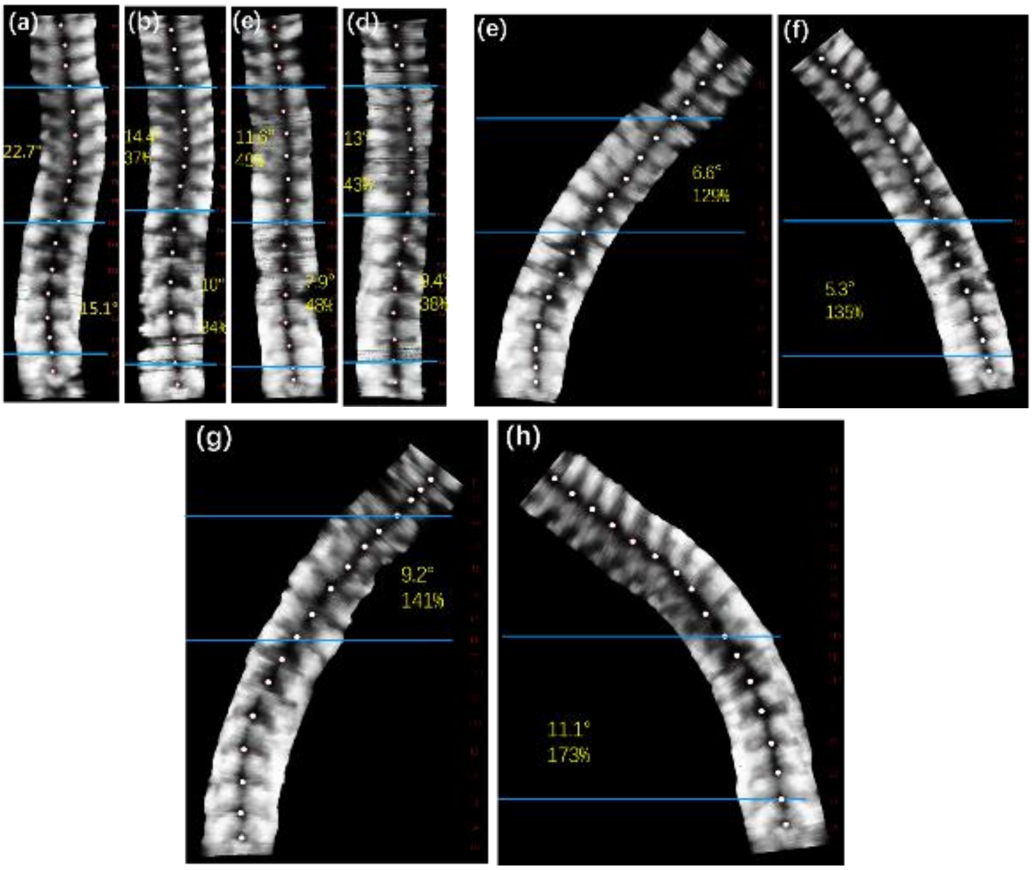

Figure 4.1 Ultrasound images of a patient

(a) Standing position (b) Supine position (c) prone position (d) In-orthosis position (e)(f) prone with lateral bending positions (g)(h) Sitting with lateral bending positions. The right thoracic curve ranged from T5 to T10 (apex at T7) with the curve angle of 22.7°, 14.4°, 11.6°, 13°, -6.6°, -9.2° in standing, supine, prone, in-orthosis, prone with lateral bending and sitting with lateral bending position respectively. The left lumbar curve ranged from T10 to L4 (apex at L1) with the magnitude of 15.1°, 10° 7.9°, 9.4°, -5.3°, -11.1° in standing, supine, prone, in-orthosis, prone with lateral bending and sitting with lateral bending position respectively. The negative value means the curvature was corrected to the opposite side. The curve angle was measured from T4 rather than T5 (end-vertebrae on X-ray image) because the upper endplate of the T5 locates closer to the spinous process of T4.

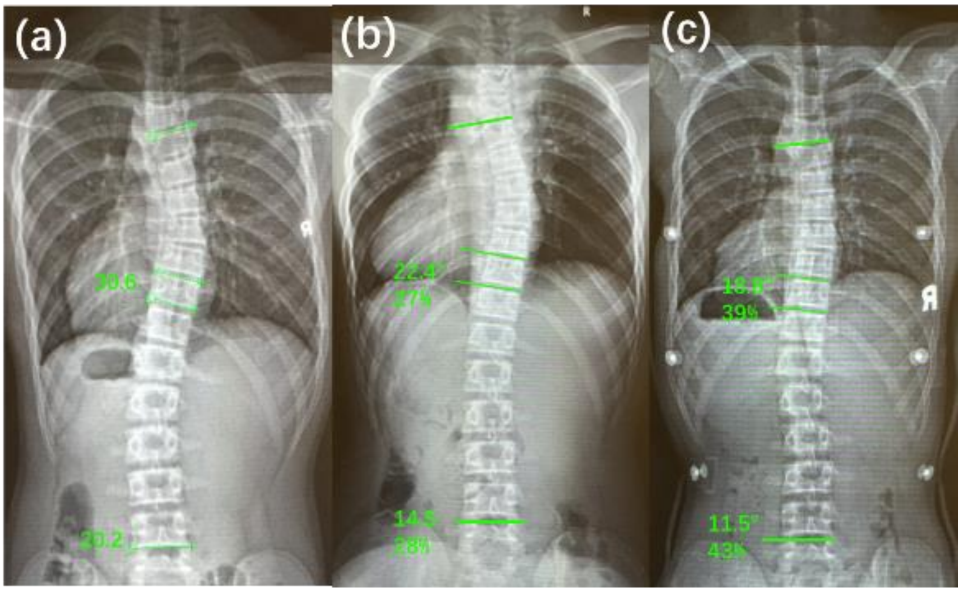

Figure 4.2 X-ray images of a patient

(a) Standing position (b) Supine position (c) In-orthosis position. The right thoracic curve ranged from T5 to T10 (apex at T7) with the curve angle of 30.6° in standing position, 22.4° in supine position, 18.8° in in-orthosis position. The left lumbar curve ranged from T10 to L4 (apex at L1) with the magnitude of 20.2° in standing position, 14.5° in supine position, 11.5° in in-orthosis position.

4.2 Validity analysis

The validity analysis was performed by comparing the US and X-ray measurements in standing, supine and in-orthosis positions. The validity analysis was not performed in prone and lateral bending positions, because extra radiation exposure induced ethical concerns which made it less feasible to acquire radiographs in these positions.

The results of US and X-ray measurements in standing, supine and in-orthosis positions were presented in Table 4.2. The results of comparison and correlation analyses were presented in Table 4.3. The curve angle assessed by US was significantly lower than that assessed by X-ray in all curve groups and all assessed positions, while the correction rate of US measurements was not significantly different from X-ray measurements in in-orthosis position ($P > 0.05$). The curve angle assessed by US was highly correlated with that assessed by X-ray in all the positions, US measurements calculated as percentage (correction rate) was highly correlated with X-ray measurements calculated as percentage in the in-orthosis position ($R > 0.75$). The US and X-ray measurements in the in-orthosis position demonstrated higher correlation ($R = 0.84$) than in supine position ($R = 0.82$) than in standing position ($R = 0.77$).

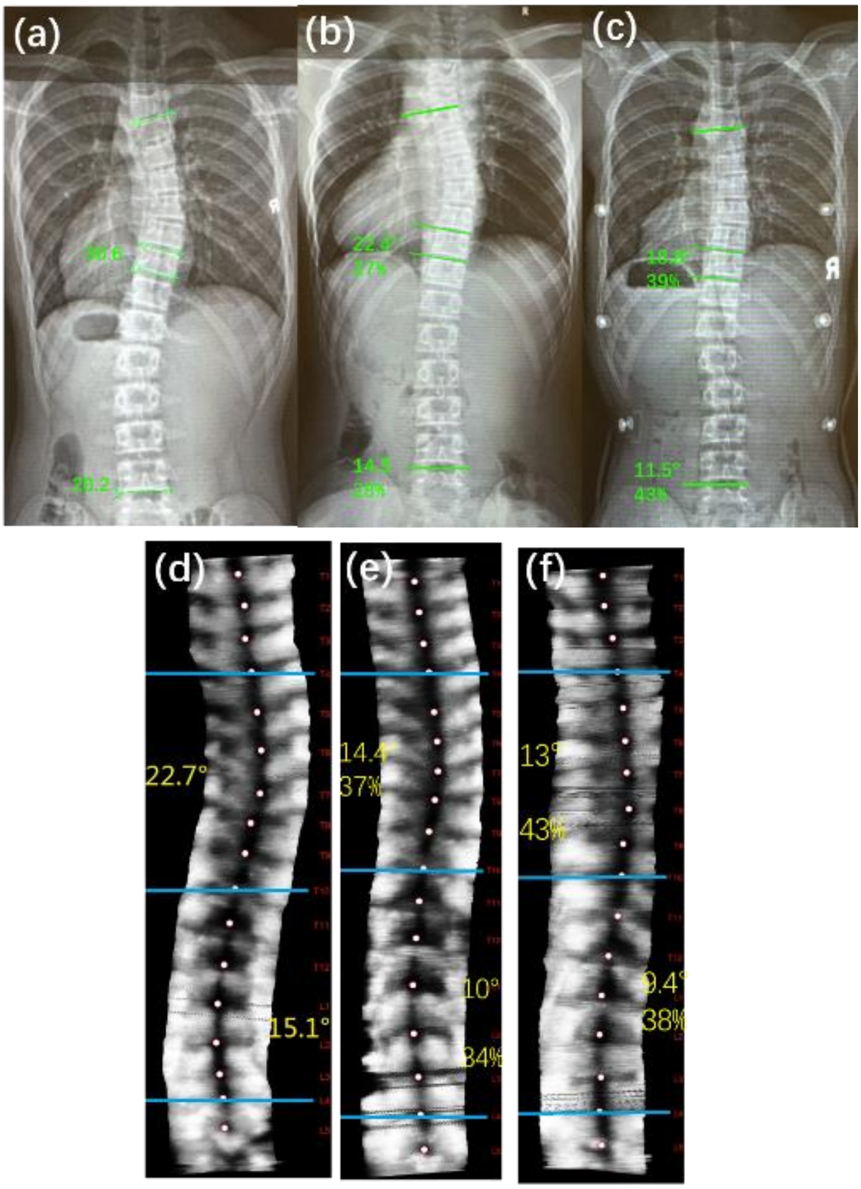

Figure 4.3 X-ray and ultrasound images in standing, supine and in-orthosis position.

