DESIGN AND DEVELOPMENT OF ANISOTROPIC TEXTILE BRACE FOR ADOLESCENT IDIOPATHIC SCOLIOSIS (AIS)

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Design and Development of Anisotropic Textile Brace for Adolescent Idiopathic Scoliosis (AIS)

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ABSTRACT

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional (3D) deformation of the spine, affect 2%-4% of children during their puberty. To date, there is still no clear etiology of this condition. Three possible risk factors for the progression of spinal curvature is pointed out by researchers that are immature skeleton, female gender and large curve magnitude. AIS not only leads to posture and appearance problems for patients including uneven shoulders, scapular asymmetry, abnormal shape of the spine, and pelvis obliquity, but also causes other psychological and health issues for severely affected patients, such as back pain, leg numbness, as well as cardiopulmonary diseases. More importantly, spinal progression is found in scoliotic cases, especially the one before skeletal maturity. Proper treatment is therefore the key for all patients with AIS.

For patients with Cobb's angle above 20°, bracing treatment, rigid bracing in particular, is recommended by doctors, which is a common non-invasive treatment for AIS. It aims to control the progression of spinal curvature or even correct the curve. Even if the corrective performance of rigid braces has been proven, its physical and psychological consequences like low self-esteem and low patient compliance due to discomfort, bulkiness of the brace, inconvenience and even the stigma of wearing a hard brace cannot be neglected as they may result in failure of bracing. To cope with these shortcomings, non-rigid braces are developed, for instance SpineCor, TriaC, and functional intimate apparel. However, there are other problems caused by such orthoses, including ambiguous bracing effect, insufficient corrective forces provided by the braces, skin irritation and so forth. Thus, the aim of this study is to design and develop a non-rigid brace for AIS patients to anticipate an alternative choice or even a more comfortable and better option for bracing treatment, and halt the progression of spinal

deformity as well as enhance body image.

This study consists of three main goals to (1) contribute to the knowledge gap in non-rigid brace designs and provide a comfortable yet effective option for bracing treatment for AIS patients, (2) conduct a series of physical tests to select the most appropriate materials for developing this new brace, and more importantly, (3) conduct a systematic clinical trial that periodically monitors the compliance rate and situation of human subjects during bracing treatment with the newly designed brace, including changes in their spinal curvature, body contours, sitting posture, and Health-Related Quality of Life (HRQOL) items.

Apart from low compliance rate of treatment with existing braces and ambiguity in the non-rigid bracing effectiveness, few studies and little research effort on the use of non-rigid braces was also found in another literature review which was done by using citation network analysis (CNA) in this study to thoroughly understand the background and the potential study areas in the field of nonsurgical treatments. Moreover, the findings also highlighted the importance of patient compliance with the brace treatment and the tightness of the brace in a bracing treatment.

In response to the research gaps found in the background study, an anisotropic textile brace for AIS was designed in this study. Due to the satisfactory in-brace correction of functional intimate apparel, the proposed brace design was inspired by it. This newly brace design adopted the same mechanism on spinal correction and similar design concepts as functional intimate apparel with the aim to maintain the bracing effectiveness of previous brace, meanwhile, minimize its design limitations like fit, comfort and durability. During this process of design and development, a design framework, a modified functional, expressive and aesthetic (FEA) model for designing a medical textile or scoliosis brace, was adopted. At last, the final anisotropic textile brace was designed as a one-piece garment with a hinged artificial backbone, corrective bands with pads, and pelvis belt. Besides, a series of physical tests were carried out to select the most appropriate materials for brace fabrication.

More importantly, a preliminary 2-hour wear trial and 3-6 month clinical trial were conducted respectively to investigate the initial bracing outcomes and a short-term effect of proposed brace. Changes in Cobb's angle, body contours, interface pressure measurement, quality of life, and user comments were focused on in the preliminary trial. It was indicated that almost all recruited subjects achieved 5 or more degrees in their initial in-brace reduction of spinal curvature, in which the average correction was 29.6%. Although the rate of initial spinal improvement was still lower than the functional intimate apparel, it is comparable to some types of existing braces in the market. As for the initial changes in body contours, it was found a severer shoulder oblique problem in most of cases in this study whereas most cases shown a better improvement on shoulder rotation. Even if the value of posterior trunk symmetry index (POTSI) obviously reduced up to 60%, no correlation had been detected between all changes above and spinal correction. Furthermore, in considering the corrective forces in interface pressure value, there was no significant difference between the prior functional intimate apparel and the newly developed brace that implied the proposed brace could still contribute a similar performance on spinal correction. In terms of health-related test, no significant correlation was found between initial changes in Cobb's angle and any item of questionnaires. Surprisingly, significant better patient acceptance towards proposed brace was found compared with the functional intimate apparel.

Only with 5 degrees or above initial in-brace correction, subjects were invited in the 3-6 month clinical trial to examine the short-term effectiveness of anisotropic textile brace in terms of the correction of spinal curvature, body contours, sitting posture, quality of life, compliance rate, and user feedback of wear experience. Follow-up session was carried out as periodical monitoring for each subject every month. It was found that the spinal deformity of all recruited subjects was under control, and even one of them got 32% spinal improvement after 3 months of bracing. Such improvement had no positive correlation with the changes of body contours. With regard to their changes in their sitting posture, prior study stated the assumption that more even pressure distribution between left and right buttock regions represents a better sitting posture. Even if there is no significant difference shown in the changes in their body alignment, their pressure distribution significantly shown much more even in the buttock regions after 2nd month of intervention that was considered as improved sitting posture after bracing. Besides, no obvious changes were found in health-relative tests after 3rd month of intervention but a significant improvement in an aspect of physical functioning in the Brace Questionnaire that showed the proposed bracing treatment did not affect their quality of life. In addition, most subjects had a good brace compliance and their bracing effectiveness of spinal correction relied on the brace compliance, for instance the rate of the best compliant subject was up to 98.3% who also achieved the most pleasing reduction in Cobb's angle after 3-month bracing. Overall, no negative effect was found that affected quality of life of subjects during bracing and they were all satisfied with the proposed brace treatment, even if there was still room for improvement on the durability and fitting problems of hinge bone.

PUBLICATIONS ARISING FROM THE THESIS

Journal papers:

- **Wong, S.H.** , Yip, J., Lo, K.Y.C. , Cheung, K. M. C., Cheung, J. P. Y., Kwan, K. Y. H., Yick, K.L., & Ng, S.P. (2020). Non-invasive Treatment of Adolescent Idiopathic Scoliosis: Systematic Literature Review by Using Citation Network. *Spine and Surgery.*
- **Wong, S.H.**, Yip, J., Yick, K.L., & Ng, S.P. (2020). The Study of Correlation Between Sitting Pressure Distribution and Adolescent Idiopathic Scoliosis. [IN PREPARATION]

Conference papers:

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- Cheung, M.C., Yip, J., **Wong, C.S.H.** (2019). Quality of Life among Young Female Adolescents with Regular Daily Use of Electronic/Video Games in Hong Kong. *IISES International Academic Conference*, London, United Kingdom, 21-24 May.
- Cheung, M.C., Yip, J., **Wong, C.S.H.** (2019). Influence of Computer and Smartphone Usage on Quality of Life in Young Female Adolescents in Hong Kong. *2019 International Symposium on Education and Psychology (ISEP 2019)*. Fukuoka International Congress Center, Fukuoka, Japan, 1-3 April.
- **Wong, S.H.**, Yip, J., Yick, K.L., & Ng, S.P. (2020). Preliminary Wear Trial of Anisotropic Textile Brace for Adolescent Idiopathic Scoliosis. *International Society for Engineering Research and Development International Conference (ISERD International Conference)*, Zurich, Switzerland, 16-17 February.
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LIST OF ABBREVIATIONS

A

AIS	Adolescent Idiopathic Scoliosis
ALV	Apical Lumbar Vertebrae
AP	Anteroposterior
ASIS	Anterior Superior Iliac Spines
ATB	Anisotropic Textile Brace
ATR	Angle of Trunk Rotation

B

BrQ	Brace Questionnaire
BS	British Standard

C

C7	7th Cervical Vertebra
CB	Coronal Balance
CD	Coronal Compensation
CERP	Carbon Fibre Reinforced Polymer
CNA	Citation Network Analysis
CS	Core Stabilization
CSVL	Central Sacral Vertical Line

CT	Computer Tomography
CTLSO	Cervico-Thoraco-Lumbo-Sacral Orthosis

D

DM	Double Major

F

FAI-A	Frontal Asymmetry Index Axillar
FAI-C7	Frontal Asymmetry Index C7
FAI-T	Frontal Asymmetry Index Trunk
FE	Finite Element
FEA	Functional, Expressive, and Aesthetic
FIA	Functional Intimate Apparel

G

GCS	Global Citation Score

H

HDI-A	Height Different Index Axillar
HDI-S	Height Different Index Shoulder
HDI-T	Height Different Index Trunk
HKAI	Hong Kong Advanced Imaging
HRQoL	Health-Related Quality-of-Life

K

KES-F7	Kawabata Evaluation System- F7

L

LCS	Local Citation Score

M

MIU	Mean Friction Coefficient
MMD	Fluctuation of Mean Frictional Coefficient
MT	Main Thoracic

P

P&O	Prosthetist-Orthotist
PLA	Poly Lactic Acid
PMMA	Polymethyl Methacrylate
POM	Polyoxymethylene
POTSI	Posterior Trunk Symmetry Index
PSIS	Posterior Superior Iliac Spine
PT	Proximal Thoracic

R

RAB	Rotational Angular Breathing

S

SF-36	Short Form 36 Health Survey
SLRs	Systematic Literature Reviews
SMD	Surface Roughness
SOSORT	Society on Scoliosis Orthopaedic and Rehabilitation Treatment
SPSS	Statistical Package for Social Science
SRS	Scoliosis Research Society
SRS-22	SRS-22 Health-related Quality-of-life Questionnaire
SSE	Scoliosis-Specific Exercise
SVA	Sagittal Vertical Axis
T	
TAPS	Trunk Appearance Perception Scale
TL/L	Thoracolumbar/Lumbar
TLSOs	Thoracic-Lumbo-Sacral Orthoses
TM	Triple Major
W	
WoS	Web of Science
WVT	Water Vapor Transmission
3D	Three-dimensional

CHAPTER 1 – INTRODUCTION

1.1 Background of research

Adolescent idiopathic scoliosis (AIS) is the most prevalent three-dimensional (3D) spinal deformity, accounts for 80% of the diagnosed scoliosis cases and affects 2%-4% of children during their pubertal growth spurt, especially those who are between the ages of 10 and 16 prior to skeletal maturity (Reamy & Slakey, 2001; Scoliosis Research Society Terminology Committee, 1976; Weinstein, Dolan, Cheng, Danielsson, & Morcuende, 2008). Although the etiology of this condition is still unknown, Weiss et al. (2006) and Sun et al. (2013) pointed out that the three possible risk factors for the progression of spinal curvature is the immature skeleton, female gender and large curve magnitude.

AIS not only leads to posture and appearance problems for patients including uneven shoulders, scapular asymmetry, abnormal shape of the spine, and pelvis obliquity, but also causes other psychological and health issues for severely affected patients, such as back pain, leg numbness, as well as cardiopulmonary diseases (Dewald, 2003; Harvard Medical School, 2013). Moreover, epidemiologic studies have indicated that once mild idiopathic scoliosis has developed, the progression of the spinal curve in 10-15% of adolescent patients worsen before skeletal maturity (Asher & Burton, 2006; Modi et al., 2010; Reamy & Slakey, 2001; Soucacos et al., 2000). Nearly 10% of patients with AIS have to consider surgery due to the progression of their spinal deformity (USC Center for Spinal Surgery, 2005). Thus, monitoring and controlling spinal curvature are key priorities for all patients with AIS.

Nowadays, medical care for AIS patients is mainly in the form of observation, non-surgical treatment, and surgical correction depending on the progression of the spinal curve (Dolan, Donnelly, Spratt, & Weinstein, 2007; Weinstein et al., 2008). Researchers believe that successful bracing is the most effective conservative treatment for AIS. It is also the main treatment for moderate scoliosis cases with a Cobb's angle between 20° and 45°, especially for those with a spinal curvature that is 20°- 30° (Lonstein, 2006; Negrini, Marchini, & Tomaello, 2006; Richards, Bernstein, D'amato, & Thompson, 2005). However, there are various factors that may affect the effectiveness of bracing treatment, such as low patient compliance due to discomfort, bulkiness of the brace, inconvenience and even the stigma of wearing a hard brace (Schiller, Thakur, & Eberson, 2010; Weinstein et al., 2008; Wiley, Thomson, Mitchell, Smith, & Banta, 2000).

Although non-rigid braces provide a more comfortable wear experience, potential concerns include an insufficient corrective effect and low compliance of the patient, especially for flexible braces (Liu et al., 2014).

Due to the substantial number of moderate scoliosis cases (those who have a Cobb's angle of 20°- 45°), the purpose of this study is to develop an anisotropic textile brace for patients with AIS who have a Cobb's angle that is less than 45°. This is a garment-like semi-rigid brace for AIS patients that applies corrective forces through the use of rigid, semi-rigid and flexible materials. The aim is to provide non-invasive treatment for patients to control the progression of their spinal deformity and correct their posture and body shape. A clinical trial is conducted in Hong Kong to evaluate the efficacy of this newly developed anisotropic brace in treating AIS curves.

1.2 Research rationale

1. Physical and psychological concerns of AIS patients towards hard braces

As rigid plastic braces are designed to encase the entire trunk of patients, they are usually bulky which makes it difficult for wearers to conceal the brace underneath their clothing and thus may greatly affect their self-image during puberty. For girls, wearing a bulky and rigid brace may cause low self-esteem, depression, stigma and other psychological issues (Olafsson, Saraste, & Ahlgren, 1999; Sapountzi-Krepia et al., 2001). Thus, these potential problems may result in low compliance with treatment and affect the efficacy of bracing.

Apart from psychological concerns, there are various physical problems that could reduce the wear compliance of hard braces including discomfort, limitations in movement and lack of ventilation (Altaf, Gibson, Dannawi, & Noordeen, 2013). Even though soft braces are available, pain and pressure sores are also prevalent with their use. To address these shortcomings, a new brace design should focus on these concerns of the parents of AIS patients and the AIS patients themselves, as well as the wear comfort by using suitable materials.

2. Insufficient corrective forces exerted by flexible braces

Unlike rigid braces, flexible braces mainly use soft materials like elastic bands and fabrics to construct the brace. However, the use of softer materials may cause difficulties when inadequate corrective forces are exerted onto the trunk of the patients which result in ambiguous efficacy for AIS patients (Liu, 2015; Liu et al., 2014).

1.3 Research aim and objectives

The notable demand for effective bracing treatment of moderate scoliosis cases (those with a Cobb's angle of 20°- 45°) and the limitations of existing treatment methods have inspired this research study. The project aims to design and develop an anisotropic textile brace with rigid, semi-rigid and flexible materials that can exert corrective forces for AIS patients who have a Cobb's angles that is less than 45°. It is anticipated that this newly designed brace is an alternative choice or even a more comfortable and better option for bracing treatment, and halt the progression of spinal deformity as well as enhance body image. Furthermore, a clinical trial is conducted in Hong Kong to evaluate the effectiveness of the anisotropic textile brace towards controlling the progression of spinal deformity and correcting posture and body shape.

The main objectives of this research project are:

1) To provide background information of AIS and the current treatment methods, and a conduct systematic review on the various mechanisms of scoliosis braces;

2) To design and develop an anisotropic textile brace for adolescents with idiopathic scoliosis on the basis of clinical applications and materials science as well as garment technology with the aim to correct the spinal deformity, reduce the possibility of spinal curve progression, and address the needs of the patients as well as take their psychological concerns into consideration;

3) To conduct physical and mechanical tests in order to select the appropriate materials to fabricate the anisotropic textile brace; and

4) To conduct a clinical study to evaluate the efficacy of the anisotropic textile brace by examining the spinal deformity and body shape through non-invasive methods as well as collecting user feedback on their health-related quality of life (HRQOL).

1.4 Project originality and significance

AIS is a prevalent chronic condition that gradually leads to the 3D deformity of the spine. Such lateral curvature often increases in severity in youths during puberty. Although AIS patients with spinal curvature that is less than 45° are not considered to be as urgent as the severe cases who need to undergo surgical treatment, they are recommended to receive different treatments to monitor and control their spinal deformity. If they have a Cobb's angle of 25° to 45°, bracing, especially rigid bracing, is the most common treatment. The brace applies external mechanical forces to guide the repositioning of the spine and restore normal alignment. The effectiveness of hard braces has been largely proven (Peterson & Nachemson, 1995; Rowe et al., 1997) but the physical and psychological issues, such as discomfort, health impacts and low self-esteem, all undoubtedly limit the efficacy of current bracing treatments. Almost all of these concerns are resultant of the bulky appearance of the hard braces and the non-breathable materials used. As such, non-rigid braces like semi-rigid and flexible braces have been developed to remedy the problems of rigid braces. Nevertheless, there are few studies and the corrective performance of non-rigid braces is still debatable, especially the corrective force of non-rigid braces. Therefore, it is worthwhile to carry out further work in this area to provide a better bracing option for patients aside from rigid braces.

In this study, an anisotropic textile brace which is a semi-rigid brace, is developed by using breathable and comfortable textile materials, with the aim to control the spinal curvature progression through corrective forces of the materials and enhance body image and remedy the posture issues of wearers. The brace has good potential to reduce the risk of surgery while enhancing the quality of life during bracing.

The goals of this study are to (1) contribute to the knowledge gap in non-rigid brace designs and provide a comfortable yet effective option for bracing treatment for AIS patients, (2) conduct a series of physical tests to select the most appropriate materials for developing this new brace, and more importantly, (3) conduct a systematic clinical trial that periodically monitors the compliance rate and situation of human subjects during bracing treatment with the newly designed brace, including changes in their spinal curvature, body contours, sitting posture, and HRQOL items. All of these factors can advance the progress of corrective orthoses for AIS, especially non-rigid braces.

1.5 Outline of thesis

There are a total of eight chapters in this thesis (see Figure 1.1). Chapter 1 provides the background information of AIS, conception, problem statement, objectives, originality and significance, as well as the outline of this study.

Chapter 2 is the literature review, which provides a review of studies on scoliosis, the primary types of treatments, associated problems, and potential research direction of AIS treatment by using a citation network analysis.

Chapter 3 includes the research plan and methodology of this study. Different types of equipment, standards, and evaluation methods that further advance the design and development of the proposed anisotropic textile brace are discussed and explained in detail.

Chapter 4 describes the process of designing the anisotropic textile brace. The design and efficacy of a brace in the form of a functional intimate apparel in Fok (2020) are studied and modified with the goals of maintaining its corrective mechanisms but reducing its limitations. The preliminary research ideas, design criteria, inspiration elements provided by the functional intimate apparel, preliminary review of the prototype, and design refinement are also discussed in this chapter.

Chapter 5 describes the process of developing the newly designed brace, including selecting the appropriate materials based on the performance of the sourced materials in terms of comfort, fit, properties and durability. Apart from fabricating the brace and developing other components like the artificial back bone and silicone padding, adjustments to the fit of the brace are made based on the fitting problems and feedback of AIS patients.

Chapter 6 reports the results on initial bracing effectiveness of the proposed anisotropic textile brace in a preliminary wear trial, including in-brace performance in spinal curvature, changes in body contour, user feedback, and health-related test.

Chapter 7 includes the results on short-term bracing effect of newly designed brace for 3-6 month wear trial. Correction on spinal curvature, changes in body contour and sitting posture, user feedback, health-related test, as well as compliance rate are all evaluated in such periodical monitoring.

The last chapter, Chapter 8, provides a general conclusion of this research study. Suggestions are also offered for future studies based on the limitations found in this work.

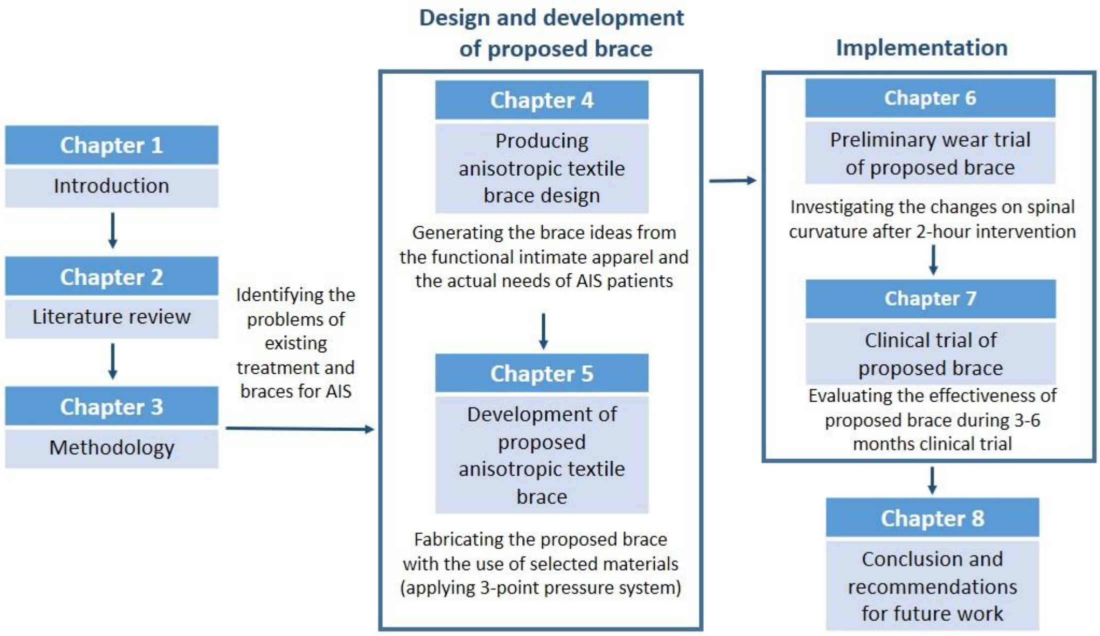


Figure 1.1 Study flowchart

CHAPTER 2 - LITERATURE REVIEW

2.1 Introduction

An overview of the previous research studies on scoliosis is provided in this chapter. As there are many different scoliotic patterns among the AIS cases, the classification of AIS, and the assessment of scoliosis, including methods of identifying scoliosis and means of diagnosing the condition are discussed as well. After that, current treatments of AIS are further reviewed by using a citation network analysis (CNA), in particular two common non-invasive treatment options - bracing treatment and different exercises for training posture. The potential research areas and knowledge gaps can be subsequently obtained. Finally, a proper design framework is also discussed to provide a systematic design process for this study.

2.2 Brief Overview of Scoliosis

2.2.1 Introduction on Scoliosis

"Scoliosis", a term that emerged from the Greek word "skoli-osis" which means crooked or bent (Matthews & Crawford, 2006), is the sideways curvature of the spine. This kind of curvature is found in the spinal column and is a rotation away from the midline abnormally, and thus a three-dimensional (3D) deformity of the spine and one of the characteristics of a skeletal defect. In general, those whose lateral curves are 10 degrees or higher in the frontal plane based on standard spinal imaging are diagnosed as having scoliosis (İzgi, 2013).

There are three main types of scoliosis which are classified based on their origins, which are secondary to congenital malformation, neuromuscular, and idiopathic disease (J Lonstein & J Carlson, 1984). The first type of scoliosis is a birth defect associated with problems in the formation of the vertebrae during development which may be even related to malformation of other organs like the heart and kidneys. Also, neuromuscular scoliosis can be due to neurological and muscular disorders, such as cerebral palsy and muscular dystrophy. Besides, degenerative joint conditions may also increase the chances of scoliosis in adults. Yet, they all are not the primary origins of scoliosis, in comparison with idiopathic scoliosis, which accounts for at least 80 percent of the diagnosed scoliosis cases.

To date, the etiology of idiopathic scoliosis is still unknown (Negrini et al., 2012; Reamy & Slakey, 2001). Based on the age in which a patient is diagnosed, idiopathic scoliosis patients can be further grouped into infantile (under the age of 3), juvenile (between 3 and 10 years old) or adolescent (over the age of 10), of which the latter or AIS is the most common type of structural scoliosis and spinal deformity (Scoliosis Research Society Terminology Committee, 1976; Weinstein et al., 2008). Nearly 10% of all AIS patients are girls, who have some degree of spinal curvature or deformity during their pubertal period (Weinstein et al., 2008). This well-known predominance of AIS among females is also validated in Raggio (2006) with a female-to-male ratio of 10:1. Therefore, this research study will focus on female patients with AIS because of the prevalence of this condition among girls.

The spine is a complex and 3D structure, which consists of 7 cervical vertebrae, 12 vertebrae, 5 lumbar vertebrae and a sacrum composed of 5 fused sacral vertebrae. Harvard Medical School (2013) indicated that a C or S shape of the spine can form in scoliosis cases due to trunk rotation or abnormal spinal shifts (as shown in Figure 2.1). Regardless of the spinal shape found in scoliosis, anatomical asymmetries are apparent symptoms of this condition. For patients with scoliosis, they might not only have uneven shoulders or hips but also scapular asymmetry and raised ribs on one side of the body. They tend to lean to one side during sitting and standing. Also, back pain and fatigue might emerge after prolonged periods of sitting, and even breathing difficulties of those who suffer from severe scoliosis. Ascani et al. (1986) reported that nearly 20% of AIS patients suffer from real psychological disturbances in which the majority are patients with severe spinal curvature.

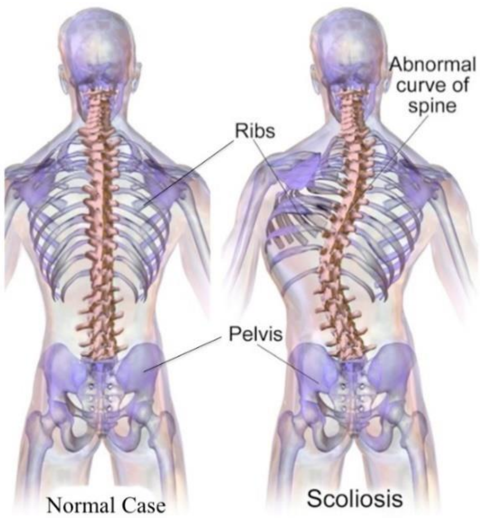


Figure 2.1 Human spine: normal vs. scoliosis

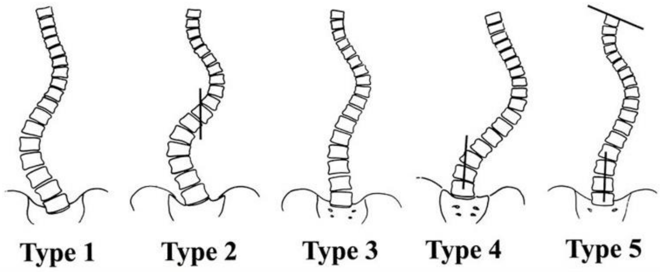
(Spine & Joint Specialists, 2019)

2.2.2 Classification Methods of Scoliosis

2.2.2.1 The King's classification system

To more comprehensively categorize the C and S shapes of the spine of those who suffer from idiopathic scoliosis, many different types of classification systems have been proposed in the literature. In 1983, a radiographic classification system called the King's classification system was introduced and subsequently widely used for a while as the standard classification system for AIS in which groups curves into five different categories (King, Moe, Bradford, & Winter, 1983). The King classification system is shown in Figure 2.2, and it can be seen that Types 1 and 2 are S-shaped curves with both thoracic and lumbar curves that cross the midline in which the lumbar curve is larger than the thoracic curve in Type 1 but the opposite is true for Type 2. In Type 3, there is a single thoracic curve but both the thoracic and lumbar curves do not cross the midline. Like Type 3, Type 4 is also a single thoracic curve, but is long so that the lowest vertebrae in the lumber spine (L5) is centered over the sacrum and the second lowest vertebrae (L4) tilts into the long thoracic curve. Finally, a double thoracic curve is found with Type 5, with the first thoracic vertebrae spine (T1) tilted into the convexity of the upper curve and the upper curve is on the side-bending.

With the evolution of 3D curvature correction approaches in the late 1980s, some of the deficiencies of the King's classification system emerged. Certain types of curves were found to be omitted, such as primary thoracolumbar, lumbar, double and triple major curves (Richards, Sucato, Konigsberg, & Ouellet, 2003). In addition, the lack of classification details on sagittal alignment and poor inter and intraobserver reliability in the use of the King system also affected its reliability and reproducibility (Cummings, Loveless, Campbell, Samelson, & Mazur, 1998; Hannes, Karlmeinrad, Michael, & Martin, 2002; Lenke et al., 1998; Richards et al., 2003).



Type I	S-shaped curves in which both thoracic and lumbar curves cross mid-line. Lumbar curve is larger. The thoracic curve is more flexible than the lumbar on supine-bending films
Type II	S-shaped curves in which both thoracic and lumbar curves cross mid-line. Thoracic curve is equal to or larger than the lumbar curve. The thoracic curve is more flexible than lumbar curve on supine-bending films
Type III	Single Thoracic curve in which the lower level does not cross the mid line
Type IV	Single long thoracic curve in which L5 is centered over the sacrum but L4 tilts into the long thoracic curve
Type V	A double thoracic curve in which T1 is tilted into the convexity of the upper curve (the upper curve is structural on supine-bending film)

AIS = Adolescent idiopathic scoliosis

Figure 2.2 King's classification system (King et al., 1983)

2.2.2.2 Lenke classification system

In order to address the shortcomings of the King's classification system, Lenke et al. (2001) developed a new classification system for AIS, called the "Lenke classification system" (Figure 2.3), which considers more different types of scoliosis curves than the King's classification system, such as double major (DM) and triple major (TM) curves. As such, scoliosis can be classified according to type of curve (1 to 6) combined with a lumbar spine modifier (A, B, or C) and a sagittal thoracic modifier (-, N, or +).

There are 3 regions in this system, which are the proximal thoracic (PT), main thoracic (MT) and thoracolumbar/lumbar (TL/L) areas. After measuring the regional curves to assess where the curve is found among the 3 regions and identifying the largest curve, minor curves can then be examined if they are structural; here, a structural curve means that the fixed curve is larger than 25 degrees in the coronal plane on a standing anteroposterior (AP) radiograph and does not bend out to less than 25 degrees on the bending films, or larger than 20 degrees in the sagittal plane. Following these steps, the primary curve can be identified, and then, the curve is assigned a lumbar modifier of A, B or C based on the relationship with the apical lumbar vertebrae (ALV) and central sacral Vertical line (CSVL) which can define the lumbar spine alignment in relation to the type of curve and help to examine the spinal position after spinal operation. Finally, the sagittal thoracic modifier is determined by measuring the sagittal Cobb of the entire thoracic spine (T5-T12) which can be used to define the thoracic spine alignment, especially for surgery preparation (Lenke et al., 2001). With the use of this system, scoliosis cases can be simply labeled, such as 1A-, 1AN, 6CN, and so on and so forth.

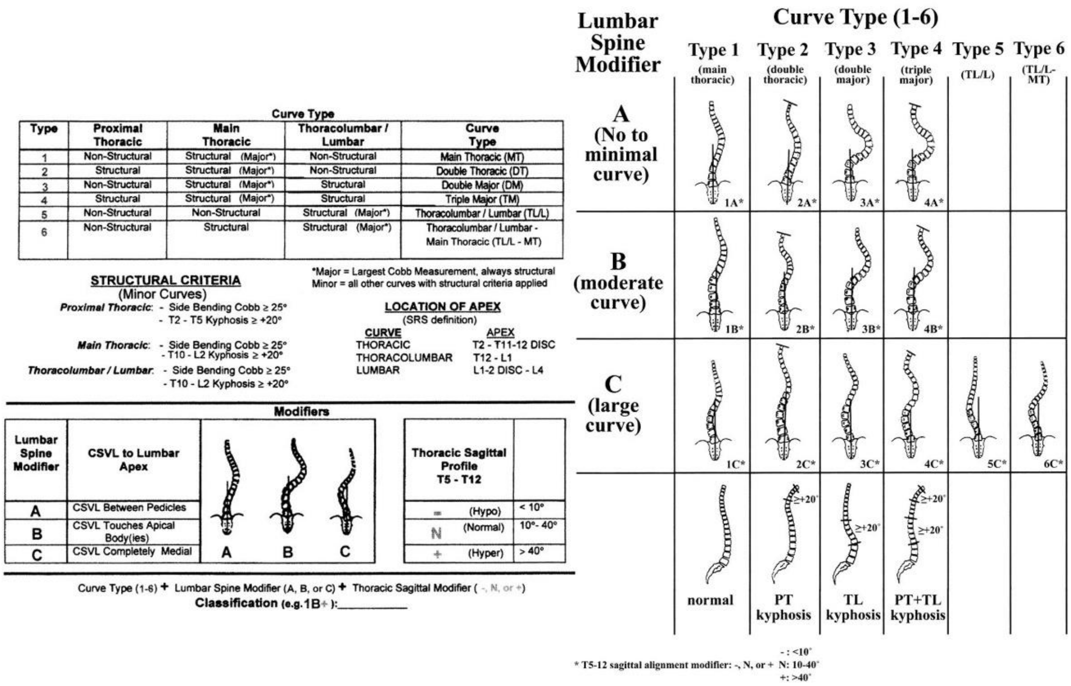


Figure 2.3 Lenke classification system (Lenke et al., 2001)

As both the coronal and sagittal images are taken into consideration for determining the curvature pattern of scoliosis through the Lenke classification, system, it is deemed as having better interobserver and intraobserver reliability in comparison to the King's classification system (Richards et al., 2003). This view is also supported by Hannes et al. (2002), who were critical of the King's classification system as having merely a moderate level of reliability. Besides, the Lenke classification system provides more comprehensive details on lumbar and sagittal thoracic modifiers, as well as more different types of spinal curvatures. Therefore, the Lenke classification system will be used in this study.

2.2.3 Detection and diagnostic methods of scoliosis

As scapular asymmetry, uneven shoulders and hips, and raised ribs on one side of the body are all signs of scoliosis, they can be used to examine and even diagnose scoliosis (Lau, 2011).

To identify whether a patient has scoliosis, the Adam's forward-bending test and Moiré topography are two widely accepted methods of detection nowadays. Negrini et al. (2012) pointed out that the Adam's forward bending test can be conducted with the aid of a scoliometer as a primary clinical evaluation method. In this test (Figure 2.4), patients are required to remove their shirt so that the spine is fully visible (Reamy & Slakey, 2001). The test is conducted by a professional such as a health care practitioner or doctor, during which the patient bends forward gradually, starting at the waist until the spine is parallel to the horizontal plane. His/her feet are placed together, palms held together, arms hanging and knees are extended. The examiner then stands at the back of the patient and observes along the horizontal plane of the spine with a scoliometer to assess whether there is abnormality of the spinal curvature, such as lordosis, kyphosis or asymmetry in the contours of the back (Reamy & Slakey, 2001). If the angle of the trunk rotation (ATR) shown on the scoliometer exceeds or is equal to 5 degrees, this is a sign of potential scoliosis (Adams, 1882; Patias, Grivas, Kaspiris, Aggouris, & Drakoutos, 2010). Further evaluation and observation are subsequently needed.

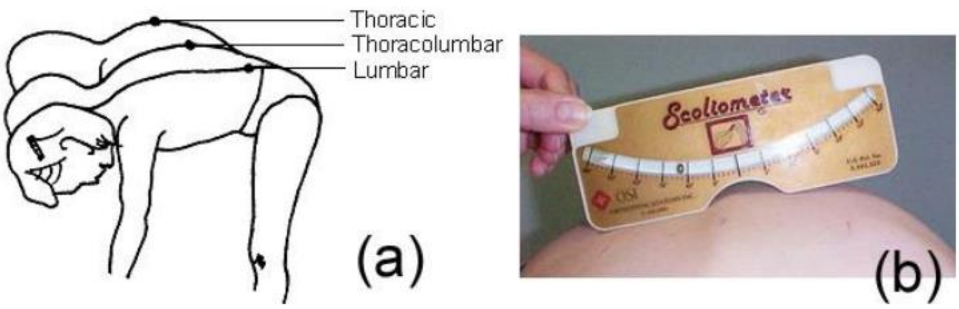


Figure 2.4 Diagnosis of scoliosis

(a) Adams forward-bending test with (b) scoliometer (Patias et al., 2010)

Moiré topography can also be used to evaluate the overall body shape (Adair, Van, & Armstrong, 1977; Willner, 1979). This is a simple contour measurement technique to define the 3D surface and identify children with an asymmetric profile due to scoliosis. As shown in Figure 2.5, a camera is used to project grating (a fringe pattern) onto the back of the patient. The fringes are straight if the back is flat. However, if the back is deformed, as is the case with scoliosis patients, curved fringe patterns are produced; see Figure 2.6. Therefore, Moiré images can be used to identify potential cases of scoliosis.

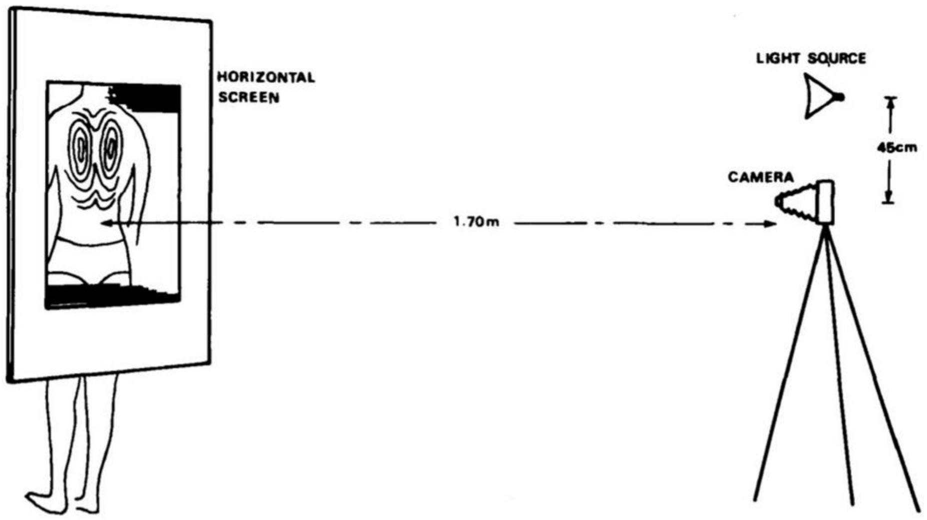


Figure 2.5 Moiré topography setup (Adair et al., 1977)

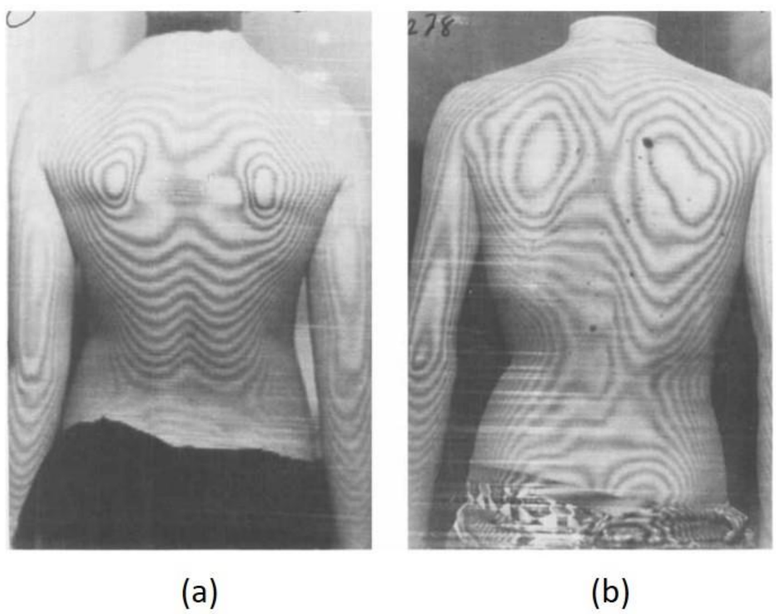


Figure 2.6 Moiré patterns: (a) no spinal curvature, and (b) scoliosis patient (Adair et al., 1977)

All of the methods discussed above can only provide some insight into the spinal curvature but would not be accurate enough. As such, individuals who might have scoliosis need to undergo further evaluation for a proper diagnosis. There are three current diagnostic methods, which are discussed below.

The first diagnostic method involves x-ray imaging. One of the x-ray imaging options is computer tomography (CT), an x-ray process that is carried out with a computer to take multiple images from different angles of certain parts of the body. Cross-sectional images of the inside of a person are obtained without the need of operation (Kalender, 2011). Apart from CT scanning, radiography is another popular x-ray imaging method. To date, standing AP and lateral scoliosis radiographs are used as the golden standard to identify and monitor the progression of scoliosis (Knott et al., 2014).

Aside from CT scanning and conventional x-ray imaging, there is a relatively new x-ray imaging option that reduces radiation exposure called the EOS™ imaging system. This x-ray machine is capable of simultaneously capturing both AP and lateral X-ray images by scanning the entire body in an upright, weight-bearing position, with the use of ultra-low doses of radiation that can be as low as 1:10 when compared to conventional radiography, and even as low as 1:100 to 1:1000 when compared to a CT scan (Illés & Somoskeöy, 2012; Wybier & Bossard, 2013). Compared to conventional X-ray imaging, the EOS™ imaging system provides higher quality, contrast, and sharpness in the images. After all, the EOS™ produces images with 30 to 50 thousand gray shades, and an image pixel resolution of 254 μm whereas conventional x-rays produce images with only a few hundred shades of gray. During the EOS imaging procedure, the patient is asked to stand in the imaging cabin; see Figure 2.7. Biplanar X-ray images are captured in a time frame of only 10-25 seconds (Dubousset et al., 2005).

Figure 2.7 EOS^{TM} imaging system (EOS imaging, 2020)

Even though Knott et al. (2014) pointed out that some x-ray imaging techniques have improved with less risk of radiation exposure, such as the use of high-speed x-ray films and 3-phase x-ray machines, both CT scanning and x-ray imaging ultimately use radiography which could cause harm such as potential oncogenic effects. Numerous studies have reported the possible relationship between radiation exposure and cancer, particularly lung and breast cancers, so the risks of using x-ray imaging should be taken into consideration for diagnosing scoliosis (Ron, 2003).

To address this issue, a radiation-free device called "Scolioscan" was developed by Cheung and Zheng (2010) which uses 3D ultrasound techniques to provide 3D images of the spine without the risk of radiation (Figure 2.8). This is a new system used in clinics to identify scoliosis through coronal images of the spine generated through 3D ultrasound volume projection imaging. A comparison of the spinal images obtained from Scolioscan with those of conventional radiography well demonstrates the reliability of this new equipment (Zheng et al., 2016). As Scolioscan is safer and relatively lower in cost, it plays an important role in clinical evaluations. Unfortunately, the images produced by Scolioscan can only show the spinal curvature and Cobb's angle of patients. Unlike CT scans and radiography, AP and lateral images cannot be acquired so that there is no information on the cervical vertebrae, rib cage and pelvis of patients.