X-ray images in (a) Standing position (b) Supine position (c) In-orthosis position. US images in (d) Standing position (e) Supine position (f) In-orthosis position

For curve angles of overall curves, US measurements were significantly lower than that of X-ray measurements in standing (RMS = 8.7°), supine (RMS = 7.8°) and in-orthosis position (RMS = 4.1°). US curve angle was highly correlated with X-ray curve angle in standing (R = 0.77), supine (R = 0.82) and in-orthosis position (R = 0.84). For correction rate of overall curves, US measurements were significantly higher than X-ray measurements in supine position (RMS = 8.7%) and similar in in-orthosis position. US measurements were highly correlated with X-ray measurements in in-orthosis position (R = 0.88) but moderately correlated with X-ray measurements in supine position (R = 0.71).

For curve angles of subgroups, US measurements were significantly lower than X-ray measurements ($P < 0.05$) except for the in-orthosis angle of mild lumbar curves (P = 0.38). In standing position, US and X-ray measurements showed moderate correlation in all subgroups ($0.5 < R < 0.75$) except for the mild lumbar curves (R = 0.88). In supine position, US and X-ray measurements showed high correlation in moderate thoracic and mild lumbar curves ($R > 0.75$) and moderate correlation in mild thoracic and moderate lumbar curves ($0.5 < R < 0.75$). In in-orthosis position, US and X-ray measurements showed high correlation in all subgroups ($R > 0.75$) except for moderate thoracic curves (R = 0.67). For correction rate of subgroups, US measurements were not significantly different from X-ray measurements ($P > 0.05$) except for the supine flexibility of moderate thoracic curves and the in-orthosis correction of moderate lumbar curves ($P < 0.05$). In supine position, US measurements were moderately correlated with X-ray measurements ($0.5 < R < 0.75$) in all subgroups except for moderate thoracic curves (R = 0.88). In in-orthosis position, US measurements were highly correlated with X-ray measurements in all subgroups ($R > 0.8$).

Table 4.2 X-ray and ultrasound measurements in standing, supine and in-orthosis position

Group	Standing		Supine		In-orthosis	
	X-ray	US	X-ray	US	X-ray	US
T<25° (n=7)	22.0° ± 2.5°	15.4° ± 3.1°	**35.7% ± 17.4%** 14.0° ± 3.7°	**43.1% ± 18.7%** 8.6° ± 2.7°	**38.7% ± 23.8%** 13.4° ± 5.5°	**35.6% ± 16.9%** 9.7° ± 2.4°
25°<T<45° (n=15)	32.5° ± 4.9°	20.0° ± 4.1°	25.9% ± 13.4% 24.1° ± 5.9°	37.9% ± 20.1% 12.3° ± 4.5°	**33.2% ± 19.0%** 21.7° ± 6.4°	**34.3% ± 16.3%** 13.0° ± 3.8°
L<25° (n=7)	19.0° ± 4.6°	14.7° ± 2.8°	**52.1% ± 18.2%** 9.6° ± 5.0°	**57.5% ± 16.5%** 6.3° ± 2.6°	**59.2% ± 23.5%** **8.2° ± 5.8°**	**54.1% ± 16.7%** **7.1° ± 3.6°**
25°<L<45° (n=14)	31.0° ± 6.0°	20.9° ± 3.8°	**35.0% ± 13.6%** 20.0° ± 4.6°	**42.5% ± 15.7%** 12.1° ± 4.5°	45.4% ± 24.3% 17.0° ± 8.0°	42.1% ± 21.1% 12.1° ± 5.0°
Overall (n=43)	28.1° ± 7.2°	18.7° ± 4.4°	34.7% ± 16.9% 18.8° ± 7.2°	43.5% ± 18.6% 10.7° ± 4.5°	**42.3% ± 23.4%** 16.6° ± 8.0°	**40.3% ± 18.9%** 11.2° ± 4.4°

Bold fonts: no significant difference between US and X-ray measurements ($P > 0.05$).
Underlined fonts: high correlation between US and X-ray measurements ($R \geq 0.75$).

Table 4.3 Comparison and correlation analyses between US and X-ray measurements in standing, supine and in-orthosis position

Group	X-ray curve angle & US curve angle (°)						X-ray correction rate & US correction rate (%)			
	Standing		Supine		In-orthosis		Supine		In-orthosis	
	P	R	P	R	P	R	P	R	P	R
T<25° (n=7)	0.00	0.68	0.00	0.69	0.05	0.76	**0.25**	0.64	**0.56**	0.84
25°<T<45° (n=15)	0.00	0.67	0.00	0.88	0.00	0.67	0.00	0.88	**0.71**	0.80
L<25° (n=7)	0.00	0.88	0.03	0.85	**0.38**	0.91	**0.30**	0.74	**0.37**	0.81
25°<L<45° (n=14)	0.00	0.57	0.00	0.69	0.00	0.86	**0.12**	0.34	0.00	0.94
Overall (n=43)	0.00	0.77	0.00	0.82	0.00	0.84	0.00	0.71	**0.25**	0.88

P: probability value, R: Pearson correlation coefficient
Bold fonts indicate no significant difference (P > 0.05).
Underlined fonts indicate high correlation (R ≥ 0.75).

4.3 Correlation analysis

The spinal flexibility and in-orthosis correction was assessed by two imaging techniques (US and X-ray), one-to-one correspondence analysis were performed: (1) X-ray spinal flexibility versus X-ray in-orthosis correction; (2) X-ray spinal flexibility versus US in-orthosis correction; (3) US spinal flexibility versus X-ray in-orthosis correction; (4) US spinal flexibility versus US in-orthosis correction.

4.3.1 X-ray spinal flexibility and X-ray in-orthosis correction

The typical X-ray images of a patient in the supine and in-orthosis position were shown in Figure 4.4. The results of X-ray spinal flexibility and X-ray in-orthosis correction (° and %) were presented in Table 4.4. The results of comparison and correlation analyses were presented in Table 4.5. For the X-ray measurement, significant higher curve angle (lower correction rate) in supine position than in in-orthosis position was found. The supine measurements (° and %) was moderately correlated with the in-orthosis measurement.

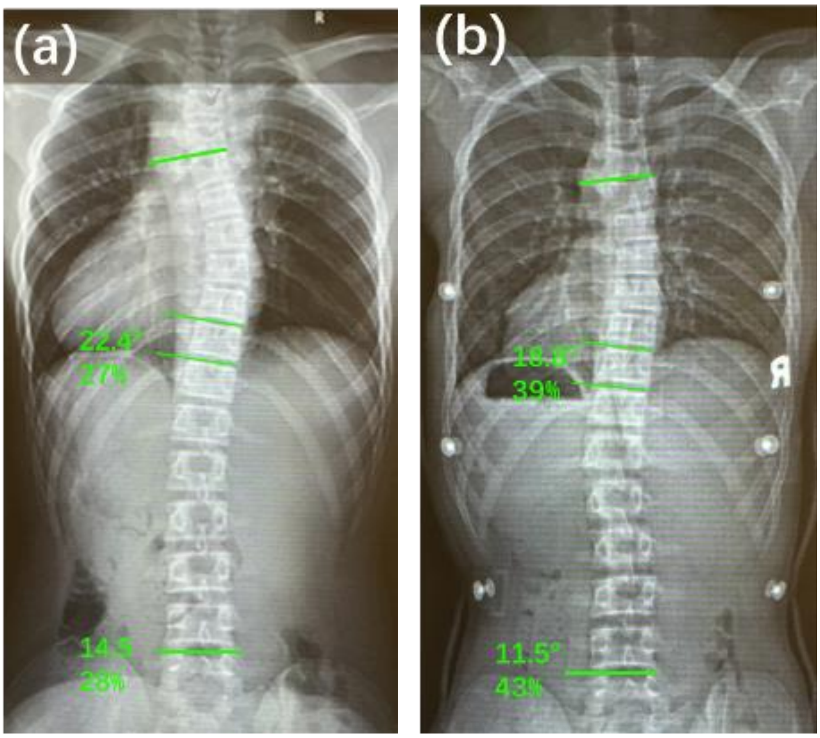

Figure 4.4 X-ray images in supine and in-orthosis position

(a) supine position (b) in-orthosis position. The right thoracic curve with the angle of 22.4° (27% correction) in supine position and 18.8° (39% correction) in in-orthosis position. The left lumbar curve with the angle of 14.5° (28% correction) in supine position and 11.5° (43% correction) in in-orthosis position.

For overall curves, higher curve angle (lower correction rate) in supine position than in in-orthosis position (P < 0.01) was found. Supine measurements were moderately correlated with in-orthosis measurements (R = 0.73 and 0.71 for curve angle and correction rate respectively). For subgroups, supine measurements and in-orthosis measurements (° and %) were significantly different in moderate curves (P < 0.05) while not significantly different in mild curves (P > 0.05). Supine measurements showed moderate correlation (0.5 < R < 0.75) with the in-orthosis correction in all subgroups except for the mild lumbar curves (R > 0.75).

Table 4.4 X-ray spinal flexibility and X-ray in-orthosis correction

Group	Supine (X-ray)	In-orthosis (X-ray)
T<25° (n=10)	**34.6% ± 19.2%** **14.3° ± 4.4°**	**38.0% ± 20.9%** **14.2° ± 5.0°**
25°<T<45° (n=24)	23.7% ± 12.7% 24.0° ± 5.1°	33.1% ± 19.0% 21.0° ± 6.1°
L<25° (n=13)	**40.5% ± 20.8%** **11.9° ± 4.8°**	**48.0% ± 24.4%** **9.9° ± 5.5°**
25°<L<45° (n=20)	35.2% ± 12.6% 20.0° ± 6.0°	47.7% ± 24.3% 31.0° ± 6.0°
Overall (n=67)	32.0% ± 16.6% 19.0° ± 6.7°	41.1% ± 22.6% 16.4° ± 7.6°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).
Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

Table 4.5 Comparison and correlation analyses between X-ray spinal flexibility and X-ray in-orthosis correction

Group	Supine & In-orthosis (°)		Supine & In-orthosis (%)	
	P	R	P	R
T<25° (n=10)	**0.93**	0.68	**0.46**	<u>0.76</u>
25°<T<45° (n=24)	0.00	0.69	0.01	0.62
L<25° (n=13)	**0.08**	<u>0.75</u>	**0.09**	<u>0.80</u>
25°<L<45° (n=20)	0.01	<u>0.78</u>	0.01	0.66
Overall (n=67)	0.00	0.73	0.00	0.71

P: probability value, R: Pearson correlation coefficient

Bold fonts indicate no significant difference (P > 0.05).

<u>Underlined</u> fonts indicate high correlation (R ≥ 0.75).

4.3.2 X-ray spinal flexibility and US in-orthosis correction

The typical images of X-ray measurements in the supine position and US measurements in-orthosis position to reveal the X-ray spinal flexibility and US in-orthosis correction were shown in Figure 4.5. The results of X-ray spinal flexibility and US in-orthosis correction (° and %) were presented in Table 4.6. The results of comparison and correlation analyses were presented in Table 4.7. Significant higher curve angle (lower correction rate) in supine position than in in-orthosis position was found. Supine measurements (° and %) was moderately correlated with in-orthosis measurement.

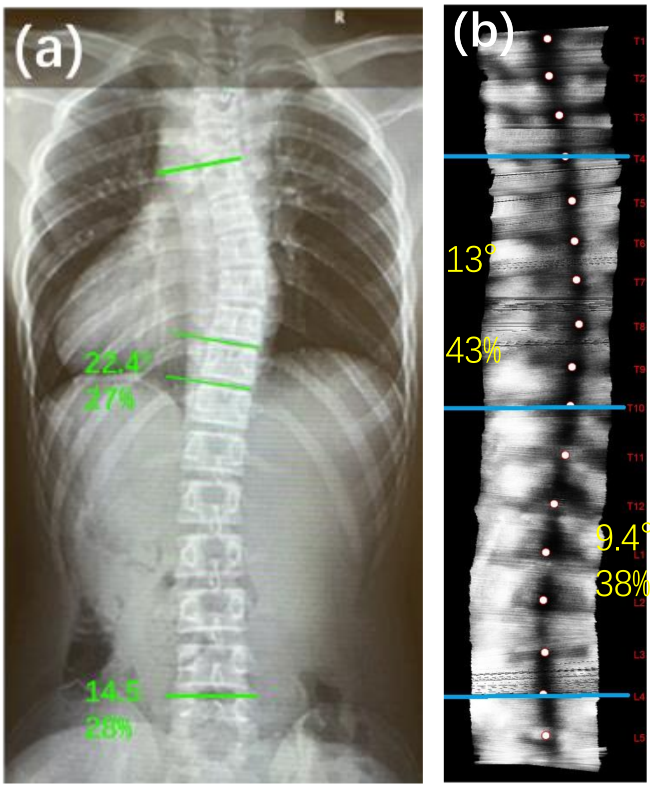

Figure 4.5 X-ray image in supine position and ultrasound image in in-orthosis position

The right thoracic curve with the angle of 22.4° (27% correction) on supine X-ray image and 13° (43% correction) on US in-orthosis image. The left lumbar curve with the angle of 14.5° (28% correction) on X-ray supine image and 9.4° (38% correction) on US in-orthosis image.

For overall curves, higher curve angle (lower correction rate) in supine position than in in-orthosis position ($P < 0.02$) was demonstrated. Supine measurements were moderately correlated with in-orthosis measurements ($R = 0.72$ and 0.67 for curve angle and correction rate respectively). For subgroups, supine measurements were significantly higher than in-orthosis measurements in all subgroups when calculating as curve angle ($P < 0.05$), while no significant difference was found when calculating as correction rate for all subgroups ($P > 0.05$) except for moderate thoracic curves ($P = 0.01$). Supine measurements showed moderate correlation with the in-orthosis correction in most subgroups, except for the high correlation with in-orthosis curve angle in mild lumbar curves (R = 0.85) and high correlation with in-orthosis correction rate in mild thoracic and lumbar curves (R = 0.76 and 0.79 for thoracic and lumbar curves respectively).

Table 4.6 X-ray spinal flexibility and ultrasound in-orthosis correction

Group	Supine (X-ray)	In-orthosis (US)
T<25° (n=7)	**35.7% ± 17.4%** 14.0° ± 3.7°	**35.6% ± 16.9%** 9.7° ± 2.4°
25°<T<45° (n=15)	**25.9% ± 13.4%** 24.1° ± 5.9°	**34.3% ± 16.3%** 13.0° ±3.8°
L<25° (n=7)	52.1% ± 18.2% 9.6° ± 5.0°	54.1.0% ± 16.7% 7.1° ± 3.6°
25°<L<45° (n=14)	**35.0% ± 13.6%** 20.0° ± 4.6°	**42.1% ± 21.1%** 12.1° ± 5.0°
Overall (n=43)	34.7% ± 16.9% 18.8° ± 7.2°	40.3% ± 18.9% 11.2° ± 4.4°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).
Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

Table 4.7 Comparison and correlation analyses between X-ray spinal flexibility and ultrasound in-orthosis correction

Group	Supine & In-orthosis (°)		Supine & In-orthosis (%)	
	P	R	P	R
T<25° (n=7)	0.01	0.56	**0.46**	0.76
25°<T<45° (n=15)	0.00	0.62	0.01	0.62
L<25° (n=7)	0.05	0.85	**0.66**	0.79
25°<L<45° (n=14)	0.00	0.60	**0.16**	0.53
Overall (n=43)	0.00	0.72	0.02	0.67

P: probability value, R: Pearson correlation coefficient
Bold fonts indicate no significant difference (P > 0.05).
Underlined fonts indicate high correlation (R ≥ 0.75).

4.3.3 US spinal flexibility and X-ray in-orthosis correction

The results of US spinal flexibility and X-ray in-orthosis correction (° and %) were presented in Table 4.8. The results of comparison and correlation analyses were presented in Table 4.9. The typical images of a patient were shown in Figure 4.5. Recumbent measurements were significantly lower than the in-orthosis measurements in curve angle ($P < 0.05$) but was not significantly different in correction rate ($P > 0.05$). Recumbent measurements (° and %) was moderately correlated with in-orthosis measurement ($0.5 < R < 0.75$). Significant difference

(P < 0.05) and low correlation (R < 0.5) between side bending measurements and in in-orthosis measurements were found no matter in curve angle or correction rate.

For recumbent measurements of overall curves, the curve angle in both supine and prone position were significantly lower (P < 0.01) and moderately correlated (R = 0.67 and 0.63 respectively) with the in-orthosis curve angle. The correction rate in both supine and prone position was not significantly different (P = 0.67 and 0.59) from the in-orthosis correction, the prone flexibility was highly correlated (R = 0.75) and supine flexibility was moderately correlated (R = 0.66) with the in-orthosis correction. For subgroups, the curve angle of prone and the supine position were significantly lower (P < 0.05) and moderately correlated (0.5 < R < 0.75) with the in-orthosis curve angle in all subgroups except for no significant difference in mild lumbar curves (P > 0.05). The correction rate in supine and prone position was close to the in-orthosis correction without significant difference (P > 0.05). The correction rate in supine position showed moderate correlation with the in-orthosis correction (0.5 < R < 0.75) in all subgroup except high correlation in mild thoracic curves (R = 0.82). The correction rate in prone position showed high correlation with the in-orthosis correction (R > 0.75) in all subgroups except for moderate correlation in moderate thoracic curves (R = 0.67).

For lateral bending measurements of overall curves, the average spinal curvatures were corrected to the opposite direction therefore demonstrated a negative curve angle and more than 100% curve correction. The curve angle in lateral bending positions was significantly different and did not correlate with the in-orthosis angle (R < 0.25). The correction rate in sitting and prone with lateral bending was significant higher (P < 0.01 and < 0.01) and did not correlated (R = 0.04 and 0.03) with the in-orthosis correction as well. For subgroups, the measurements (° and %) in lateral bending position revealed significant higher curve correction ($P < 0.05$) and low correlation with the in-orthosis correction ($R < 0.5$) as well.

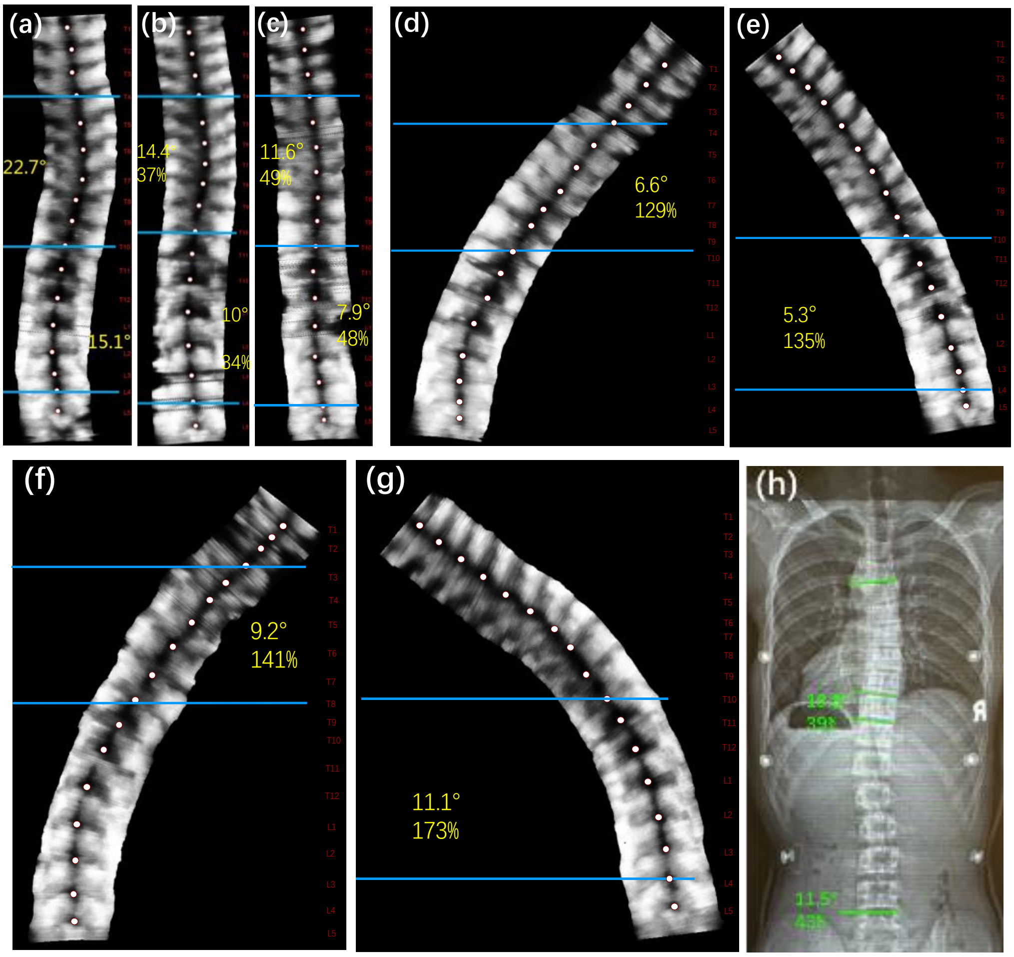

Figure 4.6 Ultrasound images in five assessed positions and X-ray image in in-orthosis position

On the US image, the right thoracic curve with the magnitude of 22.7°, 14.4° (37%), 11.6° (49%), -6.6° (129%), -9.2° (141%) in standing, supine, prone, prone with lateral bending and sitting with lateral bending position respectively. The left lumbar curve with the magnitude of 15.1°, 10° (34%), 7.9° (48%), -5.3° (135%), -11.1° (173%) in standing, supine, prone, prone with lateral bending and sitting with lateral bending position respectively. On the X-ray image, the in-orthosis correction of the right thoracic curve was 18.8° (39%) and the left lumbar curve was 11.5° (43%). US images in (a) Standing position (b) Supine position (c) prone position (d)(e) prone with lateral bending position (f)(g) Sitting with lateral bending position. X-ray image in (h) in-orthosis position.