Figure 2.8 Scolioscan (Medgadget, 2015)

Regardless of the type of diagnostic method used, it is recommended that the spinal curve is determined by measuring the Cobb's angle based on spinal radiographs (Cobb, 1948; Safari, Parsaei, Zamani, & Pourabbas, 2018). To obtain the Cobb's angle following the measurements in Figure 2.9, two perpendicular lines are first drawn at the top of the top vertebrae and bottom of the bottom vertebrae of the major curve. The angle is then measured between these two intersecting lines as the Cobb's angle (Cobb, 1948; Patias et al., 2010). The Cobb's angle of the minor curve can also be obtained in the same way if needed. This evaluates the degree of coronal plane deformity for scoliosis classification. For bracing treatment of AIS, the Cobb's angle is also utilized to evaluate its effectiveness, such as the bracing effect with in-brace radiographs (Negrini et al., 2012).

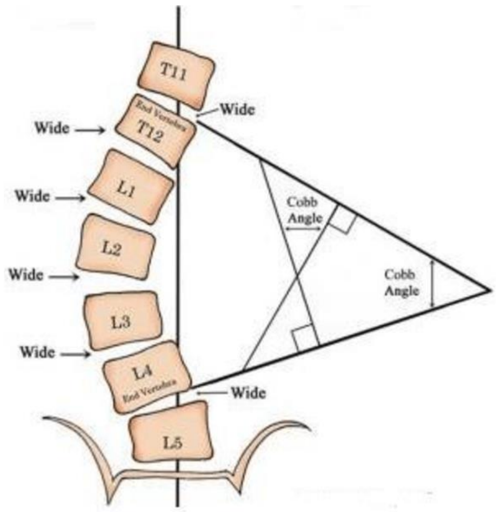


Figure 2.9 Measurement of Cobb's angle (Safari et al., 2018)

2.3 Current treatment options for AIS

2.3.1 Treatment options

Different treatment options are available to AIS patients based on the severity of their spinal curvature and their anticipated tolerance of the treatment. The growth status of patients is also another concern when choosing a suitable treatment as the effectiveness of some of the treatment options depends on the extent of skeletal maturity. To assess skeletal maturity, doctors or researchers evaluate the Risser sign, which uses the degree of ossification of the iliac apophysis found on radiographs (Risser, 1958). There are six stages of ossification based on the Risser sign, namely, Risser 0 to 5, where Risser 0 is the most immature skeleton while Risser 5 is a mature and stable skeleton. Based on the Cobb's angle of the spinal curvature, AIS patients are then categorized into three main cases generally, which are mild, moderate and severe cases.

Patients with a small lateral curvature of less than 20 degrees are considered to be mild scoliotic cases. Their main treatment is observation, and their spinal situation is monitored every 6-12 months. Sometimes, exercise or physiotherapy is also recommended by doctors. Patients with a Cobb's angle between 21 and 45 degrees are considered to be moderately scoliotic. They are prescribed bracing treatment, the most common non-invasive means of controlling the further progression of spinal curvature. Although this treatment covers a wide range of spinal curvatures, patients who receive bracing treatment usually have a Cobb's angle that ranges from 20 to 30 degrees with Risser signs 0-2 (Lonstein, 2006; Negrini et al., 2006; Richards et al., 2005). By contrast, previous studies have indicated that bracing is not the best option for a child who has almost completed growth with Risser 4 or 5, or a growing child with a spinal curvature that exceeds 45°, or less than 25° without documented progression of the curvature, thus showing the contraindication of bracing (Asher & Burton, 2006; Lonstein & Winter, 1994; Nachemson & Peterson, 1995). Some exercises and physiotherapy regimes designed for scoliosis such as those for mild cases are often prescribed in combination with bracing for moderately scoliotic patients as well. Bracing and exercise are two main treatment options for mild and moderate AIS patients. Yet, all of the mentioned treatments are not appropriate for patients with severe scoliosis, that is, a spinal curvature that is more than 45 degrees. They are then faced with surgery options, like spinal fusion.

2.3.2 Non-invasive treatment: Bracing

To minimize the further progression of spinal deformity and the rate of the progression of the spinal curvature, as well as the need for surgical intervention, different non-operative treatments have been designed for AIS patients, in which bracing treatment is the most prevalent and considered the effective treatment option. Bracing is recommended for patients with a spinal curvature of 21 to 45 degrees. They are to wear the orthosis for generally 23 hours a day for a few years until their physical growth has completed (Negrini, Atanasio, Fusco, & Zaina, 2009). The purpose of bracing is to guide the development of the spine and biomechanically correct the deformity through external forces exerted onto the trunk (Negrini et al., 2015).

In general, there are three main types of orthoses for AIS patients in the market, including rigid, semi-rigid and flexible braces.

2.3.2.1 Rigid braces

There are many types of rigid orthoses designed for AIS; for instance, the Boston, Wilmington, Milwaukee, and Charleston bending braces, to name a few. Almost all of them are tailor made from rigid plastic materials based on body shape and specific needs in terms of the amount of corrective force to treat various spinal curvatures. Among these hard braces, the three prevailing bracing therapies are applying traction pushing on the trunk and side-bending. The former is a two-point system, while the latter two are three-point pressure systems.

The Milwaukee brace is a cervico-thoraco-lumbo-sacral orthosis (CTLSO) using a two-point system (Figure 2.10). The corrective forces act on the frontal and horizontal planes of the body through active elongation in order to prevent the mobility of the trunk and collar (Blount & Moe, 1973).

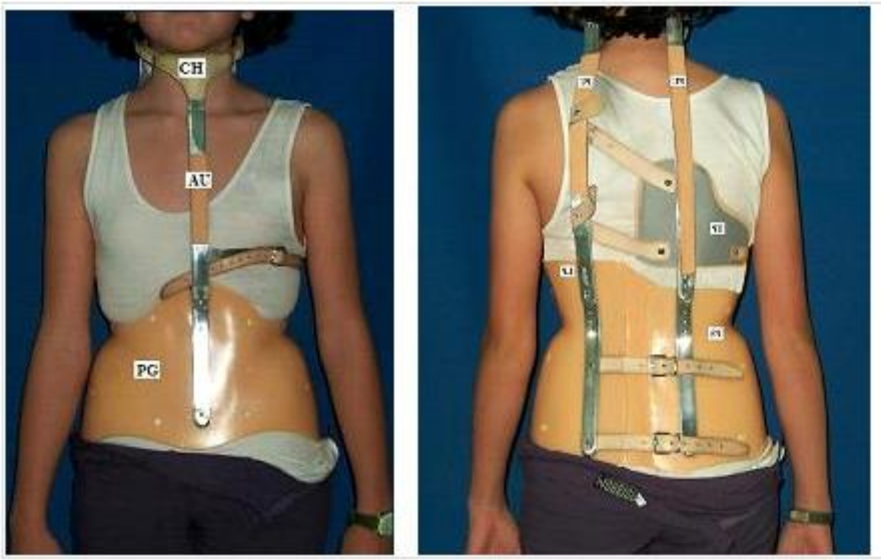


Figure 2.10 Milwaukee brace

(a) anterior and (b) posterior view of brace

(The Scoliosis Patients and Practitioner Information Network, 2008)

Moreover, the three-point concept is the most common mechanism used in corrective orthoses, especially thoracic-lumbo-sacral orthoses (TLSOs). The Boston, Lyon and Wilmington braces are rigid braces developed with this pressure concept (Bassett & Bunnell, 1986; Stagnara, 1985; Watts, Hall, & Stanish, 1977; Willers, Normelli, Aaro, Svensson, & Hedlund, 1993). Similar to the Boston brace shown in Figure 2.11, most TLSOs are designed with asymmetrical components to provide room to wearers so that their trunk can be shifted from the convex to the concave side through the transverse force applied by the apical pads.

Figure 2.11 Boston brace

(a) anterior and (b) posterior view of brace (Scoliosis & Spine Associates, 2019)

By applying side-bending, the night-time Charleston bending brace in Figure 2.12 can encase the wearers in an over-corrected position to stretch their soft tissues and unload the plates of the spine (Price, Scott, Reed, & Riddick, 1990). The wear time of this brace is much less than that of the other rigid braces and only takes requires 8 to 10 hours of wear a day.

Figure 2.12 Charleston bending brace (Fayssoux, Cho, & Herman, 2010)

Nevertheless, previous studies have demonstrated that AIS patients tend to have treatment low compliance towards hard braces due to the aesthetically unpleasing appearance and physical constraints. Semi-rigid and flexible braces have thus been developed in response.

2.3.2.2 Semi-rigid braces

Unlike rigid braces, the type of material used in semi-rigid braces is relatively wider in range, including all hard and soft materials. Most semi-rigid braces are produced by using the three-point pressure concept, such as the TriaC brace. This brace was developed in the 1990s with the aim to incorporate a three-point pressure system to treat all types of spinal curves but the patients who have a curve with an apex at the 12th thoracic and 1st lumbar vertebra due to the limitation of brace design. Its corrective forces are only focused on the coronal plane and thoracic region in the sagittal plane (Veldhuizen, Cheung, Bulthuis, & Nijenbanning, 2002).

As shown in Figure 2.13, three main components are used in this type of brace, such as the frame, elastic elements and pelottes (Bulthuis, Veldhuizen, & Nijenbanning, 2008; Veldhuizen et al., 2002; Zeh, Planert, Klima, Hein, & Wohlrab, 2008). Compared with rigid braces, less hard materials like metals and plastics are utilized in the TriaC brace, which is thus supposed to less limit body movement and dissatisfaction around aesthetic appearance should be reduced (Veldhuizen et al., 2002). However, some possible physical problem like skin irritation and pain sores may also be found in this brace.

Figure 2.13 TriaC brace

(a) posterior, (b) anterior and (c) side view of brace (Wynne, 2008)

In 2018, a new semi-rigid brace in the form of a functional intimate apparel was developed by Fok, Yip, Yick, and Ng (2018). The garment was also designed to correct and control the spinal deformation of adolescents with scoliosis by using a three-point pressure system. Unlike the TriaC, the main components used in this brace are hinge bone made of polyurethane, stretchable fabric, elastic bands, and silicone rubber, in which silicone padding is placed on the apex of the curvature of wearers to provide the corrective force. Figure 2.14 shows the front and back views of this brace. Yet, there is still a improvement in its brace design in terms of fit, comfort and durability.

Figure 2.14 Functional intimate apparel

(a) anterior and (b) posterior view of brace (Fok et al., 2018)

2.3.2.3 *Flexible braces*

A dynamic flexible brace called the "SpineCor dynamic corrective brace" was developed (Coillard, Leroux, Zabjek, & Rivard, 2003) with a spinal coupling mechanism for AIS patients to minimize the negative impacts of bracing and improve compliance, see Figure 2.15. It is one of the most representative soft braces used by patients based on their specific curve, with the aim to re-train and maintain the neuromuscular control of spinal movement through active mechanical biofeedback (Coillard, Circo, & Rivard, 2008; Coillard et al., 2003).

As only flexible materials like elastic bands are used in this type of brace, it allows wearers a full range of movement while relieving the spinal progression. However, some limitations are pointed out in Wong et al. (2008), such as difficulties experienced by the wearer when going to toilet.

Figure 2.15 SpineCor dynamic corrective brace

(a) anterior and (b) posterior view of brace (Utah spine Specialist, 2013)

Besides, another flexible brace is a tailor-made posture correction girdle by Liu et al. (2014) which is designed for early scoliosis with the use of point-pressure in a supporting system (Figure 2.16). Like other flexible braces such as the SpineCor dynamic corrective brace, this girdle is mainly made of soft materials, such as fabrics and elastic bands that can provide a more comfortable wear experience.

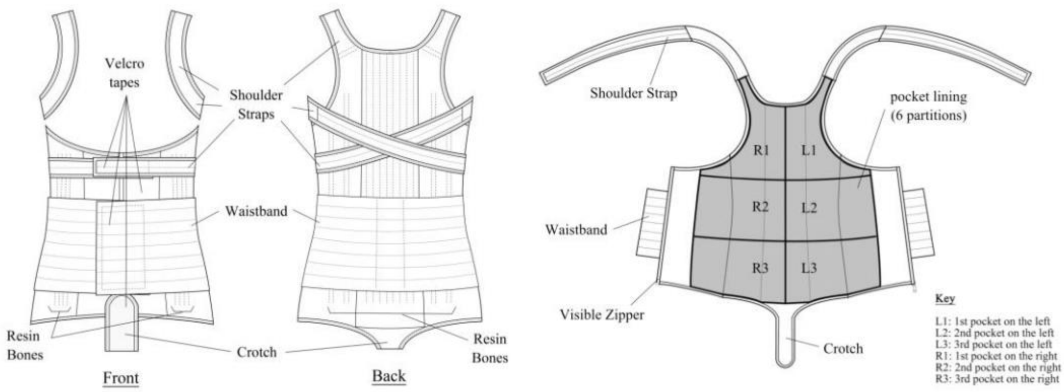


Figure 2.16 Tailor-made posture correction girdle (Liu et al., 2014)

2.3.3 Non-invasive treatment: Exercise

Exercise is always part of the plan for treating AIS as it can reduce the progression of the spinal curvature, thereby reducing the risk of impairment, and even reducing the likelihood of brace wear. Exercise may be the main treatment for milder cases, and serves as an additional form of therapy in more severe cases (Romano et al., 2012). Even though physical exercises are routinely prescribed in France, Germany, Italy, and a number of other countries, they are not recognized in the United Kingdom and the United States as they are considered ineffective (Romano et al., 2012; Romano et al., 2013). The efficacy of exercise remains still controversial.

There are many different types of exercises for AIS, for example, physiotherapy, aerobic exercise, Schroth's exercise, task-oriented exercise, yoga and so on and so forth

(Gur, Ayhan, & Yakut, 2017; Kumar et al., 2017; Kuru et al., 2016; Monticone, Ambrosini, Cazzaniga, Rocca, & Ferrante, 2014; Negrini, Zaina, Romano, Negrini, & Parzini, 2008). Some of them are briefly listed in Table 2.1.

Table 2.1 Exercises for AIS

Exercises for AIS				
Core stabilization training (Gür et al., 2017)	Active self-correction & task-oriented exercises (Monticone et al., 2014)	Task-oriented exercises (Kumar et al., 2017)	Scientific Exercises Approach to Scoliosis (version 2002) (SEAS.02) (Negrini, 2006; Negrini, 2008)	Schroth's exercise (Kuru, 2016)
A exercise approach aims at improving postural balance and preventing compensatory movements by controlling the position of the trunk in static postures and activities	A rehabilitative technique tailored to the type of curve scoliosis that aims to strengthen spinal deep muscles and improve neuromotor control of the spine and limbs	A exercise aims at recovering coordination and balance	A exercise continuously changes based on the results published in the literature An individualized exercise program adapted to all situations of conservative treatment of scoliosis	A physiotherapeutic approach with a breathing pattern that uses isometrics and other exercises to strengthen or lengthen the asymmetrical muscles

2.3.3.1 Schroth's three-dimensional exercise

Schroth's three-dimensional exercise, one of the scoliosis-specific exercise (SSE) methods, is designed for patients with scoliosis, and developed based on the sensorimotor and kinesthetic principles of rehabilitation specialist, Katharina Schroth (Negrini, Atanasio, Zaina, & Romano, 2008).

This exercise program emphasizes the correction of posture and breathing patterns through rotational angular breathing (RAB), which is the most significant element of this exercise (Lehnert-Schroth, 1979). A series of movement that applies proprioceptive and exteroceptive stimulation and mirror control is recommended for patients based on their own curvature pattern. Patients can therefore recognize the changes in their own spinal structure and restore the structure (Kim & Park, 2017). Figure 2.17 shows the Schroth's three-dimensional exercise method.

Figure 2.17 Schroth's three-dimensional exercise

2.3.3.2 Core stabilization training

In order to enhance the postural balance and avoid compensatory movement, core stabilization (CS) training as shown in Figure 2.18 is a relatively new exercise approach developed to control the trunk position during static posture and functional activities (Akuthota & Nadler, 2004; Ayhan, Unal, & Yakut, 2014; Muthukrishnan, Shenoy, Jaspal, Nellikunja, & Fernandes, 2010).

Emery, De Serres, McMillan, and Côté (2010) stated that stronger core muscles can better correct and maintain the alignment of the spine after core stabilization training due to the stronger muscular stabilization around the spine. Its effectiveness has been proven and reported in Koumantakis, Watson, and Oldham (2005) and Akuthota and Nadler (2004).

Figure 2.18 Core stabilization training (Kavcic, Grenier, & McGill, 2004)

2.3.4 Issues with existing AIS treatment

2.3.4.1 Issues with bracing treatment

Regardless of the corrective mechanisms of hard braces, most of them are primarily made of rigid components, such as rigid plastic materials and metals. After all, these materials are non-breathable. Sweat cannot be adequately absorbed and carried away from the body. Lack of ventilation, poor tolerance of patients of the discomfort and even skin irritation may result which all lead to low wear compliance, especially during the summer. A tightly fitting brace may also create ulcers and induce pain. Furthermore, almost all rigid braces are designed to tightly encase the entire trunk of the wearer with rigid materials so as to control the further progression of the spinal curvature. They not only limit the daily movement of patients but also bring about the risk of muscular atrophy. This is because wearers tend to rely on the brace and reduce the usage of their spinal muscles when the brace is worn for a long time.

Besides, it is difficult for wearers to hide a bulky orthosis underneath clothing, which may result in unwanted attention from others and the pressure of looking different. This treatment is prescribed during the most socially awkward period of life so wearing the brace may have psychological effects. The teenage scoliosis patient is concerned about his/her self-image, particularly the girls, and wearing a bulky brace does little to alleviate these concerns.

As such, some patients may experience psychological and mental health problems, such as depression, low self-esteem, shame and other negative feelings because of the bracing. To date, rigid corrective orthoses have been demonstrated to be effective for the majority of moderate AIS if treatment is prescribed in the early stages and the patient is willing to wear the orthosis with good compliance. However, all of the mentioned issues above are possible reasons that reduce the wear compliance of patients. Therefore, low treatment compliance with the brace is always a concern as it could greatly affect the bracing outcome, or even lead to further progression of the spinal curvature (Negrini et al., 2015).

Even if semi-rigid and flexible braces have already been designed and are available on the market, they still have limitations that have not been addressed yet. Wong et al. (2008) conducted a related study to investigate the outcome and user feedback of a rigid spinal orthosis and SpineCor. They found that discomfort, inconvenience and feeling hot are still the concerns around bracing although fewer flexible brace users feel that their brace causes them to feel more uncomfortable as opposed to rigid braces. To reduce the discomfort, all of them even remove the brace or loosen the straps after eating, which could affect the spinal corrective effect. Besides, some wearers of flexible braces have significant trouble in removing the orthosis when using the toilet.

In addition, it is found that an effective corrective effect cannot be easily realized by using soft materials on a flexible brace which could possibly affect the efficacy of the bracing treatment (Liu, 2015; Liu et al., 2014).

To provide a better understanding on the current situation around bracing, the difference between rigid, semi-rigid and flexible braces are summarized in Table 2.2. Despite the effectiveness of hard orthoses on relieving spinal progression, more physical and psychological issues are found in comparison with non-rigid braces which cannot be ignored. By contrast, the emergence of semi-rigid and flexible braces has addressed some of the physical and psychological problems with their lighter and better appearance. Yet, there is insufficient evidence to support the efficacy and corrective effect of such braces. Currently, there continues to be a lack of consensus on which type of brace has the best corrective performance and wear comfort.

Table 2.2 Comparison of different types of braces

	Rigid brace **Boston Brace**	**Semi-rigid brace** **TriaC Brace**	**Flexible Brace** **SpineCor Brace**
Invention Period	1940s	1990s	Early 1990s
Corrective Mechanism	3-point pressure system	3-point pressure system	Spinal coupling
Materials Used	Rigid plastic, metal and pads	Thermoplastics, metal, elastic bands and pads	Thermo-deformable plastics, cotton for bolero and elastic bands
Characteristic	Rigid and heavy	Semi-rigid, lighter than rigid brace	Soft and Light
Appearance (with brace)	Bulky and awkward	More natural look than that of rigid brace	Natural look
Possible Physical Problems	• Skin irritation, breathing disturbance • Possible permanent deformation of ribcage or soft tissues • Impeding the sports participation	• Skin irritation • Pressure and pain sores • Slight impeding the sports participation	• Pressure and pain sores • Facing difficulties when going to toilet
Possible Psychological issues	• Lower self-esteem, more fatigue and lower compliance	• Fewer negative impacts on self-esteem of patients, less fatigue and higher compliance	• Fewer negative impacts on self-esteem of patients, less fatigue and higher compliance

<u>Knowledge Gap 1:</u>

Low compliance rate of treatment with existing braces

Physical and psychological concerns such discomfort, inconvenience, low self-esteem and shame possibly reduce the motivation to adhere to the bracing treatment. Even though lightweight and breathable non-rigid braces can address some of the issues above, other problems cannot be ignored, such as difficulties in donning the brace and skin irritation.

<u>Knowledge Gap 2:</u>

Ambiguity in the effectiveness of non-rigid braces

Insufficient evidence to prove the corrective effect of semi-rigid and flexible braces, even if some previous studies have evaluated and reported their effectiveness.

2.3.4.2 Issues with exercise training

A number of exercises for AIS have been developed and widely used in much of the world, especially SSE in Europe (Bettany-Saltikov, Parent, Romano, Villagrasa, & Negrini, 2014; Rigo & Grivas, 2010). However, their efficacy remains controversial as there is insufficient supportive evidence to prove that they are effective (Romano et al., 2012; Weiss & Goodall, 2008). Some exercises have never been rigorously assessed, such as physiotherapy. Some specialists feel that all physical exercises for AIS are similar and considered as "alternative treatments". The inconsistency of the evaluation of these exercises means that the efficacy of these exercises remains doubtful and uncertain (Negrini et al., 2012).

2.4 Further analysis by using CNA

As mentioned earlier, the variability of non-operative treatment, lack of consensus on bracing treatment options, as well as uncertainty around exercises for AIS, are all issues for the non-invasive treatment of AIS. In order to determine a potential research area for non-invasive treatment of AIS, a citation network analysis (CNA) is carried out in this study, which is a tool used to determine the dynamics of a field via a computer-based systematic analysis of its bibliographic data (Colicchia & Strozzi, 2012). This is the first systematic citation literature review done for this field. Unlike commonly found systematic literature reviews (SLRs), analysis with a CNA is done without judgement of the authors which can prevent subjective bias and increase the reliability of the results.

For this further analysis, a search of journal articles was conducted by using the Web of Science (WoS) database to collect sample articles for the literature review with a CNA. According to common keywords used in existing reviews and relevant research studies, the terms, "adolescent idiopathic scoliosis", "curvature deformation", "spinal curvature", "Cobb's angle", "exercise", "brace treatment", "quality of life", "conservative treatment" and "non-operative treatment" were inputted as the reference keywords. Similar phrases and specific types of treatment, such as "Boston brace" and "physiotherapy", were also included so as to reduce the possibility of omitting articles. All operative procedures like surgery were not included and discussed in the search.

Out of 1594 articles, 237 were considered to be relevant after scanning all of the collected articles. After all, review articles always review part or all non-invasive treatment options of AIS simultaneously. It is difficult to categorize them into certain research clusters with the use of CNA. As such and also due to insufficient evidence of proceedings papers, meeting abstracts and letters, they were all eliminated. Finally, 146 articles were selected as the sample for further analysis. The flow of the citation network literature review is shown in Figure 2.19.

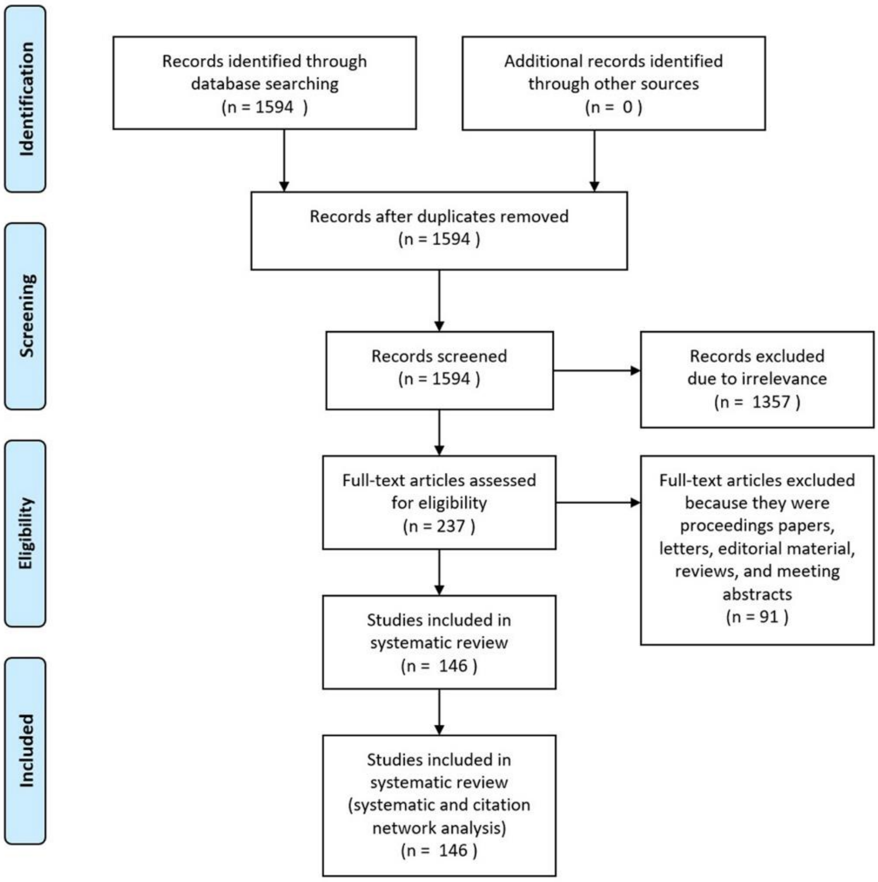


Figure 2.19 Flow diagram of literature review of citation network

The main results of this analysis can contribute to the literature and efforts towards non-invasive treatment of AIS.

2.4.1 Research interest on non-invasive treatment

Apart from the increasing number of recent studies on non-invasive treatments for AIS, research interest in this particular area has also been demonstrated through the most dominant papers, that is, the most highly cited papers. Influential articles are often cited multiple times by other scholars, which demonstrates the importance and influence of their work in the field (Pilkington & Meredith, 2009).

The most cited articles, that is, publications with the highest local citation score (LCS), which is based on the total number of citations within a specific database, are listed and ranked in Table 2.3 (Bunnell, 1986; Chase, Bader, & Houghton, 1989; Emans, Kaelin, Bancel, Hall, & Miller, 1986; Goldberg, Moore, Fogarty, & Dowling, 2001; Karol, 2001a; J Lonstein & J Carlson, 1984; Nachemson et al., 1995; Noonan, Weinstein, Jacobson, & Dolan, 1996; Rowe et al., 1997; Wong, Mak, Luk, Evans, & Brown, 2000). The table shows that not only are these studies closely related but also popular globally with a score of 100 or higher for their global citation score (GCS) which shows the number of citations cited by other papers worldwide.

However, the results do not mean that there are sufficient research studies in this field. The majority of the cited articles or 7 of the 10 articles which have the highest LCS focus on rigid bracing as a treatment for AIS, such as the Boston brace (Emans et al., 1986) and Milwaukee brace (Noonan et al., 1996). Even if there are studies that examine semi-rigid and flexible braces, training of the posture through exercise or other nonsurgical treatments, none of the influential papers focus on these areas (Bunnell, 1986; Rowe et al., 1997). This shows the relative lack of interest of other researchers in these areas or the neglect of these areas of study.

Table 2.3 Articles with highest LCS

Rank	Author	Title	LCS
1	Nachemson, A. L., & Peterson, L. E. (1995)	Effectiveness of Treatment with A Brace in Girls Who Have Adolescent Idiopathic Scoliosis- A Prospective, Controlled-Study Based On Data From The Brace Study of The Scoliosis-Research-Society	37
2	Emans, J. B., Kaelin, A., Bancel, P., Hall, J. E., & Miller, M. E. (1986)	The Boston Bracing System for Idiopathic Scoliosis- Follow-up Results in 295 Patients	27
3	Lonstein, J. E., & Carlson, J. M. (1984)	The Prediction of Curve Progression in Untreated Idiopathic Scoliosis During Growth	19
4	Noonan, K. J., Weinstein, S. L., Jacobson, W. C., & Dolan, L. A. (1996)	Use of The Milwaukee Brace for Progressive Idiopathic Scoliosis	19
5	Rowe, D. E., Bernstein, S. M., Riddick, M. F., Adler, F., Emans, J. B., & Gardner-Bonneau, D. (1997)	A Meta-Analysis of The Efficacy of Non-Operative Treatments for Idiopathic Scoliosis	18
6	Bunnell, W. P. (1986)	The Natural-History of Idiopathic Scoliosis Before Skeletal Maturity	14
7	Wong, M. S., Mak, A. F. T., Luk, K. D. K., Evans, J. H., & Brown, B. (2000)	Effectiveness and Biomechanics of Spinal Orthoses in The Treatment of Adolescent Idiopathic Scoliosis (AIS)	12
8	Goldberg, C. J., Moore, D. P., Fogarty, E. E., & Dowling, F. E. (2001)	Adolescent Idiopathic Scoliosis- The Effect of Brace Treatment On The Incidence of Surgery	12
9	Karol, L. A. (2001)	Effectiveness of Bracing in Male Patients with Idiopathic Scoliosis	12
10	Chase, A. P., Bader, D. L., & Houghton, G. R. (1989)	The Biomechanical Effectiveness of The Boston Brace in The Management of Adolescent Idiopathic Scoliosis	11

2.4.2 Overall research efforts on non-invasive treatment

The clusters of the examined publications were labeled after a review. Five main domains were established (bracing treatment, posture training through exercise, 3D analysis of braces, corrective force management of braces and quality of life with bracing treatment) whereas the remainder of the articles were 1 or 2 articles with no linkages to the other articles, and therefore grouped into "Other clusters".

The distribution of the articles based on cluster is plotted in Figure 2.20. Consistent research interest on bracing can be observed. That is, the largest research cluster is bracing treatment with 56 articles (38.4%), followed by posture training through exercise with 29 articles (19.9%), then 3D analysis of braces with 11 articles (7.5%), and finally, two other relatively smaller clusters which include studies on corrective force management of braces and quality of life with bracing treatment for a total of 7 articles (4.8%) respectively. The citation network structure of these six research domains which includes other clusters are shown in Figure 2.21.

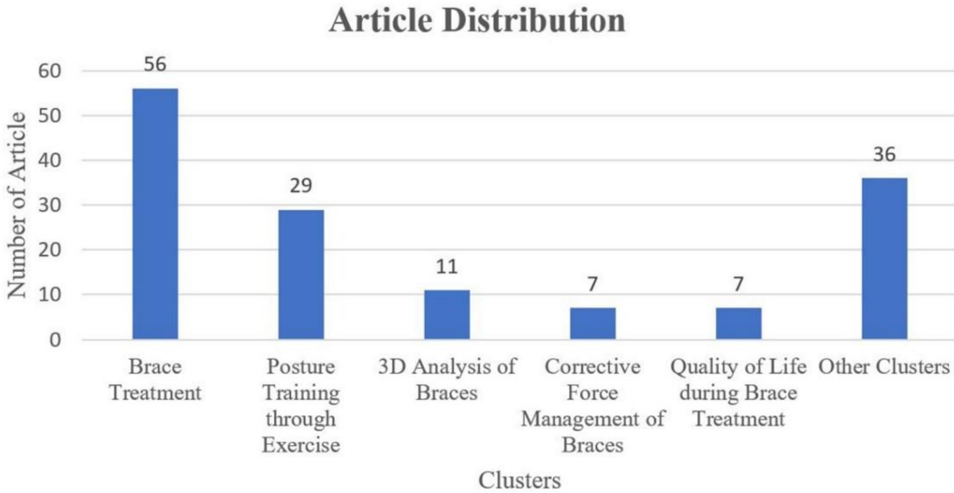


Figure 2.20 Classification of research clusters

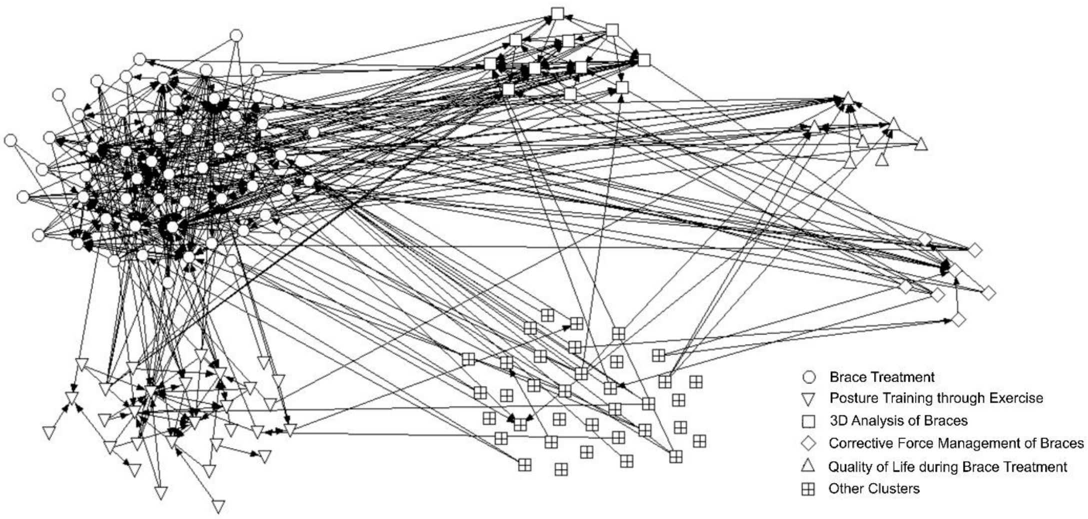


Figure 2.21 Citation network structure of non-invasive treatment of AIS

In the research cluster of brace treatment, 24 of the 56 articles examined the effectiveness of rigid braces. Most of these articles (20 articles, 83.3%) agreed that spinal correction can be carried out effectively by wearing a hard brace whereas the remainder (4 articles, 16.7%) had doubts of their corrective effect, as found in the male or overweight cohorts in their study. Nevertheless, 10 out of these 24 articles (41.7%) focused on the two greatest concerns that might affect the bracing effect, which are patient compliance with the bracing treatment and the tightness of the brace.

To further investigate the specific studied contents of the two main clusters of research studies (brace treatment and posture training through exercise), all of the included articles were differentiated by the type of brace and exercise. After categorizing the studies that focused on more than one brace or type of exercise into “multiple braces” or “multiple exercises”, respectively, the Boston brace is found to be the most popular brace used for scoliosis treatment in the cluster with 20 relevant papers (35.7%) while physiotherapy is the most common form of treatment in the cluster with 5 articles on posture training through exercise (17.2%) (Figure 2.22).

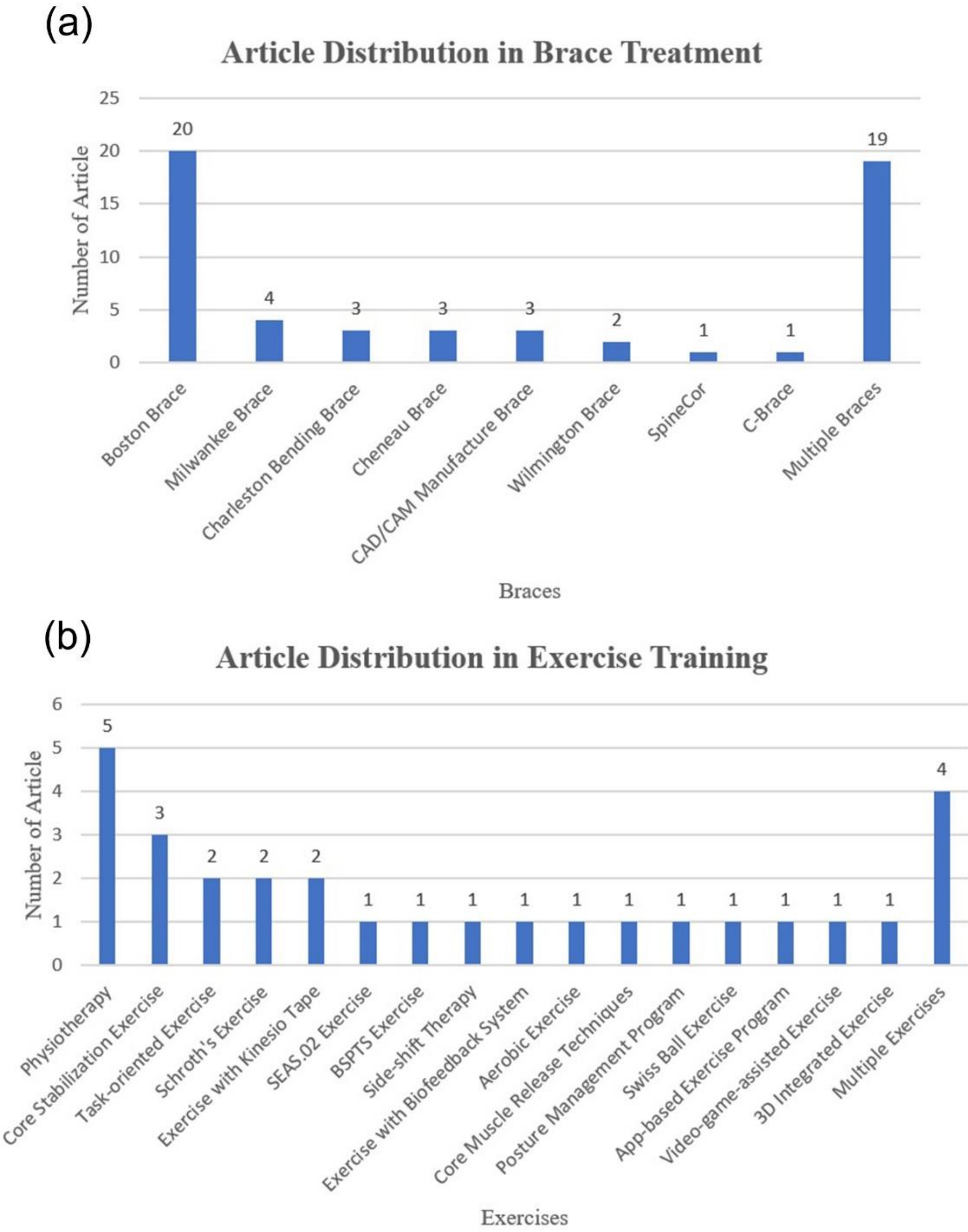


Figure 2.22 Distribution of articles of two main clusters:

(a) brace treatment and (b) posture training through exercise

The findings might be due to the wide use of rigid braces to treat AIS and their proven outcome on halting spinal curvature progression. The research cluster of brace treatment is evidently the largest research domain, with 35 articles on rigid braces (62.5%) and only 2 articles on non-rigid braces (3.6%). Hard orthoses not only comprise the subject of the majority of the studies on brace treatment, but also the other three main research clusters (corrective force management of braces, 3D analysis of braces, and quality of life during brace treatment). Therefore, this significant difference in quantity of studies and research effort show the research gap in non-rigid braces.

On the other hand, almost 70% of the mentioned exercises are proposed by only one article which shows the potential research areas and the need for further studying how training posture through exercise and other nonsurgical treatments can help treat AIS, including exercising with biofeedback systems, posture management programs and the exercises that have only been studied by the one article in the database. However, such related exercises will not be the focus of this research study since there are more AIS patients who are undergoing bracing in comparison to training the posture through exercise, thus demonstrating the relatively imperative need for the design and development of a new non-rigid brace.

Knowledge Gap 3: Few studies and little research effort on non-rigid braces for AIS Previous studies have pointed out the potential of various semi-rigid and non-rigid braces. Although the corrective performance of existing non-rigid braces is still debatable, there is still the need to further study them and develop a new non-rigid brace to provide an alternative option for patients.

2.5 Design framework

To achieve a comprehensive process of design and development in this study, the flow and direction of related design frameworks can be taken as references. Two design frameworks will be discussed in this section – the three-stage design process and functional, expressive, and aesthetic (FEA) consumer needs model. One of them will be applied in this study accordingly.

2.5.1 Three-stage design process

To design a textile product, a design framework called the "three-stage design process" has been proposed in (LaBat & Sokolowski, 1999). The framework emphasizes that there are three main stages, which are problem definition and research, creative exploration and implementation, to carry out a textile design project. The detailed guidelines of this framework are illustrated in Figure 2.23.

The problem and limitations are investigated in the first stage. Then, the design ideas are created based on user expectation and needs that are found in the first stage. Prototype development and performance evaluation of the prototype are also included in the second stage. Subsequently, amending the design in terms of its efficacy and production is done in the third stage.

I. Problem Definition & Research	II. Creative Exploration	III. Implementation
A. Initial Problem Definition • Client definition	A. Preliminary Ideas • Expansive, all realm of possibilities	A. Production Refinement • Cost to produce • Time to produce • Methods of production • Sales potential
B. Research • User Needs: -Function -Aesthetic -Economic • Market: -Assess current products -Competitive Analysis -Economic conditions	B. Design Refinement • User constraints: -Function -Aesthetic -Economic • Production Constraints -Cost to produce -Time to produce -Methods of production -Sales potential	B. Phase 1: Immediate Production • Changes in product or production that can be accomplished immediately
C. Working Problem Definition • Defined by industry client & university designer • Design criteria established	C. Prototype(s) Development • Meshing design criteria and constraints to develop workable ideas	C. Phase 2: Improvement/Refinement • Further development that may be delayed
	D. Evaluation of Prototype • Preliminary: by university designer • Final: by university designer and industry client	

Figure 2.23 Framework of three-stage design process

(LaBat & Sokolowski, 1999)

2.5.2 A modified FEA model for designing a medical textile or scoliosis brace

A functional, Expressive, and Aesthetic (FEA) consumer needs model is a user-oriented model that advocates the establishment of design criteria based on the needs and desires of users. Lamb and Kallal (1992) proposed the combining of FEA criteria and the design process into one design framework to improve each design process so that it is user-based. Fung, Yip, and Yick (2017) also further modified this framework by taking the emotional needs of wearers into consideration (Figure 2.24).

Compared to the Three-stage Design Process, this modified FEA model for designing a medical textile or scoliosis brace is more suitable for this research study as it is applicable to the topic of this study, which is focusing on a new brace design for AIS patients. In addition, this framework encourages the continuous amendment of the design and returning to the previous stage to start again if problems with the proposed design are round. The model ultimately provides a more systematic brace design and greatly aids the development process in this study.