Table 4.8 Ultrasound spinal flexibility and X-ray in-orthosis correction

Group	X-ray	US					X-ray
	Standing	Standing	Supine	Prone	Siting bending	Prone bending	In-orthosis correction
T<25° (n=10)	21.9° ± 2.1°	16° ± 3°	**41% ± 22%** 9.3° ± 3.8°	**43% ± 18%** 8.7° ± 2.7°	159% ± 46% -8.8° ± 7.2°	135% ± 20% -5.3° ± 3.1°	38% ± 21% 14.2° ± 5.0°
25°<T<45° (n=24)	31.6° ± 5.3°	21° ± 5°	**36% ± 19%** 12.9° ± 3.8°	**37% ± 20%** 12.4° ± 4.2°	126% ± 39% -5.0° ± 8.6°	116% ± 35% -2.8° ± 7.1°	33% ± 19% 21.0° ± 6.1°
L<25° (n=13)	19.6° ± 4.2°	15° ± 3°	**46% ± 23%** **7.9° ± 3.2°**	**45% ± 14%** **8.5° ± 2.5°**	174% ± 66% -10.3°± 10.0°	149% ± 34% -7.0° ± 5.3°	48% ± 24% 9.9° ± 5.5°
25°<L<45° (n=20)	30.6° ± 5.1°	22° ± 4°	**42% ± 16%** 13.0° ± 4.4°	**46% ± 17%** 12.4° ± 4.0°	137% ± 64% -7.9° ± 13.7°	121% ± 35% -4.5° ± 7.9°	48% ± 24% 16.2° ± 8.2°
Overall (n=67)	27.5° ± 6.9°	19° ± 5°	**40% ± 19%** 11.4° ± 4.4°	**42% ± 18%** 11.1° ± 4.0°	143% ± 56% -7.5° ± 10.4°	127% ± 34% -4.5° ± 6.6°	41% ± 22% 16.4° ± 7.6°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

Table 4.9 Comparison and correlation analyses between ultrasound spinal flexibility and X-ray in-orthosis correction

group	Supine & In-orthosis (°)		Supine & In-orthosis (%)		Prone & In-orthosis (°)		Prone & In-orthosis (%)		Siting bending & In-orthosis (°)		Siting bending & In-orthosis (%)		Prone bending & In-orthosis (°)		Prone bending& In-orthosis (%)	
	P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R
T<25 (n=10)	0.01	0.70	**0.44**	<u>0.82</u>	0.02	0.64	**0.27**	<u>0.75</u>	0.00	-0.03	0.00	-0.27	0.00	-0.04	0.00	-0.50
T>25 (n=24)	0.00	0.61	**0.45**	0.67	0.00	0.53	**0.21**	0.67	0.00	0.32	0.00	0.08	0.00	0.26	0.00	-0.12
L<25 (n=13)	**0.32**	0.54	**0.71**	0.60	**0.78**	0.71	**0.52**	<u>0.88</u>	0.01	-0.29	0.00	-0.18	0.00	-0.10	0.00	0.02
L>25 (n=20)	0.02	0.62	**0.18**	0.60	0.02	0.58	**0.56**	<u>0.77</u>	0.00	0.22	0.00	0.10	0.00	0.24	0.00	0.12
Overall (n=67)	0.00	0.67	**0.67**	0.66	0.00	0.63	**0.54**	<u>0.75</u>	0.00	0.23	0.00	0.04	0.00	0.26	0.00	0.03

P: probability value, R: Pearson correlation coefficient.

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

<u>Underlined</u> fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

The results of comparison and correlation analyses among flexibilities were presented in Table 4.10. For recumbent measurement, the supine and prone measurements (° and %) were not significantly different ($P < 0.05$) and highly correlated ($R > 0.75$). For lateral bending measurement, sitting with lateral bending measurements were significantly higher ($P < 0.05$) and highly correlated ($R > 0.75$) with that in the prone with lateral bending position.

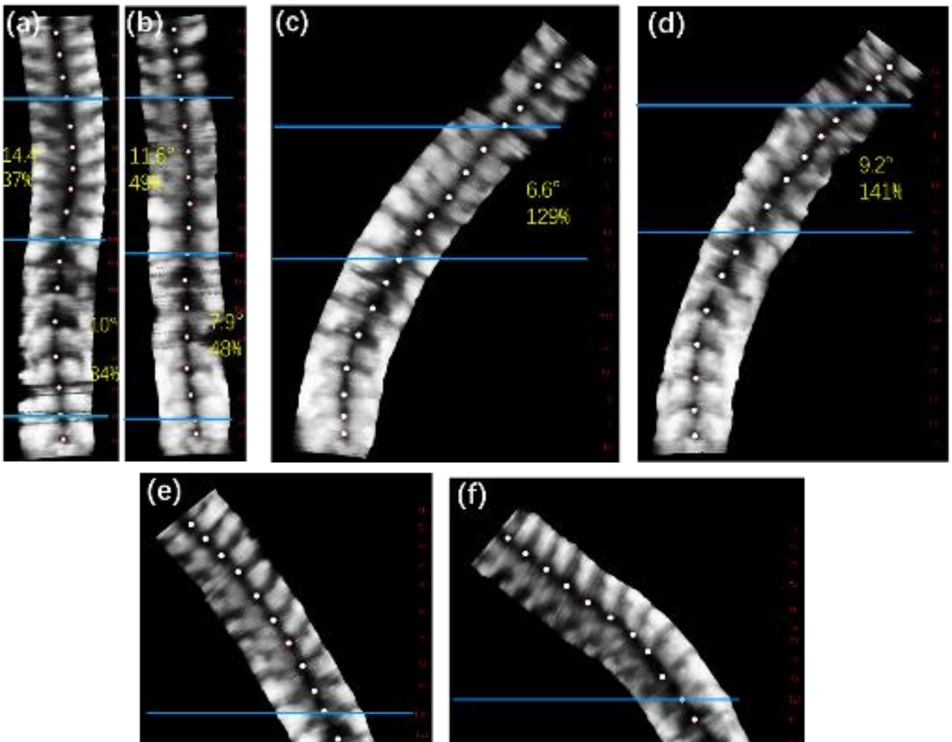

Figure 4.7 Ultrasound images in supine and lateral bending positions

The right thoracic curve with the magnitude of 14.4° (37%), 11.6° (49%), -6.6° (129%), -9.2° (141%) in supine, prone, prone with lateral bending and sitting with lateral bending position respectively. The left lumbar curve with the magnitude of 10° (34%), 7.9° (48%), -5.3° (135%), -11.1° (173%) in supine, prone, prone with lateral bending and sitting with lateral bending position respectively. US images in (a) Supine position (b) prone position (c)(e) prone with lateral bending position (d)(f) Sitting with lateral bending position.

Comparing recumbent measurements of overall curves, the supine and prone measurements (° and %) were not significantly different ($P = 0.53$ and 0.23 for curve angle and correction rate respectively) and highly correlated in curve angle ($R = 0.76$ and 0.72 for curve angle and correction rate respectively). For subgroups, the measurements (° and %) in supine and prone position were not significant different ($P > 0.05$). The supine and prone measurements (° and %) were highly correlated in mild thoracic and moderate lumbar curves ($R > 0.75$) and moderately correlated in moderate thoracic and mild lumbar curves ($0.5 < R < 0.75$).

Comparing lateral bending measurements of overall curves, sitting with lateral bending measurements (° and %) was significantly higher ($P < 0.01$) and highly correlated ($R > 0.8$) with that in the prone with lateral bending position. For subgroups, the curve angle (°) of sitting with lateral bending was not significantly different with that of prone with lateral bending position in all subgroups ($P > 0.05$) except moderate thoracic curves ($P = 0.04$). While the correction rate (%) of sitting with lateral bending was higher than that of prone with lateral bending without significant difference ($P > 0.05$). The measurements (° and %) of sitting with lateral bending and prone with lateral bending were highly correlated in all subgroups ($R > 0.82$) except for mild thoracic curves ($R = 0.61$).

Table 4.10 Comparison and correlation analyses among spinal flexibilities

group	Supine & Prone				Siting bending & Prone bending			
	Curve angle (°)		Correction rate (%)		Curve angle (°)		Correction rate (%)	
	P	R	P	R	P	R	P	R
T<25 (n=10)	**0.81**	<u>0.77</u>	**0.57**	<u>0.89</u>	**0.53**	0.61	**0.07**	0.61
T>25 (n=24)	**0.67**	0.60	**0.58**	0.69	0.04	<u>0.82</u>	**0.05**	<u>0.82</u>
L<25 (n=13)	**0.17**	0.51	**0.95**	0.59	**0.08**	<u>0.82</u>	**0.06**	<u>0.80</u>
L>25 (n=20)	**0.63**	<u>0.86</u>	**0.12**	<u>0.78</u>	**0.14**	<u>0.90</u>	**0.06**	<u>0.89</u>
Overall (n=67)	**0.53**	<u>0.76</u>	**0.23**	0.72	0.00	<u>0.84</u>	0.00	<u>0.82</u>

P: probability value, R: Pearson correlation coefficient
Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).
<u>Underlined</u> fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

4.3.4 US spinal flexibility and US in-orthosis correction

The results of US spinal flexibility and US in-orthosis correction were presented in Table 4.11. The results of comparison and correlation analyses were presented in Table 4.12. The typical images of a patient were shown in Figure 4.8. Recumbent measurements (° and %) was not significantly different from the in-orthosis measurement (P > 0.05). The correction rate of recumbent positions was highly correlated with that of the in-orthosis position (0.5 < R < 0.75). Side bending measurements and in in-orthosis measurements (° and %) were significantly different ($P < 0.05$) and lowly correlated ($R < 0.5$).