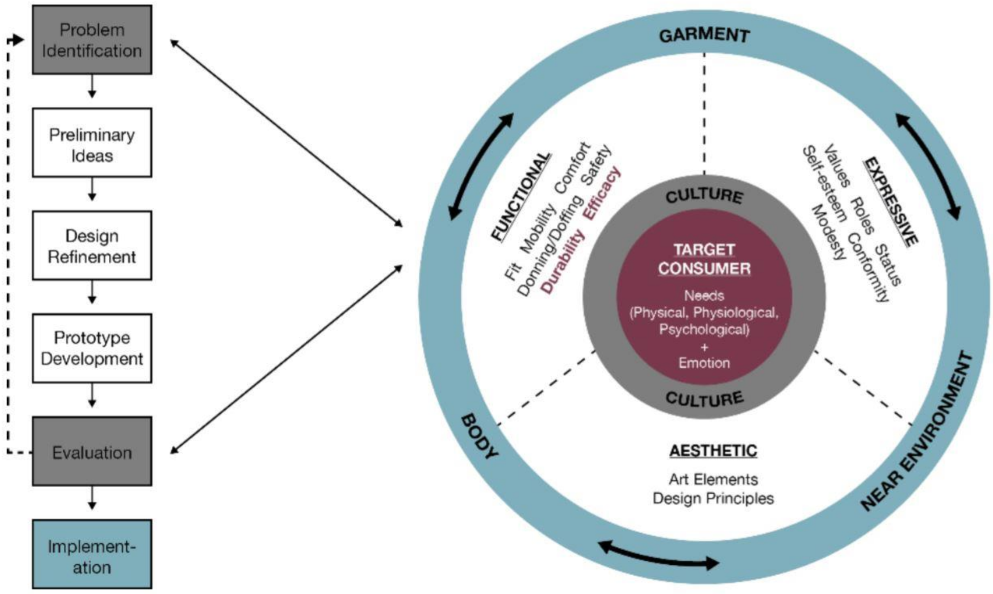


Figure 2.24 Modified FEA model for designing a medical textile or scoliosis brace (Fung et al., 2017)

2.6 Chapter summary

In this chapter, the background information of AIS, current treatment options, corrective mechanisms of different types of braces, as well as identification of the potential trends in research or research areas by using a CNA have been discussed.

AIS is an abnormal spinal deformity without a clear etiology and the most common form of scoliosis in young people. Patients are often diagnosed with AIS during their adolescent growth spurt years. If they have a Cobb's angle equal or greater than 10 degrees, a diagnosis of scoliosis is provided. Unlike normal spines, the spine of an AIS patient is formed like a C or S rather than a straight line. After scoliosis advances, it is risky to allow the spinal curvature to progress as untreated individuals may experience more severe health issues. In general, different treatments are recommended to patients with AIS based on their Cobb's angle in which bracing is the most prevalent non-operative option for moderate cases. Nowadays, there are various types of braces designed for AIS. They can be briefly classified as 3 main types in terms of the materials used, which are rigid, semi-rigid and flexible braces. Traction (two-point system), pushes on the trunk (three-point pressure system) and side-bending concepts involve three mechanisms that are always applied in spinal correction. Even if the corrective performance of rigid braces has been proven, its physical and psychological consequences like low self-esteem cannot be neglected as they may result in low compliance and failure of bracing. To overcome these limitations, semi-rigid and soft braces are developed. However, they can only resolve some of the barriers. There are also other problems for wearers of non-rigid orthoses, for instance insufficient corrective forces provided by the flexible braces, skin irritation and inconvenience when using the toilet.

The variability of non-invasive treatments, lack of consensus on bracing options and uncertainty around exercises for AIS have been identified in this chapter. In order to determine the potential areas of study in the field of nonsurgical treatments, another review of studies has been done by using CNA. It is found that non-operative treatment options have caught the interest of scholars but there are still few studies and little research effort on the use of non-rigid braces. This points to the research gap which will be addressed in this study.

Based on these problems and the research gap found in studies on existing bracing treatment, a comfortable textile brace that can effectively correct the malalignment of the spine, poor posture and poor body image is extremely important to meet the expectations and actual needs of AIS patients. Almost all of the evidence-based orthoses are made of rigid materials, since it is considered that hard materials may have better control around spinal deformity than other types of materials. Using both rigid and flexible materials on a semi-rigid brace may provide a balance between comfort and effectiveness and thus offer an alternative option for patients apart from rigid orthoses.

To develop a new anisotropic brace for AIS, this study follows a design framework, which is " Modified FEA model for designing a medical textile or scoliosis brace". Some lightweight and comfortable materials are recommended for constructing the brace, such as fabrics with net structures, which are soft and breathable. The wear compliance rate may be thus improved due to the experienced comfort, flexibility of the brace and heat stress reduction. The problem with the bulky appearance of the brace is resolved by applying a semi-rigid brace design so the psychological concerns of bracing can be relieved as well. In addition, a three-point pressure system is the main bracing mechanism used to correct the spinal deformity, and an important corrective principle for the preliminary brace design in this study.

CHAPTER 3 – RESEARCH METHODOLOGY

3.1 Introduction

In this chapter, the methods used to design and develop an anisotropic textile brace for AIS are discussed in detail. A modified FEA model for designing a medical textile or scoliosis brace is followed in the research flow of this study. Apart from identifying the problems of existing braces for AIS, the chapter includes a discussion on 1) producing a design for a proposed anisotropic textile brace, 2) further developing the design for the proposed brace, 3) conducting a preliminary wear trial, and 4) implementing a clinical trial of the proposed brace to evaluate its bracing effectiveness.

3.2 Experimental Design

Figure 3.1 shows the flow chart diagram for this study. After reviewing the background information around AIS, the problems with current bracing treatments are identified, which provide the direction for designing the proposed anisotropic textile brace. As mentioned in the Chapter 2, a non-rigid brace in the form of a functional intimate apparel was designed in 2018 (Fok et al., 2018) and the results of its clinical study was announced in Fok (2020). They are all used as reference in this study. An anisotropic textile brace for AIS is subsequently designed and developed which retains the advantages of the design features but reduces the limitations of the functional intimate apparel. Moreover, a preliminary wear trial and a 3-6 month clinical trials (with follow ups after 3 and 6 months of wear) are subsequently carried out to assess the bracing performance of the proposed brace in this study.

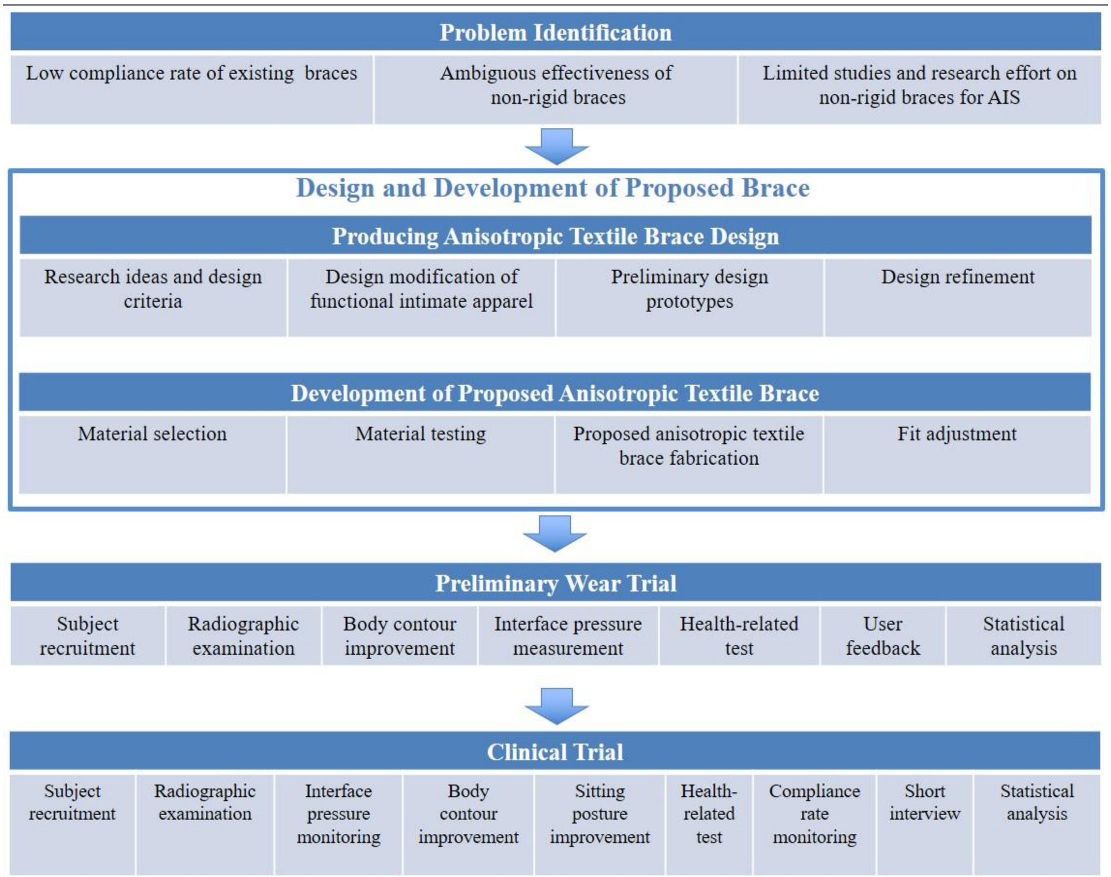


Figure 3.1 Research flow chart

3.3 Producing anisotropic textile brace design

To address the low rate of treatment compliance with existing spinal braces, the ambiguous efficacy of non-rigid braces, and the few studies and little research effort on non-rigid braces for AIS, the research ideas, design criteria, and modified elements of the original functional intimate apparel in Fok (2020) are mainly discussed in this section.

3.3.1 Research ideas and design criteria

To cope with the problems that are discussed in the background section of this study, the preliminary research ideas focused on addressing the low patient compliance and questionable bracing outcomes of non-rigid braces. The anisotropic textile brace was then proposed as a means to enhance the wear experience to avoid the physical and psychological problems caused by bracing treatment so as to increase wear compliance. Also, efforts were put into the anisotropic textile brace to enhance the bracing performance. Aside from the above, the functional, aesthetic and expressive considerations of the modified FEA model are discussed as part of the design criteria of the proposed brace.

3.3.2 Modifying design of functional intimate apparel

Previous studies on non-rigid braces like the functional intimate apparel developed by Fok et al. (2018) were taken into the consideration in the brace design stage. The functional intimate apparel in Fok et al. (2018) is a semi-rigid brace designed as a flexible shapewear or an undergarment with elastic materials and supporting resin bones to control the spinal deformity of wearers with good wear comfort and flexibility. As there is no difference in the brace design between Fok et al. (2018) and Fok (2020), latter study is focused on which not only contains its brace design but also includes a systematic clinical study of their developed brace.

In their study, 5 human subjects with AIS underwent a short clinical trial, in which the percentage of in-brace correction reached 88.7% (Fok, 2020). Compared to other non-rigid braces like the posture correction girdle (Liu, 2015), this degree of in-brace correction is exceptional. Due to its potential success of treating scoliosis, the corrective mechanism and brace design of the brace in Fok (2020) are thus taken into the consideration when designing the anisotropic textile brace in this study. However, there are several limitations in their brace design, such as problems with fit, discomfort, and the lack of durability.

Therefore, the functional intimate apparel design in Fok (2020) was modified with the goals of applying its corrective elements while enhancing its fit, comfort, and durability.

3.3.3 Preliminary design prototypes and design refinement

In order to ensure that the proposed design would fit on a human body, the preliminary prototypes were fitted onto a mannequin and female youth. All of the issues were recorded. The design of the anisotropic textile brace was then refined and finalized after multiple adjustments.

3.4 Development of proposed design

When the modifications to the anisotropic textile brace design were completed, the next step was to choose the appropriate materials to fabricate the brace for further assessment. More importantly, the materials used should provide a better performance in terms of comfort, durability, and fit, in comparison to the original functional intimate apparel in Fok (2020). To achieve this goal, this section discusses the material selection and testing, fabrication, and fit adjustment processes.

3.4.1 Material selection

This proposed brace is not only close fitting but also controls and corrects the progression of the spinal curvature. To develop a tightly fitting garment, the fit, mobility, comfort, safety, durability, as well as ease of donning and doffing were taken into consideration.

Lightweight and breathable materials should be used to construct the new brace so as to reduce the heat stress of the users. Apart from selecting potential materials with a good hand feel, thermal comfort and breathability, strong and stretchable fabrics with good elastic recovery were also considered because they would fit well on the human subjects. Therefore, knitted fabrics which have good texture, air and moisture permeabilities, thermal conductivity, elasticity and recovery, were considered as the target materials for constructing the brace.

To meet the material criteria above, knitted fabrics made of synthetic fibers were selected as they tend to be light in weight, easy to care for and breathable, can easily dry, and have a good hand feel with excellent abrasion and pilling resistance. Knitted fabrics with a net structure, such as powernet and satinnet, are potential materials that have these properties because of their porosity.

3.4.2 Material testing

As the brace design of the functional intimate apparel in Fok (2020) has room for improvement, the materials used are also evaluated and compared after subjected to a series of tests in order to determine the best fabric performance in terms of comfort, fit, mechanics, and durability.

As mentioned, low compliance with bracing treatment may be caused by the lack of ventilation of the brace, poor tolerance of patients of the discomfort during bracing and even skin irritation. Meanwhile, low compliance is often a concern as it could greatly affect the bracing effectiveness, and even result in treatment failure (Negrini et al., 2015). To optimize the wear experience and increase compliance rate, the perceived wear comfort of the brace is one of the essential elements which the proposed brace will take into consideration. In this section, the thermal comfort of all of the original and newly selected materials are evaluated and compared with the use of international standard tests for thermal conductivity, air and water vapor permeabilities and hand feel.

For the fit, the elasticity and recovery of the sourced fabrics were assessed with related physical tests. The aim is to select suitable fabrics to offer a tightly fitting bracewear with a better fit, compared to the functional intimate apparel in Fok (2020).

As for the brace mechanics, the appropriate amount of corrective forces is key for AIS braces. According to the clinical study in Fok (2020), the immediate spinal correction offered by their functional intimate apparel is satisfactory. The best case scenario in their study is approximately a 20 degree in-brace reduction of the Cobb's angle which is up to an 88.7% reduction in the curvature. Applying the three-point pressure system, their functional intimate apparel has a rigid back bone to allow the straps to pass through them and the corrective components to remain on the body of the wearers. While the artificial hinge design of the brace has been retained in the proposed anisotropic textile brace, the corrective components like wide elastic bands and velcro were also tested for stretchability and recovery and peel strength, in order to maintain or even enhance the mechanical performance of the original functional intimate apparel.

Finally, the last goal of the material selection process and testing is to ensure durability which is one of the design criteria of the proposed brace. In this research study, the designed brace is tested by human subjects in a 3-6 month clinical trial with follow ups after 3 and 6 months of wear. The subjects wear the brace every day to ensure the durability of the materials. Pilling resistance, changes in the dimensions of the fabric after home laundering, and repeated stretching are all examined to minimize the deterioration of the material with long term use.

Prior to the commencement of the experiments, all of the fabric specimens of the 5 types of fabrics were prepared and conditioned in the same conditions, at temperatures of 20 ± 1ºC and relative humidity of 65 ± 2% for at least 24 hours in accordance with ASTM D 1776 Standard Practice for Conditioning and Testing Textiles. All of these tests are listed in Table 3.1 and the details are subsequently discussed.

Table 3.1 Material tests of anisotropic textile brace materials

(to be continued in the next page)

Physical test/ Material		**Knitted fabric**		**Wide elastic bands**	**Elastic Straps**	**Velcro**
		Upper part of brace	**Bottom part of brace**			
		Shell fabric, lining	Shell fabric	Corrective components	Shoulder straps, underband, waistband, compensating straps	Corrective components
Comfort	Thermal conductivity test	√	√	√		
	Air permeability test	√	√	√		
	Water vapor permeability test	√	√	√		
	Hand feel	√	√	√		√
Fit	Elasticity and recovery test	√	√	√		
Mechanics	Stretchability and recovery test (for elastic straps)				√	
	Peel strength test					√
	Pilling resistance test	√	√			

Durability	Dimensional changes of fabrics after home laundering	√	√	√	√	
	Repeated stretching test			√		

3.4.2.1 Thermal conductivity test

The thermal conductivity test is used to evaluate the ability of a material or in this case, textile fabric, to conduct heat. In the experiment, the Kawabata Evaluation System- F7 (KES-F7) Thermo Labo II tester was used to measure the constant thermal conductivity of each fabric specimen (Figure 3.2).

Figure 3.2 KES-F Thermo Labo II

During the testing, the temperature of the water box of the KES-F Thermo Labo II was set at room temperature (20°C) whereas that of the heat plate of the BT-Box, which approximates the temperature of the human body, was set to a constant temperature (30°C). The weight of the BT-Box is 150 g while the surface area of the measured heat plate is 25 cm^2. A fabric sample with dimensions of 5 x 5 cm was then placed between the water box and the BT-Box and completely in contact with the heat plate. The measurement of the heat loss through the fabric sample from the BT-Box to water box was recorded. The measurement of the pressure load is calculated by using:

$$P= 150 /25 = 6 \text{ gf/cm}^2 \qquad (3.1)$$

To obtain the thermal conductivity (k) in watts/cm°C, the following equation is used:

$$K(W/cm°C)= (W \times D)/A\triangle T_0 \qquad (3.2)$$

where,

W= Reading on the digital panel meter, which shows the heat consumption of the BT-Box

D= Thickness of the sample (cm)

A= Area of the heated plate of the BT-Box (cm^2)

$\triangle T_0$= Change in temperature between the BT- Box and water box (10°C)

3.4.2.2 Air permeability test

An air permeability tester, KES-F8-AP1, (Figure 3.3) was used to determine the breathability of the fabric samples, which is directly related to the perceived wear comfort.

Figure 3.3 KES-F8-AP1 Air Permeability Tester

Simply put, fabric that allows more air to pass through or more air permeable is defined as breathable fabric that is comfortable to wear when used for a garment. Following ASTM D737 Standard Test Method for Air Permeability of Textile Fabrics, the amount of air flow that passes through a fabric sample for a specific period of time is measured in order to evaluate the air flow resistance in units of kPa · s/m. Ten fabric specimens were taken from each type of fabric and tested. Then, the average value was recorded.

3.4.2.3 Water vapor permeability test

A textile fabric that can readily transfer moisture well can better wick sweat away from the body, which is also one of the factors that can determine whether the fabric would be comfortable to wear. ASTM E96 Standard Test Methods for Water Vapor Transmission of Materials was used to carry out the water vapor permeability test. The dimensions of the fabric specimens could not extend beyond the outer edges of the test dishes. Before simulating the sweating condition, the tested dishes were filled with distilled water until they were ¾ full. The specimens were then adhered facedown to the mouth of the test dish with a water-resistant glue to simulate the transfer of water vapor from the skin to the outside environment. After 24 hours, the results of the water vapor transmission (WVT) were collected by calculating the change in weight with a balance that has an accuracy of 0.01 g. The water vapor transmission is calculated with Equation 3.3.

$$\mathrm{WVT} = \frac{\mathrm{G}}{\mathrm{tA}} \quad (3.3)$$

where,

G= change in weight (grams)

t= time duration (hours)

A= Area of the tested dish (m^2)

3.4.2.4 *Hand feel*

Since the surface roughness of a material would also affect the perceived wear comfort, the hand feel of all of the fabrics and corrective bands were tested by using the KESFB4-AUTO-A Automatic Surface Tester (Figure 3.4). This is an automated tester designed to measure the surface properties of fabrics, paper, nonwovens, and film-like materials. In this study, only the frictional properties and geometrical surface roughness of the knitted fabrics and corrective elastic bands are examined.

Only one specimen (25 cm x 25 cm) was taken from each material sample for the subsequent testing. After the specimen was placed onto the automatic surface tester, the roughness sensors were automatically positioned to start the measurement. After each measurement which consisted of 3 cycles was completed, the sensor moved to measure a different area of the specimen. Both the right and wrong sides of the materials in the warp and weft directions were measured. In each case, the mean friction coefficient

(MIU), fluctuation of mean frictional coefficient (MMD), and surface roughness (SMD) were recorded.

Figure 3.4 KESFB4-AUTO-A Automatic Surface Tester

3.4.2.5 Elasticity and recovery test

The elasticity and recovery of the fabrics were tested by using the Instron 4411 tensile strength tester (Figure 3.5) in accordance with ASTM D6614-07 Standard Test Method for Stretch Properties of Textile Fabrics.

Figure 3.5 Instron 4411 Tensile Strength Tester

The dimensions of the tested fabric specimens are 35 x 5 cm. They were stretched at a constant rate of load (4 lbs) for 5 minutes, respectively. Then, the crosshead of the tensile tester returned to the original position and the specimen was held for another 5 minutes. After that, the length of the specimen without slack was measured. Thus, the fabric stretch and fabric growth were calculated by using Equations 3.4 and 3.5 after calculating the difference in the length of the specimens before, during and after loading.

$$\text{Fabric stretch } (\%) = \frac{(B-A)}{A} \times 100 \qquad (3.4)$$

$$\text{Fabric growth } (\%) = \frac{(C-A)}{A} \times 100 \qquad (3.5)$$

where,

A= the initial length of specimen

B= the length of specimen during loading (4 lb.)

C= the length of specimen after loading without slack

3.4.2.6 Stretchability and recovery test (elastic straps)

To determine the performance of the narrow elastic straps like the shoulder straps and underband elastic, the British Standard (BS) EN 14704-3 Determination of the Elasticity of Fabrics was adopted. The Instron 4411 tensile strength tester was also used to determine the stretchability and recovery of the specimens. Three specimens were taken from each elastic strap sample with dimensions of 100 mm in length and 25 mm in width (full width for shoulder straps and compensating straps). As the full width of the underband elastic is 17 mm, the sample itself was directly tested. Before the testing, reference marks were made on each specimen. According to the testing standard, each sample had to be extended by using a fixed load of 53 N at a constant rate of 500 mm/min for 5 cycles, and then held at the maximum force for 1 minute. The force decay and unrecovered elongation are calculated by using Equations 3.6 and 3.7:

$$\mathrm{A} = \frac{\mathrm{V}-\mathrm{W}}{\mathrm{V}} \times 100 \quad (3.6)$$

where,

A= force decay with time/due to extension (%)

V= the maximum force after the 5th cycle (N)

W= the maximum force of the 5th cycle after the holding period (N)

$$\mathrm{C} = \frac{\mathrm{Q}-\mathrm{P}}{\mathrm{P}} \times 100 \qquad (3.7)$$

where,

C= unrecovered elongation (%)

Q= distance between the reference marks after a period of recovery (mm)

P= initial distance between the reference marks (mm)

3.4.2.7 Peel strength test

To ensure that the corrective components can be well adhered onto the loop side of the velcro panel, the peel strength of the hook and loop touch fasteners was tested in accordance with ASTM D5170 Standard Test Method for Peel Strength. Four specimens of 203 mm± 6 mm were slit from the center of both the original (functional intimate apparel in Fok (2020)) and newly sourced velcro fasteners. Each specimen was marked with an arrow to indicate the direction that the fastener was unwound from the roll. Four specimens of each hook and loop sample were taken to characterize the peel strength of each of the configurations. A flat steel plate that weighted 4 pounds was placed on the closure slowly and completely without applying extra hand pressure for 2 seconds, which created a hook and loop engagement for the following testing steps. After that, all of the closure specimens were prepared in accordance with the specific requirements and one inch of closure was separated at the end gently. The separated end was placed into the clamp of the Instron 4411 tester and placed 25.4 ± 3 mm apart (Figure 3.6). The point of separation is centered and aligned approximately parallel to the clamps. A peel speed of 305 ± 13 mm/min was used, and each specimen was subjected to five cycles of attach and detach, which were recorded. Thus, the average peel force, average of the highest peak value of each specimen, and average integrator values were obtained.

Figure 3.6 Instron 4411 tester used for peel strength test

3.4.2.8 Pilling resistance test

The design of the proposed brace incorporates many hoop and loop fasteners, including for the compensating straps, corrective components, and the crotch. However, these fasteners might stick or even pill and fuzz which affect the wearability and appearance of the brace. As such, a pilling resistance test was conducted to determine the resistance to the formation of pills and other related surface changes on the selected textile fabrics. In accordance with ASTM D4970 Standard Test Method for Pilling Resistance and Other Related Surface Changes of Textile Fabrics, four pairs of circular specimens were cut from each fabric sample and the hoop side of the Velcro with a diameter of 140 mm and 38 mm, respectively. The larger specimens were placed onto the specimen holders of a Martindale abrasion tester (Figure 3.7) and the velcro specimens were placed on a disk with 3 mm of polyurethane foam, which was used to hold the location of velcro, as the abradant. This is to ensure that the face of both specimens is exposed. The spindle was inserted into the holder to apply pressure (3 kPa) onto the fabric specimen. The specimen was cycled run 100 times to produce wear. After that, the 4 specimens of each sample were evaluated by using the apparatus for fabric evaluation (Figure 3.8) and the amount of pilling and fuzzing was assessed. Average results of specimens was obtained as the performance of each material sample.

Figure 3.7 Martindale abrasion tester

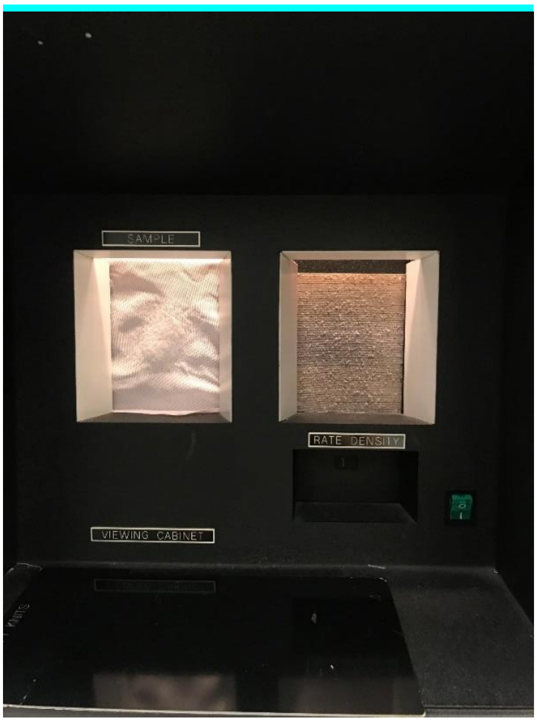


Figure 3.8 Apparatus for fabric evaluation

3.4.2.9 Dimensional changes of fabrics after home laundering test

Following AATCC 135 Test Method for Dimensional Changes of Fabrics after Home Laundering Purpose, the changes in the dimensions of the selected fabrics after laundering were assessed. Three specimens from each sample material were used for the test. Specimens with dimensions of 50 cm x 50 cm were taken from all of the fabrics and wide elastic bands, and marked with a benchmark of 25 cm. For the elastic straps, 50 cm specimens at their full width were also prepared. A benchmark of 25 cm was made as well. To simulate home laundering, all of the specimens were washed in a laundering machine under a normal wash cycle with warm water (41°C), rinse cycle at a temperature of 29°C, as well as subjected to 2 hours of tumble drying. Besides, the total weight of the specimens and dummy load was ensured to be 1.8 kg whereas 60 g of detergent was used for the laundering.

After laundering and drying, the percentage of dimensional change based on the benchmark was obtained by measuring the length along the benchmark on each specimen with the following equation:

$$\text{Percentage of dimensional change after laundering} = \frac{(B-A)}{A} \times 100\% \quad (3.8)$$

where,

A= original dimensions of the benchmark

B= dimensional change of the benchmark after laundering

3.4.2.10 Repeated stretching test

The durability of the corrective components, especially the wide elastic bands, is imperative for a corrective brace, as the tightness of the brace is one of the main concerns of bracing treatment. To ensure that the tightness of the corrective components is adequate even after 3 and 6 months of wear, a repeated stretching test was carried out for all of the sourced elastic bands.

The repeated stretching test was conducted by using the Instron 5944 electro-mechanical tension testing system. Three specimens were taken from each elastic sample with dimensions of 9 cm x 2 cm and a 2 cm mark made at the end of both edges as the benchmark. Using the clamps to fix the specimen at the benchmark, the distance between the two clamps was set to be 5 cm apart (Figure 3.9). To simulate the daily use of the corrective bands, all of the specimens were stretched 1000 times by 30% at a rate of 300 mm/minute. The force applied while stretching the elastic samples was recorded and plotted in a graph. The elastic band which shows the a better stretching performance than the original functional intimate apparel in Fok (2020) was considered to be the most suitable material for use as the corrective band of the anisotropic textile brace.

Figure 3.9 Instron 5944 used for repeated stretch test

3.4.3 Fabrication of proposed anisotropic textile brace

After conducting the physical tests for the sourced fabrics, the most appropriate fabrics were selected to construct the newly designed anisotropic brace based on their fabric properties. The materials used, garment pattern and production methods of the brace are discussed as follows.

3.4.3.1 Pattern drafting

The brace pattern was constructed by using and modifying a basic womenswear block pattern. The basic bodice block is shown in Figure 3.10, which can be used to make different women tops (Dove, 2013). To improve the fit for the designed brace, a 10% shrinkage of the actual body measurements is also incorporated in the pattern draft for all of the stretchable fabrics.

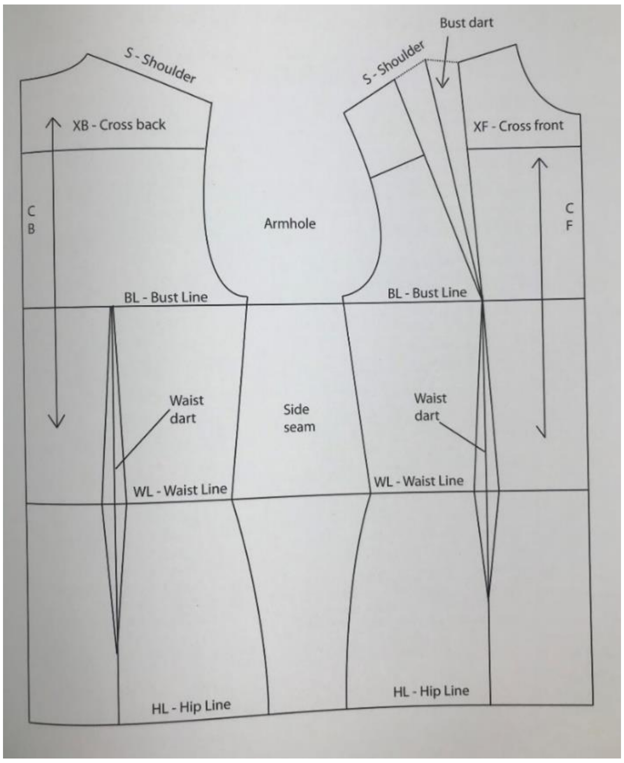


Figure 3.10 Basic bodice block (Dove, 2013)

3.4.3.2 Pattern grading

As the proposed brace in this study cannot be universally fitted onto all wearers with different body shapes by adjusting the strap as is the case in the original functional intimate apparel in Fok (2020), three different brace sizes were considered. To do so, pattern grading was carried out, which is the process of scaling different garment sizes from the base size with reference to a size chart/specifications. In this study, the pattern grading of the main component of the anisotropic textile brace was based on ASTM D6192M Standard Tables of Body Measurements for Girls, Sizes 2 to 20 (Reg & Slim) and Girls Plus. After searching the related studies on size grading for teenagers between 10 and 13 years old, the measurement chart for slim bodies was referenced as AIS patients tend to have a slimmer body profile and are lighter in weight compared to normal adolescents (Fung, 2020). Therefore, sizes 12S, 14S and 16S were adopted which denote small, medium and large sizes, respectively. Table 3.2 shows the corresponding measurement chart of these sizes for drafting and grading the patterns. A visual reference of the 17 key body measurements is provided in Figure 3.11.

Table 3.2 Fit chart: Girls - 12S to 16S

Size		**12S**	**14S**	**16S**
Body weight (mean), kg		84	99	109
Body weight (range), kg		79-89	93-104	103-114
A	Height (cm)	147.55	155.18	159
B	Upper-chest girth (inches)	27	28 1/4	29 7/8
C	Chest/ Bust girth (inches)	27 1/2	29	30 1/2
D	Under-bust girth (inches)	25 1/4	26 3/8	27 5/8
E	Waist girth (inches)	24	25	26
F	High-hip girth (inches)	26 5/8	27 7/8	29 1/8
G	Hip/ Seat girth (inches)	28	29 1/2	31
H	Shoulder length (inches)	3 5/8	3 3/4	3 7/8
I	Centre front waist length (inches)	11 3/4	12 3/8	12 3/4
J	Centre back waist length (inches)	13 1/8	13 7/8	14 1/4
K	Scye depth (inches)	5 1/2	5 1/2	5 3/4
L	Cervicale height (inches)	49 3/4	52 1/4	53 5/8
M	Waist height (inches)	36 3/4	38 7/8	39 7/8
N	Bottom scye to waist height (inches)	7 1/2	7 7/8	8
O	Waist to high-hip height (inches)	3 3/8	3 5/8	3 6/8
P	High-hip to hip/seat height (inches)	3 1/4	3 1/2	3 3/4
Q	Hip/Seat to crotch height (inches)	2 1/2	2 5/8	2 3/4

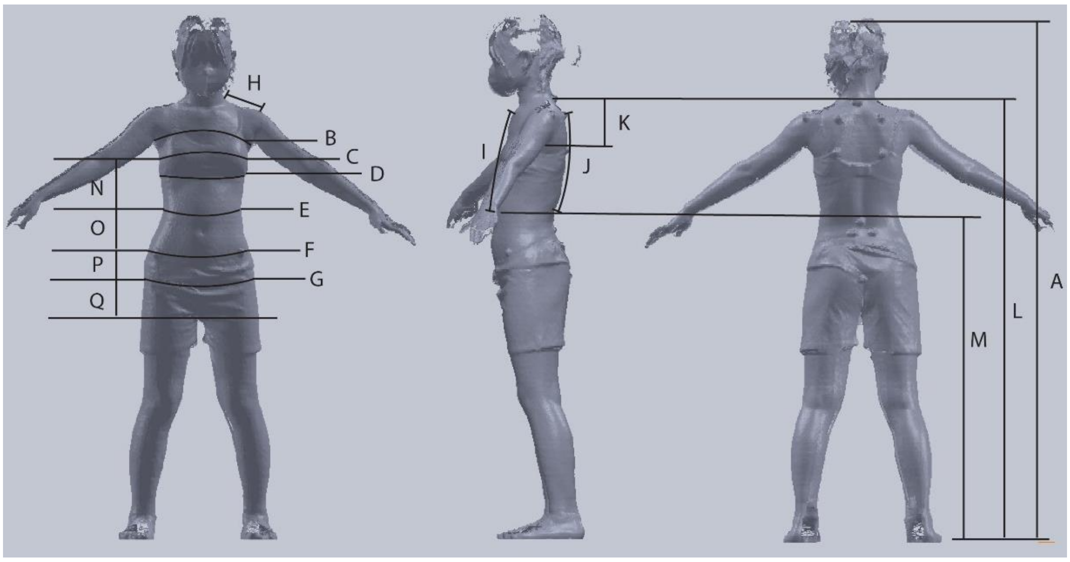


Figure 3.11 Seventeen key body measurements

3.4.3.3 Sewing brace sewing and constructing corrective pad

For the proposed brace, a series of sewing stitches were used to join the fabric panels together and create a tightly fitting garment. To maintain the stretchability of the fabrics and stabilize the seams, 3-thread (ISO #504 Overedge) and 4-thread overlocks (ISO #514 Overedge) were used to sew the overedge seams of the entire brace (Figure 3.12 and Figure 3.13).

A v-fold elastic was also sewn onto all of the edges of the fabric and corrective components panels with a zig zag stitch (ISO #304 Zig Zag) to prevent fraying of the raw edges of the materials, enhance the hand feel, and retain the elasticity of the panels. This lockstitch is formed as a symmetrical zig zag pattern as shown in Figure 3.14. Besides, the lockstitch was used to attach the underband and waistband elastics.

Unlike other knitted fabrics and elastic bands, hoop and loop fasteners are rigid. To affix the velcro onto the brace, a lockstitch (ISO #301 Lockstitch) was used instead (Figure 3.15). This is a common stitch used to join fabric, especially for non-stretchable fabrics. For the final phase of the brace fabrication, a bar-tack stitch was used on the edges of the seams for reinforcement purposes.

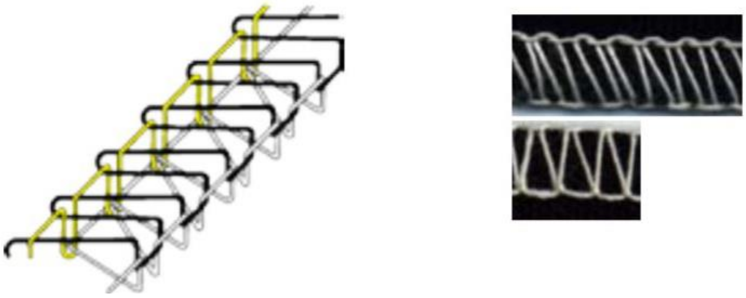


Figure 3.12 ISO#504 Overedge (Dewellton LLC, 2008)

Figure 3.13 ISO#514 Overedge (Dewellton LLC, 2008)

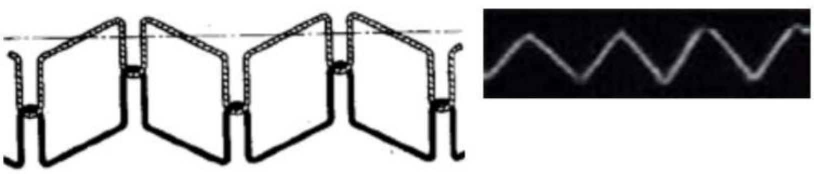


Figure 3.14 ISO#304 Zig Zag (Dewellton LLC, 2008)

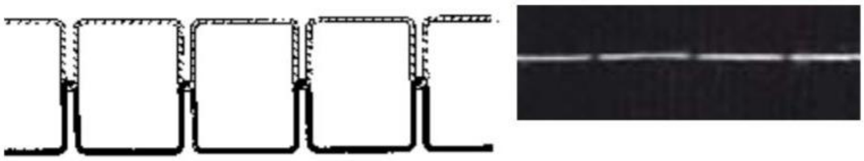


Figure 3.15 ISO#301 Lockstitch (Dewellton LLC, 2008)

The corrective pad is a part of the corrective components used to enhance the lateral force to reduce the spinal curvature. The use of a corrective pad was developed in Fok (2020) and preliminarily shown to be effective in reducing spinal deformity. The design of their pad, which is made of silicone, was therefore used in the proposed anisotropic textile brace. The silicone pad was constructed based on Fok (2020).

3.4.4 Fit adjustment

After fabrication of the prototype anisotropic textile brace, a female youth was invited to don the prototype to determine the fit. Apart from input on the appearance of the brace, feedback was also solicited on the fit of the brace to better understand their wear comfort. The participant donned and doffed the brace independently without help , and also walked and sat for a while wearing the brace. All of the fit problems and user feedback were recorded to modify the prototype design. The final brace design was subsequently developed and constructed for further assessment of fit through a clinical trial.

3.5 Preliminary wear trial of anisotropic textile brace

A clinical trial was subsequently conducted to evaluate the bracing efficacy of the proposed anisotropic textile brace, which consisted of two phases: a preliminary wear trial and 3-6 month clinical trial (with follow ups after 3 and 6 months of wear). The following section discusses the former, which is a 2-hour preliminary wear trial to evaluate and determine the fit and cut, and solicit user feedback, as well as understand the efficacy of the corrective effect in reducing the spinal curvature.

3.5.1 Subject recruitment

A scoliosis screening programme was held in primary and secondary schools in Hong Kong during the academic year of 2019-2020 to recruit subjects for the wear trial. The programme was available to all Primary 5 to Form 1 students. In July 2020, 5 schools had signed up to voluntarily participate in the school screening programme.

As mentioned in Chapter 2, the Adam's forward bending test is a quick means to identify whether students have the symptoms of scoliosis. A professional prosthetist-orthotist (P&O) therefore took part in the programme to carry out the Adam's forward bending test during the school screening process. The students had to bend forward gradually, starting at the waist until their spine was parallel to the horizontal plane. Their feet were placed together, palms held together, arms hanging and knees extended. The P&O then stood at the back of the student and observed along the horizontal plane of the spine with a scoliometer to assess whether there is abnormality of the spinal curvature, such as lordosis, kyphosis or asymmetry in the contours of the back (Figure 3.16). If the ATR shown on the scoliometer exceeded or was equal to 5 degrees, then it was a sign of potential scoliosis (Adams, 1882; Patias et al., 2010).

Figure 3.16 Scoliometer used in school programme

Due to the design of proposed brace, target subject in this study only focused on female. After that, all potential female subjects took a low radiation dosage x-ray without the brace donned through the EOS^{TM} imaging system at Hong Kong Advanced Imaging. The Cobb's angle, Risser sign, coronal compensation (CD) and sagittal balance were measured on the radiographic images. The female students who met the criteria for scoliosis were invited to participate in the preliminary wear trial. All of the female participants and their parents/ guardian signed a consent form before they began to take the X-rays and participate in wear trial.

3.5.1.1 Inclusion and exclusion criteria for subject recruitment

To assess the feasibility and corrective effect of the proposed anisotropic textile brace, the female participants had to have a spinal curvature between 18 to 45 degrees to take part in the wear trial. They are young female AIS patients between the ages of 10 and 13 with Risser signs 0-2. They have the ability to speak in English or Chinese which would ensure that they can understand the bracing instructions and share their thoughts coherently.

Anyone who had previously undergone a spinal operation, bracing treatment for AIS, or experienced a trauma, mental disorder or skin allergies, could not take part in the study.

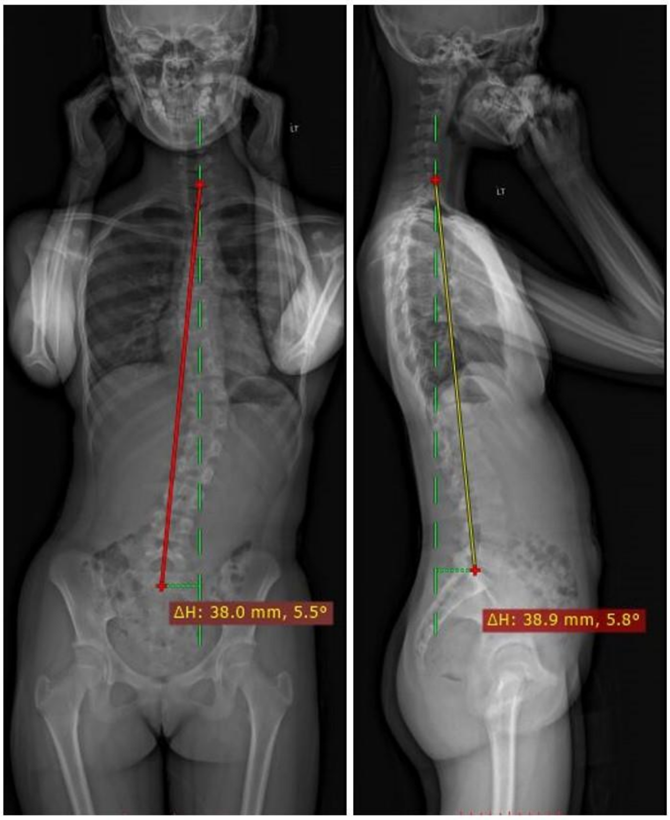
3.5.2 Radiographic examination

Negrini et al. (2012) stated that in-brace x-rays should be done as one of the means of examining the effectiveness of bracing. In this study, all of the recruited subjects are still at risk of facing the progression of the spinal curvature due to skeleton immaturity and so their spinal curvature is prone to be affected by external forces. Li, Wong, Luk, Wong, and Cheung (2014) pointed out that with only 2 hours of bracing, the maximum effect of orthotic treatment is already demonstrated. Therefore, the participants underwent a wear trial which took place at the Hong Kong Polytechnic University and arrangements were made to wear the proposed anisotropic textile brace for at least 2 hours and then undergo a radiography of their entire spine while wearing the brace. EOS™ imaging was used to acquire a high-quality in-brace x-ray image and evaluate the change after a 2-hour intervention. The radiographic images taken before the preliminary trial at the Hong Kong Advanced Imaging were used as the pre-treatment images.