For recumbent measurements of overall curves, the curve angle in both supine and prone position was not significantly different ($P = 0.27$ and 0.16 respectively) and highly correlated ($R = 0.76$ and 0.87 respectively) with the in-orthosis angle. The correction rate in both supine and prone position was not significantly different ($P = 0.20$ and 0.14 respectively) with the in-orthosis angle, prone flexibility was highly correlated ($R = 0.77$) and supine flexibility was moderately correlated ($R = 0.64$) with the in-orthosis angle. For subgroups, the measurements (° and %) in supine and prone position was not significantly different from in-orthosis correction ($P > 0.05$), except for mild thoracic curves ($P < 0.05$). The measurements (° and %) in supine position showed moderate correlation with the in-orthosis correction ($0.5 < R < 0.75$) in all subgroups except that except for mild thoracic curves ($R > 0.75$). The measurements (° and %) in prone position showed high correlation with the in-orthosis correction ($R > 0.75$) in all subgroups except for mild thoracic curves ($0.5 < R < 0.75$).

For lateral bending measurements of overall curves, the average spinal curvatures were corrected to the opposite direction therefore demonstrated a negative curve angle and more than 100% curve correction rate. Sitting and prone with lateral bending revealed significant higher curve correction ($P < 0.01$) and low correlation ($R < 0.3$) with the in-orthosis correction. For subgroups, the measurements (° and %) in lateral bending position revealed significant higher curve correction ($P < 0.05$) and low correlation with the in-orthosis correction ($R < 0.5$) as well. The results of comparison and correlation analyses among flexibilities were presented in Table

4.13. For recumbent measurement, the supine and prone measurements (° and %) were not significantly different ($P > 0.05$) and highly correlated ($R > 0.75$) in curve angle. For lateral bending measurement, sitting with lateral bending measurements (° and %) were significantly higher ($P < 0.05$) and highly correlated ($R > 0.75$) with that in the prone with lateral bending position.

Table 4.11 Ultrasound spinal flexibility and ultrasound in-orthosis correction

Group	X-ray	US					US
	Standing	Standing	Supine	Prone	Siting bending	Prone bending	In-orthosis correction
T<25° (n=7)	22.0° ± 2.5°	15.4° ± 3.0°	43.1% ± 18.7% 8.6° ± 2.7°	**45% ± 17%** **8.4° ± 3.0°**	143% ± 46% -5.6° ±6.2°	130% ± 22% -4.3° ± 2.9°	35.6% ± 16.9% 9.7° ± 2.4°
25°<T<45° (n=15)	32.5° ± 4.9°	20.0° ± 4.1°	37.9% ± 20.1% **12.4° ± 4.5°**	**37% ± 21%** **12.6° ± 4.6°**	118% ± 40% -3.3° ± 7.9°	106% ± 37% -0.9° ± 7.4°	34.3% ± 16.3% 13.0° ± 3.8°
L<25° (n=7)	19.0° ± 4.6°	14.7° ± 2.8°	57.5% ± 16.5% **6.3° ± 2.6°**	**51% ± 16%** **7.4° ±3.3°**	185% ± 69% -12.2° ± 10.5°	154% ± 39% -7.7° ± 6.4°	54.1.0% ± 16.7% 7.1° ± 3.6°
25°<L<45° (n=14)	31.0° ± 6.0°	20.9° ± 3.8°	42.5% ± 15.7% **12.1° ± 4.5°**	**45% ± 15%** **11.6° ± 4.3°**	137% ± 72% -7.4° ± 15.2°	120% ± 38% -3.9° ± 8.3°	42.1% ± 21.1% 12.1° ± 5.0°
Overall (n=43)	28.1° ±7.3°	18.7° ± 4.4°	43.5% ± 18.6% **10.7° ± 4.6°**	**43% ± 17%** **10.7° ±4.5°**	139% ± 60% -6.5° ±11.1°	122% ± 38% -3.5 °±7.2°	40.3% ± 18.9% 11.2° ± 4.4°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

Table 4.12 Comparison and correlation analyses between ultrasound spinal flexibility and ultrasound in-orthosis correction

group	Supine & In-orthosis (°)		Supine & In-orthosis (%)		Prone & In-orthosis (°)		Prone & In-orthosis (%)		Siting bending & In-orthosis (°)		Siting bending & In-orthosis (%)		Prone bending & In-orthosis (°)		Prone bending & In-orthosis (%)	
	P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R
T<25° (n=7)	0.03	0.92	0.02	0.94	**0.20**	0.64	**0.15**	0.61	0.00	0.37	0.00	0.37	0.00	0.54	0.00	0.50
25°<T<45° (n=15)	**0.44**	0.71	**0.39**	0.64	**0.51**	0.83	**0.45**	0.80	0.00	0.59	0.00	0.52	0.00	0.53	0.00	0.32
L<25° (n=7)	**0.50**	0.60	**0.64**	0.38	**0.61**	0.90	**0.49**	0.76	0.00	0.02	0.00	0.22	0.00	0.08	0.00	0.24
25°<L<45° (n=14)	**0.99**	0.66	**0.95**	0.50	**0.38**	0.89	**0.37**	0.85	0.00	0.24	0.00	0.18	0.00	0.29	0.00	0.22
Overall (n=43)	**0.27**	0.76	**0.20**	0.64	**0.16**	0.87	**0.14**	0.77	0.00	0.36	0.00	0.30	0.00	0.41	0.00	0.30

P: probability value, R: Pearson correlation coefficient

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

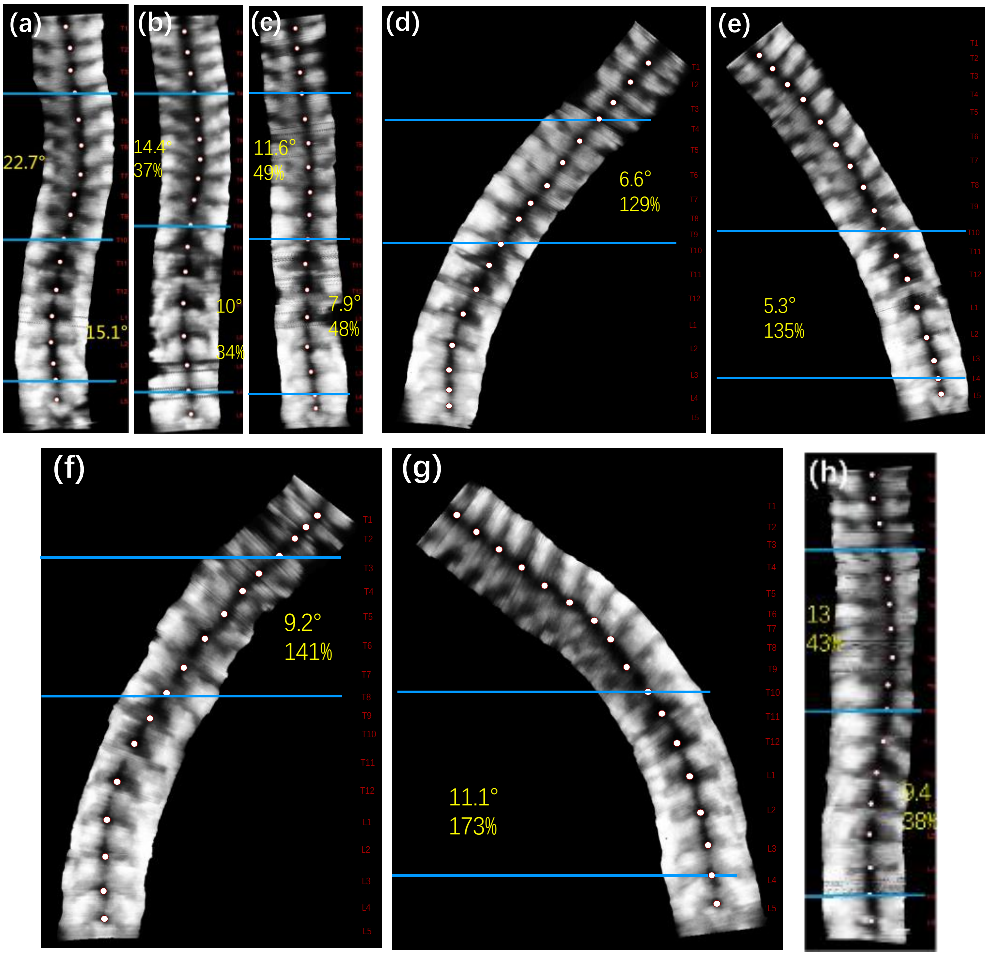

Figure 4.8 Ultrasound images in six assessed positions.

The right thoracic curve with the magnitude of 22.7°, 14.4° (37%), 11.6° (49%), -6.6° (129%), -9.2° (141%) in standing, supine, prone, prone with lateral bending and sitting with lateral bending position respectively. The left lumbar curve with the magnitude of 15.1°, 10° (34%), 7.9° (48%), -5.3° (135%), -11.1° (173%) in standing, supine, prone, prone with lateral bending and sitting with lateral bending position respectively. The in-orthosis correction of the right thoracic curve was 13° (43%) and the left lumbar curve was 9.4° (38%). (a) Standing position (b) Supine position (c) prone position (d)(e) prone with lateral bending position (f)(g) Sitting with lateral bending position (h) in-orthosis position.

Comparing recumbent measurements of overall curves, the supine and prone measurements (° and %) were not significantly different ($P > 0.05$) and highly correlated in curve angle ($R = 0.84$ and 0.73 for curve angle and correction rate respectively). For subgroups, the measurements (° and %) in supine and prone position were not significant different ($P > 0.05$) with high correlation ($R > 0.75$) in thoracic curves and moderate correlation in lumbar curves ($0.5 < R < 0.75$).

Comparing lateral bending measurements of overall curves, sitting with lateral bending measurements (° and %) was significantly higher ($P < 0.01$) and highly correlated ($R > 0.8$) with that in the prone with lateral bending position. For subgroups, the measurements (° and %) of sitting with lateral bending position was not significantly different with that of prone with lateral bending position in all subgroups ($P > 0.05$) except for moderate thoracic curves. The measurements (° and %) of sitting with lateral bending and prone with lateral bending were highly correlated in all subgroups ($R > 0.8$) except for mild thoracic curves ($R < 0.6$).

The thoracic curves showed similar lateral bending flexibility and recumbent flexibility with the lumbar curves regardless of curve magnitude, while the thoracic curves showed lower in-orthosis correction than the lumbar curves in >25° curves. Besides, moderate curves showed lower lateral bending flexibility ($P < 0.05$), similar recumbent flexibility ($P > 0.05$) and in-orthosis correction ($P > 0.05$) with <25° curves regardless of curve location. Furthermore, the standing curve angle assessed by ultrasound was significantly lower but highly correlated with that assessed by X-ray ($P < 0.01$, $R = 0.77$).