After obtaining the DICOM file of the x-ray images from Hong Kong Advanced Imaging, two independent members of the research team with experience but are not involved in this project conducted the radiographic measurements, including the Cobb's angle, CD, and sagittal balance, by using RadiAnt DICOM Viewer (64-bit) software. To reduce subjective bias, they were blind to the information of the subjects. The rate of change in the spinal curvature with the in-brace condition was calculated with Equation 3.12, where a negative value denotes a reduction of the spinal curvature and vice versa.

$$\text{Rate of change of spinal curvature} = \frac{\text{Cobb's angle}_{in-brace} - \text{Cobb's angle}_{without\ brace}}{\text{Cobb's angle}_{without\ brace}} \times 100\% \quad (3.12)$$

Besides, coronal compensation (CD) and sagittal balance of each subject was measured on the radiographs with the use of same software, which aims to assess the changes of spinal curve in both coronal and sagittal plants (see Figure 3.17). For the former (Figure 2.18(a)), it is also called coronal balance (CB), which is defined as the vertical alignment between the midpoint of C7 plumb line and center sacral vertical line in the coronal plane (Lenke, 2015). When this vertical distance is more than 2 cm, it is usually reported as spinal coronal imbalance. As for the latter (Figure 3.17(b)), sagittal vertical axis (SVA) is an important index of sagittal balance of the trunk, which is the distance from the plumb line from the center of the C7 to the posterior edge of the upper sacral endplate surface. Sagittal alignment can be classified into balanced if the value of SVA is below 40mm.



(a) Coronal balance (b) Sagittal balance

Figure 3.17 The spinal measurement on radiographs

(a) Coronal balance (b) Sagittal balance

3.5.3 *Three-dimensional body scanning*

As with the clinical study in Fok (2020), 3D body scanning was conducted as a secondary outcome measure to evaluate the asymmetry of the body contours. As mentioned in Chapters 1 and 2, an asymmetrical body shape is one of the apparent symptoms of AIS patients, such as uneven shoulders, scapular asymmetry, abnormal shape of the spine, and pelvis obliquity. To determine the efficacy of the proposed brace in changing the body shape, a 3D body scanner (Anthroscan System, Human Solutions) was used to scan the body shape of the recruited subjects, once before the bracing and once after the bracing; that is, pre-intervention and post-intervention scanning of immediate bracing at 2-hour wear trial. Figure 3.18 shows the 3D body scanner used in this study.

The participant was required to wear a plain light colored bra top and tight shorts during the scanning process to provide a more accurate image without noise. The 3D body images of the participants were obtained applying optical triangulation technology with a laser light without any radiation or contact, which also allows the body dimensions to be obtained accurately and automatically with an error of 1mm (Carniciu et al., 2014; Human Solutions GmbH, 2015). In order to prevent the difficulties of analysis, 12 anatomical landmarks created by the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) were used as the reference points (Kotwicki et al., 2009). They are located at the pelvis and back of the subjects, including their 7th cervical vertebra (C7), L4 spinous process, acromial angle of the shoulders, superior and inferior angles of the scapulae, and posterior superior iliac spine (PSIS), as shown in Figure 3.19.

To compare the immediate changes in the asymmetry of the body contours made by the original functional intimate apparel in Fok (2020) and the proposed anisotropic textile brace in this study, all of the subjects donned both of the braces and underwent 3D body scanning respectively during the preliminary wear trial. After the subjects donned the brace, they were instructed to stand on the footprint images in the 3D scanner and stand as they normally do with slightly open arms. Their 3D body images were then captured and appeared on the computer system after a few minutes.

Figure 3.18 3D body scanner (Anthroscan System, Human Solutions)

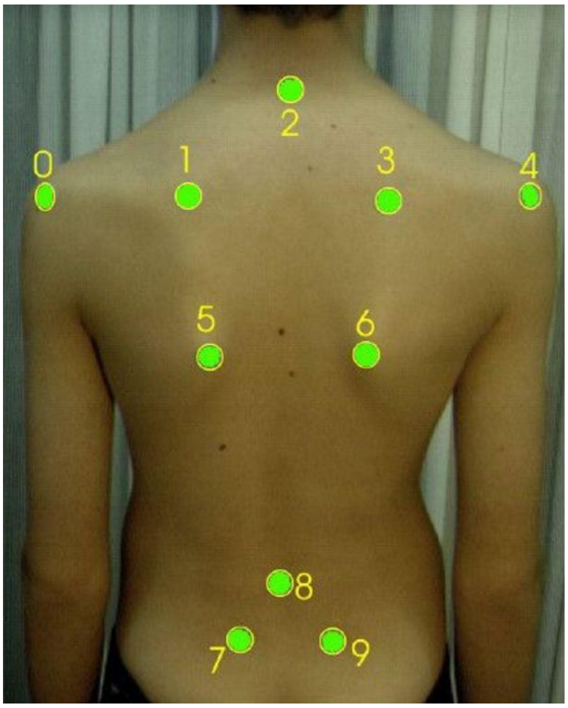


Figure 3.19 Anatomic landmarks (Patias et al., 2010)

According to Duong, Mac-Thiong, and Labelle (2009), such captured 3D images can be used to assess the external trunk geometry, in particular, the changes in the physical profile of patients with AIS. By analyzing the images, the changes in the shoulder orientation, trunk imbalance, spine length, and thoracic and lumbar humps can be obtained. In this study, all collected 3D images were processed by using Solidworks 2018 software. The changes in the shoulder orientation were determined by measuring the angle of the acromion in the frontal and transverse planes, which would determine the effectiveness of the proposed brace. Figure 3.20 and Figure 3.21 present the shoulder obliquity and rotation measured through the software, respectively.

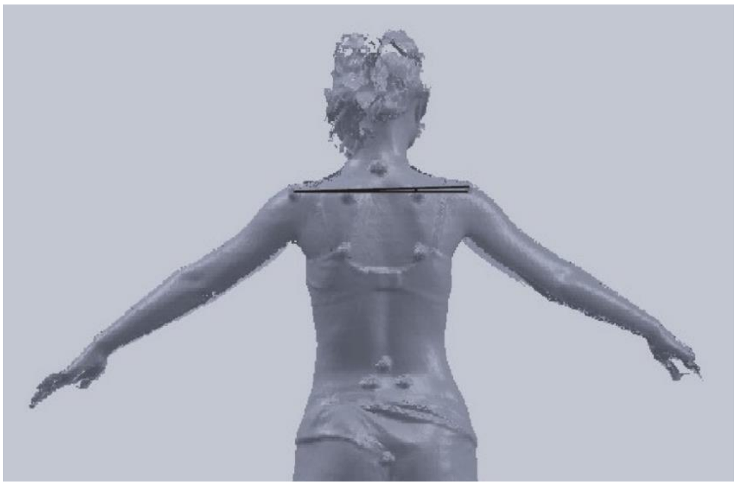


Figure 3.20 Shoulder obliquity measured in the frontal plane

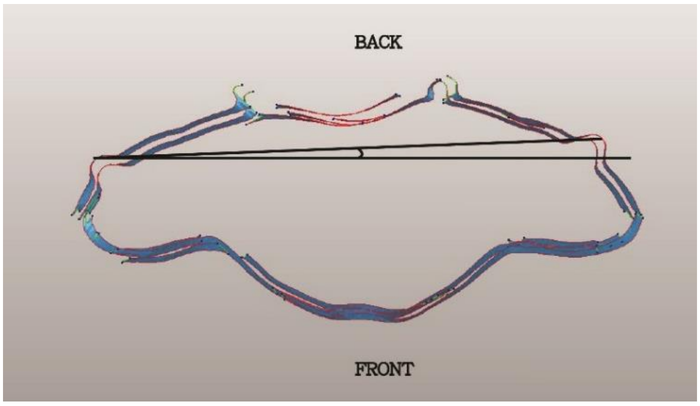


Figure 3.21 Shoulder rotation measured in the transverse plane

As landmarks cannot be placed on human subjects when they are wearing the brace, all assessments of the in-brace body contours could not be done by using the Solidworks 2018 software, except for the shoulder orientation. To analyze the immediate effect of the two braces, the Posterior Trunk Symmetry Index (POTSI) was also used to examine the trunk asymmetry found in scoliosis. The POTSI value is calculated as the sum of 6 indices from the frontal asymmetry and height difference indexes which are determined by dividing the difference of the distance between each point on the edge of the trunk to the center line through the width and length of the trunk (Durmała, Blicharska, Drosdzol-Cop, & Skrzypulec-Plinta, 2015; Suzuki, Inami, Ono, Kohno, & Asher, 1999). To measure the length of the trunk, the natal cleft of the subjects was also located with landmarks during the 3D body scanning process. Figure 3.22 shows frontal plane asymmetry indices of POTSI.

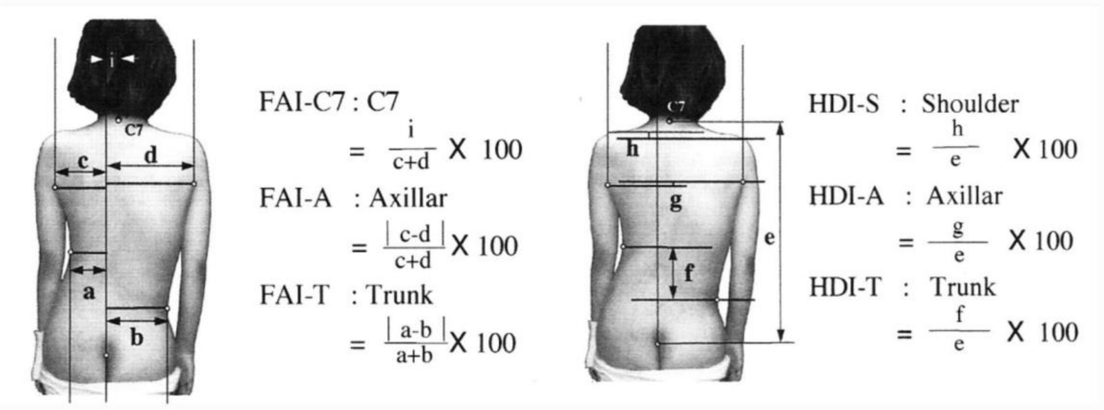


Figure 3.22 Frontal plane asymmetry indices of POTSI

(Inami et al., 1999; Suzuki et al., 1999)

3.5.4 Interface pressure measurement

In order to obtain a better understanding of the corrective effect and the biomechanics of the proposed brace, the interface pressure of both the functional intimate apparel in Fok (2020) and anisotropic textile brace was recorded and compared during a 30 minute trial. The Pliance®-xf-16 system (Novel, Munich, Germany) with 6 single sensors (Figure 3.23) was used to measure the interface pressure. Each of these sensors can measure a pressure that ranges from 0 to 60 kPa within an area of 78 mm^2. During the pressure measurement, the sensors were placed at the apex of the corrective pad, opposite side of the convexity, and both left and right anterior superior iliac spines (ASIS). The subjects were asked to stand in their normal posture for at least 1 minute and the interface pressure was collected.

Figure 3.23 Pliance® pressure sensors

3.5.5 *Health-related test*

Ascani et al. (1986) and Durmała et al. (2015) concluded that concerns around aesthetics may cause low confidence and other negative feelings of AIS patients. Not all existing braces are aesthetically pleasing and therefore may cause self image problems. Nevertheless, an effective bracing treatment for AIS should not deteriorate self confidence around body image and negatively affect the quality of life of wearers.

To examine whether the proposed brace has any impacts on self confidence, the Chinese version of the Trunk Appearance Perception Scale (TAPS) and Brace Questionnaire (BrQ) were used for the preliminary wear trial. All of the participants completed TAPS before the trial and BrQ after the 2-hour wear trial. TAPS is a valid instrument to self-assess trunk deformity, including 3 sets of sketched figures of the trunk from 3 viewpoints: looking toward the back, looking toward the head with the patient bending over, and looking forward the front (Bago, Sanchez-Raya, Perez-Grueso, & Climent, 2010). For each question, the respondents are required to choose one drawing that best represents their current spinal situation, based on a score of 1 (greatest deformity) to 5 (smallest deformity). The Chinese translated version of BrQ in this study was translated by Chan (2014). This is a questionnaire specifically designed for youths who are between 9-18 years old and are receiving bracing as a treatment, which consists of 34 Likert scale questions based on 8 domains: general health perception, physical and emotional functioning, self-esteem and aesthetics, vitality, school activity, bodily pain, and social functioning. The total score is multiplied by 20 and divided by 34 to yield an overall score ranging from 20 to 100, where higher BrQ scores mean better quality of life (Aulisa et al., 2010).

Although the subjects only underwent a preliminary 2-hour trial of the proposed brace, the collected data were also compared with the results in Fok (2020) for a brief comparison of the two braces.

3.5.6 User feedback on brace design

To prevent subjective bias, all of the recruited subjects and their parents were blind to the appearance of the proposed brace. Both the functional intimate apparel in Fok (2020) (Brace A) and anisotropic textile brace (Brace B) were given to the participants in consecutive order. The research members helped them don the braces, which were each worn for 30 minutes. They were then asked to perform any movement that they would do on a daily basis freely in a room for 30 minutes, such as walking, sitting and even bending forwards. A short interview was then conducted to solicit their input about each brace in terms of the fit and wear, in order to understand the limitations of the two braces and determine if the proposed brace can really provide wearers with improved wear experience. The interview questions are as follows.

1. Please share your feelings and wear experience during this wear trial.
2. Please rate the comfort of Braces A and B on a scale of 1-10, where “1” is very uncomfortable and “10” is very comfortable? Why?
3. Which brace (Brace A or B) would you prefer for your bracing treatment?

Regardless which brace that they respondent chose for Question 3, they still wore the anisotropic textile brace in a consecutive 2-hour wear trial. Even though their answers would not affect the trial, it is still very important that the participants indicate their preference between the two braces.

Also, Stokes and Black (2012) indicated that if a product cannot meet the needs of adolescents, they often refused to wear that specific garment. Thus, all of the recruited subjects were invited to comment on the proposed anisotropic textile brace (Question 1) in terms of the comfort, convenience or other physical and psychological aspects through a simple interview after 2-hour of bracing so as to identify further issues for improvement for the proposed design. The feedback contributed to further modifications of the brace design prior to implementation in a clinical trial.

3.5.7 Statistical analysis

To investigate the changes in the spinal curvature, POTSI results and quality of life feedback after the 2-hour intervention, The Statistical Package for Social Science Version 26 (SPSS; IBM, New York, United States) was adopted, and the confidence interval was set at 95% ($p < 0.05$), in which a Wilcoxon signed-rank test, a nonparametric statistical hypothesis test, was used to determine if there are significant differences before and after the intervention which would contribute to determining the effectiveness of the proposed brace. A Mann-Whitney U test which is a nonparametric independent test was conducted to compare the scores of wear comfort between two braces. Kendall's tau-b test, a nonparametric rank correlation test, was also carried out to investigate if any correlations are found between these initial bracing outcomes.

3.6 Three-six month clinical trial of anisotropic textile brace

If the Cobb's angle is reduced by 5 degrees after the 2-hour intervention, the proposed anisotropic textile brace would be considered as a potential effective treatment for the specific participant. The individual would undergo the 3-6 month clinical trial, which is the second phase of the wear trial of this study. The aim is to provide participants with periodical monitoring and evaluate the bracing outcomes of the proposed brace in terms of its spinal correction, ability to create changes to the body contours and sitting posture, health-related issues, and compliance rate, through a simple interview about their wear experience.

As such, 5 evaluation methods were used periodically during the bracing treatment. Table 3.3 is the overview of the experimental plan of the clinical trial.

Table 3.3 Evaluation methods during bracing period

	Month (follow-up every month)						
	0	1st	2nd	3rd	4th	5th	6th
Radiographic examination (Radiography)	√			√			√
Interface pressure monitoring (Point pressure)	√	√	√	√	√	√	√
Body contour improvement (3D body scanning)	√	√	√	√	√	√	√
Sitting posture correction (Pressure distribution)	√	√	√	√	√	√	√
Aesthetic image evaluation (Health-related test)	√			√			√
Compliance rate monitoring (Temperature logger)	√	√	√	√	√	√	√
Simple interview (Few questions)				√			√

√ Means that evaluation method is conducted at that stage.

3.6.1 Subject recruitment

Basically, the participants in this clinical trial are not new subjects because all of them took part in the preliminary wear trial. They were invited to participate in the 3-6 month clinical trial only if they had fulfilled the criteria listed below.

3.6.1.1 Inclusion and exclusion criteria for subject recruitment

To take part in the 3-6 month clinical trial, the recruited subjects had to demonstrate at least 5 degrees of reduction in spinal curvature after the 2-hour intervention, in order to possibly minimize the negative effects from prolonged bracing. The other inclusion criteria are similar to those in the preliminary pilot study. According to Weinstein et al. (2008), AIS is always first diagnosed during puberty before skeletal maturity, which is around 10 to 16 years old. Female AIS patients with a moderate Cobb's angle between

18 to 45 degrees before skeletal maturity (Risser signs 0-2) were recruited for the wear trial. As with the pilot study, the target subjects should be able to effectively communicate in English or Chinese.

As with the exclusion criteria of the preliminary wear trial, all subjects who had previously undergone a spinal operation, bracing treatment for AIS (except for the preliminary trial of the proposed brace), or have been subjected to trauma, or have a mental disorder or skin allergies, would not be eligible. Moreover, all of the participants, who demonstrate apparent discomfort with the wear experience, skin allergies, or even difficulties in breathing were not allowed to participate.

3.6.2 Radiographic examination

As stated in the preliminary wear trial, the corrective performance of the brace on the spine measured by using radiography is always taken into consideration for bracing effectiveness. Since the spinal curvature would no longer be affected after doffing the brace following the 2-hour intervention, x-rays were taken before treatment could still be used as the spinal image prior to treatment. In this study, all of the subjects underwent x-ray imaging both with and without the brace worn once every 3 months which means at their 3rd and 6th follow-up sessions. This would allow periodical monitoring during the anisotropic orthosis treatment.

To reduce the chances of spinal curvature progression, the most recent spinal situation of all of the subjects was monitored based on their radiographies and related measurements. If their measured Cobb's angle on the radiographic images had an increase of over 5 degrees compared to their own pre-treatment images, they might be asked to withdraw from the bracing treatment after a discussion with an experienced doctor so that there would not be any repercussions. The effectiveness of the designed brace was also assessed by measuring the Cobb's angle, CD, and pelvis and sagittal balance, as well as comparing the pre and post-treatment differences.

3.6.3 Interface pressure monitoring

The main difference between conventional rigid orthoses and textile-based braces is the material used. Generally, the rigid material of conventional braces means a tight fit around the wearer. The brace shape cannot be easily modified due to material fatigue. However, this problem could also be found in non-rigid braces. As almost all of the components used in the proposed anisotropic textile brace are made of elastic and stretchable materials, their properties may deteriorate after repeated usage, even if their recoverability is satisfactory. According to the literature review in Chapter 2, the tightness of a brace is deemed as one of the reasons that may result in failure of the bracing treatment.

For the proposed brace, spinal deterioration may be even found in wearers after a long period of use due to the gradual reduction in spinal control and corrective effect of the brace. To address this problem, interface pressure monitoring was conducted every month. The tension of the corrective bands was adjusted if needed. This would ensure that the pressure exerted onto each subject is similar to that provided during the 2-hour intervention.

3.6.4 Body contour improvement

As with the 30-minute wear trial prior to the 2-hour intervention, all of the participants were required to follow the specific instructions and stand as they normally do so during the 3D imaging process with 3D body scanner. To monitor the changes in the body contours of the recruited subjects, their body was scanned with and without the brace at every follow-up session.

For each scoliotic case, the 3D images collected at each follow-up were analyzed by measuring the shoulder obliquity, shoulder rotation, and POTSI values, which were then plotted to illustrate the changes at different time points.

3.6.5 Sitting posture correction

The AIS patients were found to have poor posture and tend to lean towards one side when they were sitting and standing. Back pain and fatigue might result after prolonged periods of sitting, or even breathing difficulties for some of the more severe scoliotic cases. Recent studies (Blomkvist, Olsson, & Eek, 2018; Plewka et al., 2013) have concluded that bracing treatment, particularly with the use of rigid orthoses, can enhance the posture of AIS patients during sitting, which is taken into consideration in this study.

To observing the differences in sitting posture, a Novel Pliance pressure sensing mat was utilized, which is a pressure mat designed for use during sitting (Figure 3.24). The mat has 256 sensors (16 x16) which can measure a pressure that ranges from 2 to 60 kPa with a maximum scanning rate of 78 Hz. Unlike 3D body scanning, the pressure mat is a means to collect the pressure distribution of the AIS patients in real time. As the height of the chair would likely affect the performance of the pressure distribution, all of the recruited subjects sat on the mat with knees at a 90 degree angle in the beginning to adjust the height of the chair. If they were sitting correctly, the pressure distribution of the left and right sides is similar and even. Gram and Hasan (1999) and Smidt et al. (1994) suggested that the start of the pressure distribution recording should be done after sitting for 10 minutes in order to obtain the habitual sitting posture rather than the studious posture (Figure 3.25), which was followed in this study. To evaluate the potential changes in the sitting posture of the subjects while wearing the brace, the pressure mat was used to identify the sitting posture of both the scoliotic and non-scoliotic subjects recruited from the school screening as a prior study. The pressure mapping had been divided into 4 main regions, which are left buttock, left thigh, right buttock, and right thigh (Figure 3.26). Based on the findings and assumption obtained in this prior study, it is also applied to examine the posture of AIS patients before and after undergoing the anisotropic textile brace treatment. This sitting posture trial was also carried out at every follow-up to periodically monitor their sitting posture. All of the recruited subjects of 3-6 month clinical trial participated without wearing the brace to compare and analyze the difference in performance between various time points.

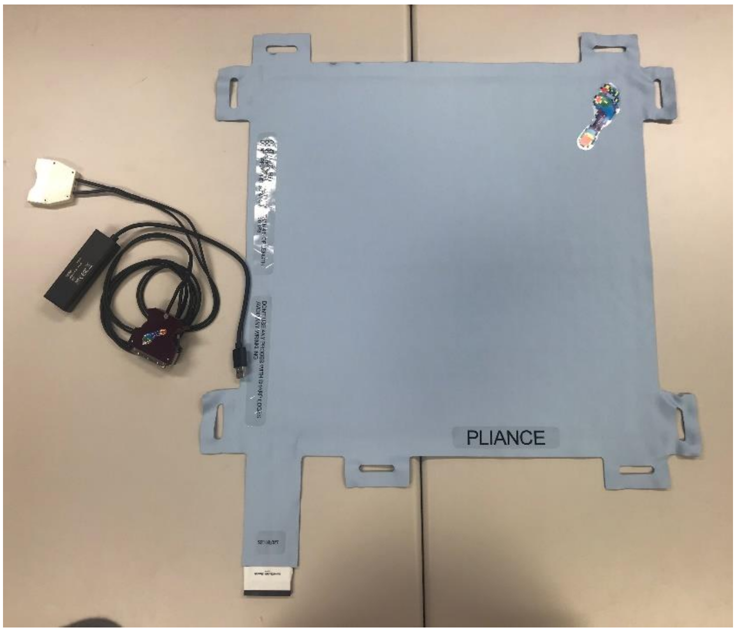


Figure 3.24 Novel Pliance pressure mat

Figure 3.25 Sitting on the pressure mat at a 90 degree angle

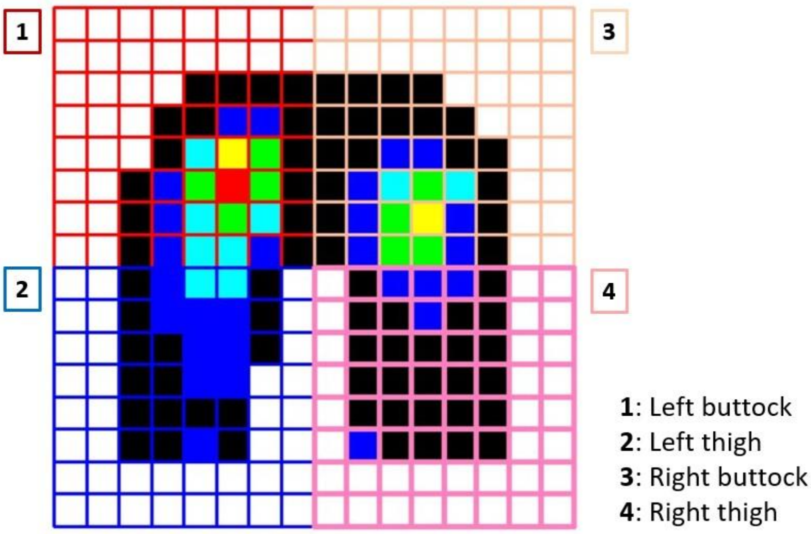


Figure 3.26 The 4 main regions of data analysis

3.6.6 Health-related quality-of-life (HRQoL)

To assess the bracing outcome, The Scoliosis Research Society (SRS) health related quality of life questionnaire was used, which was developed to evaluate the outcome of the health-related quality-of-life (HRQoL) of patients with a spinal deformity (Haher et al., 1999). The further modified version which reduced the determinants from 55-items to 22-items has been widely adopted (Ashe, Lai, Burton, & Manna, 2003; Cheung, Cheng, Chan, Yeung, & Luk, 2007). This is called the SRS-22 Health-related Quality-of-life Questionnaire (SRS-22). Even though some studies have pointed out another HRQoL questionnaire called the Short Form 36 Health Survey (SF-36) can be used for patients with scoliosis (Asher, Lai, & Burton, 2000; Ware Jr, 2000), nevertheless, Lai, Asher, and Burton (2006) stated that SF-36 cannot adequately capture some of the important aspects of teenagers such as self-image and confidence for self-management. In this study, the Chinese version of SRS-22, BrQ and TAPS are applied due to their user-friendly design, satisfactory internal consistency, reproducibility, and responsiveness to changes in QoL (Ashe et al., 2003; Vasiliadis, Grivas, & Gkoltsiou, 2006).

In the SRS-22 questionnaire, 20 of the questions are grouped into four domains, which are related to function, pain, self-perceived image, and mental health (Cheung et al., 2007). There are 2 additional questions that focus on the satisfaction with treatment but these are replaced by the satisfaction with preliminary 2-hour wear trial at the pre-treatment (before the 3-6 month clinical trial) so as to compare with functional intimate apparel in (Fok, 2020). Each domain includes five questions, except for satisfaction with treatment, which only has two questions. Each question carries 5 scores in total, from 1 (worst possible) to 5 (best possible). The higher scores represent a higher HRQoL in each area. As for satisfaction with treatment, the scores are calculated at the 3rd and 6th month follow-ups in this study with the aims to determine satisfaction with the bracing treatment.

For the BrQ and TAPS, they have been discussed in the preliminary wear trial. These three questionnaires were routinely allocated to all participants for HRQOL valuation of proposed brace before and after the bracing (0, 3rd and 6th month follow-ups), except for BrQ, which was only completed at the 3rd and 6th month follow-ups.

3.6.7 Compliance rate monitoring

As mentioned in Chapter 2, the efficacy of bracing is very much related to the compliance with the treatment. To objectively monitor the compliance rate, temperature loggers were equipped with the bracewear as done in Hasler, Wietlisbach, and Büchler (2010). In this study, all of the participants are required to wear the anisotropic textile brace for at least 8 hours each day as per Fok (2020). Thermochron™ iButton sensors were attached to the centre of the back of the proposed brace to record the wear time by collecting the temperature data. This 16 mm temperature data logger as shown in Figure 3.27 would not cause discomfort as it allows water vapor to pass through. Also, it is able to collect the data for the treatment period of 12 weeks which means that it can yield 8192 time stamp at 15 minute intervals. More evaluation would be needed if the treatment period is longer than 3 months in time. When the subjects patients came in for their monthly assessments, the related data were collected by using the Blue Dot™ receptor. After that, the loggers were reset and continued to monitor the users.

Hasler et al. (2010) pointed out that a body temperature of 30°C indicates that the brace is being worn. However, summer in Hong Kong is very hot and humid with occasional showers and typhoons, so that the temperature often exceeds 30°C during the day. The recorded temperature data might not be accurate to indicate that the brace is being worn. Therefore, the threshold of the temperature in this study is modified to around normal body temperature (36°C) instead after a discussion with experienced doctors and the P&O at The Duchess of Kent Children's Hospital at Sandy Bay.

Figure 3.27 (left) Blue Dot™ receptor and (right) Thermochron™ iButton sensors

3.6.8 Short interview

At the 3rd and 6th month follow-ups, a short interview was carried out again to collect feedback on wear experience and the limitations of the designed brace during the bracing treatment. The following questions were asked during the short interview.

1. Please share your feelings and wear experience during the bracing treatment.
2. Did your friends/classmates find out/could see that you were wearing a brace? If yes, did that upset you?
3. Did the anisotropic textile brace affect your daily life/ school life?
4. Have you any regrets in participating in the 3-6 month clinical trial?
5. Which part of the brace would you like us to modify for future studies?

3.6.9 Statistical analysis

As with preliminary 2-hour wear trial, the Statistical Package for Social Science Version 26 (SPSS; IBM, New York, United States) was applied, and the confidence interval was set at 95% ($p < 0.05$). A Wilcoxon signed-rank test was carried out to determine the differences in the spinal curvature, shoulder orientations, POTSI results and quality of life feedback after 3 and 6-month bracing treatment, as well as to compare these changes before and after the bracing treatment. As for Kendall's tau-b test, this is used to examine the correlations between various bracing outcomes.

Due to normal distribution, independent sample T-test and paired sample T-test were adopted to investigate if there are any significant differences shown in the demographics of recruited subjects between Scoliotic and Non-scoliotic groups, and the changes at different time points.

3.7 Chapter summary

After conducting a background information search on AIS and defining the problems of the current treatments for AIS, a research plan is provided in this chapter with a work flow based on a modified FEA model to design a medical textile or scoliosis brace by based on Fung et al. (2017). There are four main components in the research process, which are: 1) producing the design of the proposed anisotropic textile brace, 2) further developing the design of the proposed brace, 3) conducting a preliminary wear trial of the proposed brace, and 4) carrying out a 6 month clinical trial with follow ups after 3 and 6 months of wear with the proposed brace. All of the research methods applied have been discussed in detail.

To enhance the brace design for patients with AIS, the limitations of related treatments which are found from a background study and the previous clinical study done by Fok (2020) have been taken into the consideration. In the short clinical trial, the functional intimate apparel in Fok (2020) achieved a satisfactory in-brace correction but there is still room for improvement in terms of the brace design. Thus, the proposed brace is designed to address low patient compliance, the corrective mechanism, and bracing problems of the functional intimate apparel like fit, discomfort and durability.

After producing the brace design, the materials are sourced from the market and then been evaluated under a series of physical and mechanical testing, in order to find the most appropriate materials for the proposed brace. The brace is then fabricated with the selected materials and subjects don the brace for a preliminary evaluation of the fit. The brace design is then further adjusted.

After the brace design has been made into a prototype, a preliminary 2-hour wear trial and 3-6 month clinical trial are conducted. The former investigates the outcome of the anisotropic textile brace in terms of its in-brace correction, immediate changes to the body contours, and biomechanics, obtains the user comments, as well as the physiological and psychological assessment results of the wearers.

The 3-6 month clinical trial is carried out for subjects who have a reduction of 5 degrees or more of their Cobb's angle after the 2-hour intervention. All of the recruited subjects wore the anisotropic textile brace for at least 8 hours per day. A series of monitoring procedures are followed for each follow-up session, such as changes in body contours and sitting posture, duration of the wear time during bracing. At the 3rd and 6th month follow-ups, their initial degree of spinal curvature reduction, changes in physiological and psychological health and user feedback about the bracing treatment are also examined.

CHAPTER 4 – PRODUCING ANISOTROPIC TEXTILE BRACE DESIGN

4.1 Introduction

After reviewing the previous studies in the literature to obtain background information and current treatment options for AIS in Chapter 2, three problems are subsequently identified. They are: 1) low compliance rate of treatment with existing braces, 2) ambiguity in the effectiveness of non-rigid braces, and 3) few studies and little research effort on non-rigid braces for AIS. Recently, a functional intimate apparel in Fok (2020) has been developed to cope with these limitations. In their short clinical trial, a satisfactory in-brace correction has been achieved but there is still room for improvement. Therefore, this chapter discusses the designing of an anisotropic textile brace that not only uses the effective corrective mechanism of the functional intimate apparel in Fok (2020) but also overcomes its disadvantages, thus increasing compliance with the bracing treatment. The preliminary research ideas, design criteria, inspiration from the functional intimate apparel, preliminary review of the prototypes, and modifications to the design are discussed in this chapter.

4.2 Preliminary research ideas

The 2 main research ideas were obtained based on the problems identified after conducting the background study. The first research idea is to increase patient compliance with the bracing treatment. Given the fact that the rate of failure of bracing treatment is always affected by the wear compliance, in which poor compliance with the treatment is mainly attributed to physical and psychological problems with the brace, such as discomfort and negative emotions, there is the need to focus on increasing compliance by solving the problems related to bracing.

The second research idea is to control the progression of the spinal curvature by applying corrective forces. Despite that the rate of compliance is related to the bracing outcome, good wear compliance might not lead to a good outcome without the proper corrective mechanisms in place, such as those of the SpineCor brace (Wong et al., 2008). This is an important factor that deserves more attention.

4.3 Design criteria

In following the considerations of the modified FEA model, the design criteria are listed in Table 4.1. The functional, expressive, and aesthetic considerations are incorporated into the design.

Table 4.1 Design criteria of anisotropic textile brace

(to be continued in the next page)

Consideration	**Design criteria**	**Comment**
Functional	Spinal control and correction	Sufficient corrective forces provided by the brace can offer good in-brace correction of spinal curvature and minimize spinal deterioration due to progression of the spinal curvature.
	Fit	The form of the brace needs to accommodate the body contours well.
	Mobility	The wearer can move around freely on a daily basis without restrictions.
	Comfort	Soft and breathable materials are used to offer

		good wear comfort.
	Safety	The wearer would not be affected or injured even when sweating or rotating their body respectively.
	Durability	The performance of the selected materials and appearance of the brace can be maintained after even after a long period of bracing.
	Ease of donning and doffing	Wearers can don and doff the brace without help from others.
Expressive	Flexibility	The brace is not bulky.
	Light in weight	The brace should be lighter than conventional rigid braces.
Aesthetic	Slim profile	The brace design should be reduced in bulkiness and the brace can be worn underneath clothing.
	White/ light color	The brace is not visible underneath the school uniform.

4.3.1 Functional considerations

In terms of the functional aspects of the brace, successfully reducing the spinal curvature is always considered as the key means of determining whether an AIS treatment option has been effective. This should be a major consideration for all AIS treatments. The three-point pressure system is the main mechanism used in bracing to reduce spinal deformities nowadays which is assumed to be an effective way to control and reduce the lateral curvature. To exert external forces transversely at the apical curve and additional forces at the upper and lower parts of the major curve simultaneously, pads can be inserted in the bracewear, which has been done in most evidence-based hard orthoses like the Boston brace (Watts et al., 1977; Willers et al., 1993). To ensure that the corrective forces are adequately acting on the trunk of the AIS patient, semi-rigid or rigid brace materials may be more suitable to be used as the padding instead of softer materials. Moreover, elastic straps or bands may also help to derotate the trunk and reduce the spinal deformity through pulling and transverse forces, respectively.

Also, fit, mobility, comfort, safety, durability, as well as ease of donning and doffing are suggested for the referenced model as these are all secondary functional considerations of the design so that the brace can be worn as a normal garment. For instance, wearers can move in any way that they wish without restrictions, like bending forward with the brace worn, and putting on and taking off the brace by themselves. Using stretchable, soft and breathable materials in the proposed new brace might be the potential way to achieve these requirements, especially wear comfort. After all, physical and psychological problems are likely caused due to discomfort during bracing.

4.3.2 Expressive considerations

AIS patients often experience depression, lack confidence, and have low self-esteem and feelings of shame due to their asymmetrical trunk and misaligned posture from AIS. These psychological issues cannot be entirely addressed even if the patients are undergoing bracing treatment, especially wearing a hard orthosis with a bulky and awkward appearance. To address their negative emotions, the new brace design should focus on flexibility and is at least lighter in weight and less bulky than conventional bracewear.

4.3.3 Aesthetic considerations

Regardless of their physical health, adolescents desire cute, fashionable and stylish clothing (Stokes & Black, 2012). AIS patients are no different. Therefore, the color and profile of the proposed brace should consider the needs of the wearers who are youths between the ages of 10 and 13, even though the brace is just designed to be worn underneath clothing. To allow AIS patients to wear the new brace at school with more ease, a slim profile brace that is white or has a light color should be constructed which can prevent the brace from being visible underneath the school uniform (this study is tailored for AIS patients in Hong Kong and recognizes that while children in other parts of the world might not need to wear a uniform, a light or white color brace is still less visible under any type of clothing).

4.4 Inspiration from functional intimate apparel

Figure 4.1 shows the preliminary design of a brace that resembles a functional intimate apparel and applies the three-point pressure system in Fok (2020). This semi-rigid brace has two components: a bra top and pants. Basically, the entire functional intimate apparel is fabricated with elastic straps and velcro fasteners which can be adjusted based on the body profile of the wearer.

Figure 4.1 Preliminary design of semi-rigid brace with three-point pressure system (Fok, 2020)

To apply the three-point pressure system, a rigid back bone is constructed and fixed at the centre of the back of the brace . The back bone contains hinges with striped grooves to allow straps to pass through them and stabilize the corrective components on the surface of the body. As the design incorporates several plates connected by the hinges, the limitations of movement are reduced because wearers can bend forward. The design of the hinge for the artificial back bone is shown in Figure 4.2(a).

Furthermore, silicone pads were used with wide elastic bands to provide transverse and additional forces onto the trunk of wearers based on the principles of the three-point pressure system. To ensure that the pads can accommodate the contours of the wearer and exert a relatively sufficient degree of corrective force onto the trunk, they were made of semi-rigid silicone materials rather than rigid and soft materials. Such pads are designed to be inserted into the pocket of the elastic bands as shown in Figure 4.2(b).

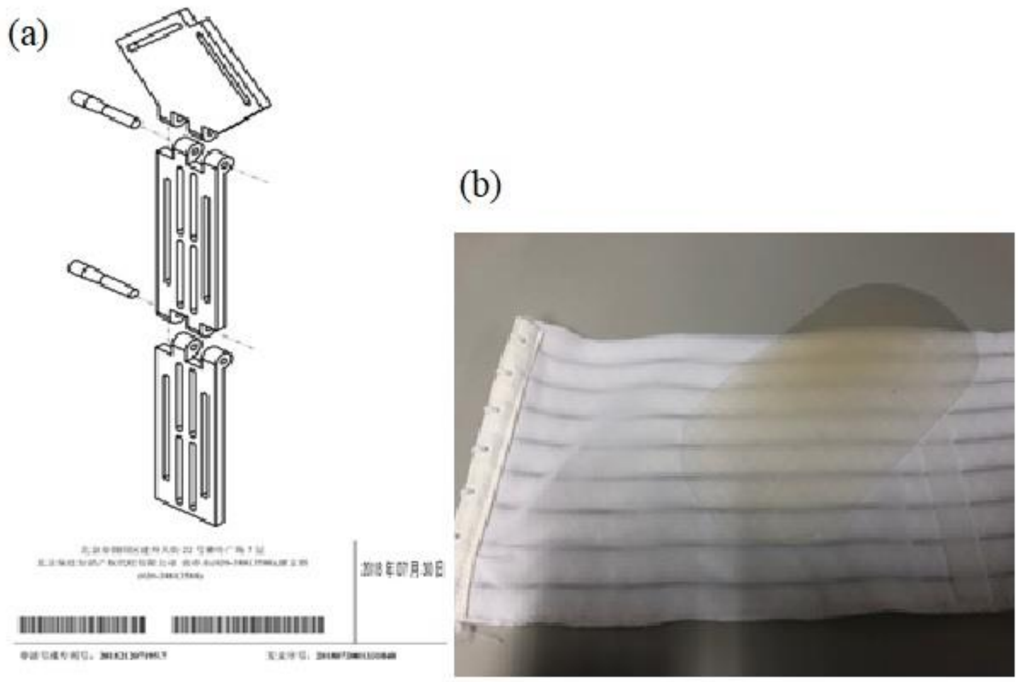


Figure 4.2 Corrective components of functional intimate apparel

(a) Hinges and components of artificial back bone (b) Silicone pad (Fok, 2020)

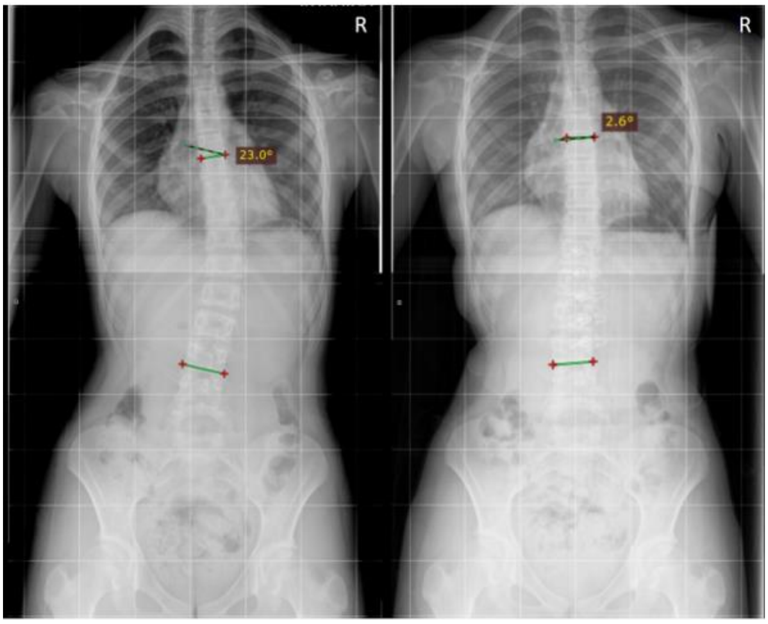
The brace design in Fok (2020) offers an average initial in-brace reduction of 26.4%, and a significant corrective effect (88.7%) was found in one of the cases in the study. According to a radiographic image, the thoracic curve is reduced from 23 degrees to 2.6 degrees after two-hours of bracing (Figure 4.3). This over 20 degrees of reduction in spinal curvature has proven the potential effectiveness of this brace design even if only a small number of subjects participated in the wear trial. Due to the potential success, the brace design, hinge design for the backbone and silicone pad in Fok (2020) are taken into consideration in this research study.

However, the brace in Fok (2020) still requires modifications, such as the fit, perceived comfort, and durability. The bra cup of the brace in Fok (2020) is designed in only one size, which means that different body sizes might be accommodated. The elastic straps are also directly in contact with the skin. Dimpling of the body components causes areas with fat to be more obvious which may affect the appearance of garments and the mental and emotional satisfaction of the wearers with their body, especially since they are youths.

The straps directly encircle the wearer in the brace design in Fok (2020). However, previous studies state that applying bands of elastic material on the body directly might cause skin irritation, pressure sores and pain (Wong et al., 2008). Similar issues were also found in the wear trial in Fok (2020). As shown in the user feedback collected from short interviews, the wearers pointed out that the straps and velcro came into contact with their skin and rubbed against their skin, which made them feel uncomfortable. To prevent the prickly hand feel of velcro and direct contact with the body, another type of velcro with a better hand feel or a layer of lining is considered in this study.

In order to provide wearers with greater perceived comfort, the hand feel of the materials used in the functional intimate apparel in Fok (2020) also needs to be improved, especially the hand feel of the corrective band. It was found that corrective bands used on the functional intimate apparel not only have a rough surface with poor hand feel but also lack the appropriate binding of its raw edges which caused a prickly sensation. The discomfort increased in severity after repeated stretching (Figure 4.4). Moreover, the wide elastic band used in the functional intimate apparel is strong but its recovery and durability are still questionable, and have not been evaluated in comparison to the other bands in Fok (2020). Related tests like stretch and recovery testing and repeated stretching testing thus need to be conducted in this study.

More importantly, Fok (2020) only focused on the corrective mechanism of the brace and modelling. A few AIS patients were invited to undergo 2-hour of bracing and only one of them took part in a 3-month bracing treatment. No systematic and consistent clinical trials were carried out for more than 2 hours, let alone several months. The rate of compliance of the functional intimate apparel in Fok (2020) and the corrective performance for the relatively long term could not be obtained in her study. Therefore, a new brace design can resolve these limitations and facilitate monitoring and a better wear experience for AIS patients.



a b

Figure 4.3 Radiographic image of subject

(a) Cobb's angle before intervention and (b) Cobb's angle after intervention

(Fok, 2020)

Figure 4.4 Appearance of corrective bands used in functional intimate apparel after repeated stretching

4.5 Preliminary brace design and review of prototypes

To address the current issues of braces and fulfil the design objectives that are inspired by the functional intimate apparel in Fok (2020), a few prototypes of the proposed anisotropic textile brace were designed. The back bone design in functional intimate apparel with hinges that allows wearers to bend forward and inhibits body rotation was taken into consideration. The hinge has four components: a V-leaf, hinge pin, middle leaf and end leaf. All of the leaves have two obround slots to secure the corrective components, and compensating and shoulder straps and allow them to be easily attached to the orthosis. They also facilitate adjustment of the placement of the corrective bands to provide lateral corrective forces onto the spine. Therefore, the concepts of hinges of the backbone of the brace, wide elastic bands and silicone pads in Fok (2020) were all applied to the proposed brace. That is, the corrective mechanism and components applied are all similar to those of the original functional intimate apparel.

4.5.1 First prototype

The first brace prototype consisted of two components: a bra top for the upper part of the body and short pants for the lower part of the body. The purpose of these two panels is the same as that of the functional intimate apparel. The bra top is cupless, which differs from the full-bra cup design of the functional intimate apparel in order to prevent problems with fit, such as wrinkles and loose bra cup, due to the different torso size of the wearers. Also, this design allows for the breast development of the female wearers without causing compression.

Apart from applying hook and eye openings on the bra top to accommodate the different body circumference proportions, a length of hooks and eyes was also attached to the front of the bra top with velcro, which replaces the velcro fastener in the functional intimate apparel. This makes it more convenient for wearers and practitioners to adjust the corrective bands for tightness. Wearers can therefore follow the instructions to attach the corrective bands with the silicone pad onto the specified length of hooks and eyes (Figure 4.5).

However, some problems emerged with the first prototype which was fabricated with stretchable knitted fabrics, including powernet and single jersey. As shown in Figure 4.6(a) and Figure 4.6(b), the length of the hooks and eyes does not sit on the center of the front of the bra top because that may affect the appearance of the brace so the length of the panel between the bra top opening and the hooks and eyes needs to be shortened. Furthermore, Figure 4.6(c) shows that the underbust of the bra top is too low and curved. Therefore, the bra top might not stay in place with daily movement and the thoracic corrective component which is intended to exert the corrective forces against the scoliotic spine may shift from the lateral of the body. To resolve the problem, the underbust was modified so that it does not cause such issues with fit.

Figure 4.5 Bra top of first prototype

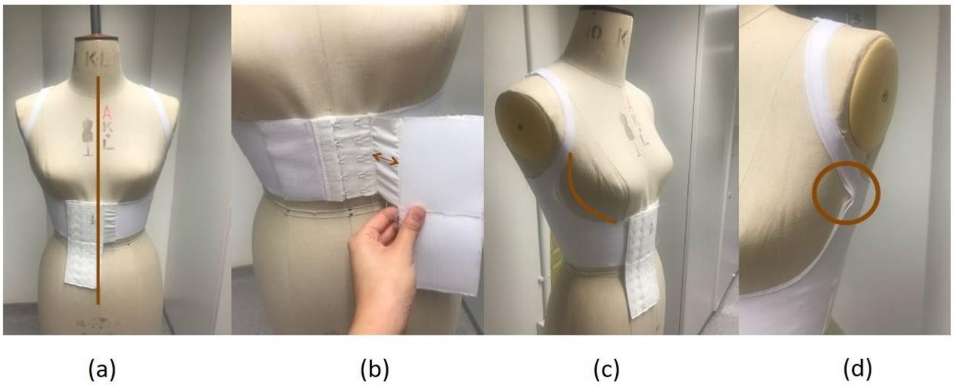


Figure 4.6 Adjustment of first prototype: (a) hooks and eyes are not centred at the front of the bra top, (b) length of the panel between the bra top opening is too long, (c) underbust is too low and curved and (d) extra fabric is placed at underbust

4.5.2 Second prototype

In consideration that the brace needs to be donned and doffed, the two separate components of the first prototype were eliminated to simplify the use of the brace. The second prototype is a one-piece garment (Figure 4.7), still cupless, and made of stretchable fabrics. The length of the hooks and eyes was extended to the bottom of the brace which corresponds to the lower abdomen, and adhered at the center of the front of the brace by using velcro. Unlike the functional intimate apparel in Fok (2020), wearers would need to put on their own bra top first before putting on the brace. Panties are not worn underneath the brace. Also, cushioning pads are placed at the back of the hinges in the functional intimate apparel to prevent discomfort or pain caused by the rubbing of the rigid components of the artificial back bone. The same concept is applied here, but with a knitted spacer fabric instead of cushioning pads.

By retaining the open crotch design of the functional intimate apparel (Fok, 2020), wearers will find it more convenient than the SpineCor brace which requires the brace to be taken off when the wearer uses the toilet. Due to the temporary lack of materials for the hinges, silicone was used instead for the back bone and constructed into a similar shape to demonstrate how the back bone would be placed on the brace. Although this simple silicone back bone is constructed without the hinges and therefore the actual back bone used in the functional intimate apparel design, it can still provide a visual means for further adjustment of the brace.

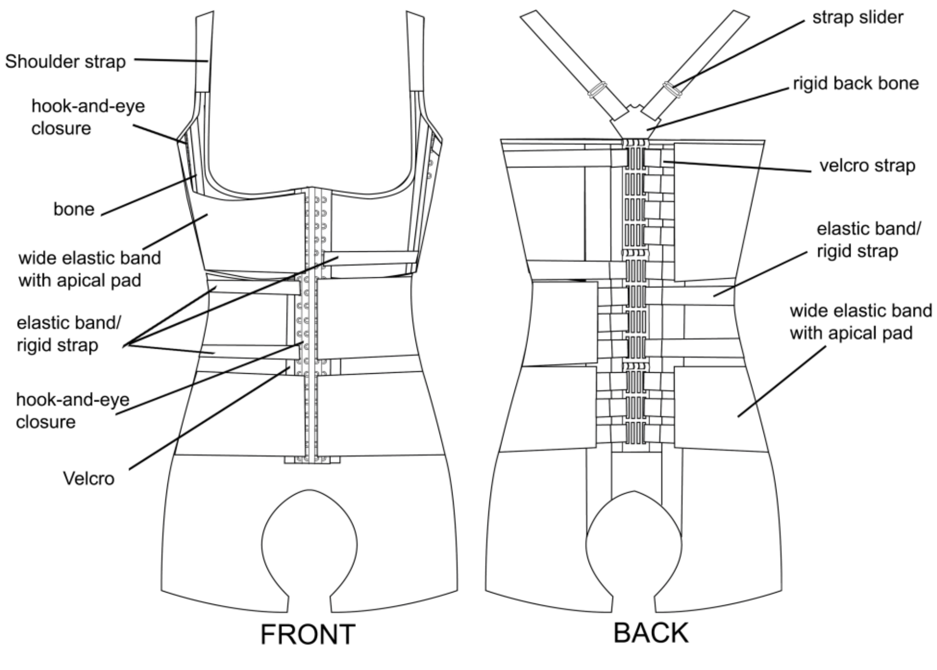


Figure 4.7 Design sketch of second prototype

A female youth who is not diagnosed with scoliosis participated in the wear trial for the second prototype. Her demographics are listed in Table 4.2. Figure 4.8 presents the front and back views of the second prototype on the subject. The appearance and fit was deemed to be satisfactory. Yet, when the subject sat down, she felt uncomfortable and the appearance of the brace substantially changed (Figure 4.9). The component near the abdomen bulged due to the length of hooks and eyes. To resolve this problem and reduce the thickness and rigidity of the panel itself, thinner and softer velcro was sourced as a replacement but without success. Thus, the amount of velcro used on the length of the hooks and eyes was reduced. After this was done, the same subject wore the brace again with the modifications made to the length of hooks and eyes (Figure 4.10). Nevertheless, the problem persisted and the idea of using a length of hooks and eyes was abandoned. Only a shorter length of hooks and eyes was attached to the upper part of brace which would stabilize the thoracic corrective straps.

Table 4.2 Demographics of subject with no scoliosis

Subject code	**Age**	**Height (cm)**	**Weight (kg)**	**BMI**	**Cobb's angle (degrees)**	**Size of proposed brace**
N001	24	158	49.5	19.8 (Normal)	N/A	M

FRONT BACK

Figure 4.8 Front and back views of second prototype

Figure 4.9 Problems with second prototype

Figure 4.10 Modifications to length of hooks and eyes

4.5.3 Different types of leg openings

The functional intimate apparel in Fok (2020) has no front opening. The short pants appears to be like a normal pair of short pants with an open crotch when the user needs to use the toilet. Otherwise, the user would have to take off the entire brace to do so. Even though no feedback was collected in Fok (2020) on the inconvenience of wearing the brace while using the toilet, an optimal wear experience is the focus in this study so this issue will be examined. In the event that users might experience difficulties with using the toilet due to the leg opening of the short pants, especially during their period, a front opening is designed so that they can tear away the leg opening easily if needed. Figure 4.11 shows three different types of front openings: no front opening, front opening using velcro, and front opening with plastic buttons. Other than the brace with no front opening, the other two braces allow wearers to tear away the leg opening if needed. As shown in the Figure 4.12, the version made of plastic buttons cannot hold the edges of the panels well during sitting in particular, thus causing puckering which affects the appearance of the brace. Even though these buttons can attach the fabric tightly and form an opening, it was not considered for the front opening. After comparing all of the different openings as shown in the Figure 4.11, the front opening that uses velcro was shortlisted due to its better appearance and ease of tearing away the leg opening.

(a) Without front leg opening (b) Front leg opening made by hook and loop fastener (c) Front leg opening made by plastic buttons

Figure 4.11 Three different front openings

Figure 4.12 Puckering caused by plastic buttons of front opening during sitting

4.6 Design refinement of anisotropic textile brace

4.6.1 Vest design with comfortable materials

After two prototypes of the anisotropic textile brace were fabricated, the brace design was modified so that the brace has a cupless top in a vest style which allows for the breast development of the female youths without causing compression, and is easier to fit on different patients. To reduce the physical and psychological problems and improve the wear compliance of wearers, lightweight and breathable fabrics are used for most of the components of this brace. Besides, the brace is designed to reduce heat stress and prevent direct contact between the elastic straps and skin which would be more comfortable for wearers with less likelihood of the development of pressure sores and pain.

4.6.2 Application of three-point pressure system

According to previous studies (Bulthuis et al., 2008; Wiley et al., 2000), the three-point pressure system can well reduce the spinal curvature, which in particular is exemplified in Fok (2020). Based on the assumption that brace design can offer an appropriate level of corrective forces on patients with AIS, the artificial hinge and apical pads developed in Fok (2020) are also used in this proposed anisotropic textile brace. Following Fok (2020), the pad is placed to counter the major curve of the spine, thus acting as a transverse force whereas two more compensating forces act above and below the major curve on the opposite side of the spine.

Also, brace designs that also use the three point pressure system, such as the Boston and TriaC braces, and functional intimate apparel in Fok (2020) always place fixed components around the body which form a frame to provide lateral forces onto the spine. The velcro and rigid back bone designed in Fok (2020) should therefore be attached at the centre of the front and back of the new brace respectively to ensure that the corrective forces are exerted onto the trunk. In order to prevent the hinges from shifting to one side with the corrective forces which may affect the appearance of the brace and even lead to pain during bracing, velcro is placed on the knitted spacer fabric to affix the hinges to the back of the wearer. This not only provides a fixed point at the center of the back of the wearers but also a cushioning effect to relieve pain caused by the rigid back bone during daily movement.

4.6.3 Convenience of donning and doffing brace

The proposed brace is a one-piece textile garment instead of two separate components of a bra top and pants (i.e., like the functional intimate apparel) which might be very convenient for wearers as they can easily don and doff the brace.

In addition, the open crotch design in Fok (2020) is retained as it is more convenient than the design of the SpineCor brace which requires users to remove the brace when they use the toilet. To further optimize the design, a front opening using velcro is used so that the wearer can use the toilet with ease. The velcro allows tearing away of the leg opening, which would increase the size of the crotch opening to provide even more convenience to the wearers when they have their period.

4.7 Technical sketches of final anisotropic textile brace

To summarize the final version of the different prototypes and incorporate the design changes, technical sketches of the final anisotropic textile brace are presented in Figure 4.13. In order to improve the flexibility and use of the corrective bands, a shorter length of hooks and eyes which was supposed to be attached to the upper part of brace is no longer used. Only corrective bands with hook and eye fasteners can be hooked on the length of hooks and eyes to create corrective forces to act on the thoracic curve of wearers. For human subjects with other types of spinal curvature like thoracolumbar and lumbar curves, these corrective panels cannot be used due to the velcro placed at the lower part of the brace which can only be gathered together with the velcro. With further considerations of the various body profile of wearers and the flexibility of the corrective components, velcro is chosen to be used for both the upper and bottom parts of the proposed brace instead. Besides, the discomfort of the user due to the dimpling at the underarm cannot be prevented if the corrective band exerts lateral force to the upper thoracic curve of the wearer. Unlike the functional intimate apparel, the underarm of the proposed brace which is cupless cannot withstand such forces. To do so, the optional front panel (of the chest area) needs to be attached depending on the type of spinal curvature and the needs of the wearer.

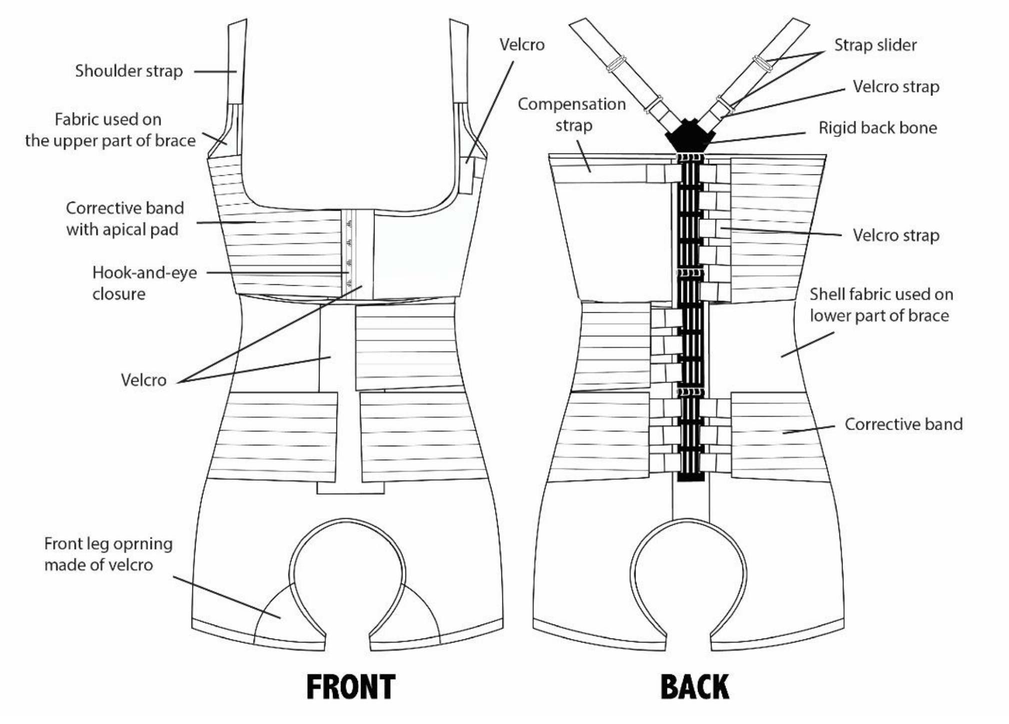


Figure 4.13 Technical sketches of final anisotropic textile brace

4.8 Chapter summary

A new anisotropic textile brace has been designed based on the actual needs of AIS patients and the design limitations of a previous brace by Fok (2020). The design criteria are listed and discussed in accordance with the guidelines developed by using a modified FEA model to design a medical textile or scoliosis brace. In this study, three prototypes are established. The final version of the proposed brace design is a one-piece garment with a hinged artificial backbone, corrective bands with pads, and pelvis belt which maintain the corrective performance of the functional intimate apparel while minimizing the negative impacts of current brace designs and bracing treatments.

CHAPTER 5 – DEVELOPING DESIGN OF ANISOTROPIC TEXTILE BRACE

5.1 Introduction

The design criteria and prototypes of the proposed anisotropic textile brace have been discussed in Chapter 3 along with the actual needs of AIS patients and the appearance of the brace. Using the preliminary brace design, various materials such as textile fabrics and silicone are sourced from the market and assessed in this chapter to select the most appropriate materials for fabricating the proposed brace.

The materials of the proposed anisotropic textile brace are subjected to further assessment and laboratory tests. Then, the artificial hinge bone and pad are further investigated. Last but not least, adjustment of fit is carried out based on the fitting problems and feedback from an AIS patient.

5.2 Material selection

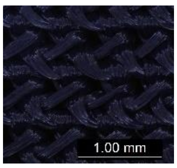
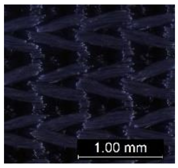
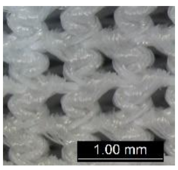
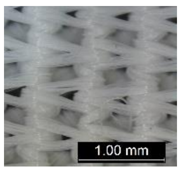
Fit, mobility, comfort, safety, durability, as well as ease of donning and doffing are all design criteria of the proposed anisotropic textile brace, especially its perceived comfort, fit and durability, which were issues in the functional intimate apparel in Fok (2020). The proposed brace is based on the functional intimate apparel.

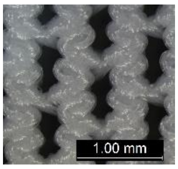
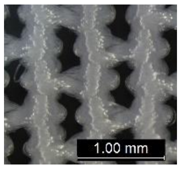
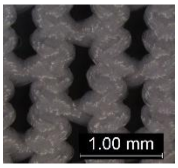
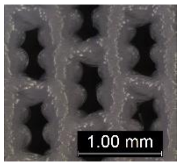
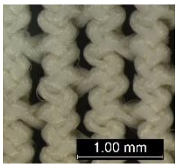
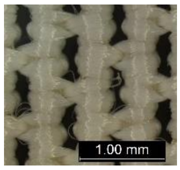
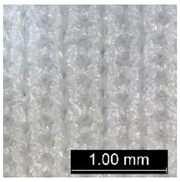
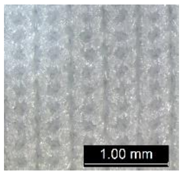
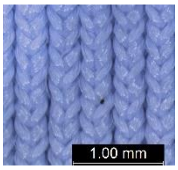
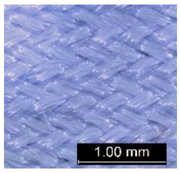
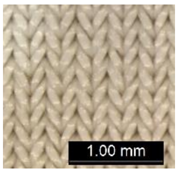
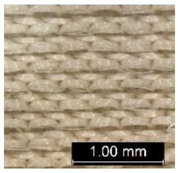
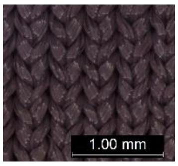
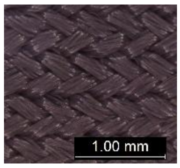
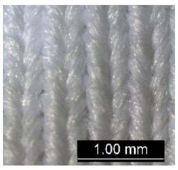
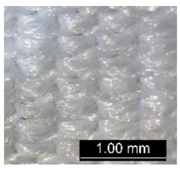
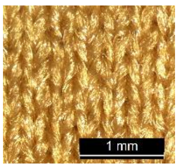
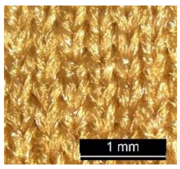
In order to provide wearers with enhanced wear comfort and a good fitting brace, lightweight and breathable materials with exceptional hand feel, but with good stretchability and recoverability should be used for the proposed brace. Knitted fabrics made of synthetic fibers are thus preferred. Synthetic fiber fabrics like nylon spandex tend to be light in weight, easy to care for and breathable, can easily dry, and have a good hand feel with excellent abrasion and pilling resistance. Knitted fabrics with a net structure, such as powernet and satinnet, are potential materials that have these properties because of their porosity.

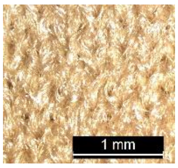
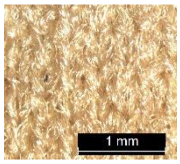
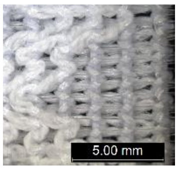
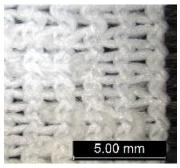
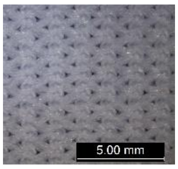
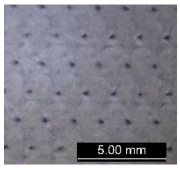
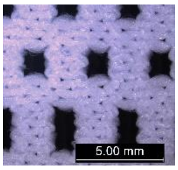
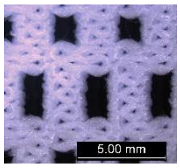
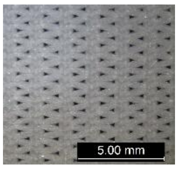
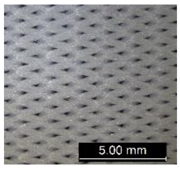
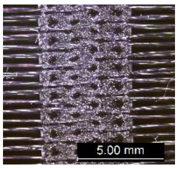
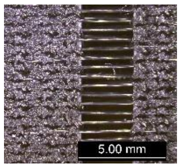
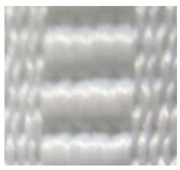
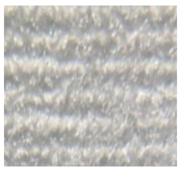
The functions of the different components of the proposed brace mean that their fabric properties cannot be the same. Basically, both the upper and lower parts of the brace have a similar role which is to form a frame to encircle the body and prevent direct contract of the skin with the elastic straps. However, fabrics with a net structure are porous so they cannot be used for the bottom part of the proposed anisotropic textile brace, as this might cause embarrassment of the wearers since the material could be see-through. Besides, other materials like the corrective bands and elastic straps are also sourced and evaluated to provide a more comprehensive understanding of their properties. In the end, 12 types of fabrics, 5 types of elastic bands, 3 types of elastic straps, and 2 types of velcro are sourced from the market. Table 5.1 shows the specifications and microscopic views of the sourced fabrics.

Table 5.1 Specifications of selected materials

(to be continued in the next page)

Material Sample	**Structure/ Type**	**Composition**	**Weight (g/m^2)**	**Thickness (mm)**	**Microscopic View**	
					Front view	**Back view**
U1	Satinnet	77% Polyamide 23% Spandex	2.385	0.562		
U2	Satinnet	80% Polyamide 20% Spandex	2.252	0.612		

U3	Satinnet	77% Polyamide 23% Spandex	1.691	0.444		
U4	Powernet	83% Polyamide 17% Spandex	1.887	0.492		
U5	Powernet	59% Polyamide 41% Spandex	1.992	0.434		
L1	Simplex	25% Spandex 75% Micro Nylon	3.122	0.568		
L2	Tricot	76% Polyamide 24% Elastane	1.721	0.493		
L3	Single jersey	86% Polyamide 14% Elastane	1.767	0.402		
L4	Tricot	80% Polyamide (AQUA-X) 20% Elastane	2.181	0.548		
L5	Single jersey	70% Polyamide 30% Elastane	2.425	0.556		
L6	Simplex	53% Xtra Life Lycra 47% Nylon	3.308	0.123		

L7	Simplex	36% Spandex 64% Nylon	2.390	0.120		
E1	Wide elastic	N/A	5.444	1.650		
E2	Wide elastic	N/A	5.717	1.433		
E3	Wide elastic	N/A	3.599	1.117		
E4	Wide elastic	N/A	5.857	1.096		
E5	Wide elastic	N/A	4.503	1.380		
V1	Velcro	N/A	7.658	2.367		N/A
V2	Velcro	N/A	5.610	1.314		N/A
S1	Elastic strap	85% Nylon 15% Spandex	7.548	1.960		

S2	Elastic strap	86% Nylon 14% Spandex	7.106	1.990		
S3	Elastic strap	84.5% Nylon 14.5% Spandex	4.170	1.490		

5.3 Results of material testing

As mentioned in Section 3.4.2 of Chapter 3, a series of tests were done to evaluate the performance of the selected materials in terms of their comfort, fit, mechanics, and durability. The results are presented in this section.

5.3.1 Thermal conductivity test

The extent that a fabric offers wear comfort is partially through its ability to conduct heat. A fabric with a higher thermal conductivity value shows its ability to transfer heat from the human body to the surface of the fabric (Yip, Chan, Sin, & Lau, 2002). In the thermal conductivity test, the ability of the 12 sourced fabrics and 5 sourced elastic bands to conduct heat were examined and the results are plotted in Figure 5.1. It can be observed that all of these fabric samples have similar properties in heat transfer except for L6 which is simplex. Even though simplex has the same fabric structure as L1 and L7, its performance lags behind the other two types of fabric which might be due to its different thickness, density, and yarn conductivity. Besides, U1, U2, L1, L4, L5 and L7 all have a relatively higher thermal conductivity value. This could be due to their simplex structure and lower stitch density, especially the two samples with a net structure, U1 and U2.

This could also explain why the wide elastic bands, E2, E4 and E5, have better thermal conductivity among the 5 elastic samples. However, it is surprising that E2 which is a relatively thicker and heavier elastic material with filaments has a more outstanding performance compared to the other elastics that have a thinner and similar structure like E1 and E5.

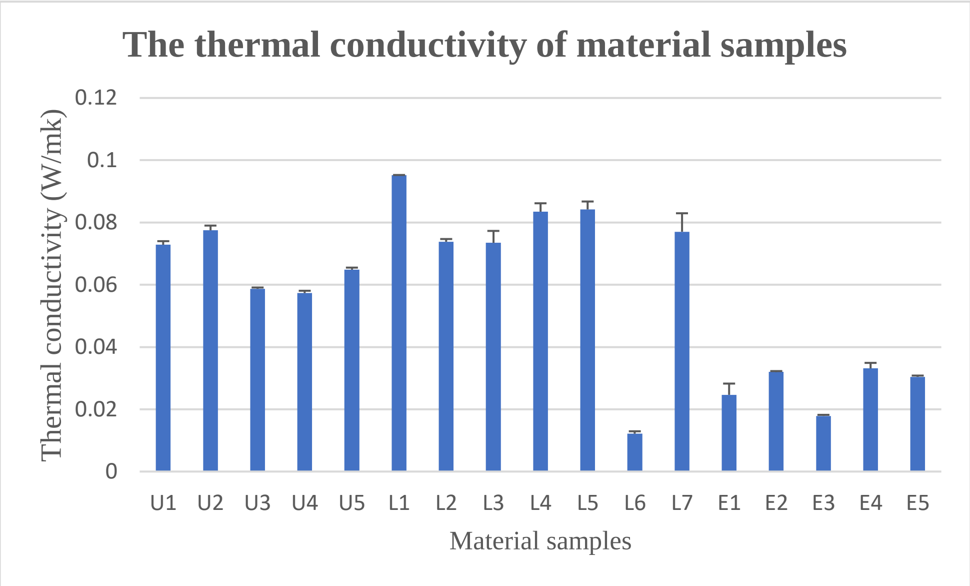


Figure 5.1 Thermal conductivity results of material samples

5.3.2 Air permeability test

The air permeability test is used to determine the breathability of the fabric samples, or their air resistance. A higher air resistance value means that it is more difficult for air to pass through the fabric otherwise known as poor air permeability. The air permeability of each fabric can be different, depending on the fiber fineness, fiber shape, fabric cross-section and structure, and surface characteristics, thickness and density of the fabric (Mukhopadhyay, Ishtiaque, & Uttam, 2011; Yip & Ng, 2008).

The test results are shown in Figure 5.2 and U3 has the lowest air resistance which means that it is the most breathable fabric among the 12 types of sourced fabrics. The fabrics sourced for the upper part of the brace, that is, the powernet fabrics (U3, U4, U5), are also relatively more air permeable than the satinnet fabrics (U1 and U2). This might be due to the fabric structure of the warp knitted powernet fabric which has high porosity and conducive to air flow. Moreover, the results of L1 to L7 show a positive correlation to their weight. For the elastic bands, almost all of them are air permeable, except for E4. E4 is more air resistant because it does not have any meshes or filaments.

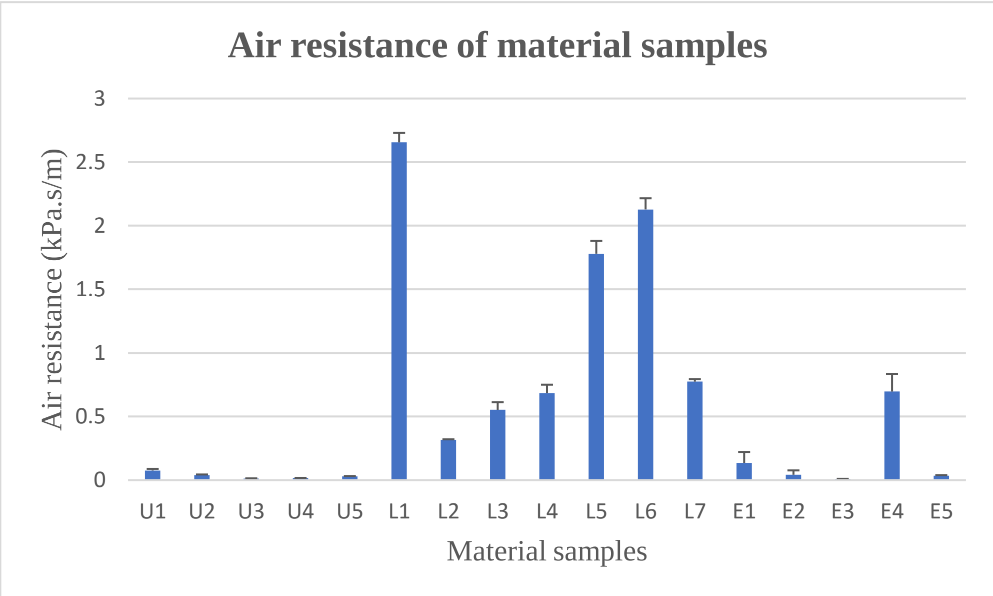


Figure 5.2 Air permeability of material samples

5.3.3 Water vapor permeability test

The water vapor permeability test focuses on the water vapor transmission (WVT) of the fabric samples, which is related to transfer of moisture (or sweat). Wear comfort can be greatly increased if the fabric readily transfers moisture and wick sweat away. The rate that water vapor can penetrate the fabric from the body to the surrounding environment was evaluated. A higher WVT rate shows that the fabric can well transfer moisture away from the body. Figure 5.3 shows that a satinnet fabric, U3, has the highest WVT rate, followed by two powernet fabrics, U4 and U5. A comparison of the other samples show that the powernet fabrics U3, U4 and U5 show a higher rate of WVT than the simplex fabrics L1, L6 and L7. This might be because their fabric structure is different, for instance, they are a thinner fabric with a low yarn density. Aside from the sourced fabrics, it can be observed that the elastic bands with filaments (E1, E2 and E5) have a relatively better ability to wick away sweat or moisture from the body than the other elastic structures like mesh (E3) and that without any meshes or filaments (E4).

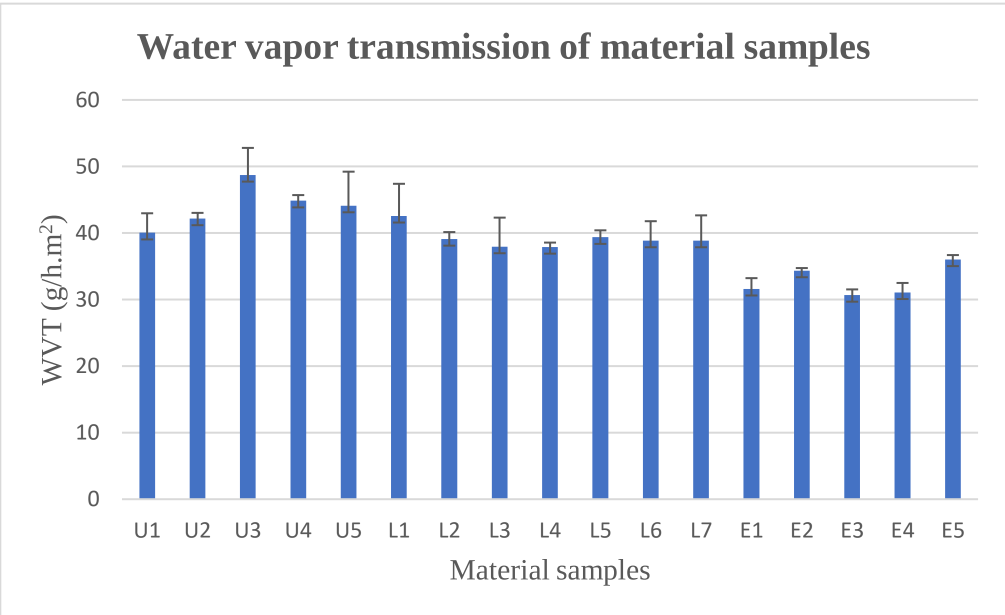


Figure 5.3 Water vapor transmission rate of material samples

5.3.4 Hand feel test

To provide wearers with a comfortable brace that has a good hand feel, the surface properties of the fabric and velcro were assessed through a hand feel test. The mean friction coefficient (MIU), the fluctuation of mean frictional coefficient (MMD) and surface roughness (SMD) of the fabrics were obtained and presented in Table 5.2 and Figure 5.4. The tested materials are considered to be comfortable to wear and smooth if they have a lower MIU, MMD and SMD value, and vice versa.

U2 and L4 have relatively lower MIU, MMD and SMD values which mean that they are the most smooth and slippery feeling among all of the fabric samples sourced for the proposed brace. If only the SMD value is taken into consideration, as shown in Figure 5.4, the SMD of all of the sourced fabrics for the lower part of the brace (L1 to L7) is outstanding. This might be because these fabrics are knitted without a net or mesh structure like satinnet and powernet which reduces the unevenness of the fabric surface. Moreover, the hand feel of the elastics, that is, E1 and E5, has a relatively more rough feeling compared to the other elastic samples as there are embroidered elements on their surface. This also holds true for the velcro samples. The hook and loop of V1 is more rough than that of V2 and thus V1 has a higher surface roughness.

Table 5.2 Hand feel of material samples

(to be continued in the next page)

Material sample	**Mean friction coefficient (MIU)**				**Fluctuation of mean frictional coefficient (MMD)**				**Surface Roughness (SMD)**			
	Warp		Weft		Warp		Weft		Warp		Weft	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
U1	0.15	0.01	0.13	0.00	0.01	0.00	0.01	0.00	5.08	0.22	8.67	0.47
U2	0.13	0.00	0.11	0.00	0.01	0.00	0.02	0.01	7.01	0.50	6.27	0.21
U3	0.15	0.00	0.12	0.00	0.00	0.00	0.01	0.00	1.20	0.11	19.87	0.05
U4	0.15	0.00	0.13	0.00	0.01	0.00	0.01	0.00	1.21	0.06	18.88	0.12
U5	0.20	0.01	0.17	0.00	0.00	0.00	0.02	0.00	0.94	0.07	18.46	0.38
L1	0.16	0.00	0.18	0.01	0.00	0.00	0.00	0.00	0.52	0.03	1.13	0.12
L2	0.13	0.00	0.16	0.00	0.00	0.00	0.01	0.00	0.76	0.01	1.29	0.06

L3	0.15	0.00	0.18	0.00	0.00	0.00	0.01	0.00	0.87	0.08	0.54	0.01
L4	0.11	0.00	0.13	0.00	0.00	0.00	0.01	0.00	0.87	0.11	0.96	0.09
L5	0.16	0.00	0.18	0.00	0.00	0.00	0.06	0.01	0.71	0.01	1.95	0.15
L6	0.23	0.00	0.41	0.00	0.00	0.00	0.01	0.00	0.94	0.81	1.35	0.03
L7	0.36	0.00	0.41	0.00	0.01	0.00	0.01	0.00	0.15	0.06	0.98	0.11
E1	0.19	0.01	0.23	0.01	0.04	0.01	0.33	0.01	11.61	0.00	8.00	0.00
E2	0.21	0.04	0.15	0.01	0.02	0.00	0.02	0.00	8.28	0.96	7.39	0.10
E3	0.28	0.01	0.18	0.00	0.03	0.00	0.01	0.00	8.19	0.38	9.17	0.70
E4	0.15	0.00	0.15	0.01	0.02	0.00	0.02	0.00	5.98	0.70	9.34	0.95
E5	0.27	0.01	0.28	0.02	0.04	0.00	0.05	0.01	10.25	2.72	5.81	2.24
V1	0.33	0.15	-	-	0.31	0.70	-	-	13.13	4.42	-	-
V2	0.41	0.42	-	-	0.02	0.01	-	-	10.20	6.61	-	-

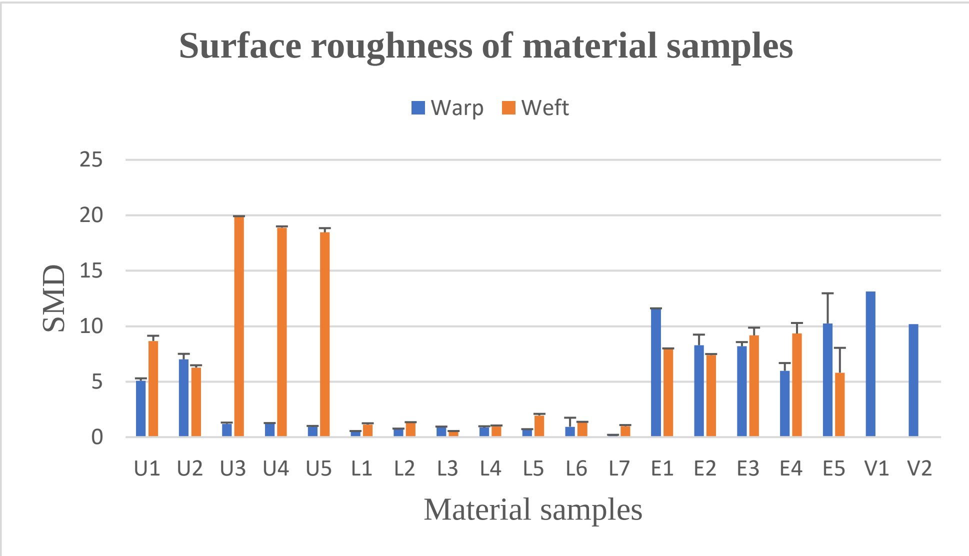


Figure 5.4 Surface roughness of material samples

5.3.5 Elasticity and recovery tests

The proposed anisotropic brace is designed for AIS patients to wear for a few months if its effectiveness can be proven in a preliminary wear trial. However, the elasticity of the brace might be reduced after a period of use, which may change the fabric dimensions and affect its efficacy. To withstand repeated usage, materials with good elongation and recovery should be used for the brace. Table 5.3, Figure 5.5 and Figure 5.6 present the results of the elasticity and recovery tests.

Table 5.3 Elasticity and recovery test results

(to be continued in the next page)

Material sample	**Wale**			**Course**		
	Extension (avg.)	Growth (avg.)	Recovery (avg.)	Extension (avg.)	Growth (avg.)	Recovery (avg.)
U1	110.7%	4.1%	96.3%	40.9%	3.1%	92.8%
U2	134.9%	2.2%	98.4%	28.9%	3.1%	89.2%
U3	127.9%	5.6%	95.6%	82.0%	3.8%	95.4%
U4	111.1%	5.0%	95.5%	75.1%	6.4%	91.5%
U5	81.3%	2.8%	96.5%	89.8%	-0.3%	-
L1	71.1%	4.5%	99.0%	62.4%	5.7%	98.2%
L2	172.1%	18.4%	88.4%	96.9%	5.0%	97.6%
L3	182.6%	8.8%	95.0%	140.5%	11.0%	94.2%
L4	122.0%	12.7%	96.5%	83.2%	5.6%	99.4%
L5	186.3%	5.6%	92%	172.7%	9.5%	94.5%
L6	64.3%	2.5%	96.1%	64.2%	5.0%	92.2%
L7	145.3%	13.4%	97.8%	107.4%	5.0%	95.2%
E1	48.3%	3.2%	93.3%	-	-	-
E2	57.5%	1.6%	97.2%	-	-	-

E3	75.2%	3.8%	94.9%	-	-	-
E4	70.8%	3.3%	95.4%	-	-	-
E5	55.1%	3.9%	93.0%	-	-	-

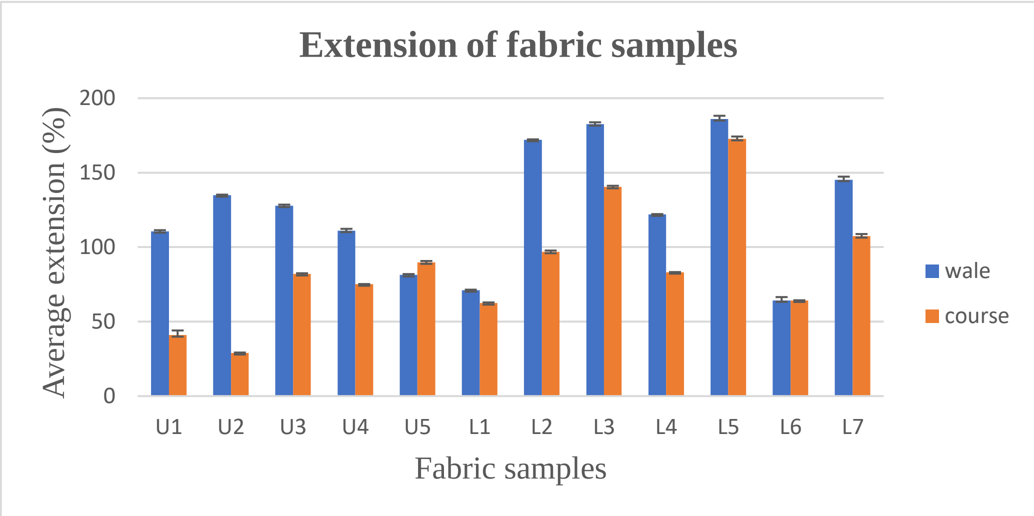


Figure 5.5 Extension of fabric samples

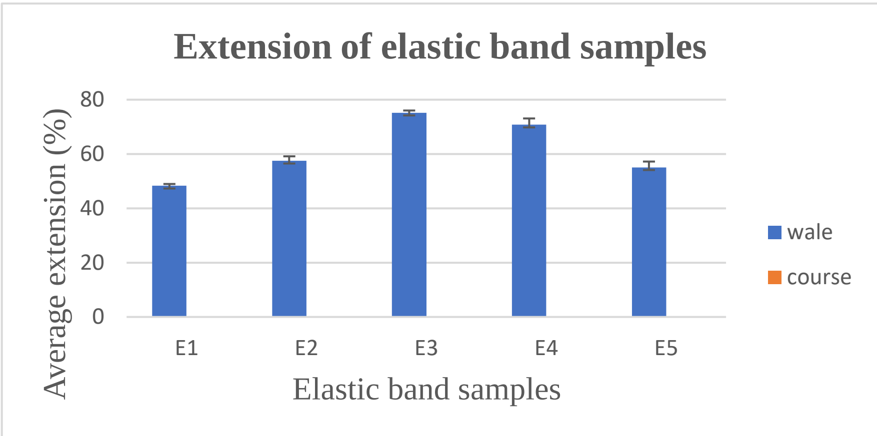


Figure 5.6 Extension of elastic band samples

The results show that for the materials considered for the upper part of the brace, U2 and U3 have a relatively higher rate of extension whereas U5 has the lowest rate of extension. As for the lower part of the brace, L1 and L6 also show a relatively low rate of extension, which might be due to their fabric structure and composition. As the final brace design is a one-piece garment, adequate extension of both the upper and lower parts is necessary so that the user can easily don and doff the brace. Therefore, L1 and L6 were not shortlisted for the final version of the brace design.