Table 4.13 Comparison and correlation analyses among spinal flexibilities

group	Supine & Prone				Siting bending & Prone bending			
	Curve angle (°)		Correction rate (%)		Curve angle (°)		Correction rate (%)	
	P	R	P	R	P	R	P	R
T<25° (n=7)	**0.81**	0.83	**0.66**	0.83	**0.53**	0.51	**0.38**	0.63
25°<T<45° (n=15)	**0.78**	0.81	**0.78**	0.76	0.04	0.86	0.04	0.87
L<25° (n=7)	**0.32**	0.61	**0.33**	0.48	**0.08**	0.89	**0.08**	0.88
25°<L<45° (n=14)	**0.43**	0.84	**0.45**	0.68	**0.14**	0.92	**0.14**	0.91
Overall (n=43)	**0.90**	0.84	**0.88**	0.73	0.00	0.87	0.00	0.87

P: probability value, R: Pearson correlation coefficient

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

4.4 Summary

The validity of US measurements was proved via comparing with X-ray measurements (gold standard). The result and analysis of US and X-ray measurements were demonstrated in Table 4.14. The US measurements were significantly lower than X-ray measurements in the three studied positions (P < 0.05), except for in-orthosis measurements calculated as correction rate (P > 0.05). The US measurements were highly correlated with the X-ray measurements (R > 0.75) except for supine measurements calculated as correction rate (R = 0.71). The

US and X-ray measurements demonstrated higher correlation in in-orthosis position than in supine position than in standing position (R = 0.84, 0.82 and 0.77 respectively).

Table 4.14 Ultrasound and radiographic measurements in standing, supine and in-orthosis position

Group	Standing	Supine	In-orthosis
US in-orthosis group (n=43)	28.1° ± 7.2°	34.7% ± 16.9% 18.8° ± 7.2°	**42.3% ± 23.4%** 16.6° ± 8.0°
X-ray in-orthosis group (n=67)	18.7° ± 4.4°	43.5% ± 18.6% 10.7° ± 4.5°	**40.3% ± 18.9%** 11.2° ± 4.4°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).
Underlined fonts: high correlation with the corresponding in-orthosis correction (R > 0.75).

Table 4.15 Comparison and correlation analyses between ultrasound and radiographic measurements in predicting in-orthosis correction

		Standing		Supine		In-orthosis	
		P	R	P	R	P	R
US vs X-ray	**(°)**	0.00	0.77	0.00	0.82	0.00	0.84
	(%)	-	-	0.00	0.71	**0.25**	0.88

P: probability value, R: Pearson correlation coefficient
Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).
Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

The corresponding analysis of spinal flexibility and in-orthosis correction (assessed by US and X-ray, calculated as curve angle and correction rate) shown in Table 4.16. It is found that (1) The highest correlation (R = 0.87) was demonstrated between the US curve angle in prone position and the US curve angle in in-orthosis position. (2) The X-ray in-orthosis correction was less predictable than US in-orthosis correction.

Table 4.16 Spinal flexibility and in-orthosis correction of ultrasound in-orthosis group and X-ray in-orthosis group

Group	Standing		Supine		Prone	Siting bending	Prone bending	In-orthosis correction	
	X-ray	US	X-ray	US	US	US	US	X-ray	US
US in-orthosis group (n=43)	27.5°± 6.9°	19° ± 5°	32% ± 17% 19.0° ±6.7°	**40% ± 19%** **11.4°± 4.4°**	**42% ±18%** **11.1° ± 4°**	143%±56% -7.5 ±10.4°	127%±34% -4.5°± 6.6°	41% ± 23% 16.4°±7.6°	-
X-ray in-orthosis group (n=67)	28.1° ±7.3°	18.7°±4.4°	35% ± 17% 18.8° ±7.2°	**44% ± 19%** 10.7°± 4.6°	**43% ±17%** 10.7°±4.5°	139%±60% -6.5°±11.1°	122%±38% -3.5°±7.2°	42% ± 23% 16.6°±8.0°	40%±19% 11.2°± 4.4°

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

Underlined fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

Table 4.17 Comparison and correlation analyses of angle and percentage in predicting in-orthosis correction

Group		Supine				Prone	
		X-ray		US		US	
		P	R	P	R	P	R
US in-orthosis group (n=43)	(°)	0.00	0.72	**0.27**	<u>0.76</u>	**0.16**	<u>0.87</u>
	(%)	0.02	0.67	**0.20**	0.64	**0.14**	<u>0.77</u>
X-ray in-orthosis group (n=67)	(°)	0.00	0.73	0.00	0.67	0.00	0.63
	(%)	0.00	0.71	**0.67**	0.66	**0.54**	<u>0.75</u>

P: probability value, R: Pearson correlation coefficient

Bold fonts: no significant difference with the corresponding in-orthosis correction (P > 0.05).

<u>Underlined</u> fonts: high correlation with the corresponding in-orthosis correction (R ≥ 0.75).

CHAPTER 5 DISCUSSION

Based on the results analyzed in the last chapter, explanation is attempted to be given. Focus is placed on the effective method for initial in-orthosis correction prediction (the position that shows the closest value to and highest correlation with the initial in-orthosis correction). Findings in alignment / contrast with previous studies are also discussed. Limitations of this study and potential clinical applications are pointed out in the end.

5.1 Validity analysis

Ultrasound imaging technique was firstly applied in this study to assess the spinal flexibility on the patients with AIS. The feasibility and validity of US measurements were approved via comparing to the X-ray measurements (gold standard).

The ultrasound images in the proposed positions could be acquired with sufficient information. The location of landmarks required for image measurement were clear and identifiable. The purpose-developed software could process the images in different positions for both reconstruction and measurement. In addition, the in-orthosis assessment by ultrasound system was feasible, with a four-point fixture system as described in previous studies (Li et al. 2012, Li et al. 2014). The width of posterior opening could be regarded as a direct and relative practical parameter for the indication of orthosis tightness, when using the fixture system to mimic the in-orthosis configuration.

US measurements revealed lower curve angle than X-ray measurements in this study. This was in alignment with previous studies that reported the underestimation of US curve angle in comparison with X-ray Cobb angle (Li et al. 2015, Zheng et al. 2016). The main reason could be the difference of landmarks used for ultrasound and radiographic image measurement. Ultrasound scanning was conducted posteriorly and only the posterior part of vertebrae could be captured, on which the sharp delineation of spinous process was more identifiable than the other spinal components. Hence the spinous process was identified as landmarks and the profile formed by spinous processes was used for the angle measurements on ultrasound image. While on the radiographic image, the endplates of the end-vertebrae (identified from vertebrae body) were used for Cobb angle measurements.

US curve angle showed high correlation with the X-ray curve angle in standing, supine and in-orthosis position (R = 0.77, 0.82, 0.84 respectively). This agreed with the previous studies which reported the high correlation between US and X-ray measurements (Li et al. 2015, Wang et al. 2015, Zheng et al. 2016).

US technique allows repetitive measurements of spinal curvature in various body positions without radiation, it also enables an efficient assessment that takes approximately 30 seconds for one scanning and 3 minutes for one position with real-time image display and immediate feedback of curve angle. These advantages make ultrasound a potential technique to supplement X-ray in assissting orthotic treatment planning on the patients with AIS.

5.2 Correlation analysis

5.2.1 Spinal flexibility

The recumbent test was performed in supine and prone position in this study. The supine test was conducted on a purpose-designed couch with a central rectangular slot that exposed the scoliotic spine of patients for ultrasound scanning. The lateral bending test was performed in sitting and prone position in this study, rather than the most commonly adopted supine with lateral bending position. Because supine with lateral bending test required patient to lie down on a supporting surface that blocked the spine for ultrasound scanning, a single slot on the supporting surface could not suite for every patient while multiple slot on the supporting surface was less feasible. To expose the spine for ultrasound scanning, the lateral bending test was performed in prone position instead. A pilot test was also tried in the standing with lateral bending position, however, the procedure of ultrasound scanning was affected by the body swing and the leg discrepancy in standing position. Hence sitting with lateral bending test was performed instead, which allowed hip and knee joint flexion to facilitate posture stability.

In an erect position, gravity added longitudinal load on the spine, muscles maintained the trunk alignment and balance. In a recumbent position, the longitudinal load on the spine was reduced and some muscle groups were at relaxation, meanwhile the supporting surface exerted an upward force to the spine which changed the sagittal configuration of the spine. Therefore, recumbent position resulted in spinal curve correction and demonstrated recumbent flexibility.

Lateral bending movement of the trunk would increase the activity of muscles on two sides of the spine, but more muscle recruitment and higher myoelectric signals on the bending side than the contralateral side (Morris et al. 1962). This indicated that the movement of lateral bending was achieved via imbalanced forces on the spine: the active forces generated from agonistic muscle overcome the resisting forces generated from antagonistic muscle. Along with imbalanced force on two sides of the spine and the change of the center of gravity during lateral bending, soft tissues and bone structures cooperated to reallocate the vertebrae and intervertebral disc which tend to reduce the curvature of the scoliotic spine to reach a rebalanced configuration.

Supine position

Supine position induced average 8° (43%) curve correction comparing to standing position in this study, which was slightly lower than previous findings with more than 10° curve correction (Torell et al. 1985, Hwang et al. 2008). While the correction rate (supine flexibility) in this study (43%) was found higher than previous studies (25-30%) (Yazici et al. 2001, Hwang et al. 2008). The inconsistency may due to the difference of included patients and assessment techniques. Previous studies mainly investigated the patients with severe curves who tended to demonstrate larger magnitude of corrected angle than the patients with mild to moderate curves in this study, however, lower spinal flexibility (correction rate) was also possible due to larger magnitude of original curve angle. In addition, the lower ultrasound measurements in this study than the X-ray measurements in previous studies could also lead to lower corrected angle along with positional change.

Prone position

Prone position induced average 8° (43%) curve angle correction comparing to standing position in this study, while previous literatures provided little reference for comparison. In most studies, prone position was adopted to assess the vertebrae rotation in transverse plane instead of lateral curvature in coronal plane, because the transverse plane deformity (vertebral rotation and ribcage shape) could be accurately determined by CT which was mainly conducted in prone position (Krismer et al. 1996). Abul-kasim et al. measure the AVR of the patients with severe scoliosis on the CT image, and reported 15% correction of the AVR from standing to prone position (Abul-Kasim et al. 2010).