With regard to the fabric elongation after loading, U2 shows good dimensional stability, with only 2.2% of fabric growth. On the other hand, U5 shows a negative fabric growth in the course direction, which means that this sample tends to shrink after loading. Therefore, U5 cannot be used for the textile brace which is a stretchable and tightly fitting garment. The fabric growth of the other samples ranges from 2.5% to 18.4%.

As for recovery, almost all of the samples show a rate of recovery that exceeds 90%. L1 has the highest rate of recovery after loading (99.0%). All of the samples generally perform well in this aspect and therefore fabric deformation and fatigue can be avoided.

Besides, the recovery test results of all 5 elastic band samples indicate that E3 has the highest elasticity (75.2%) whereas the elastic used in the functional intimate apparel (E1) has the lowest elasticity (48.3%). Since the corrective effect for spinal curvature relies on the amount of corrective forces that are exerted by wide elastic bands, it does not mean that those with the highest elasticity could exert the highest external forces onto the trunk. To determine the most suitable material, E1 is used as the standard due to its satisfactory spinal corrective results in Fok (2020).

5.3.6 Elasticity and recovery tests (for elastic straps)

Apart from fit and durability, the ability of elastic materials to stretch and recover is also a factor that affects the biomechanics of an orthosis (Xiong & Tao, 2018). In this study, the elasticity and recovery of the elastic materials influence the corrective effect of the brace. Therefore, elasticity and recovery test is not only carried out for the fabrics used for the main components of the brace but also all other types of accessories like the elastic straps. The requirements for selecting the appropriate materials are the same as those in Fok (2020). The material has to be high in modulus, low in force decay with time and exercise, as well as offer exceptional recoverability. Among the three different types of elastic straps, Figure 5.7 shows that E2 has a relatively lower force decay due to both time and movement. Fok (2020) also found that a higher modulus material usually has a higher force decay and unrecoverable elongation. Although E1 shows a relatively higher force decay, it has exceptional recoverability.

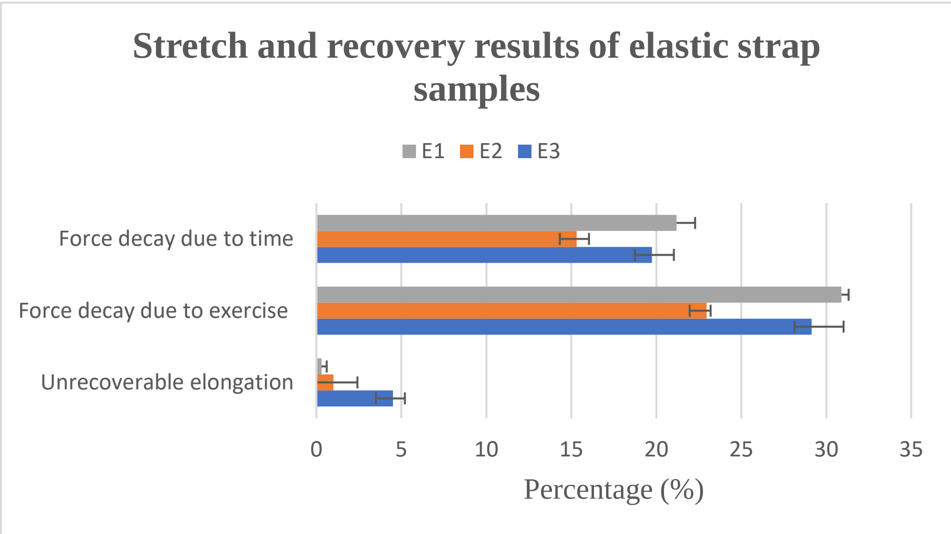


Figure 5.7 Stretch and recovery test results of elastic strap samples

5.3.7 *Peel strength test*

The primary component used to attach the corrective elastic bands onto the proposed anisotropic textile brace is a velcro. However, less effective spinal corrective forces and inconvenience may result if the velcro peels off easily during use of the brace. To prevent the velcro from peeling off accidentally or unintentionally, its peel strength is essential. Table 5.4 shows that V2 has an obvious higher peel strength than V1 when subjected to the same amount of loading which means the hook side of V2 can adhere more stably onto the loop side and bear higher forces during bracing. On the other hand, V1 requires a larger force or load to engage the hook and loop together and therefore may peel apart more easily.

Table 5.4 Peel strength test results

Possible direction contingent for closure	Mean value of five highest peaks (lb)		S.D.	
	V1	V2	V1	V2
1	0.065	8.490	0.003	0.478
2	0.060	17.424	0.007	0.591
3	0.068	10.184	0.004	0.470
4	0.069	15.425	0.005	0.991
Average Load (lb)	**V1**		**V2**	
	0.085		**17.708**	

5.3.8 Pilling resistance test

In order to assess the performance of the fabrics used for the shell or outer part of the brace in terms of pilling and fuzzing resistance, a 5-scale rating from 1 to 5 was used to rate the face of each specimen in comparison to the photographic standards by observing its appearance after repeated friction with the hook and loop fastener. A higher rating represents better pilling and fuzzing resistance, and vice versa. In this study, the results of each sourced material are presented in Figure 5.8 and Figure 5.9. Figure 5.8 shows that the powernet fabrics or U3 and U5 have excellent resistance to pilling followed by the simplex fabrics or L1, L6 and L7. This is probably because their fiber mobility is relatively lower which inhibits the formation of balls of tangled fibers.

Almost all of the samples have moderate resistance to fuzzing and score less than 4.

For instance, the simplex knit fabric is made of fine yarn and relatively dense and thick. As such, it may resist pilling, but its fibers may still be broken by repeated friction of the hook side of the velcro.

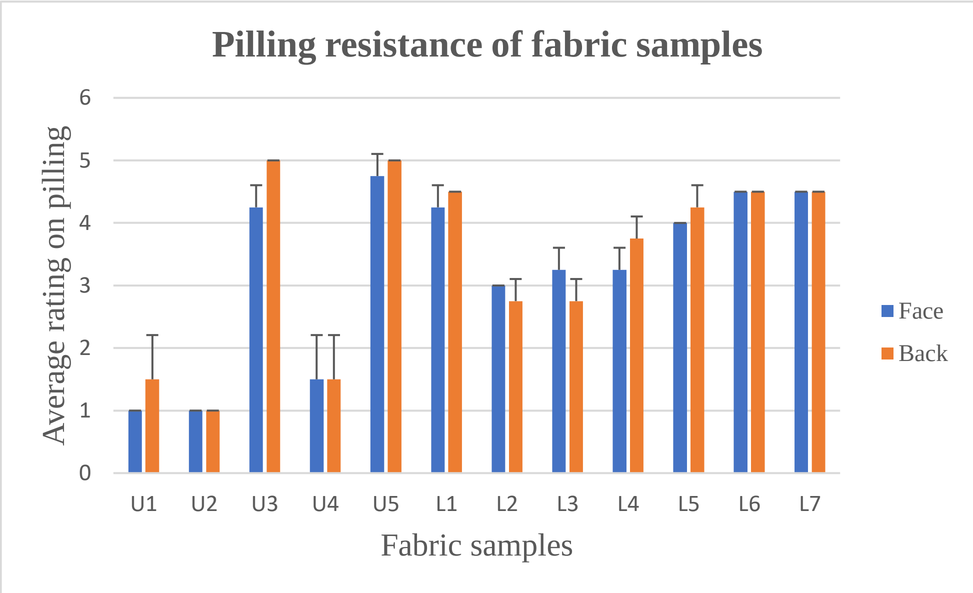


Figure 5.8 Pilling resistance of fabric samples

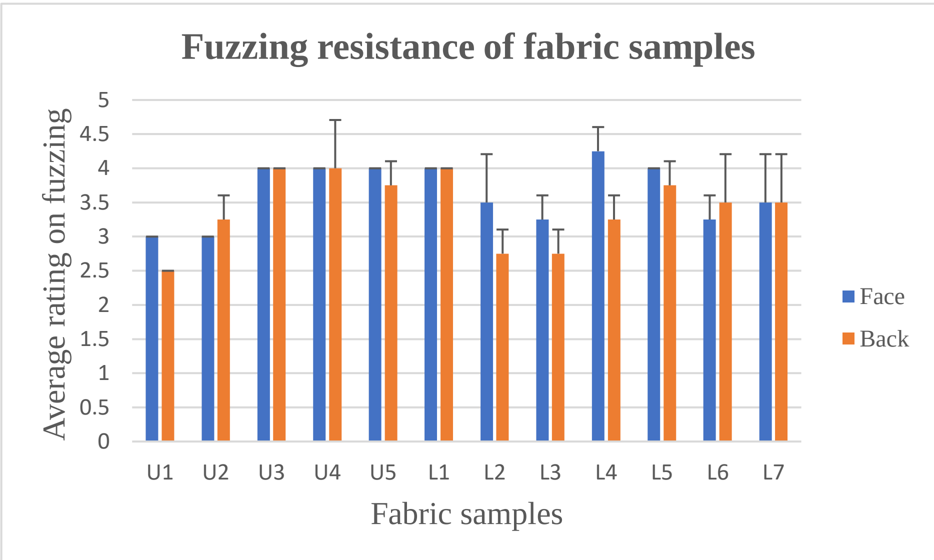


Figure 5.9 Fuzzing resistance of fabric samples

5.3.9 *Dimensional changes of fabrics after home laundering test*

To ensure the dimensional stability of the proposed anisotropic textile brace even after laundering, the tendency of all the sourced materials to shrink was tested. The acceptable dimensional change of elastic fabric when subjected to laundering should be within 5% in accordance to ASTM D7019-14 Standard Performance Specification for Brassiere, Slip, Lingerie and Underwear Fabrics. Even if none of the samples fail in this test (see Figure 5.10), shrinkage could be identified in most of the wide elastic bands (E1 to E5) except for E2. The shell fabric and corrective band used in the functional intimate apparel in Fok (2020) or L1 and E1 respectively have a relatively higher rate of dimensional change compared to the other materials. As such, other types of materials should be considered.

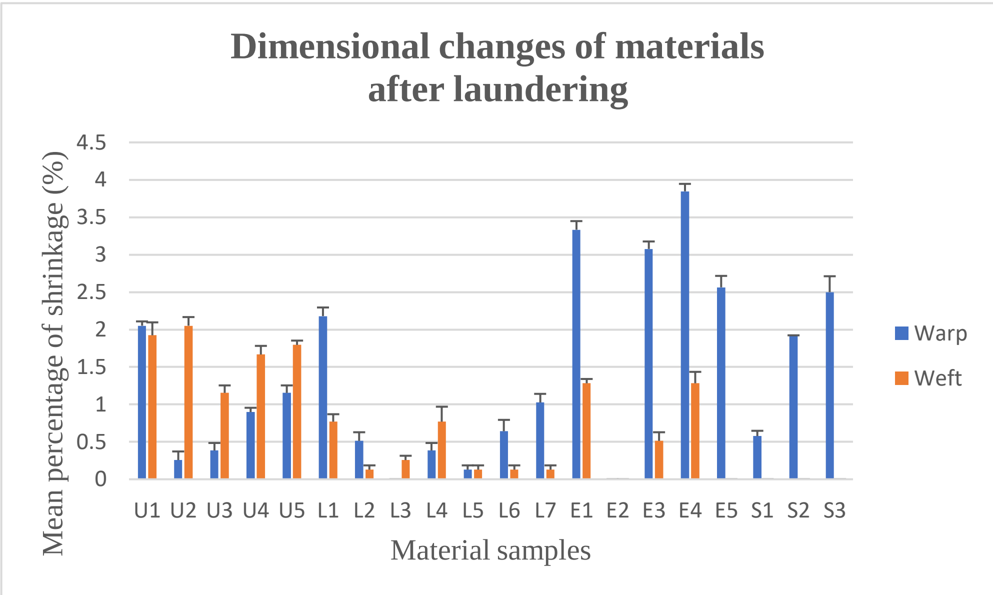


Figure 5.10 Dimensional changes of materials after laundering

5.3.10 *Repeated stretching test*

To determine the robustness of the elastic materials after repeated episodes of stretching, which is important for the brace, Figure 5.11 shows the force applied to each elastic sample during repeated stretching. E3 requires the least amount of force to stretch whereas E4 requires a large amount of force. In general, the force that is used to stretch the elastic band samples should be gradually reduced due to elastic fatigue. However, elastic rigidness is found during the testing, which means more force is needed after several rounds of stretching because the elastic increases in rigidity. This is not an ideal situation because the materials become stiffer and not easier to be deformed that may not be able to be stretched and act a corrective force on body contours. E3 becomes rigid after being stretched 100 times, followed by E1 which becomes rigid after being stretched around 200 times. E2 has the best performance since it becomes rigid after being stretched 400 times.

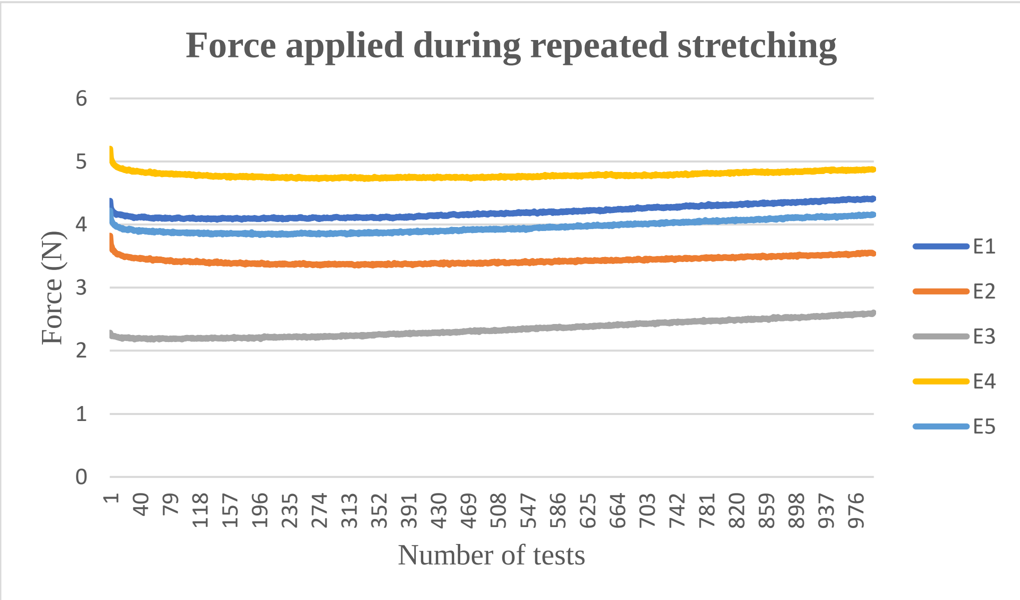


Figure 5.11 Repeated stretching test results

5.4 Overall review of material testing

5.4.1 Fabric for upper part of the brace

Fit, comfort, and durability are all taken into consideration for the material used for the upper part of the brace, especially its performance in terms of elasticity and recovery, wear-comfort, pilling resistance, and dimensional stability. Table 5.3 shows that U5 shrinks after stretching so it is not ideal for the proposed anisotropic textile brace. However, U2 and U3 have exceptional fabric recovery and good fabric extension so they are good material candidates for the brace.

As for the wear-comfort, Figure 5.1 to Figure 5.3 show that both U2 and U3 have good ability to transfer heat, air, sweat and moisture from the skin to the fabric surface. Even though U3 has a relatively poor hand feel in the weft direction in comparison to U2, it is selected as the shell fabric for the upper part of the brace due to its satisfactory performance in other aspects, including transfer of moisture and sweat, fabric extension and recovery and so forth. Meanwhile, U2 is chosen as the lining fabric to remedy the surface roughness of U3.

The decision to select these fabrics is not only due to their performance in terms of fit and wear-comfort but also their durability. Figure 5.8 shows that all of the powernet fabrics, including U3, show outstanding pilling resistance against the velcro. U3 is therefore an excellent material to use as the shell fabric because the velcro is used for attaching elements, such as the corrective panel and comes into contact with the shell fabric often. Therefore, the ability of the shell fabric to resist pilling and fuzzing is important in this brace design. Although U2 pills easily, it is used as a lining fabric so there is relatively little contact with the velcro and not important even if it does come into contact with the velcro. Last but not least, the dimensional changes of U2 and U3 are acceptable, with both showing less than 2% in shrinkage. U2 and U3 are thus chosen as the shell and lining fabrics for the upper part of the brace, respectively.

5.4.2 Fabric for lower part of the brace

As with the upper part of the brace, the criteria for selecting the fabric to construct the lower part of the brace are fit, comfort, and durability, which are determined through the performance of the fabric in terms of elasticity and recovery, wear-comfort, pilling resistance, and dimensional stability. Even if the fabrics selected for the upper part of the brace have good fit, are comfortable to wear and durable, they are not used for the lower part of the brace as they have a net structure which exposes the skin of the wearer and possibly lead to embarrassment. This problem can be fixed for the upper part of the brace by wearing a bra top underneath but panties cannot be worn for the lower part of the brace since it is designed to be worn without panties.

As mentioned, the proposed brace is a one-piece garment, so the lower part of the brace should not have a low rate of extension. Otherwise, the lower part of the brace might not be stretch enough to allow the patients to put on the brace. According to Table 5.3, the original fabric for the functional intimate apparel in Fok (2020) or L1 would not be considered, and the same applies to L6 because it has a low rate of extension. The other samples have good rates of extension and recovery in general.

In terms of the wear-comfort, L1 has the highest thermal comfort and water vapor permeability, and best hand feel, but is not suitable due to its low rate of extension. Apart from L1, three other samples, that is, L4, L5 and L7, have similar thermal comfort, water vapor permeability, and hand feel so they were taken into consideration for the lower part of the brace. In order to provide better wear comfort, L5 was eliminated as it is less air permeable than L4 and L7 (see Figure 5.2).

As for durability, Figure 5.8 shows that L1 has outstanding ability to resist the formation of pills, followed by L7 whereas L4 has a relatively poor performance. However, even though both L1 and L7 show good dimensional stability after laundering, L7 is shortlisted due to its good performance in all of the fabric tests.

5.4.3 Corrective component for proposed brace

To ensure that the corrective component does not irritate the user and maintain its effectiveness in reducing the spinal curvature, the sourced elastic bands should also have a good fit, comfort and durability, such as good elasticity and recovery, hand feel, ability to withstand repeated episodes of stretching, as well as dimensional stability after laundering. Due to the satisfactory corrective effect of the elastic band or E1 used in Fok (2020), E1 is used as the standard which means that the newly sourced elastic bands with the most similar properties and the fewest issues compared to E1 would be used for the proposed anisotropic textile brace. According to Table 5.3 and Figure 5.6, E3 and E4 have a high rate of extension that exceeds 70% while E1 is has a rate of 48.3%. However, to select a fabric sample with similar properties as the corrective components, E2 and E5 are subsequently shortlisted with the elimination of E3 and E4. In terms of the recoverability, E2 and E5 also show a good performance, especially E2.

As for the wear-comfort, E2 and E5 have a similar and even better performance than E1 in the assessments of thermal comfort, and air and water vapor permeabilities. However, E2 is relatively less rough since there are some embroideried designs on the surface of E1 and E5 (Figure 5.4).

E2 also has outstanding durability. Figure 5.10 shows its excellent dimensional stability after laundering and in comparison, the other elastic bands in this study fall short of its performance. Besides, the force required to extend E1, E2 and E5 is relatively similar which is consistent with the results of the stretch and recovery tests. Even after repeated episodes of stretching, E2 does not easily become rigid and therefore subsequently shortlisted for use in the proposed brace (Figure 5.11).

5.4.4 Other materials used for proposed brace

Aside from the fabrics and elastic bands, other materials are also used for the proposed brace, including velcro and elastic straps. To determine if the velcro used in Fok (2020), that is, V1, is the best option or if there are better options, V1 was tested and compared with a newly sourced velcro,V2, for comfort and durability. In terms of wear-comfort, V1 has a more rough surface than V2 which might be because the latter is designed for infant wear, so it has relatively smaller hooks and loops (Figure 5.4). Therefore, V2 not only provides a better hand feel but also surprisingly has a higher peel strength. It is therefore selected in lieu of the velcro used in the function intimate apparel in Fok (2020).

For the elastic straps, the aim is to find a suitable shoulder strap, underband and compensating strap with good stretchability, recoverability and dimensional stability even after laundering.

Elastic straps that have a high modulus, low force decay with time and due to movement, as well as good recoverability are considered to be appropriate materials for the anisotropic textile brace. Even through Figure 5.7 shows that E2 has a adequately low force decay due to both time and movement, E1 has a relatively better recovery ability and higher dimensional stability after laundering. E1 is thus selected as the material for the shoulder strap while E2 and E3 are chosen for the compensating strap and underband respectively. The reason is because the need for both the shoulder and compensating straps to withstand compressive forces or external corrective forces is relatively higher than that of the underband which can be adjusted with the use of the hook and eye opening instead.

5.5 Development of hinge for artificial back bone

Fok (2020) developed an artificial back bone made of hinges, and observed that the leaves which are used as the joints of their artificial back bone are not strong enough due to the poor bonding of the 3D jet printed materials. The result was broken knuckles and pins during movement. In order for the back bone of the proposed brace to maintain a lightweight structure and have enhanced tensile strength, Fok (2020) recommended aluminum leaves with steel pins as they have the best performance in terms of tensile strength and torsional torque among all of the other tested hinge materials, such as polymethyl methacrylate (PMMA), polyoxymethylene (POM), carbon fibre reinforced polymer (CERP) and aluminum alloy with iron pins.

The use of metallic materials during radiography inhibits imaging, so the hinge for the artificial back bone used in this study adopts a modified version which recommended in Fok (2020). The hinge is made of CERP with iron pins instead of aluminum (Figure 5.12). CERP is an advanced non-metallic composite material made by binding polymer with a thermoset resin, such as epoxy. For the hinge used in the proposed anisotropic textile brace, the carbon fibres have a cross-ply orientation (0/90). After producing the carbon fibre sheet, the hinges are milled from the sheet. Except for the materials used, the design of the back bone is basically the same as that in Fok (2020). Nevertheless, it is anticipated that the back bone will still have good tensile strength and torsional torque since CERP with iron pins has the highest tensile strength and torsional torque among all of the non-metallic materials in the testing results in Fok (2020).

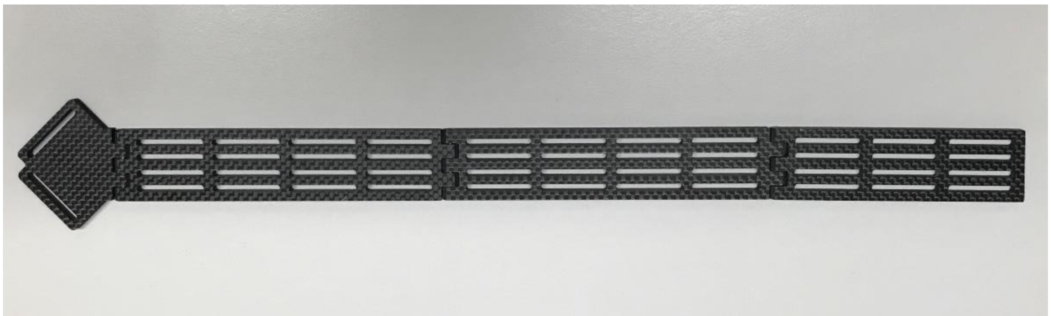


Figure 5.12 Carbon fibre hinges for back bone of brace

5.6 Development of silicone pads

As stated in Chapters 3 and 4, the aims of using silicone pads in the proposed anisotropic textile brace is to enhance the lateral forces that are exerted onto the apex of the spinal curve to correct the spinal deformity. The semi-convex pad developed in Fok (2020) reduces the spinal curvature with satisfactory results, so this pad is also used in the proposed anisotropic textile brace. To manufacture this pad, a mould is made by 3D printing poly lactic acid (PLA) onto an acrylic cover sheet (Figure 5.13). The shape and properties of the pad are the same as that in Fok (2020). The silicone rubber they used is KE-1310ST/CAT-1310 (Shin-Etsu Chemical Co). However, the silicone rubber was out of stock so another silicone, SORTA-Clear™ 40, with similar properties was sourced from the market.

With regard to the performance of these two types of silicone rubber, their density, Shore A hardness, tensile strength and percentage of elongation at break are the most important variables if the silicone used in the functional intimate apparel is replaced by the newly sourced silicone. These variables may greatly affect the degree of corrective force applied onto the spinal curvature. The specifications of SORTA-Clear™ 40 are listed in Table 5.5. In comparison with KE-1310ST/CAT-1310, SORTA-Clear™ 40 has almost the same density at 23°C and is only 0.01 g/cm^3 greater in density. Both of these silicones also have the same degree of hardness (Shore 40A) and similar tensile strength and percentage of elongation. However, the tensile strength of SORTA-Clear™ 40 is only 0.4 MPa lower but 20% higher in elongation. Therefore, SORTA-Clear™ 40 is used to construct the silicone pad due to its comparable properties.

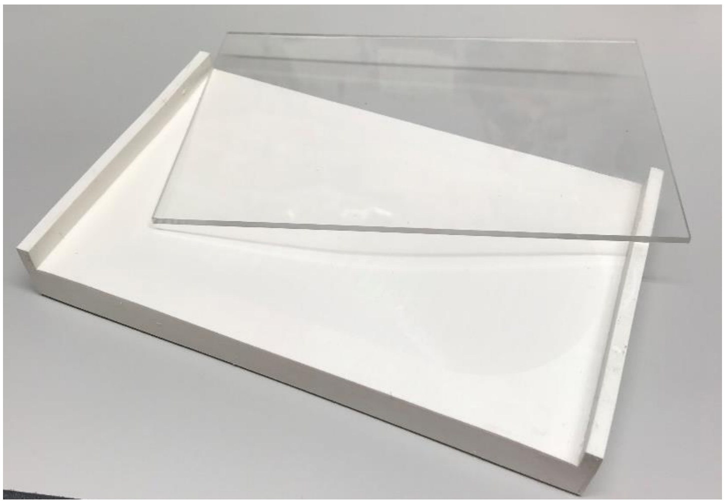


Figure 5.13 Correction pad mould

Table 5.5 Specifications of silicone rubber used

Manufacturer	Smooth-On, Inc.
Name of silicone rubber	SORTA-Clear™ 40
Curing type	Addition curing
Color	Water clear translucent
Shrinkage (in./in.)	<.001
Density at 23°C (g/cm^3)	1.08
Viscosity (cps)	35,000
Mix ratio by weight	100A:10B
Pot life	1 hour
Curing time	16 hours

Shore A hardness	40A
Tensile strength (MPa)	5.5
100% modulus (psi)	90
Elongation at break %	400
Tear strength (pli)	120

To minimize the chances that the silicone pad would erode in appearance and effectiveness, a vacuum chamber was used to degas the silicone which can prevent air bubbles on the surface during mixing. After pouring the degassed mixture into the mould, the mixture was covered with an acrylic sheet, and then pressed and placed into the oven for curing at a temperature of 40°C. The process is completed after the silicone is entirely cured (Figure 5.14).

Figure 5.14 Silicone pad

5.7 Brace fabrication

5.7.1 Creating the pattern

Before assembling the brace, a basic bodice block as discussed in Chapter 3 was used to create the pattern for the proposed brace. Besides, the preliminary pattern adjustments made in the Chapter 4, previous prototype review, were also taken into consideration.

The proposed brace is a one-piece textile brace that is cupless, and can be considered as five main fabric components: upper and lower part of brace, the centre of the back cushioning component, corrective band, and pelvis belt, where the last two components are not shown in the Figure 5.15 since they are fabricated based on the spinal curvature and the body profile of each scoliotic case. The upper part of the brace is cupless with a vest style. The hook and eye opening of this part of the brace is placed at the breast root. To insert two temperature loggers into the brace, two little pockets were also incorporated into the pattern which were placed in a back panel of the upper part of the brace. The seam allowance of each panel was adjusted depending on the component that was to be attached.

The lower part of the brace was designed as a high-waist short pants with leg openings and composed of 4 main panels. The waistband was extended upwards to the waistline from the basic block pattern. Seam allowance was reserved at the waistline as well for attaching the elastic band. The velcro opening was drawn into the pattern to allow fasteners on the leg openings.

The centre of the back cushioning component is an elongated panel with a greater width than the artificial back bone. Both a stabilizer and spacer fabric were made by following this panel with the aim to stabilize the cushioning component placed between the hinges of the back bone and the back of wearer, as well as withstand the pulling forces caused by the corrective bands.

Unlike other panels, the corrective bands and pelvis belt are all specifically made based on the spinal curvature of each wearer. For each case, the height and width of the panel are tailored. Regardless, velcro is attached onto the elastic bands and pelvic belt which connects them to the main components of the proposed brace, such as the abdominal and pelvis components.

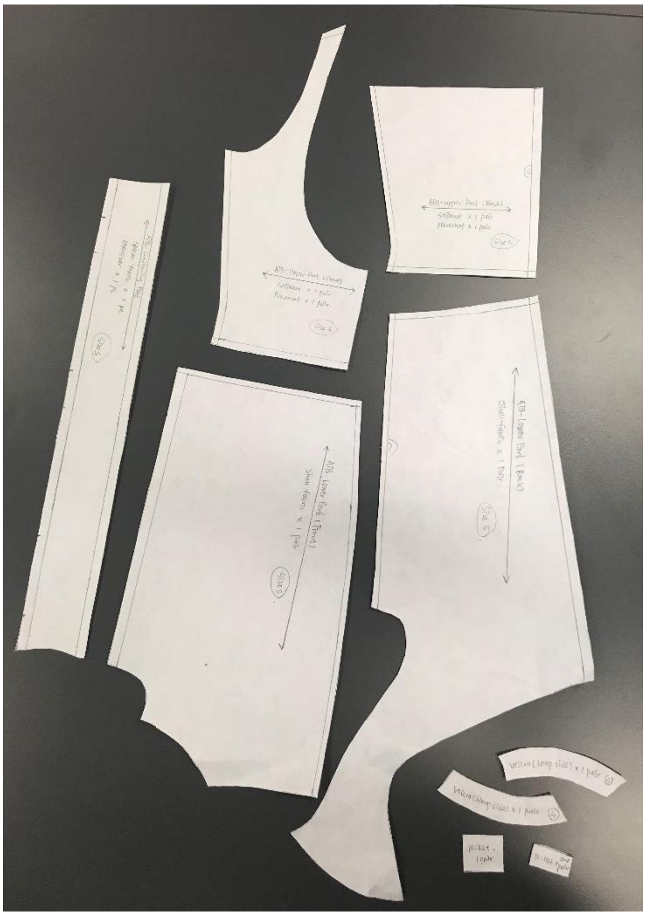


Figure 5.15 Pattern of proposed brace

5.7.2 Grading pattern size

Following ASTM D6192M Standard Tables of Body Measurements for Girls, Sizes 2 to 20 (Reg & Slim) and Girls Plus as mentioned in Chapter 3, the pattern of the brace was graded into 3 different sizes: small, medium and large (S, M and L). The corresponding pattern of these three sizes are shown in Figure 5.16.

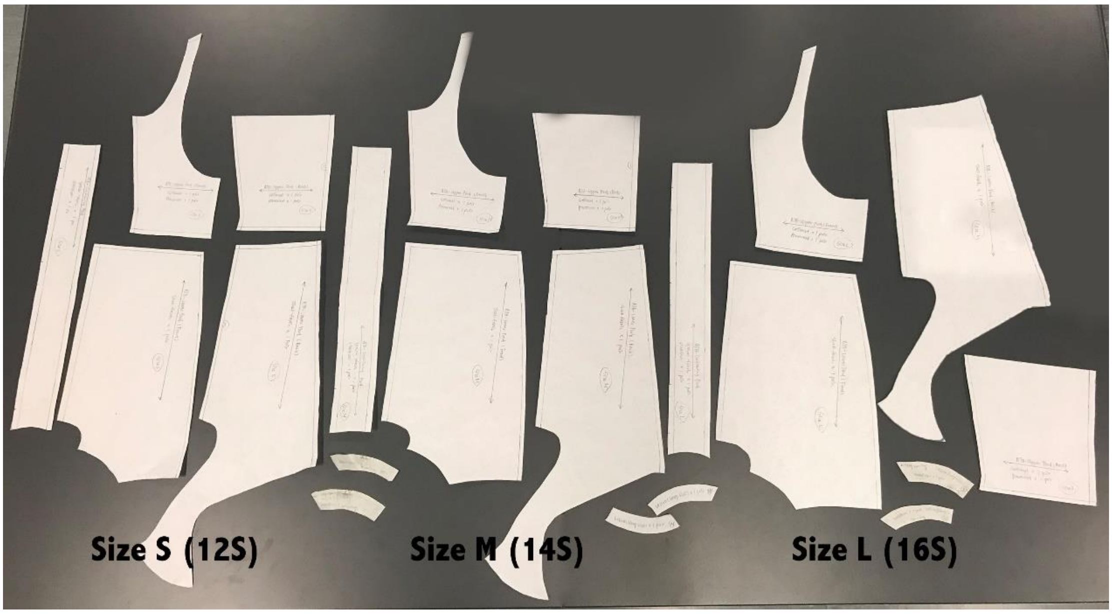


Figure 5.16 Grading patterns for brace: small, medium and large

5.8 Brace for wear trial

After the appropriate materials were selected and garment pattern was created, the proposed anisotropic textile brace was assembled, as shown in Figure 5.17. This one-piece garment has upper and lower parts, which provide the basic frame to encircle the body for attaching the corrective panels. After the spinal situation of each AIS patient is obtained, the corrective components like the corrective bands and pelvis belt are customized and placed onto the apex of the spinal curvature, as well as the compensating curve of the wearer, with the aim to exert transverse and additional forces onto the spine based on the three-point pressure system. Regardless of the type of scoliosis, all of the corrective components are designed to be attached from the artificial back bone to the front which promotes the forces to reduce the spinal curvature and provide end-point control of the pelvis. These corrective components are therefore placed on the brace as shown in Figure 5.18 based on the assumption that the wearer is an AIS patient with an S-curve.

FRONT
(with and without optional front opening panel)
SIDE
BACK

Figure 5.17 Basic fabric frame of the proposed brace

FRONT
SIDE
BACK

Figure 5.18 Proposed brace with corrective components

5.9 Adjusting fit

In order to ensure that the proposed brace fit the end users, a female subject with AIS took part in a wear trial for 2 hours. Her personal particulars and views towards the proposed anisotropic textile brace are listed in Table 5.6 and shown in Figure 5.19, respectively. No obvious problems with the fit can be found and her wear experience was positive. According to the principles of the three-point pressure system, no external force should be exerted onto the concave area of the body. Therefore, one of the compensating straps placed on her lower thoracic curve was removed for her case because it may encounter the corrective forces. After all, the original purpose of inserting this strap is to prevent the hinge back bone from shifting and exert a compensative force following the principle of three-point pressure system, and otherwise has no essential function that may affect the efficacy of the brace. The strap can be therefore kept or removed based on the specific case of each subject.

Table 5.6 Personal particulars of subject

Subject code	**Age**	**Height (cm)**	**Weight (kg)**	**BMI**	**Cobb's angle (degrees)**	**Size of proposed brace**
ATB001	12	154	39.5	16.7 (Underweight)	21° (T11-T12-L2)	S

FRONT BACK SIDE

Figure 5.19 Proposed brace on subject

5.10 Chapter summary

The proposed anisotropic textile brace comprises a one-piece garment, artificial back bone made of hinges, corrective bands with silicone pads, and pelvis belt. The aim is to provide wearers with spinal control and corrective effect, as well as minimize the negative impacts of current bracing treatments. In this chapter, the materials for the brace are shortlisted based on their physical and mechanical performances. U3 is chosen as the shell fabric due to its good recovery and extension which would provide a good fit for wearers with different body profiles. U3 also has good ability to transfer heat, air, sweat and moisture from the skin to the surface of the fabric. Even though U3 has a relatively poor hand feel, the problem can be solved by using U2, a satinnet fabric for the lining. After all, satinnet also offers exceptional wear-comfort and dimensional stability. Unlike the functional intimate apparel in Fok (2020), fabric extension is important for this one-piece design. The original fabric used for the lower part of the brace in Fok (2020) (L1) is replaced with L7 as it demonstrates better extension, is more durable, and has good dimensional stability. As for the corrective component, E2 is chosen due to its good hand feel, dimensional stability after laundering and durability. Moreover, the newly sourced hook and loop fastener and elastic straps are used for the proposed brace as they have good wear-comfort and durability after repeated usage.

As for the other components used in the proposed anisotropic textile brace like the artificial back bone and silicone pads, they have all been used in the functional intimate apparel in Fok (2020) but the materials to construct them are different in the proposed brace. Fok (2020) used metallic hinges but these would inhibit imaging during radiography. As such, a modified version is constructed with carbon fibre and iron pins. Furthermore, a similar type of silicone rubber is sourced from market due to the unavailability of the previous type of silicone.

At last, there are 6 main materials selected for brace fabrication. Such materials with various hardness can be classified into “rigid” (artificial hinge bone with Shore A100), “semi-rigid” (silicone pad with Shore A40), and “flexible” materials (corrective band and all fabrics selected for the brace with Shore A14, and Shore A10-15) following the shore hardness chart (Smooth-On, 2021).

Three sizes of the proposed brace are constructed following ASTM D7019-14 Standard Performance Specification for Brassiere, Slip, Lingerie and Underwear Fabrics in order to provide a better fit and enhance the wear experience. A female adolescent with AIS was invited to participate in a wear trial with the proposed brace for 2 hours. The brace design was then modified where necessary. The effectiveness of the anisotropic textile brace in both the preliminary wear trial and clinical trial will be discussed in Chapter 6.

CHAPTER 6 – PRELIMINARY WEAR TRIAL OF ANISOTROPIC TEXTILE BRACE

6.1 Introduction

There are two phases of the wear trial in this study, which are a preliminary 2-hour wear trial and a 3-6 months clinical trial (with follow ups after 3 and 6 months of wear) of the proposed anisotropic textile brace. In this chapter, the first phase, which involves the preliminary 2-hour wear trial, is discussed in detail. The initial outcomes of the newly designed brace are described, including the interface pressure exerted by both the functional intimate apparel in Fok (2020) and the proposed brace, initial changes in the spinal curvature when the brace is worn, changes to the body contours, psychological and physiological changes as well as user feedback on wear experience.

6.2 Subject recruitment

During the period of September 2019 to June 2020, five local secondary and primary schools were recruited to participate in a school screening programme for scoliosis. In the end, seven female students with AIS who were on average 11.7 years old with BMI of 17.3, Risser grade of 0.6 and Cobb's angle of 22.9° were recruited for the 2-hour wear trial. Their demographic profiles are listed in Table 6.1.

Table 6.1 Demographic profiles

(to be continued in the next page)

Subject code	Age	Weight (kg)	Height (cm)	BMI	Risser sign	Lenke type	Type of scoliotic curve	Curve range	Apex	Cobb's angle (°)
ATB001	12	39.5	154	16.7	0	5BN	Right	T11-L3	L1	21.0

							thoracolumbar			
ATB002	12	50.3	159	19.9	2	1CN	Left thoracic	T1-T11	T9	18.8
ATB003	12	38.1	154	16.1	0	5CN	Left thoracolumbar	T10- L3	T12	22.2
ATB004	12	42.9	155	17.9	2	3BN	Right thoracic Left lumbar	T6-T11 T12-L5	T9 L1	21.8/ 16.7
ATB005	12	41.4	156	17.0	0	5CN	Left thoracolumbar	T10-L3	T12	31.3
ATB006	11	40	153	17.1	0	1BN	Right thoracic Left lumbar	T6-T11 T11-L3	T9 L1	23.1/ 27.8
ATB007	11	36.7	151	16.1	0	5CN	Left thoracolumbar	T11-L2	T12	22.0
Average	11.7	41.3	154.6	17.3	0.6	-	-	-	-	22.9
S.D.	0.5	4.5	2.5	1.3	1.0	-	-	-	-	3.9

6.3 Anisotropic textile braces designed for subjects

As Fok (2020) showed, inserting a silicone pad on the corrective component of a flexible brace could lead to a relatively higher level of pressure exerted onto the body. By borrowing from the mechanical principles of the three-point pressure system, the corrective bands and an apical pad in the brace exert corrective forces onto the apex of the spinal curve. Meanwhile, compensation forces from the corrective bands should be induced onto the upper and lower concave sides of the spine. The different body contours and types of spinal curvature of each recruited subject meant that the placement of the corrective components would not be the same and need to correspond to the spinal situation of the subjects based on their own radiographic images, which was also the case in Fok (2020). As shown in Figure 6.1, the dark grey panel represents the corrective bands with the pad whereas the light grey panel is the pelvis belt which provides a compensation force to the spine. They are all attached to the artificial rigid back bone and placed horizontally based on the level of the apex of the wearer.