Prone position test would be applicable to assist surgery planning. The measurements from prone position could help screw insertion as it generated figures of vertebral rotation measured in a position identical to that a surgeon usually faced with on the operating table. As the prone position with manual correction and prone position under general anesthesia were reported to have potential predictability to the postoperative correction (Liu et al. 2010, Chaudry and Anderson 2017), future studies were deserved to explore the feasiblity of prone flexibility to assist surgical planning.

Lateral bending position

The sitting with lateral bending test was firstly investigated in this study. In the sitting position, the hamstring and iliopsoas muscles were stretched and tended to pull the pelvis tilt posteriorly, which potentially reduced the lumbar lordosis and changed the spinal curvature. Using digital photographs, Fortin et al. (2013) not only found significant differences of the curve angle in standing and sitting positions, but also differences in head protraction, shoulder elevation, scapula asymmetry, trunk list and pelvic tilt. But the value of Cobb angle change was not reported in their study since photography could not reveal bone morphology.

The lateral bending position (both sitting and prone with lateral bending) overcorrected the spinal deformity to the opposite side (>100% curve correction) and showed no correlation with the in-orthosis correction (both US and X-ray measurement) in this study. While previous studies reported that the supine lateral bending flexibility ranged from 40 to 80% (Klepps et al. 2001, Hamzaoglu et al. 2005, Chen et al. 2011, Rodrigues et al. 2014) and was highly correlated with the surgical correction (Lenke et al. 1992, Takahashi et al. 1997). The disagreement might be due to the different assessment methods, studied patients and treatments received: supine with lateral bending versus prone with lateral bending position, patients with severe scoliosis versus moderate to mild scoliosis, prediction of surgical correction versus orthotic correction.

Electromyography (EMG) device was previously tried to be used to monitor and standardize the performance of maximum bending, however, the magnetic field of EMG device interfered the ultrasound positioning system and made it infeasible for such detection. Further attempts are still necessary to better standardize the maximum bending positions.

5.2.2 In-orthosis correction

The average in-orthosis correction was approximately 40% (both US and X-ray measurement) in the current study, which was in line with the reported 40% - 50%

in-orthosis correction of Boston orthosis (Emans et al. 1986, Yrjönen et al. 2007), but that was considerably lower than the reported 59% - 96% in-orthosis correction of asymmetric orthoses (D'amato et al. 2001, Bohl et al. 2014). It has been known that different types of orthoses lead to diverse in-orthosis correction as the design principles are different, thus the results in this study may be more applicable to the underarm TLSO with symmetric design.

5.2.3 Spinal flexibility and in-orthosis correction

Recumbent assessment & X-ray in-orthosis assessment

For the prediction of X-ray in-orthosis correction, the US measurements in prone position was superior than the US / X-ray measurements in supine position as it was not significantly different from and highly correlated with the X-ray in-orthosis measurement.

The X-ray measurements in supine position was higher than the X-ray measurements in in-orthosis position in curve angle (19° versus 16.4°) and lower in correction rate (32% versus 41%). The US measurements in recumbent positions (11.4°, 40% for supine position and 11.1°, 42% for prone position) were similar with the X-ray in-orthosis correction (16.4°, 41%) in correction rate but lower in curve angle. The curve angle difference mainly resulted from lower curve magnitude of US measurements comparing with X-ray measurements as found in the current study and reported by previous studies (Li et al. 2015, Zheng et al. 2016). Both US and X-ray measurements in supine position showed moderate correlation with the in-orthosis measurement, only the US measurements in prone position calculated as correction rate (prone flexibility) showed high correlation with the in-orthosis correction ($R = 0.75$). Therefore, the prone flexibility assessed by US was more predictive to the X-ray in-orthosis correction, comparing to US / X-ray measurements in supine position.

Recumbent measurements & US in-orthosis measurement

For the prediction of ultrasound in-orthosis correction, US measurements were better than X-ray measurement, especially the ultrasound measurements in prone position showed the highest correlation.

The X-ray measurements in supine position were higher than the US measurements in in-orthosis position in curve angle (19° versus 11.2°) and lower in correction rate (35% versus 40%). The ultrasound measurements in recumbent positions (10.7°, 44% for supine position and 10.6°, 43% for prone position) were close to the ultrasound in-orthosis correction (11.2°, 40%) in both curve angle and correction rate. Previous studies also reported that the curve angle in supine position was close to the curve angle within orthosis (Wong et al. 1994, Vidyadhara and Mak 2008). The X-ray measurements in supine position showed moderate correlation with the in-orthosis measurements, while the US measurements in both supine and prone position showed high correlation with the in-orthosis correction ($R > 0.75$). Therefore, the US measurements were superior than X-ray measurements for the prediction of US in-orthosis correction. Even though both US supine and prone measurements were not different from and highly correlated with the in-orthosis measurement, the prone measurements were more predictive to the in-orthosis correction considering higher correlation coefficient ($R = 0.87$ versus 0.77 for curve angle, $R = 0.76$ versus 0.64 for curve angle).

Supine measurements & prone measurement

No significant difference was found between the ultrasound supine and prone measurements (11.4° versus 11.1°, 40% versus 42%) in this study. In both supine and prone position, the gravity effect on the spine was eliminated axially and some muscle groups relax. The difference was that the upward force from the supporting surface was from the dorsal side in supine position and from the ventral side in prone position. The difference of force direction seems not affect the correction effect of the scoliotic spine therefore showed similar correction effect in supine and prone position. While for the patients with severe scoliosis instead of mild to moderate scoliosis in this study, more severe rib hump or anterior chest deformity may disrupt the alignment of the shoulder and pelvis hence leading to slightly different result. The supine and prone angle were reported to be close (54° versus 57° for thoracic curve and 33° versus 35° for lumbar curve) but with significant difference (Brink et al. 2017).

Higher correlation (predictability) of the prone measurements than supine measurements with the in-orthosis measurements were found in this study. Among the pairwise correlation between spinal flexibility and in-orthosis correction (assessed by US and X-ray and calculated as curve angle and correction rate), the US measurements in prone position was not significantly different and shows higher correlation (predictability) to both US and X-ray in-orthosis measurement. For the prediction of US in-orthosis correction, the curve angle in prone position assessed by US was not different and shows the highest correlation with the in-orthosis measurements ($R = 0.87$). For the prediction of X-ray in-orthosis correction, the curve correction rate in prone position assessed by US was not different and shows the highest correlation (R = 0.75) with the in-orthosis measurement. These findings suggested that the prone position could be an alternative to supine position for spinal flexibility measurements to predict the initial in-orthosis correction. For those clinics where flexibility was assessed visually according to the experience of orthotists, involving prone flexibility measurements into the routine practice would make current empirical examination more scientific and quantitative. Integrating prediction of in-orthosis correction with spinal flexibility into treatment planning would make orthosis design more scientific and evidence-based.

The X-ray in-orthosis angle was not predictable neither by supine nor by prone measurement. X-ray in-orthosis curve angle (16.4°) was significantly lower than the X-ray supine measurements (19°), significantly higher than the US recumbent measurements (approximately 11°), and moderately correlated with all these recumbent measurements. Therefore, it was more appropriate to predict the correction rate (41%) of X-ray in-orthosis correction because it was not different with and highly correlated to the US measurements in prone position (42%).

Comparing the supine measurements by US and X-ray, both showed moderate correlation with the in-orthosis measurements (except for high correlation between US supine and US in-orthosis measurement). While the X-ray supine measurements were significantly different with and US supine measurements were close to the in-orthosis measurement. Thus, US was regarded superior to the X-ray measurements for the prediction of the in-orthosis correction in this study.

Lateral bending measurements & In-orthosis measurement

Lateral bending test was the primary way to assess the maximum correctability of the scoliotic deformity. Surgeons assessed the maximum correctability because it assisted classifying curve type, determining structural / nonstructural curve and selecting fusion level for surgical planning. This study found that the correction in lateral bending position showed much higher correction (>127%) than the in-orthosis correction by a symmetric underarm rigid spinal orthosis (41%). It indicated that the maximum flexibility may be less predictive to the correction by conservative treatment. While the lateral bending flexibility seemed promising in predicting the correction effect of asymmetric spinal orthosis. Ohrt-Nissen et al. (2016) reported that the curve angle in the supine with lateral bending position were the same with the initial correction by Providence orthosis with a mean difference of 0.28°. Future studies are also needed to understand the predictability of spinal flexibility to the treatment effect of other types of orthoses. Future studies are also deserved to explore the feasibility of using US to assist surgical treatment planning, considering the potential of lateral bending flexibility to predict surgical correction and possibility of radiation-free measurements by US imaging technique.

Sitting with lateral bending measurements & Prone with lateral bending measurement

The measurements in sitting with lateral bending and prone with lateral bending position were highly correlated (R > 0.8), but the sitting with lateral bending measurements were significantly higher than the prone with lateral bending measurements (143% and 127%, respectively). The superiority of sitting bending to reveal the maximum lateral bending flexibility could because that the gravity contributed to lateral bending and assisted pelvic stabilization in the sitting position, meanwhile the flexed hip and knee joints were in a relatively stable position that facilitated spinal muscles contraction for lateral bending. Despite that the reduced gravity effect on the spine has induced curve correction comparing with sitting in the prone position, more muscle activities might involve in avoiding pelvic lateral tilting and lower extremities shifting during bending, due to less control of the lower body in lying down position.

5.2.4 Confounding factors

Initial in-orthosis effectiveness could be affected by many factors such as spinal condition (curve magnitude and location, flexibility, etc.), physical difference (BMI, maturity, etc.), orthosis design (type, tightness etc.). To better understand the relationship between spinal flexibility and the initial in-orthosis correction, some confounding factors such as curve magnitude and location were tried to be controlled via appropriate grouping strategy, while some confounding factors existed potentially thus being identified here for justification.