For example, the corrective band with the silicone pad was applied horizontally and laterally on the convex side of the apex of the thoracolumbar curve for Subject ATB001. Pelvis belts were placed on both the left and right sides of the pelvis to further stabilize the movement of the hinges of the artificial back bone as well as provide compensation force to the left side of her pelvis. Although like ATB001, ATB002 has a single curve, but the apex of her curve is different, which is an apex of the upper thoracic curve. Therefore, her corrective component with the pad was inserted on the thoracic region under her underarm. Due to the over-rotation of the pelvis and advancement of the spinal curvature caused by placing the pad on the pelvis of the subject in Fok (2020), no pad was placed onto the pelvis in this study. Even if a trunk listing problem, which is a problem of body alignment about leaning the trunk on spinal convexity side, was found in ATB002 and ATB007, only corrective bands were used on their pelvis regions.

Aside from the scoliotic cases with a single curve, the proposed brace was also used to treat patients with double curves. For instance, ATB004 and ATB006 have an S-curve in their right thoracic and left lumbar regions. The corrective bands with silicone pads should thus be placed on the right side of the upper thoracic curve and the left side of the lumbar curve. The pads applied on the thoracic region should be placed vertically or horizontally based on the actual range of the curvature and the body contours. In general, a horizontal pad on the apex can reach a higher position of the spine compared to a vertical placement which means that it may help to push lateral forces onto the thoracic curve with a higher apex. For individuals who have a relatively shorter trunk length, the thoracic pad should be placed horizontally to push the apex of the thoracic curve more easily and prevent unintentional pushing forces added to the lumbar from the length of the horizontal pad. Due to this reason, the thoracic pad was inserted horizontally for ATB004 while the vertical pad was used for ATB006.

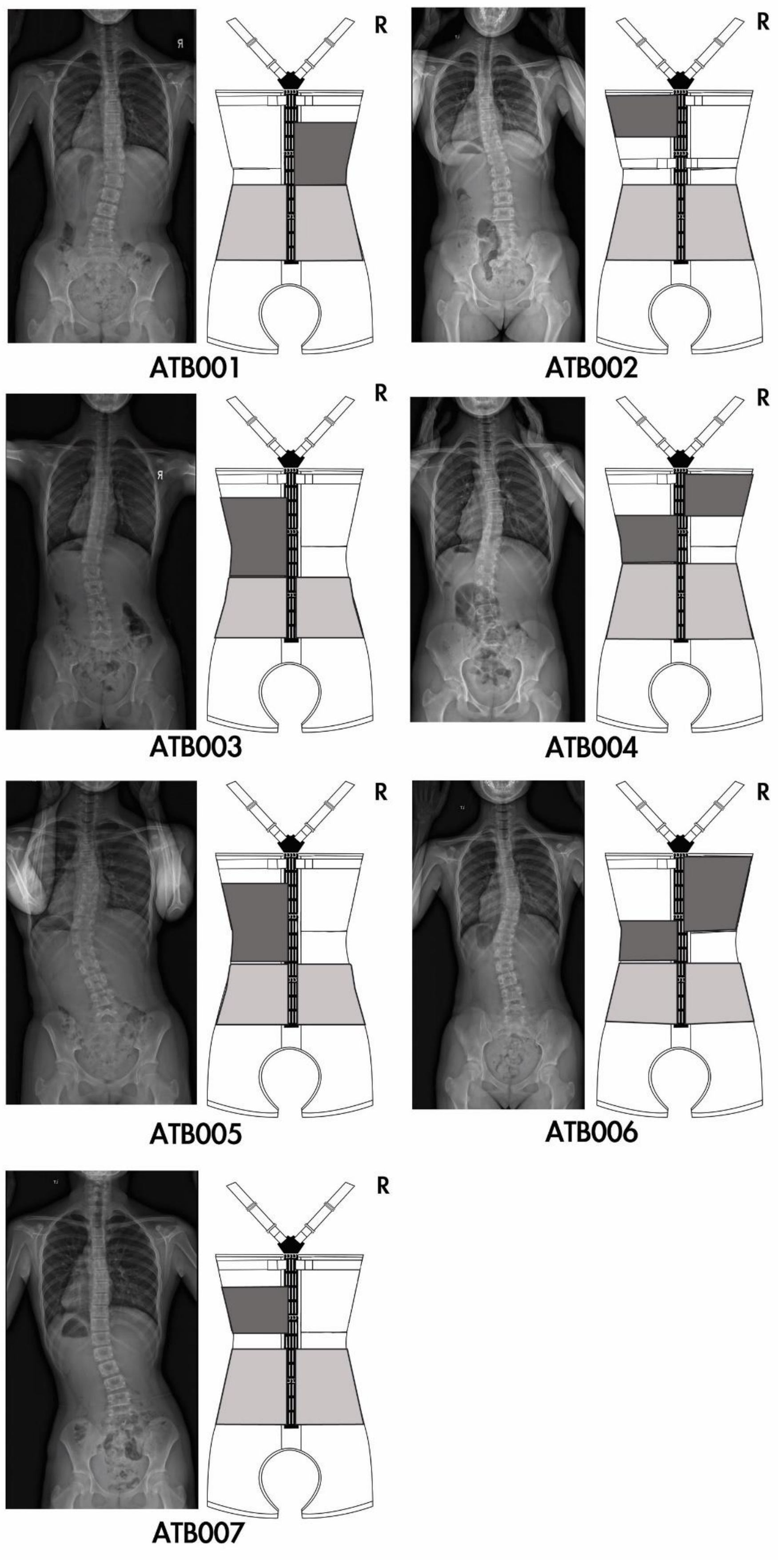


Figure 6.1 Placement of corrective components on brace for each subject

Regardless of the type of scoliosis, the pressure exerted onto the spine of the subject should follow the principles of the three-point pressure system. For those with a double curve, the finite element (FE) model used in Fok (2020) showed that the amount of lumbar loading is positively correlated with the extent of thoracic correction. More importantly, the FE model indicated that insufficient loading on the lumbar would lead to progression of the lumbar curve. To address this problem, it is recommended that only similar corrective forces exerted onto both the thoracic and lumbar curves enhance the spinal corrective effect. This finding has been applied in this study as well.

6.4 Preliminary 2-hour wear trial

All of the recruited subjects underwent the preliminary 2-hour wear trial. During the wear trial, all of them used both the functional intimate apparel and proposed brace, respectively, to take part in a series of examinations, including those done for a radiography in-brace (only with the proposed anisotropic textile brace), 3D body scanning, and interface pressure measurement. Also, the subjects were asked for their feedback, and to take part in a health-related test (only for the proposed anisotropic textile brace). All of the collected results were evaluated and subsequently discussed.

6.4.1 Initial changes in spinal curvature

An in-brace x-ray session with the EOS^{TM} imaging system was arranged for all of the recruited subjects after they had undergone bracing with the anisotropic textile bracefor 2 hours. The changes in their spinal curvature, coronal compensation (CD) and sagittal balance were measured and are discussed in the following section.

6.4.1.1 Spinal curvature

Table 6.2 shows the changes in the spinal curvature of the subjects after 2-hour of intervention with the proposed brace. All 7 subjects reduce the Cobb's angle while donned brace. By using a Wilcoxon signed-rank test, significant difference is found between the out-brace and in-brace conditions ($Z= -2.37$, $p= 0.016$). The lumbar curve of ATB004 who has a double curve is increased by 1.6 degrees after the intervention, which is considered to have no effect on her secondary curve as the measurement error is 5 degrees. ATB006 also has a double curve, and she also showed little reduction of her lumbar curve (19.4%) in comparison to her thoracic curve (35.9%). According to her spinal report provided by a Hong Kong Advanced Imaging (HKAI) radiologist, her primary curve is a thoracic curve. To better compare to the previous study done by Fok (2020), only primary curve was further analyzed and calculated. Out of the 7 subjects, 6 showed a reduction of 5 degrees or more in their spinal curve and 1 showed a reduction within 5 degrees (Table 6.2). The possible reasons for the low efficacy of the brace for ATB002 might be due to her relatively higher BMI and type of scoliosis, which is a thoracic curve.

If only the primary curve is the focus, the Cobb's angle of all of the recruited subjects is reduced by an average of 6.8 degrees, which is similar to results of the functional intimate apparel (6.1 degrees). The reduction in the Cobb's angle ranges from 4.1 to 9.8 degrees whereas the percentage of spinal curvature reduction ranges between 21.8% and 35.9%. The highest reduction in the Cobb's angle and highest percentage of reduction of the spinal curvature are shown in Figure 6.2 and Figure 6.3, respectively.

This evaluation of whether there is an in-brace reduction in the spinal curvature is always considered as an essential way of assessing whether the newly designed brace could actually inhibit the progression of the spinal curvature or even correct the spinal deformity (Negrini et al., 2012). For instance, a clinical study by Guo et al. (2014) stated that the corrective effectiveness of a rigid brace and the dynamic SpineCor brace for those who suffer from AIS with a Cobb's angle between 20 and 30 degrees is 15.9% and 21.3%, respectively. For AIS patients with a Cobb's angle between 18 and 45 degrees, another study done by Karol (2001b) also showed that the initial reduction in the Cobb's angle of male AIS subjects when conventional braces like the Milwaukee, Boston and Charleston braces are worn, is 17.4%, 35.6%, and 62.2%, respectively. Compared to the results of the existing orthoses as discussed, the initial percentage of spinal curvature reduction with the proposed anisotropic textile brace (29.6%) is comparable to some of the other existing braces but still lower than that in Fok (2020) (39%). However, 85.7% of scoliotic subjects in this study successfully correct their spinal curvature which is higher than that in Fok (2020) which is 80%. The reason might be because the brace in this study has a better and more stable performance in the initial spinal correction or might benefit cases with a specific type of curve, risser grade or body profile. This is due to the small sample size in this study, and a larger sample should be considered in future studies.

In addition, the sum of the curves as measured by the Cobb's angle, which is calculated by summing up the Cobb's angle of all of the curves of the entire spine, is suggested in Lang et al. (2019). The sum of the curves in their study showed a highly negative correlation with in-brace correction which implies that a larger total curve Cobb's angle is more likely to lead to poor results with in-brace correction. In this study, all of the cases with double curves prove the findings in Lang et al. (2019), in which only a 10.4% and 26.9% initial in-brace reduction of the spinal curvature is found for ATB004 and ATB006. In order to compare the corrective effect of the proposed brace and the earlier brace in Fok (2020), changes in the primary curve are the focus of this study instead of the sum of the curves, which was not examined in Fok (2020).

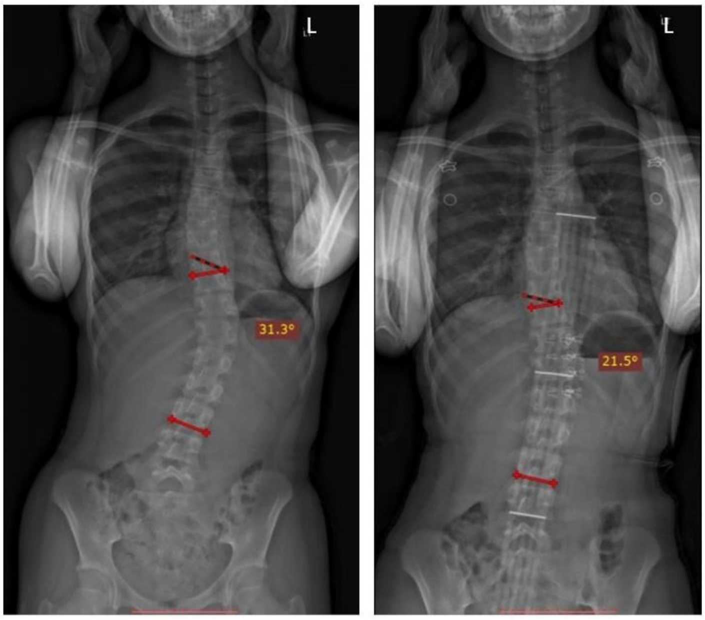
Nevertheless, these in-brace reductions of the spinal curvature cannot be considered as optimal results. After all, the success of treating spinal deformities to a large extent depends on the inherent flexibility of the spine. A subject with a flexible spine will tend to demonstrate a larger reduction in the spinal curvature as opposed to someone with a stiff spine (Cheung et al., 2018; Clin, Aubin, Sangole, Labelle, & Parent, 2010). By measuring the degree of reduction on supine lateral bending radiographs, the flexibility of the spine and more accurate results of the degree of in-brace correction can be obtained (Ohrt-Nissen, Hallager, Gehrchen, & Dahl, 2016). However, this has not been evaluated and discussed in this study due to concerns around radiation exposure while taking supine x-rays, which was also the case in Fok (2020). Unfortunately, the lack of the details on the inherent flexibility of the subjects is one of the limitations of this research study.

Table 6.2 Differences in Cobb's angle after 2-hour intervention with proposed brace

(to be continued in the next page)

Subject code	Cobb's angle before 2-hour intervention (◦) (without brace)	Cobb's angle after 2-hour intervention (◦) (in-brace)	Changes in the Cobb's angle (◦)	Percentage of reduction in spinal curvature (%)	Percentage of increase in spinal curvature (%)
ATB001	21.0	15.4	-5.6	26.7	N/A
ATB002	18.8	14.7	-4.1	21.8	N/A

ATB003	22.2	15.2	-7.0	31.5	N/A
ATB004	21.8 (Thoracic)/ 16.7 (Lumbar)	16.2 (Thoracic/) 18.3 (Lumbar)	-5.6 (Thoracic)/ +1.6 (Lumbar)	25.7 (Thoracic)	9.6 (Lumbar)
ATB005	31.3	21.5	-9.8	31.3	N/A
ATB006	23.1 (Thoracic)/ 27.8 (Lumbar)	14.8 (Thoracic)/ 22.4 (Lumbar)	-8.3 (Thoracic)/ -5.4 (Lumbar)	35.9 (Thoracic) 19.4 (Lumbar)	N/A
ATB007	22.0	14.5	-7.5	34.1	N/A



(a) (b)

Figure 6.2 Radiographs of ATB005

(a) without brace, and (b) with brace

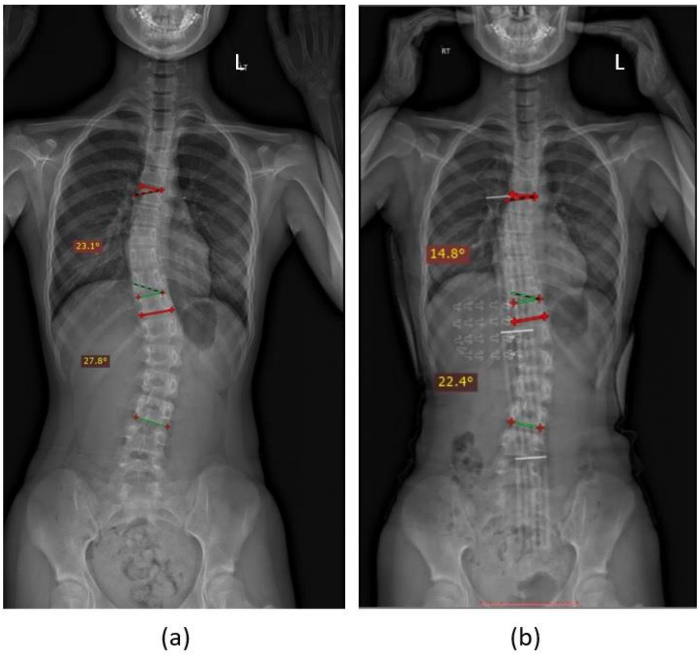


Figure 6.3 Radiographs of ATB006

(a) without brace, and (b) with brace

6.4.1.2 Coronal compensation

In this study, coronal compensation (CD) is measured on the radiographic images of each subject before and after the 2-hour intervention. Figure 6.4 shows the changes in the coronal balance after the 2-hour intervention, where a positive value means that the C7 plumb line leans to right side and vice versa. Among the 7 subjects, 4 of them achieve coronal balance, including ATB005 and ATB006, with the highest reduction in the Cobb's angle and rate of reduction of the spinal curvature, respectively. The 3 remaining subjects all showed an increase in their coronal imbalance. Even though almost all of the subjects in this study have coronal balance with the use of the proposed brace, the coronal imbalance found in ATB002 and ATB007 has not yet been effectively treated even after they used the ATB.

Aside from these two subjects, ATB005 has a relatively more severe coronal imbalance prior to participating in the 2-hour wear trial. Based on the findings in Lang et al. (2019), coronal and sagittal balances may influence in-brace correction. The findings in this study are in agreement with those of Lang et al. (2019) as these 3 subjects showed a smaller initial reduction of the spinal curvature compared with the others. However, it is surprising that both ATB005 and ATB007 show a relatively satisfactory in-brace correction, with a reduction of 30% of the spinal curvature. The sagittal balance of each subject then needs to be investigated as well.

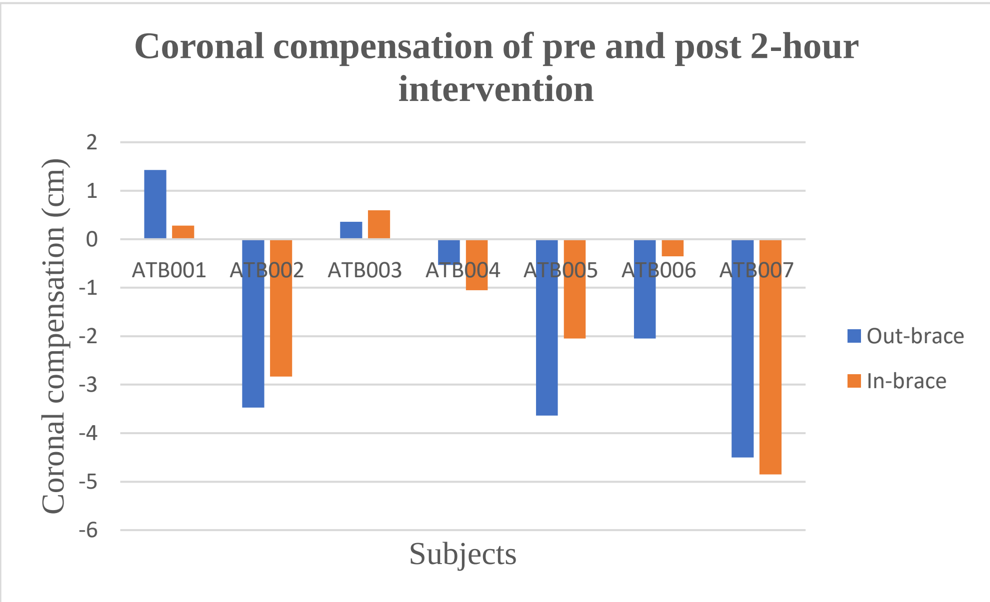


Figure 6.4 Coronal compensation in preliminary wear trial

6.4.1.3 *Sagittal balance*

As mentioned above, all of the recruited subjects underwent a low-dosage x-ray before and after the 2-hour intervention to assess the differences in their spinal deformity. Meantime, their sagittal images were also obtained simultaneously, which is one of the advantages of undergoing a radiographic examination with the EOS^{TM} imaging system. Figure 6.5 shows the changes in the sagittal balance in the preliminary wear trial, in which a positive value denotes that the C7 plumb line falls anterior and a negative value denotes that the C7 plumb line falls posterior. The sagittal imbalance of the subjects is reduced after 2-hour of bracing, except for ATB003. Among all of the subjects who demonstrated a reduced sagittal imbalance, ATB004 who suffers from inherent lordosis (see Figure 6.6) showed the best result. Surprisingly, her sagittal vertical axis (SVA) is reduced from 5.26 cm to 1.70 cm after the intervention, which is also the largest percentage of reduction (67.7%).

While sagittal imbalance can reduce the degree of in-brace correction (Lang et al., 2019), there is more than 30% reduction in the spinal curvature of ATB005. This is relatively satisfactory even if she does not show much reduction in the sagittal imbalance. The lack of reduction might be due to the limited sample size in this study, since no obvious trends could be obtained.

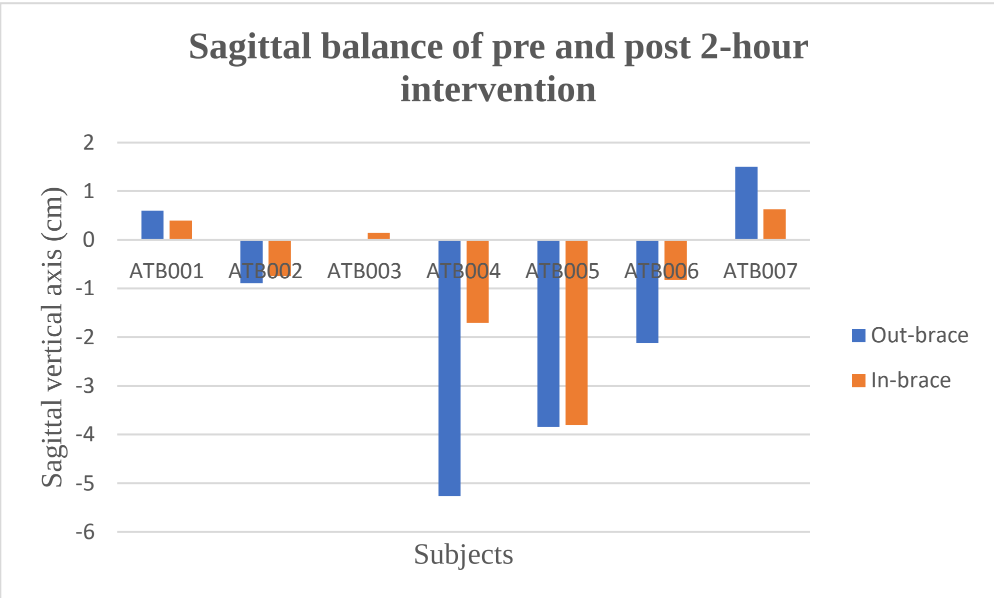


Figure 6.5 Measurement of sagittal balance in preliminary wear trial

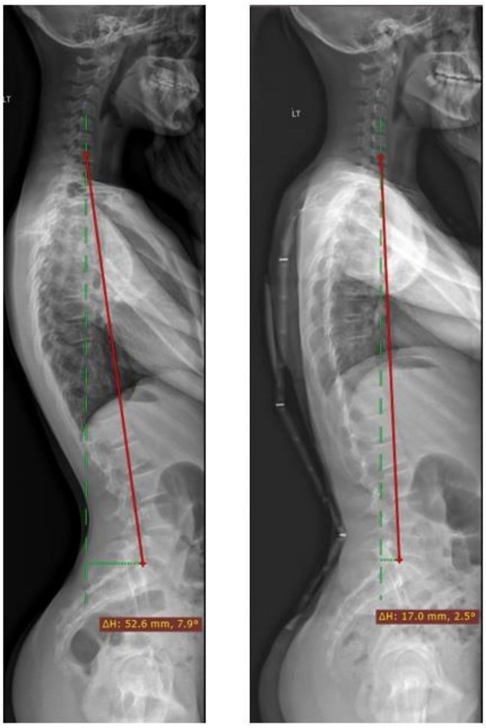


Figure 6.6 Effect of intervention on sagittal balance of ATB004

6.4.2 Initial changes in body contours

6.4.2.1 Shoulder obliquity

As mentioned in Chapter 3, the subjects wore the functional intimate apparel in Fok (2020) and the proposed anisotropic textile brace for 30 minutes in a preliminary 2-hour wear trial, respectively (see Figure 6.7). They then underwent a 3D body scan. The shoulder obliquity was then measured based on their 3D images. The results of the shoulder obliquity when the brace is not worn vs. wearing the two different braces are shown in Figure 6.8, where FIA represents functional intimate apparel and ATB represents anisotropic textile brace. However, the results of ATB002 for the functional intimate apparel are missing and not discussed since that brace did not fit her.

Almost all of the subjects demonstrate increased obliquity of their shoulders with an average increase of 0.98 degrees after using the proposed brace, and only ATB004 shows a slight reduction of 0.78 degrees. It is surprising that the 4 subjects who showed a relative reduction in their Cobb's angle after 2 hours of intervention, that is, ATB003, ATB005, ATB006 and ATB007, have more uneven shoulders. Similar findings are also found in Fok (2020). Nevertheless, the subjects also wore the brace in Fok (2020) as a means of comparison and it is found that their shoulders are more uneven except for ATB001 (Figure 6.8).

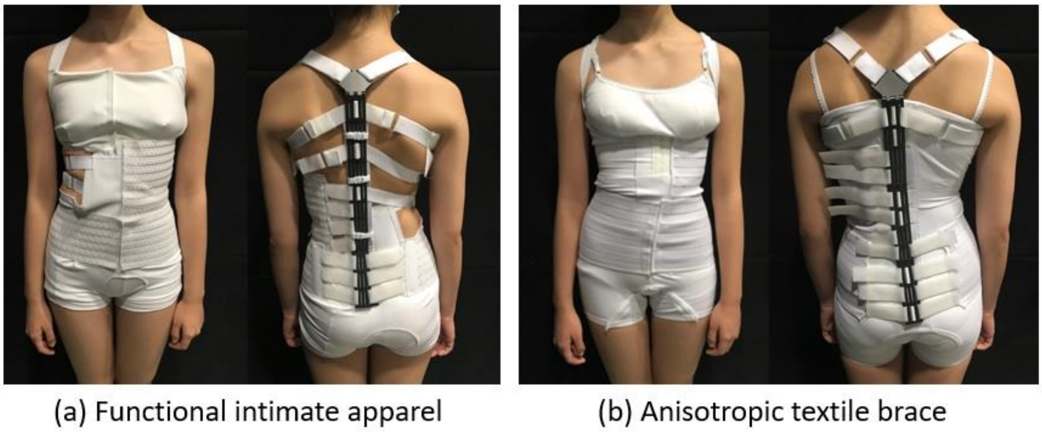


Figure 6.7 Subject wearing brace:

(a) Functional intimate apparel (b) Anisotropic textile brace

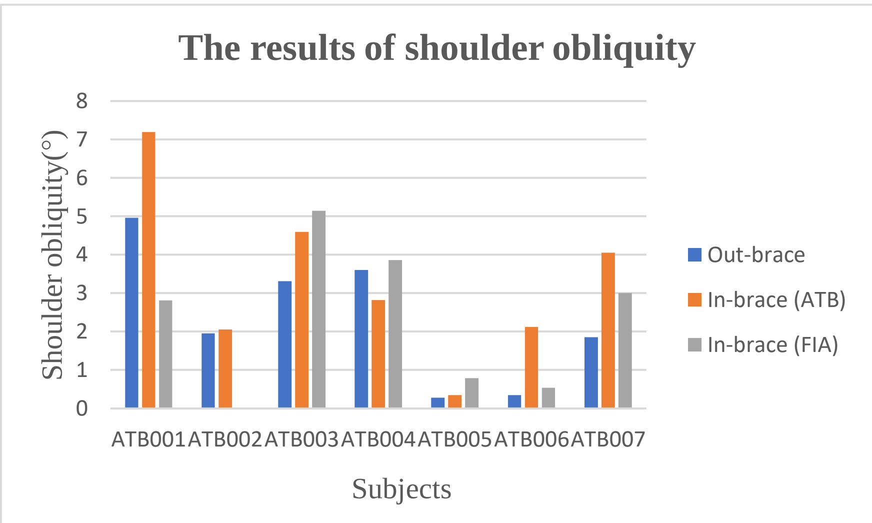


Figure 6.8 Degree of obliquity of shoulders in preliminary wear trial

6.4.2.2 Shoulder rotation

The degree of rotation of the shoulders of the recruited subjects without wearing a brace, and with the functional intimate apparel and anisotropic textile brace were measured and are presented in Figure 6.9. Of the 7 subjects, 4 show more balanced shoulders after wearing the proposed brace while the functional intimate apparel shows a similar result in which the extent of shoulder rotation is reduced. Compared to the newly designed brace, the earlier version can better reduce the shoulder rotation of some of the subjects in this study, especially ATB001 with no rotation of the shoulders after wearing the brace for 2 hours. However, this is not the case for all of the subjects, and the results after wearing the original functional intimate appeal is the same as those after wearing the proposed brace.

Even though ATB006 shows the highest reduction of her spinal curvature after the 2-hour intervention, her shoulders are not balanced and have a distinctive tilt. This is also the case in Kotwicki, Kinel, Stryla, and Szulc (2007) and Fok (2020) who all find that it is common to observe an involuntary imbalance of the shoulders during bracing for a higher rate of curvature correction.

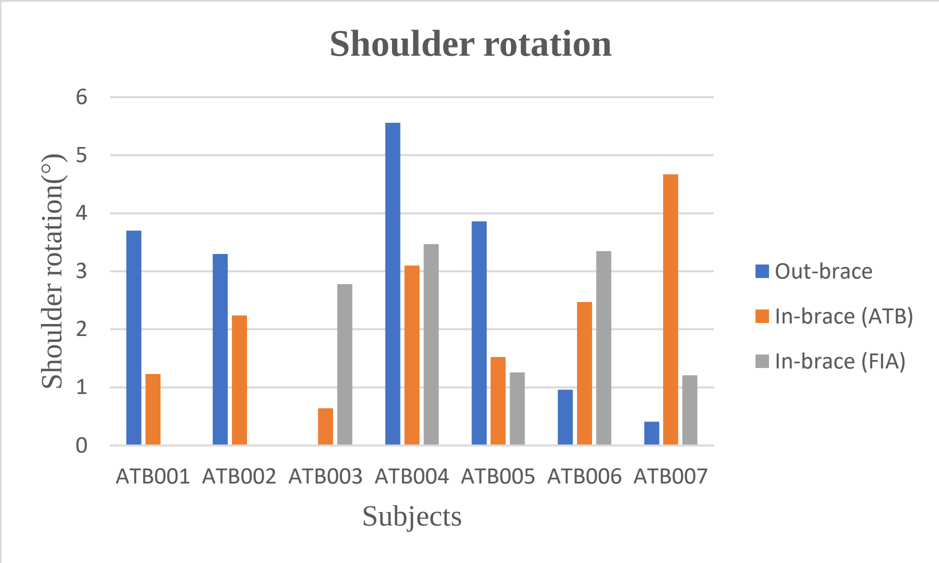


Figure 6.9 Degree of shoulder rotation in preliminary wear trial

6.4.2.3 *Posterior Trunk Symmetry Index*

The orientation of the shoulders can only show the asymmetry of the shoulders. In order to obtain more comprehensive results of the initial changes after the preliminary 2-hour intervention, the asymmetry of the back of the subjects was also examined. The posterior trunk symmetry index (POTSI) was then calculated for each subject with no brace on, and with the proposed brace and original functional intimate apparel worn, respectively (see Figure 6.10). The value positively corresponds to the asymmetry of the posterior trunk, where the ideal POTSI is 0. In this study, the POTSI value ranges from 11.2 to 75.7 without a brace, 17.0 to 47.5 with the functional intimate apparel, and 4.1 to 60.9 with the proposed brace which demonstrates its potential corrective effects in terms of the increasing the trunk symmetry. Among the 7 recruited subjects, 4 of them showed reduced posterior asymmetry after the wear trial with the anisotropic textile brace, in particular ATB006 who has a better POTSI value with a 60% reduction in her trunk asymmetry. This reduction in the posterior trunk asymmetry is even more obvious than that after wearing the functional intimate apparel. However, the waistline asymmetry might not be accurate enough due to the use of the silicone corrective pad which might affect the POTSI value after wearing the ATB or FIA. As is the case with the shoulder obliquity, the results also do not show that there is a consistent amount of correction for all of the wearers to imply any correlation between the in-brace reduction of the spinal curvature and the changes in POTSI value.

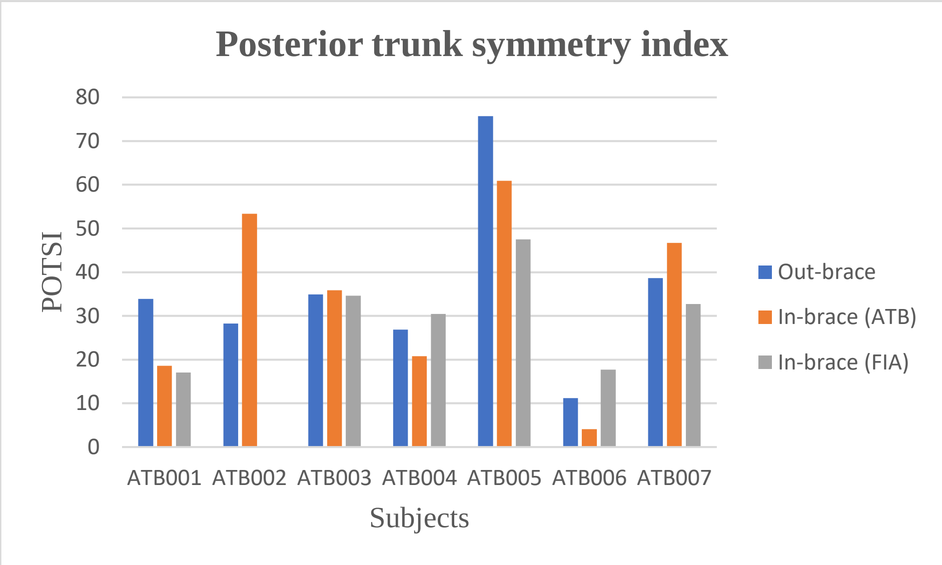


Figure 6.10 POTSI results for preliminary wear trial

6.4.3 Interface pressure

The spinal correction performance depends on the magnitude of the forces that are exerted onto the body contours. The original functional intimate apparel in Fok (2020) shows potential success in reducing spinal deformities, so the proposed anisotropic textile brace has adopted its biomechanics. In order to ensure that the amount of lateral force exerted by the proposed brace is similar to that by the original one, the interface pressure exerted by both braces was measured on each subject immediately in the preliminary 2-hour wear trial. Table 6.3 lists the interface pressure values for the different areas of the body while wearing the proposed brace and original brace, respectively. According to Fok (2020), the interface pressure increases with the use of the silicone pad. The pressure values collected when the apical pad is applied should be higher regardless whether which brace is used. Therefore, the interface pressure values at the apex are highlighted in yellow in the table below. The interface pressure at the apex with the prior developed brace ranges from 6 to 17 kPa whereas that with the newly designed brace ranges from 9 to 23 kPa which shows that the proposed brace can still exert a comparable amount of compressive force onto AIS patients even if it is modified.

Moreover, in following the principles of the three-point pressure system and the equilibrium principle of the artificial back bone as mentioned in Fok (2020), the pelvis belt placed at opposite sides of the convexity of the lumbar/ thoracolumbar curve with the corrective component always bears a higher pressure to help maintain the balance of the wearers and the back bone even if a pad is not attached to the pelvis belt. The related results are highlighted in blue in Table 6.3. The interface pressure exerted by the pelvis belt of the functional intimate apparel on the concave side ranges from 3 to 6 kPa whereas that of the proposed brace ranges from 2 to 13 kPa which shows that the proposed brace can still induce a similar amount or even higher compensation forces from the pelvis belts and produce the expected biomechanics.

In order to further investigate if the interface pressure caused by the newly designed brace is comparable to that of the prior functional intimate apparel , a Wilcoxon signed-rank test was carried out for all of the corrective components with an inserted silicone pad and the compensation forces from the pelvis belts. The findings showed that there are no significant differences between the two brace designs ($Z=-1.61$, $p= 0.125$), including for both the corrective panels and compensation panels. This implies that the proposed brace can very well provide a similar performance for spinal correction.

Although the amount of corrective forces is one of the factors that could potentially affect the reduction of the spinal curvature with bracing treatment, there is however no absolute positive correlation between spinal correction and interface pressure exerted by the corrective components by merely looking at the findings in Table 6.3. For example, the pressure added to the thoracolumbar of ATB005 is just 9 kPa but her initial in-brace correction is satisfactory with a reduction of 9.8 degrees of her Cobb's angle which corresponds to a 31.5% reduction in the spinal curvature. Even through the best case in the clinical study in Fok (2020) obtains an initial in-brace reduction of 88.7%, the interface pressure exerted by the corrective component in that case is also less than 10 kPa. Thus, the optimal amount of pressure that should be applied on AIS patients is still debatable for all non-rigid braces. Further studies are necessary in this regard. As for conventional rigid braces like the Boston brace, the interface pressure exerted is between 10 to 30 kPa (Mac-Thiong et al., 2004). This is similar to the interface pressure exerted by the proposed anisotropic textile brace (9 to 23 kPa) which might imply the possibility of using this non-rigid brace on AIS patients for effective treatment of spinal deformities.

Besides, as mentioned in Chapter 3, a good in-brace reduction of the S-curve can only be realized by using a similar amount of interface pressure on both the thoracic and lumbar regions (Fok, 2020). This finding is applied to the subjects with double curves in the wear trial, that is, ATB004 and ATB006. However, it was found that it is difficult to apply adequate pressure on the lumbar spine even if the adjustable straps are tightened, which was the case with ATB006. The pressure that was applied onto her thoracic region is 23 kPa but only 13 kPa was exerted onto her lumbar curve. These differences in pressure might be because there is fat on the lumbar region which diffuses the pressure from the apical pad while the ribcage in the thoracic region is rigid and therefore does not have this problem. Finally, 25.7% and 35.9% reductions of the spinal curvature are obtained respectively for ATB004 and ATB006, even if the latter does not show a similar interface pressure value on her thoracic and lumbar regions. This shows that the finding in Fok (2020) might not be applicable to all patients with an S-curve.

Table 6.3 Immediate interface pressure collected

(to be continued in the next page)

Subject code	**Measured region**	**Interface pressure (kPa)**	
		Anisotropic textile brace	**Functional intimate apparel**
ATB001	Right Thoracolumbar (Corrective pad)	11	17
	Left Thoracolumbar	1	0
	Right side of pelvis	4	5
	Left side of pelvis	6	6
ATB002	Right thoracic	0	-
	Left thoracic (Corrective pad)	10	-
	Right side of pelvis	5	-
	Left side of pelvis	3	-
ATB003	Right thoracic	1	0
	Left thoracic (Corrective pad)	9	7
	Right side of pelvis	13	6
	Left side of pelvis	0	1
ATB004	Right thoracic (Corrective pad)	13	6
	Left thoracic	0	0
	Right lumbar	2	0
	Left lumbar (Corrective pad)	14	15

	Right side of pelvis	2	3
	Left side of pelvis	4	4
ATB005	Right thoracolumbar	0	1
	Left thoracolumbar (Corrective pad)	10	9
	Right side of pelvis	5	5
	Left side of pelvis	4	3
ATB006	Right thoracic (Corrective pad)	23	10
	Left thoracic	0	0
	Right lumbar	0	0
	Left lumbar (Corrective pad)	13	6
	Right side of pelvis	8	10
	Left side of pelvis	2	2
ATB007	Right thoracolumbar	0	0
	Left thoracolumbar (Corrective pad)	11	8
	Right side of pelvis	8	7
	Left side of pelvis	6	2

6.4.4 Health-related test

As discussed in Chapter 3, two questionnaires, the BrQ and TAPS, were completed by the subjects during the 2-hour wear trial. The goal of these two questionnaires is to investigate the initial changes in their quality of life (QoL) after treatment with bracing (Asher, Lai, Burton, & Manna, 2003; Vasiliadis et al., 2006), as well as evaluate the correlations between perceived trunk deformity and QoL.

6.4.4.1 Brace Questionnaire

All of the subjects completed the Chinese version of the BrQ after wearing the proposed brace for 2 hours. Their scores were statistically analyzed and are listed in Table 6.4. The mean overall score of the BrQ is 83.03 (S.D.= 3.82). Lower scores can be observed for self-esteem and aesthetics (Mean= 2.29, S.D.= 1.07). Among all the questionnaire items, social functioning is affected the least by the 2-hour intervention which might be because the social relationships of the subjects are not affected during such an extremely short bracing time. The subjects were generally having lunch during the 2-hour trial which would not present difficulties during class or even cause their absence during lessons due to the bracing treatment. A Kendall's tau-b test showed that there is no significant correlation between the Cobb's angle and any item of the BrQ and its overall scores.

Table 6.4 Descriptive statistics of BrQ scores after preliminary wear trial

	After preliminary wear trial		
	Mean	S.D.	Range
Overall score (20-100)	83.03	3.82	75.88-86.47
General health perception (1-5)	4.21	0.39	4.00-4.50
Physical functioning (1-5)	3.41	0.68	3.15-3.86
Emotional functioning (1-5)	4.29	0.45	3.60-5.00
Self-esteem and aesthetics (1-5)	2.29	1.07	1.00-3.50
Vitality (1-5)	3.29	1.15	1.00-4.50
School activity (1-5)	4.71	0.40	3.00-5.00
Bodily pain (1-5)	4.83	0.22	4.17-5.00
Social functioning (1-5)	4.84	0.32	4.71-5.00

6.4.4.2 The Trunk Appearance Perception Scale

As the questions in TAPS asked subjects their perception of their current physical profile, the TAPS results were collected before the bracing intervention as a baseline. The scores are presented in Table 6.5. The highest score is found for Question 2, which is the view of the torso when looking and bending forward (Adam's test). In contrast, the lowest score is found for Question 1 (Mean= 3.43, S.D.= 0.98), which is the view of the torso when looking at the back. The results of the Kendall's tau-b test showed that there is no correlation between the BrQ and TAPS scores, including their overall scores and the scores from each questionnaire item.

Table 6.5 Descriptive statistics of TAPS scores after preliminary wear trial

	Pre-treatment		
	Mean	S.D.	Range
Total score (1-5)	3.90	0.44	2.00-5.00
TAPS Question 1 (1-5)	3.43	0.98	2.00-5.00
TAPS Question 2 (1-5)	4.39	0.76	3.00-5.00
TAPS Question 3 (1-5)	4.00	0.82	3.00-5.00

6.4.5 User feedback after preliminary wear trial

As mentioned in Chapter 3, all of the subjects were blind to the appearance of the proposed brace, and required to wear both the functional intimate apparel (Brace A) and anisotropic textile brace (Brace B), and comment on them, respectively. Except for the ATB002 who had not undergone the 30 minutes trial of functional brace, there were no fitting problems found during the trial but the subjects generally indicated that the functional intimate apparel is uncomfortable due to tight fit, prickly hand feel of the velcro and difficulties of donning and doffing the brace. The feedback is also reflected in its rating in terms of wear-comfort. The mean rating for the functional intimate apparel is 7.07 (S.D.= 1.88), which is lower than that of the anisotropic textile brace (Mean= 8.71, S.D.= 0.95). It corresponds a significant difference shown in Mann-Whitney U test, where U (6) = 9.50, Z=-1.97, and p= 0.05, and the difference between these two braces was large (r = -0.74). Overall, all of the recruited subjects prefer the proposed brace for their future bracing treatment. Even through their decision would not affect the sequent bracing arrangement of the 2-hour wear trial, their preferences can attest to the performance of the two braces and determine whether the newly designed brace can provide wearers with a better wear experience in the views of the users.

6.5 Chapter summary

Seven subjects have been recruited to participate in a preliminary 2-hour wear trial to investigate the effects of wearing the newly designed brace in terms of in-brace reduction of the spinal curvature, changes in the body contours, and impacts on quality of life, as well as obtain user feedback, in which the in-brace reduction is considered to be the primary outcome. In this trial, all of the subjects are also asked to wear both the functional intimate apparel and anisotropic textile brace for 30 minutes in succession. Three dimensional imaging of their body, interface pressure measurements, health-related tests, and user feedback are also obtained while donning these two braces. Following the principles of the three-point pressure system and the equilibrium principle, the pelvis belts that are placed at opposite sides of the convexity of the lumbar/ thoracolumbar curve with corrective component maintains the balance of wearers and the artificial back bone even if no pad is inserted on the pelvis belts. The proposed brace can therefore still contribute with a similar amount and even higher compensation forces from the pelvis belts and produce the expected biomechanics .