No influence of curve magnitude and location on the correlation between spinal flexibility and in-orthosis correction was found in this study. The correlation between recumbent flexibility and in-orthosis correction was close in mild and moderate curves ($R = 0.6 - 0.8$ and $0.6 - 0.9$ respectively), and close in thoracic and thoracolumbar / lumbar curves ($R = 0.6 - 0.8$ and $0.6 - 0.9$ respectively) as well. No correlation ($R < 0.25$) was found between the lateral bending flexibility and in-orthosis correction in all curve magnitude (mild or moderate) and locations (thoracic or thoracolumbar / lumbar curves). These findings supported that the correlation between spinal flexibility and in-orthosis correction demonstrated a consistent trend in the subgroups and overall curves. In addition, thoracic curves showed lower in-orthosis correction, but similar flexibility with lumbar curves for the moderate curves. The different in-orthosis correction of the thoracic and lumbar curves may be due to the stiffer structure of the thoracic spine resulting from the restriction of the rib cage and sternum. The similar flexibility of the thoracic and lumbar curves found in this study was inconsistent with the previous study that reported higher flexibility of the thoracolumbar or lumbar curves than the thoracic curves (Hamzaoglu et al. 2005). This might be because the range of original curve angle of the patients in this study was within a small range (15° - 45°) compared to the previous study (22° - 110°). The moderate curves showed lower lateral bending flexibilities but similar recumbent flexibilities with the mild curves. This demonstrated that curve magnitude would affect the maximum flexibility that was revealed by maximum lateral bending, but it would not affect the recumbent flexibility that was revealed by the gravity reduction. Nevertheless, a solid conclusion cannot be drawn due to the small sample size ($n \leq 13$) in the mild curve group and small difference of mean curve angle between groups (approximately 20° versus 30°). Smaller curve magnitude was usually expected with a higher in-orthosis correction (Steffan and Heinen 2014). In the present study, however, the in-orthosis correction was approximately 40% regardless of the original curve magnitude. One possible reason was that the original standing Cobb angle of most patients in this study was within small range, the trend of magnitude effect on the in-orthosis correction was not obvious. The other possible reason was that the orthotists used standard in-orthosis correction as reference for orthosis design which led to relatively consistent in-orthosis correction.

BMI and Maturity may also affect both spinal flexibility and in-orthosis correction. Li et al. (2014) found that the patient with higher BMI required longer time to achieve curvature correction after donning orthosis and the patient with lower BMI required longer time to show curvature collapse after doffing the orthosis, whether BMI would affect the magnitude of in-orthosis correction was not reported. Deviren et al. (2002) reported that the spinal flexibility decreased by 5% for every 10-year increase in age due to degenerative changes in soft connective tissue, facet joints and intervertebral discs. However, the relevant effects were not analyzed in the present study as the study group are relatively homogeneous (10 - 14 years with riser 0 - 2 and BMI 18 ± 3), in whom degenerative changes capable of decreasing the spinal flexibility probably had not yet occurred.

The correction effect of different designs of orthoses may differ greatly. For instance, Boston orthosis and Providence orthosis achieve mean in-orthosis correction of 40 -50 % (Emans et al. 1986, Yrjönen et al. 2007) and 59% - 96% (D'amato et al. 2001, Bohl et al. 2014, Ohrt-Nissen et al. 2016) respectively. Hong Kong orthosis, a kind of symmetric underarm rigid spinal orthoses, were used in this study. To reduce the bias of orthosis fabrication process, the orthoses were fabricated following the standard procedures by a team of orthotists with more than 5-year clinical experience. Besides, the strap tension was tried to be standardized to the tightest level meanwhile ensuring no self-reported intolerable discomfort. Even though some studies have quantified the average strap tension of spinal orthosis ranging from 20 N to 40 N (Wong et al. 2000, Mac-Thiong et al. 2004), these findings only provided a possible range of strap tension, different tolerance, soft tissue volume and bony prominence of individual patient made it difficult to standardize the prescribed tension to this range.

Level of the apex, number of involved vertebrae in the curvature may also affect the corrective ability of the spinal deformity (Watanabe et al. 2007). Watanabe et al. explained that as the level of the apex become more caudal, the number of involved thoracic vertebrae in the curve would decrease; or as the curve become longer, the number of lumbar vertebrae would increase in the curve. Consequently, better correction of the spinal deformity could be obtained. But these explanations are the justification of their observations and was not regarded as a solid conclusion.

5.3 Clinical significance

Assessment of spinal flexibility using radiation-free ultrasound imaging technique allows integrating spinal flexibility assessment into routine practice, which quantifies an essential parameter to guide orthosis design, modification and evaluation from the fitting process to the end of orthotic treatment.

Prediction of individualized in-orthosis correction by spinal flexibility at the pre-orthosis stage can assist clinicians to differentiate the patients who are likely or unlikely to benefit from orthotic treatment thus improving treatment planning. In addition, orthosis design according to the predicted in-orthosis correction optimize the empirical and qualitative treatment process to be more evidence-based and patient-specific.

5.4 Limitations

This study has some limitations. Firstly, the spinal flexibility in the coronal plane was analyzed in this study, the vertebrae rotation in the transverse plane will be elaborated after the 3-D image analysis software is fully developed. Secondly, the ethical issues and time restriction do not allow the reliability and validity tests in all the studied positions in the current study. Thirdly, a regression formula that transfers the prone flexibility to in-orthosis correction cannot be generated, which may because that some uncontrollable factors, such as patient's spine condition, orthosis design, compliance, confounds the linear correlation between spinal flexibility and in-orthosis correction.

CHAPTER 6 CONCLUSIONS

This chapter summarizes the major findings of the current study and suggests the directions of future studies.

6.1 Major findings

Spinal flexibility is an essential parameter for clinical decision on the patients with AIS. Various methods are proposed for spinal flexibility assessment, but which method is more effective to predict the correction within orthosis is unknown. Therefore, this study aimed to investigate an effective assessment method of spinal flexibility to predict the initial in-orthosis correction using ultrasound imaging technique.

The results of ultrasound measurements were highly correlated with the X-ray measurements, which indicated that ultrasound imaging technique could be regarded as a valid and radiation-free technique for the assessment of spinal flexibility. This novel application of US technique in clinic quantifies essential parameters to assist orthosis design, modification and evaluation from the fitting process to the end of orthotic treatment.

In addition, spinal flexibility in the prone position was found not different from and showed the highest correlation to the initial in-orthosis correction among the 4 studied positions. Therefore, the prone position test could be an effective method to predict the initial effect of orthotic treatment in the patients with AIS. This finding provides useful data basis to formulate an individualized guideline in orthosis design and contribute to an evidence-based treatment planning, thus potentially improving the effectiveness of conservative treatment and reducing the chances of surgery intervention.

6.2 Future studies

Considering scoliosis is a three-dimensional deformity of the spine, the flexibility in the sagittal and transverse plane should be studied in the future. Besides, this study focuses on the initial effect of orthotic treatment, the relationship between spinal flexibility and long-term effect of orthotic treatment needs to be investigated in follow-up studies. In addition, the posterior opening of orthosis is required to be widened for allowing in-orthosis ultrasound scanning in this study, a smaller ultrasound probe should be developed for the convenience of clinical application.

APPENDICES

Appendix I: English version of information sheet

INFORMATION SHEET

Project Title: Using spinal flexibility to predict the initial in-orthosis correction on the patients with adolescent idiopathic scoliosis

You are invited to participate in a study conducted by Dr. Man-sang WONG, Associate Professor of the Department of Biomedical Engineering, The Hong Kong Polytechnic University. Miss Chen HE who is a PhD student of Dr. Man-sang WONG, will be the assistance in this study.

The aim of this study is trying to apply ultrasound imaging technique in assessing spinal flexibility and initial in-orthosis correction effect of the patients with adolescent idiopathic scoliosis in a non-invasive approach. The Ultrasound system is a specially designed system used for the assessment of scoliosis, which is safe for human. The ultrasound images obtained from the ultrasound system will be analyzed to evaluate the spinal flexibility and initial in-orthosis correction effect.

Subjects can withdraw from the study at any time without affecting their continuous treatment.

The results of this study can contribute in scientific practice of assessment and orthotic intervention and form a data base for further developments of orthotic treatment protocol for adolescent idiopathic scoliosis.

All information related to you will remain confidential and will be identifiable by codes only known to the researcher. Subjects are at minimum risk with this study. Minimal risk means that the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life.

You have every right to withdraw from the study before or during the measurements without penalty of any kind.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss Ivy CHAU, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Room M1303, Human Resources Office of the Hong Kong Polytechnic University).

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

Thank you for your interest in participating in this study.

Principal Investigator: Dr. Man-sang WONG

Appendix II: Chinese version of information sheet

相關資料

項目名稱: 關於青少年特發性脊椎側彎患者脊柱柔韌性預測矯形器初始矯正效果的研究

誠邀閣下參加由香港理工大學生物醫學工程學院 黃文生 副教授負責執行的研究項目。此項目將由 黃文生 副教授的博士研究生 賀晨 來協助執行。

此研究的目標是使用三維超聲和影像自動識別技術來測量青少年特發性脊柱側彎病人的脊柱柔韌性和評估矯形器初始矯正效果。閣下只需要在佩戴脊柱矯形器前和佩戴脊柱矯形器時接受一項簡單的三維超聲檢查。三維超聲是在普通超聲的儀器上配置三維定位系統用於追蹤超聲掃描的探頭在三維空間中的位置，從而把二維的超聲圖像重建成為三維的圖像。此設備中的三維定位系統是用電磁波信號進行追蹤和重建的，系統中所用的信號對人體無害。由超聲儀器所測的三維脊柱圖片将会被用来评估脊柱柔韌性和矯形器的初始矯正效果。

所有的參加者都有權在任何時候選擇退出此項目，並且不影響其後續的治療。超聲波檢查已經使用多年，到目前為止還沒有出現任何安全問題報告，因此在測試的過程中將不會令閣下有任何不必要的不適。

此研究得出的結果可在矯形器的治療科學運用做出貢獻及能形成數據庫以便研究人員進一步研發能更好的治療青少年特發性脊柱側彎的矯形器。

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。

如果閣下有任何對這項研究的不滿，請隨時親自或寫信聯絡香港理工大學-人事倫理委員會秘書 周艾維（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。

首席調查員:黃文生 副教授

Appendix III: English version of consent form

CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Using spinal flexibility to predict the initial in-orthosis correction on the patients with adolescent idiopathic scoliosis

I ____________ hereby consent to participate in the captioned research conducted by Dr. Man-sang WONG (Associate Professor of the Department of Biomedical Engineering, The Hong Kong Polytechnic University), and assisted-conducted by Miss Chen HE.

I understand that the 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.

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

Name of participant: ____

Signature of participant: ____________________________________

Date: ____

Name of researcher: ____

Signature of researcher: ______________________________________

Date: ____

Name of supervisor: ____

Signature of supervisor: ______________________________________

Date: ____

Appendix IV: Chinese version of consent form

參與研究同意書

項目名稱: 關於青少年特發性脊椎側彎患者脊柱柔韌性預測矯形器初始矯正效果的研究

本人 __________特此同意參加由香港理工大學生物醫學工程學院 黃文生 副教授負責執行及加以說明的研究項目，並且該項目將由 黃文生 副教授的博士研究生 賀晨 來協助執行。

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被洩漏。

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，并可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。

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.

參加者姓名：____________________________________

參加者簽名：____________________________________

日期：____

研究人員姓名：__________________________________

研究人員簽名：__________________________________

日期：____

導師姓名：______________________________________

導師簽名：______________________________________

日期：____

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