In order to compare with the original brace design with that of the proposed brace, only the primary curve is the focus in this study. Of the 7 subjects, 6 experience a reduction of 5 degrees or more in their spinal curve and 1 experience a reduction within 5 degrees, which correspond to an average reduction of 6.8°, and therefore similar to that with the use of the functional intimate apparel. The percentage of the initial in-brace reduction ranges from 21.8% to 35.9% which is lower than the range of original brace but is still shows a significant difference before and after 2-hour intervention and comparable to some of the current braces in the market, such as the Boston brace. The coronal and sagittal balances are also measured on the radiographs to further determine the initial in-brace effect. No obvious difference or correlation is found when the brace is worn. However, the conclusion is that the in-brace corrective effect is not optimal since the flexibility of the spine has not been discussed in this study.

As for initial changes in the body contours, almost all of the subjects demonstrate more shoulder imbalance with average of 0.98 degrees increase after using the proposed brace but this is not reflected in their Cobb's angle. Moreover, by observing the POTSI values, a potential corrective effect in terms of the trunk symmetry is found with a 60% reduction in the trunk asymmetry. This is an even more obvious improvement than that found with the functional intimate apparel. As with the performance of the proposed brace for the shoulder imbalance, the proposed brace is not able to reduce the trunk asymmetry for all AIS patients, unlike the original brace.

For the interface pressure measurements, the results show that the proposed brace can still provide comparable compression forces onto AIS patients even if it has been modified based on its exertion of a similar range of pressure values with no significant difference. As with the case of the functional intimate apparel, there is no positive correlation between spinal curvature and interface pressure exerted by the corrective components. However, there is the possibility that the use of a non-rigid brace on AIS patients can provide a potentially good reduction of the spinal deformity because a similar amount of interface pressure is applied as some of the tested braces in the market.

As for the health-related test, lower BrQ scores are obtained around self-esteem and aesthetics whereas higher scores are found for social functioning because of the extremely short bracing time. Also, no significant difference can be observed between the scores of the BrQ and Cobb's angle. To understand the perception of the wearers around their own trunk, TAPS is used and in particular, a question about the view of the torso when looking and bending forward (Adam's test) results in the highest score while that about the view of the torso when looking at the back has the lowest score. Yet, there are no significant correlations between the BrQ and TAPS scores.

Last but not least, the mean wear-comfort score for the functional intimate apparel is significantly lower than that of proposed anisotropic textile brace. The subjects tend to prefer the proposed brace for their future bracing treatment which shows that the newly designed brace can provide wearers with a relatively better wear experience.

CHAPTER 7 – CLINICAL TRIAL OF ANISOTROPIC TEXTILE BRACE

7.1 Introduction

After a satisfactory reduction in spinal curvature was obtained in the initial in-brace radiographs, the subjects were subsequently invited to participate in a 3-6 month clinical trial (with monthly follow-ups and then low-dose radiographic imaging after 3 and 6 months of wear). The focus is on the short-term effects of the anisotropic textile brace with periodical monitoring, such as changes in the spinal curvature, body contours, and sitting posture, and demonstrated by the quality of life questionnaire responses, compliance rate, and user feedback during the bracing process.

7.2 Subject recruitment

To minimize the likelihood of spinal deterioration in the subsequent months caused by the proposed bracewear since the brace may not be suitable for all scoliotic patients, all of the recruited subjects had to undergo a preliminary 2-hour wear trial. Only if the initial in-brace reduction of the spinal curvature is 5 degrees or more, then the subjects could subsequently take part in the 3-6 month clinical trial. In the end, 6 of the 7 subjects participated in this part of the study, and only one subject, ATB002, withdrew from the study. Their demographics are shown in Table 7.1.

Table 7.1 Demographics of subjects in 3-6 month clinical trial

Subject code	Age	Weight (kg)	Height (cm)	BMI	Risser sign	Lenke type	Type of Scoliotic curve	Curve range	Apex	Cobb's angle (°)	
										Out-brace	In-brace
ATB001	12	39.5	154	16.7	0	5BN	Right thoracolumbar	T11-L3	L1	21.0	15.4
ATB003	12	38.1	154	16.1	0	5CN	Left thoracolumbar	T10-L3	T12	22.2	15.2
ATB004	12	42.9	155	17.9	2	3BN	Right thoracic Left lumbar	T6-T11 T12-L5	T9 L1	21.8/ 16.7	16.2/ 18.3
ATB005	12	41.4	156	17.0	0	5CN	Left thoracolumbar	T10-L3	T12	31.3	21.5
ATB006	11	40	153	17.1	0	1BN	Right thoracic Left lumbar	T6-T11 T11-L3	T9 L1	23.1/ 27.8	14.8/ 22.4
ATB007	11	36.7	151	16.1	0	5CN	Left thoracolumbar	T11-L2	T12	22.0	14.5
Average	11.7	39.8	153.8	16.8	0.3	-	-	-	-	23.6	16.3
S.D	0.5	2.2	1.7	0.7	0.8	-	-	-	-	3.8	2.6

7.3 Three to six months clinical trial

In this clinical trial, all of the subjects wore the proposed anisotropic textile brace for at least 8 hours a day. Follow-up was carried out every month to periodically monitor each subject to ensure that she could independently and correctly don the brace, and confirm that the interface pressure from the brace and brace fit were both optimal even after prolonged usage time. Moreover, the follow up was done to monitor changes in the spinal curvature, body contours, and sitting posture, and see if there were any changes in quality of life or compliance, and seek user feedback.

7.3.1 Changes in spinal curvature during third and six months of brace wear

To monitor the spinal situation of the subjects who were undergoing the bracing treatment, they underwent low-dose radiographic imaging in the 3rd and 6th months of the clinical trial. X-rays of the subjects with the brace donned and without the brace were taken. Generally, the two radiographs were taken separately at least 1 week apart, in order to minimize the unnecessary risks of radiation exposure when x-rays are taken so frequently in such a short period of time. In November 2020, all of the subjects had undergone at least 3 months of bracing. Only ATB001 used the brace for 6 months. As with the preliminary 2-hour wear trial, the effect of the bracing is further discussed based on their spinal curvature, CD, and sagittal balance in the following section.

7.3.1.1 Spinal curvature

Based on the most recent x-rays taken with and without the anisotropic textile brace donned at the 3 month imaging session, spinal deformity was measured by taking the Cobb's angle. Table 7.2 shows that 4 of the 6 subjects have a slight reduction in their spinal curvature after wearing the proposed brace for 3 months with an average of an overall 1.5 degree reduction. No significant difference is found in the changes in the Cobb' s angle ($Z= -0.94$, $p= 0.44$). Due to a 5 degree measurement error, the brace is considered to have no effect in reducing the spinal curvature. As the spinal curvature progression of moderate AIS patients with a Cobb's angle between 20-29 degrees who are between 11 and 12 years old can be up to 61%, controlling their rate of spinal deterioration is also important (J Lonstein & J Carlson, 1984). Based on the findings in this study, of 6 subjects, the spinal curvature of 5 subjects are under control. The rest of the subjects, ATB006, who gets the most obvious improvement in spinal deformity in these 3 months, has mended 7.4 degrees in her primary curve through the anisotropic textile brace treatment. Although no significant reduction is found in the average

Cobb's angle, ATB006, who showed the most obvious reduction in her spinal curvature during the first 3 months of wear, reduced her primary curve by 7.4 degrees. This reduction is demonstrated by her radiographic image without wearing the proposed brace (see Table 7.1). In comparison with the functional intimate apparel in Fok (2020), this reduction at the 3rd month of intervention (32%) is less than that of the subject in Fok (2020) (52.7%). Yet, the proposed brace has a better performance than SpineCor and the rigid braces in comparison, which only showed a 17.4% and 12.3% reduction in curvature after 3 months of bracing treatment (Wong et al., 2008). Therefore, the proposed brace can still be used to predict the bracing outcomes for a long-term treatment since this case with the highest correction of the curvature also had the best initial in-brace reduction of the spinal curvature in the preliminary 2-hour wear trial (35.9%). In other words, this subject with double curves showed the highest rate of spinal curvature reduction both in the initial in-brace wear and 3-month radiograph of her spine without the brace donned, which is different from the best case in Fok (2020) who only had a single thoracolumbar curve. This might be because the amount of interface pressure applied in this study follows the simulation results of the FE model in Fok (2020) that had not been exactly administered to the subjects in that study.

In contrast, almost all of the other subjects only showed a 0.2 to 2.1 degree reduction in their spinal curvature whereas ATB001 and ATB007 even had an increase of 0.8 and 1.6 degrees in their spinal curvature respectively. This corresponds to a rate of 0.9% to 6.7% in spinal curvature reduction, and 3.8% to 7.3% in spinal curvature progression. Even if their initial rate of in-brace spinal curvature reduction ranged from 26.7% to 34.1%, no subject showed a reduction of 5 degrees or more after 3 months of bracing. As such, no effect can be found at the 3 month mark of the intervention in this study, taking into consideration that the measurement error is 5 degrees, with the exception of

ATB006. Unfortunately, ATB005, who showed the highest reduction of 9.8 degrees in her Cobb's angle based on the initial in-brace measurements, only experienced a reduction of 2.1 degrees after three months of bracing (6.7%). Her problem of listing to one side might be one of the potential reasons as ATB007, who also lists to one side, showed a relatively low reduction of her scoliotic spine despite a 34.1% reduction (7.5 degrees) in her spinal curvature after the 2-hour wear trial. Other reasons like compliance with the brace wear will be discussed in a later section.

Even through after three months of bracing, ATB001 was unable to achieve a satisfying level of spinal curvature reduction, her in-brace radiograph showed that a similar reduction of her spinal curvature is found as that after she underwent the 2-hour long intervention (Figure 7.2). This implies that the proposed anisotropic textile brace still has a corrective effect on her scoliotic spine when she wore the brace. Thus, her continued participation in the clinical trial was recommended so as to minimize the chances of further progression of the spinal curvature. However, this situation has not been found in the other cases at their 3-month mark. Among the 3 other subjects with a slight reduction in their spinal curvature, their in-brace correction after 3-months of bracing only ranges from 0.2 to 3.3 degrees, which is not even similar to their initial in-brace performance in the 2-hour wear trial. The corrective ability of the proposed brace is thus considered to be ineffective after 3 months of bracing. The proposed brace can only prevent further progression of the spinal curvature. As monitoring was carried out periodically for each subject, both brace fit and amount of exerted interface pressure were the focus in every single follow-up session. Therefore, the potential loss of the corrective effect of the proposed brace cannot be a factor. Thus, further studies are needed in the future to address this finding.

Due to limitations in time and the restrictions of the COVID-19 pandemic during this study, the subjects could only participate in 3 months of bracing with the exception of ATB001 who completed 6 months of bracing treatment. Her spinal curvature slightly reduced from 21.8 (3rd month) to 20.3 degrees (6th month) after bracing for 3 additional months for a reduction of 1.5 degrees in her Cobb's angle. However, these results cannot testify to the efficacy of the proposed brace as the degree of change is still under 5 degrees.

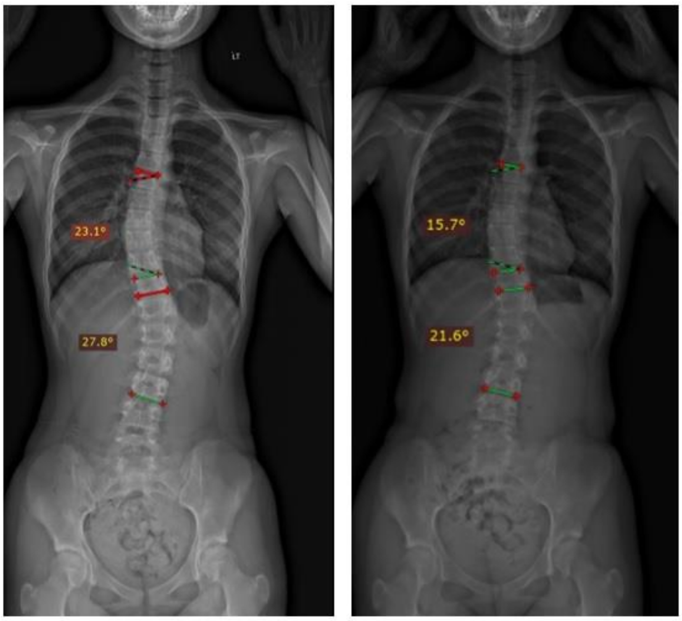
Coillard et al. (2003) and Wong et al. (2008) pointed out that some of the subjects in their clinical trial show an increase of >5° in the Cobb's angle after the 6th month of intervention with the SpineCor. A significantly poorer bracing outcome in terms of the spinal curvature control and reduction was even found in comparison to the use of rigid orthoses for a period of 45 months of observation (Wong et al., 2008). Thus, the long-term bracing efficacy of the proposed anisotropic textile brace is questionable.

Table 7.2 The bracing effect on spinal curvature at clinical trial

(to be continued in the next page)

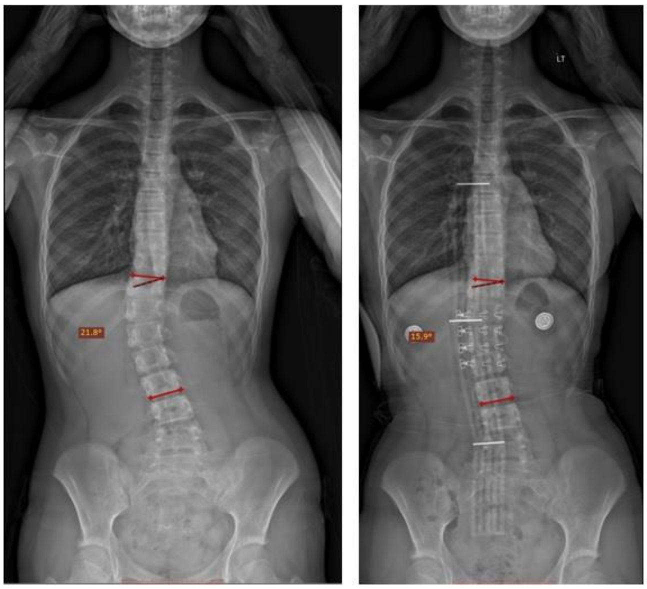
Subject code	Risser sign	Lenke type	Type of scoliotic curve	Curve range	Apex	Cobb's angle (°)					
						Pre-treatment	2-hour wear trial	3 month follow-up (3rd month)		Reduction of spinal curvature (degrees)	Increase in spinal curvature (degrees)
						No brace	In-brace	No brace	In-brace	No brace (Pre & 3-month)	
ATB001	0	5BN	Right thoracolumbar	T11-L3	L1	21.0	15.4	21.8	15.9	N/A	0.8
ATB003	0	5CN	Left	T10-L3	T12	22.2	15.2	20.8	20.4	1.4	N/A

			thoracolumbar								
ATB004	2	3BN	Right thoracic Left lumbar	T6-T11 T12-L5	T9 L1	21.8/ 16.7	16.2/ 18.3	21.6/ 19.7	18.3/ 19.6	0.2 (Thoracic)	3.0 (Lumbar)
ATB005	0	5CN	Left thoracolumbar	T10-L3	T12	31.3	21.5	29.2	29.0	2.1	N/A
ATB006	0	1BN	Right thoracic Left lumbar	T6-T11 T11-L3	T9 L1	23.1/ 27.8	14.8/ 22.4	15.7/ 21.6	11.2/ 22.9	7.4 (Thoracic) 6.2 (Lumbar)	N/A
ATB007	0	5CN	Left thoracolumbar	T11-L2	T12	22.0	14.5	23.6		N/A	1.6



Pre-treatment **After 3-month bracing (Out-brace)**

Figure 7.1 Bracing effect after 3 months of using proposed brace



After 3-month bracing (Out-brace) **After 3-month bracing (In-brace)**

Figure 7.2 The in-brace radiographs of ATB001 in 3rd month of intervention

7.3.1.2 Coronal compensation

In comparing the CD measured pre-treatment and post-treatment (after 3 months of bracing), 4 of the 6 subjects showed improved coronal balance after 3 months with an average improvement of 0.38 cm; see Figure 7.3. Yet, no significant difference is found in the coronal compensation before and after 3 months of bracing ($Z= -1.15$, $p= 0.25$). ATB005 and ATB007, who both list to one side, also show a 1.7 cm and higher coronal balance improvement. The most recent radiographs of the subjects showed that half of them have coronal misalignment, including ATB001, ATB006 and ATB007. An immensely improved coronal balance is found with ATB004 and ATB005, with improvement of 71.7% and 47.8% respectively. The coronal imbalance of the latter has been greatly reduced from -3.64 to -1.9 cm, so that the imbalance is within a normal range instead. Surprisingly, such findings do not correspond to a reduction in the Cobb's angle. ATB006 has the worst performance in terms of the coronal compensation, but also showed the greatest reduction in her spinal curvature after 3-months of intervention.

Furthermore, it is shown that the coronal compensation after 2-hour of bracing intervention cannot exactly predict the outcomes of the 3-month bracing. For instance, ATB001 showed an 80.4% improvement in coronal balance after 2-hour intervention that presents a reduction from 1.43 cm to 0.28 cm but 43.4% increase in her coronal imbalance is found after 3-month bracing. Meanwhile, the progression of the coronal balance found in the preliminary wear trial is also halted after prolonged periods of bracing, such as with ATB003, ATB004 and ATB007.

In addition, Figure 7.3 shows that the coronal imbalance caused by donning the proposed brace can no longer affect their performance when the brace is not worn for the same factors. The coronal imbalance of ATB003, ATB004 and ATB005 is further corrected even if the latest in-brace performance is not as satisfactory as the performance without the brace. Similar findings can also be found with ATB001 who completed the 6 months of the clinical trial. Her coronal balance at the 6th month of intervention is much more aligned than it was in the 3rd month of treatment, even though her coronal balance after 3 months in the in-brace condition is worse than that in the 6th month of intervention.

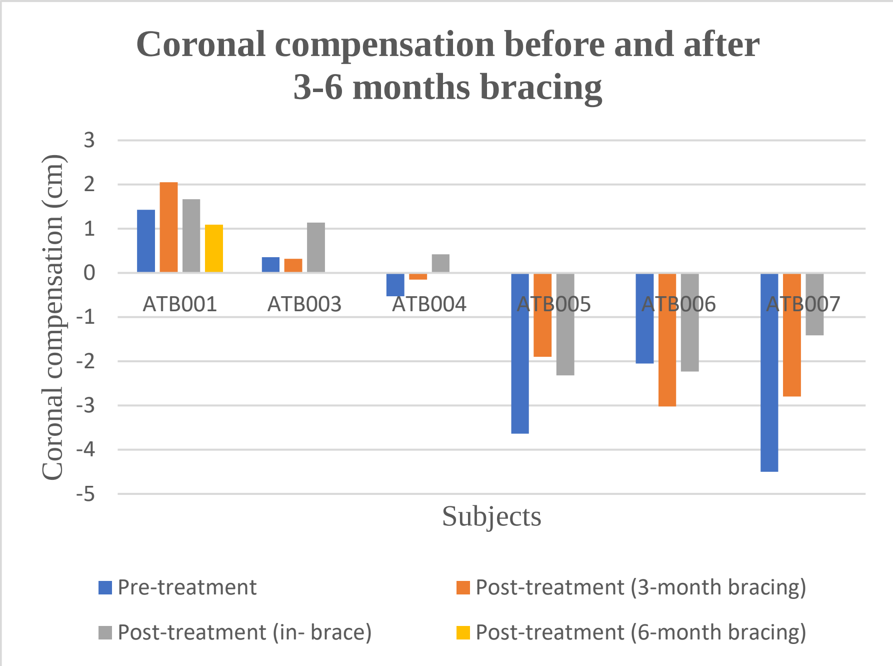


Figure 7.3 Bracing effect on coronal balance after 3-6 month

7.3.1.3 Sagittal balance

As for the sagittal balance, almost all of the subjects have a worse sagittal imbalance after 3 months of bracing, except for ATB005 (Figure 7.4). The average increase in sagittal balance is 0.42 cm but no significant difference is detected, Z= -0.41, p= 0.69, as same as the coronal compensation. Unfortunately, while ATB004 showed an immensely improved sagittal balance during the 2-hour intervention, she could not maintain the balance after 3 months of bracing. The sagittal imbalance further increased from -5.26 to -7.72 cm for her, which is still in the abnormal range. Apart from ATB004, three other subjects - ATB001, ATB003, and ATB006 also have the same problem. They have a greater sagittal imbalance after 3 months of bracing. This might be because the proposed brace cannot correct the sagittal imbalance for a longer period of time, especially for cases with inherent lordosis like ATB004.

Such deterioration (greater sagittal imbalance) cannot be remedied in all of the cases of this study even when the proposed brace is worn, such as ATB003 and ATB005. The reasons need to be further studied.

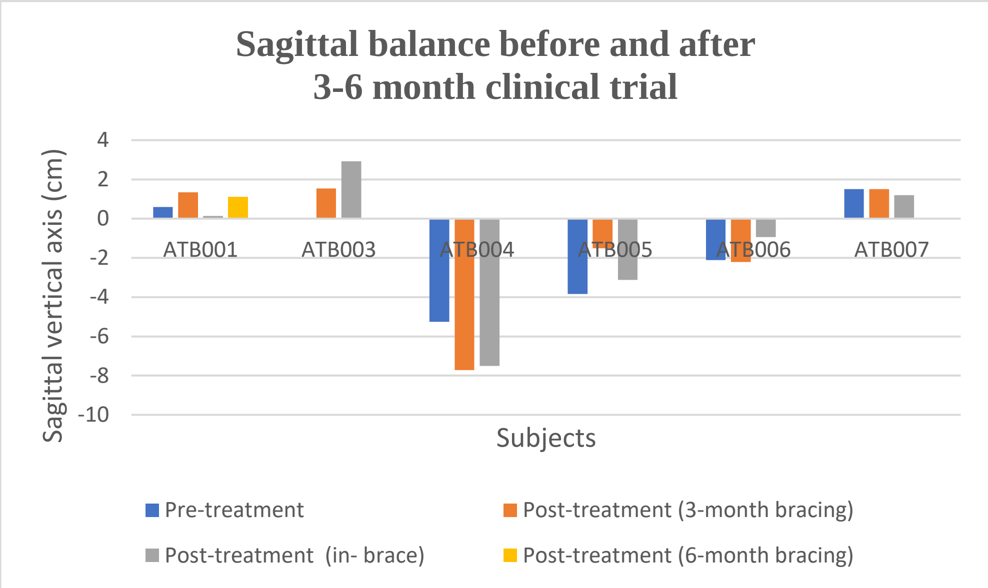


Figure 7.4 Bracing effect 3-6 month after treatment on sagittal balance

7.3.2 Changes in body contours during periodical monitoring

As with the preliminary 2-hour wear trial, the shoulder obliquity, shoulder rotation and POTSI values at different time points were measured, which are compared in the following section.

7.3.2.1 Shoulder obliquity

As shown in Figure 7.5, the shoulder obliquity overall is reduced by 0.41° after short-term bracing without significant difference (Z= -0.52, p= 0.60). Among the 6 subjects, half of them show no reduction in shoulder obliquity after 3 months of bracing, including ATB006 who shows the highest reduction in her Cobb's angle. ATB006 reduces her Cobb's angle by 32% as mentioned above. Meanwhile, it was found that her shoulder obliquity significantly worsened from 0.35 to 1.58°. Even if she wore the proposed brace for three months, her imbalance could not be corrected which led to her pre-treatment situation. A similar phenomenon is also stated as the best case in Fok (2020), whose subject showed a more severe shoulder obliquity after 3 months of bracing. The finding here is also in agreement with a previous clinical study by Kotwicki et al. (2007) as mentioned in the previous chapter of the preliminary wear trial that shoulder imbalance during bracing cannot be avoided.

Moreover, the tendency of such obliquity in the 3rd month of intervention cannot be predicted based on the 2-hour intervention as the shoulder obliquity of ATB001 and ATB003 is improved by over 40% whereas their performance is the opposite in the 3-month trial.

As for ATB001 who completed the 6-month bracing treatment, her shoulder obliquity is reduced by 2.2° in the 3rd month of intervention and finally remained constant at around 2.6° in the 6th month of bracing. Therefore, the use of the proposed anisotropic textile brace can reduce the shoulder obliquity, or even permanently correct the obliquity after short-term bracing.

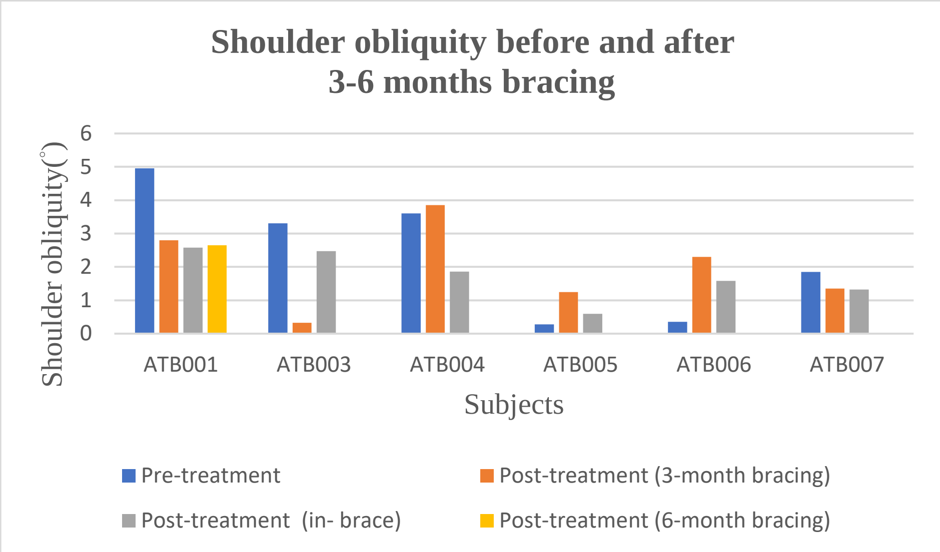


Figure 7.5 The 3-6 month bracing effect on shoulder obliquity

7.3.2.2 Shoulder rotation

With regard to shoulder rotation, Figure 7.6 shows an average reduction of 0.46° in the 3-month clinical trial with no significant difference (Z= -0.73, p= 0.46). The largest extent of reducing the shoulder rotation in this trial is also observed with ATB006. As discussed earlier, ATB006 has the largest reduction in spinal curvature. However, this improvement did not extend to her shoulder rotation after 3 months of bracing which is increased from 0.96° to 4°. In the meantime, ATB004 with a slight increase in her Cobb's angle showed an excellent outcome with even shoulders at the 3-month imaging session. This is equivalent to the findings of her shoulder obliquity which implies that there might not be a positive correlation between the Cobb's angle and shoulder orientation with short-term bracing treatment. In contrast, such a correlation with shoulder rotation can be found between preliminary wear trial and 3-month trial which can be potentially taken as prediction of the effectiveness of the anisotropic textile brace. However, it may not be applicable to the functional intimate apparel in Fok (2020) since the case in her study did not show a consistent change in shoulder rotation before and after the 3-month bracing process.

Compared to the functional intimate apparel in Fok (2020) (reduction of 1.4°), the highest reduction in shoulder rotation in this study is 5.6°. Yet, this is just a single case. Generally, the proposed brace can only provide a small reduction in shoulder rotation after 3-months of intervention. Perhaps there might be a greater reduction with a longer period of bracing. This is evidenced by the greater reduction in shoulder rotation after 6-months of bracing in the case of ATB001.

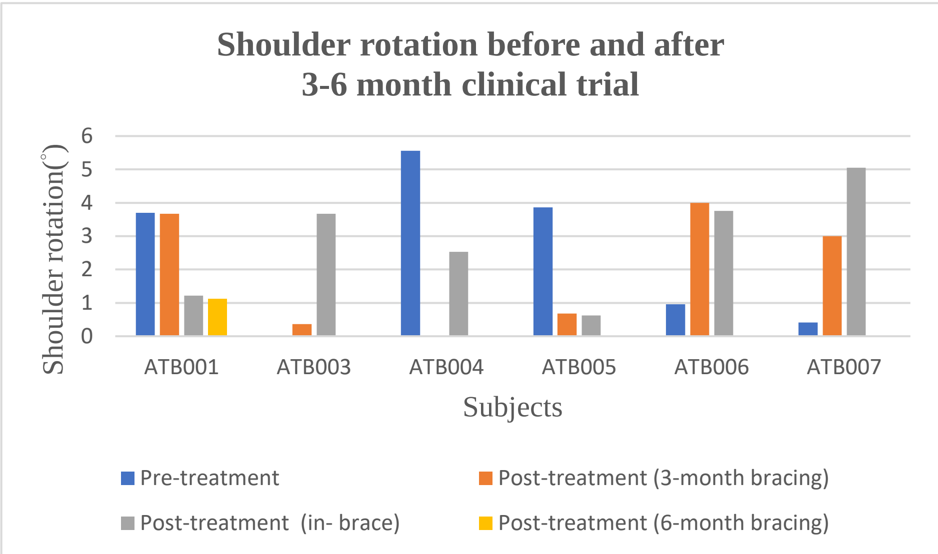


Figure 7.6 Bracing effect on shoulder rotation

7.3.2.3 POTSI

Aside from periodical monitoring of the changes in the shoulder orientation, the POTSI values were also obtained at every single follow-up session to analyze the differences at various time points. At the beginning of the clinical trial, the POTSI value of the 6 recruited subjects ranged from 11.2 to 75.7, with a mean index of 36.9 (SD= 21.4). Following the principles of POTSI, in which a higher POTSI means a greater likelihood of asymmetry in body contours, a normal POTSI value should be below 27 but 4 of the 6 subjects in this study have a higher value which shows asymmetry of the back. They are ATB001, ATB003, ATB005, and ATB007. Surprisingly, it was found that there is a commonality among their cases. All of them have a single curve. Their scoliotic spine tends to curve to one side whereas the subject with double curves does not have an asymmetry problem due to the compensating curve. Uneven body contours might thus be more likely found in the cases with a single curve. Figure 7.7 shows that there is no linear and predictable trend in the 3-6 month clinical trial and no significant difference ($p>0.05$). At the 3rd month of intervention, the problem of the asymmetry of the body is no longer an issue for half of the cases but no consistent changes are found at their 1st and 2nd months of intervention. All of the cases with a single curve have a reduced POTSI value on average of 11.1 after 3 months of bracing which demonstrates some improvement. In contrast, the problem with asymmetry is exacerbated in cases with an S-curve (ATB004 and ATB006) as these individuals have symmetry of the back before treatment. Even though ATB006 shows the highest reduction in spinal curvature after 3 months of bracing, her trunk asymmetry is also increased from 11.2 to 44.3. Such a significant difference shows that there might not be a correlation between the Cobb's angle and POTSI value in individuals with double curves and initial body contour symmetry. A similar situation is also found with ATB001 in her 6th month of intervention. Her spinal curvature was under control during the 6 months of bracing but her POTSI value suddenly increased from 19.1 to 33, which is in an abnormal range again without reason. In comparing her body symmetry before treatment, her more recent POTSI value nevertheless has improved slightly.

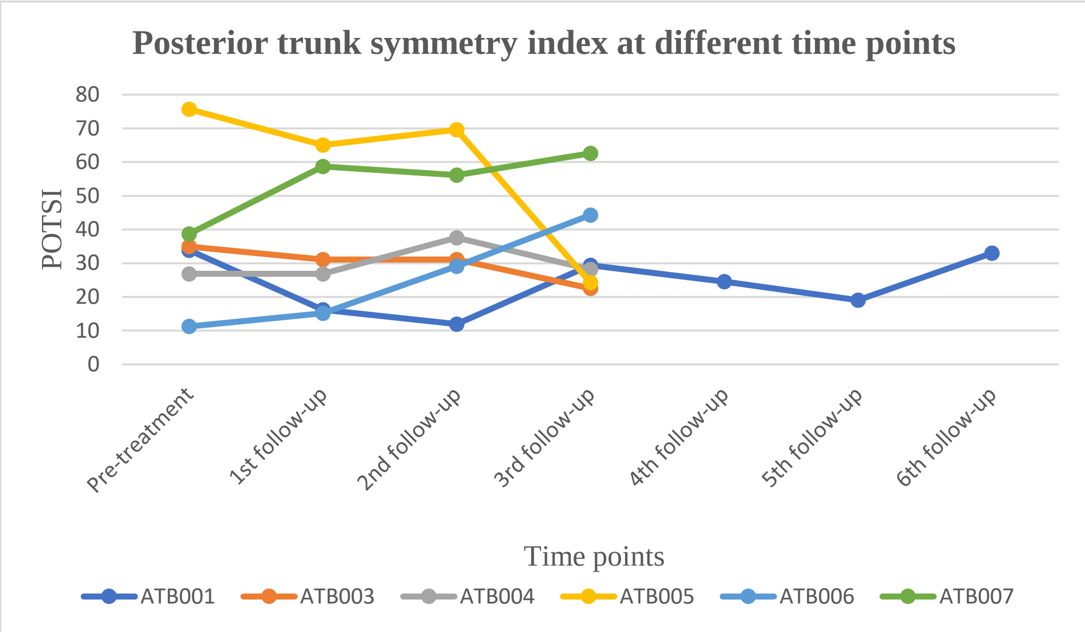


Figure 7.7 Posterior trunk symmetry index at different time points

7.3.3 Changes in sitting posture during periodical monitoring

As there are few studies that focus on monitoring the sitting posture of scoliotic subjects by analyzing the distributed pressure on their body while sitting, a pilot study was carried out to investigate if there is any correlation between them. After that, the measure would be applied to monitor the changes in the sitting posture of the subjects in the 3-6 month clinical trial as a periodical check.

7.3.3.1 Prior study for scoliotic and non-scoliotic subjects

To identify the potential differences in sitting posture between those who are scoliotic versus those who are not, 24 subjects from the school screening programme between 10 and 13 years old were invited to participate in the pilot study. Among them, 11 do not have scoliosis. Their Cobb's angle is less than 10 degrees. However, 13 of them are scoliosis patients with a Cobb's angle above 10 degrees. The Cobb's angle between the 2 groups shows a statistical significant difference (p=0.000) but no significant difference is found among the tested subjects in terms of their age, height, weight and BMI ($p>0.05$).

As mentioned in the Chapter 3, a pressure mat was utilized to collect the pressure distribution of the tested subjects. Based on the agreement of Gram and Hasan (1999) and Smidt et al. (1994), the first 10 minutes of measurements were not considered. To study the habitual sitting posture of the subjects, their measurement in the 11^{th} to 12^{th} minutes of static sitting was observed. Table 7.3 shows the mean peak pressure distribution in 4 areas of the buttocks and thighs of the subject, while Table 7.4 lists the results of the paired samples T-test to investigate the pressure differences between left and right sides. No significant differences can be found in the buttock and thigh regions on the left and right sides of the body of the group without scoliosis ($p=0.123$, and $p= 0.186$). However, the pressure distribution is statistically significant in the scoliotic group; $t(12)= 3.49$, $p= 0.04$. Even though the pressure distribution in the thigh region is found to have no significant differences, the pressure distribution in their buttocks can be potentially used to classify them as non-scoliotic or scoliotic. These findings show the situation of their sitting posture which is the tendency to lean on one side during sitting.

Table 7.3 Pressure distribution in bottom body parts of subjects

Group	N=	Region	Mean peak pressure (kPa)	S.D.
Non-Scoliotic	11	Left buttock	25.58	13.42
		Right buttock	20.21	10.29
		Left thigh	9.05	4.23
		Right thigh	7.94	3.68
Scoliotic	13	Left buttock	30.80	11.44
		Right buttock	21.56	12.01
		Left thigh	11.62	7.13
		Right thigh	10.07	5.46

Table 7.4 Results of paired samples T-test for subjects

Group	N=	Pair	Region	Mean difference of peak pressure (kPa)	S.D.	Statistical significance (p<0.05)
Non-Scoliotic	11	Pair 1	Left buttock Right buttock	5.376	10.575	0.123
		Pair 2	Left thigh Right thigh	1.107	2.584	0.186
scoliotic	13	Pair 1	Left buttock Right buttock	9.232	9.546	0.004
		Pair 2	Left thigh Right thigh	1.543	4.469	0.237

In order to further determine the correlation between the spinal convexity and the pressure distribution of the left and right sides of the body, all of the subjects who have scoliosis were separated into two groups based on their spinal convexity. The convexity of the lumbar curve was examined for those with double curves. Table 7.5 shows that the subjects with a left convex curve show a significant difference in the mean peak pressure on their left and right buttocks with a large effect size (p= 0.043) whereas no significant differences are found in the other regions, including the thighs. No significant differences are found for all of the regions in the group with a right convex curve. However, the small sample means that the correlation between the pressure distribution and extent of spinal deformity in the AIS subjects could not be further evaluated. Following the findings in this pilot study, it is assumed that a more even pressure distribution between the left and right buttocks means a better sitting posture. This assumption is also made for the 3-6 month clinical trial with the aim to investigate the changes in the sitting posture of the subjects during their bracing treatment.

Table 7.5 Results of paired samples T-test for left and right convexity

Group	N=	Pair	Region	Mean difference of peak pressure (kPa)	S.D.	Statistical significance ($p<0.05$)
Left convex curve	7	Pair 1	Left buttock Right buttock	7.985	8.232	0.043
		Pair 2	Left thigh Right thigh	1.665	5.821	0.478
Right convex curve	6	Pair 1	Left buttock Right buttock	10.612	4.687	0.073
		Pair 2	Left thigh Right thigh	2.900	3.798	0.120

7.3.3.2 Bracing effect on sitting posture

To evaluate the changes on the sitting posture of the subjects during the 3-6 month clinical trial, all of them were subjected to a posture check at each monthly follow-up. Following the assumption of the pilot study, the mean peak pressure distribution of the subjects, as well as the convexity of their single and lumbar curves are the analysis focus. In this study, all of the subjects have a scoliotic curve with left convexity except for ATB001. The convexity of the scoliotic curve might influence the pressure distribution on the left and right sides. Ideally, the convexity is then examined separately as left and right convex curves. As it is not possible to analyze the changes of a single case by using SPSS, Table 7.6 instead shows the results of paired samples T-tests of the spinal convexity and concavity for the first 3 months of follow-up instead. It is not surprising that the mean peak pressure for the thigh area of the convex and concave sides does not show a significant difference for every time point, including prior to the 3-6 month clinical trial and the last follow-up. Such findings support those in the pilot study.

In terms of the buttock region, a significant difference between their convex and concave sides is found prior to the 3-6 month clinical trial which shows an uneven pressure distribution on the buttocks ($p=0.014$) with a large effect size. This might be because the spinal convexity causes leaning to the convex side. Such a statistical significant difference with a large effect size is also found at the 1st follow-up (after they have undergone bracing for 1 month) ($p=0.019$). Yet, no further significant difference is found after that. The pressure distributed on the convex and concave sides of the buttocks is more likely to be more even at the 2nd and 3 follow-up ($p>0.05$), which shows that the sitting posture is improved after bracing has been done for a short period of time which is the assumption made in the pilot study. The effectiveness of the anisotropic textile brace might be changes in the habitual sitting posture as the data were collected when the brace was not worn. Nevertheless, the differences have no correlation with the changes in the Cobb's angle.

As for ATB001 who completed the entire 6 months of bracing, it is difficult to determine the changes in the pressure distribution by using SPSS as it is only one case. However, based on the assumption in the pilot study, using the ratio value of mean peak pressure on the convex and concave sides of the curve might be a possible way to demonstrate her results, where 1 represents a balance between the convex and concave sides. When the value approaches 1, this means that the pressure distribution between the convex and concave sides is more similar. Figure 7.8 shows the performance of ATB001 in terms of her sitting posture during the 6 months of brace wear. The pressure distribution on her buttocks between the convex and concave sides of the curve is quite even with a mean peak pressure of 0.94 at the beginning but conflicting results are found at the 3rd and 6th months, which are 0.83 and 0.71. This shows the possibility that the use of the proposed brace might not provide wearers with a long-term enhancement in the sitting posture. Nevertheless, the single case limitation and inconsistent findings of the paired samples T-test for the first 3 months of the bracing treatment mean that further studies are needed in this respect.

Table 7.6 Results of paired samples T-test

N=	Pair	Region	Mean difference of peak pressure (kPa)	S.D.	Statistical significance ($p<0.05$)
6	Pair 1 (Pre-treatment)	Convex buttock Concave buttock	8.474	5.596	0.014
	Pair 2 (1st follow-up)		10.080	7.229	0.019
	Pair 3 (2nd follow-up)		7.102	9.712	0.133
	Pair 4 (3rd follow-up)		2.2640	6.263	0.416
	Pair 5 (Pre-treatment)	Convex thigh concave thigh	0.404	3.151	0.766
	Pair 6 (1st follow-up)		0.607	1.630	0.404
	Pair 7 (2nd follow-up)		1.041	0.999	0.051
	Pair 8 (3rd follow-up)		0.672	2.886	0.593

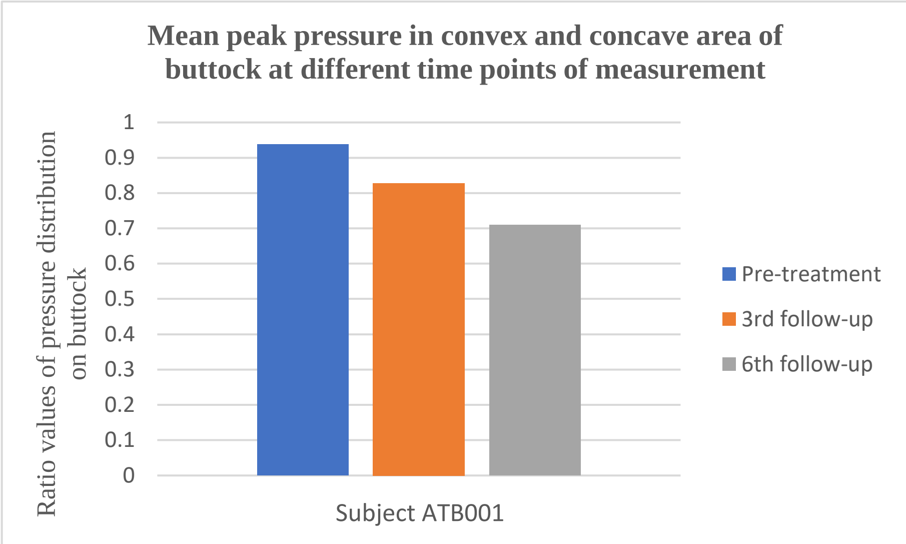


Figure 7.8 Results of sitting posture for ATB001

7.3.4 *Health-related quality-of-life assessment of 3-6 month clinical trial*

As mentioned in Chapter 3, three health-related questionnaires were administered to the subjects every three months which means that they completed questionnaires before they started the 3-6 month clinical trial, and then at the 3rd and 6th month follow-up. These questionnaires included the Chinese version of TAPS and BrQ and the SRS health related quality of life questionnaire.

7.3.4.1 *Scoliosis Research Society Questionnaire*

With regard to the SRS health related quality of life questionnaire (SRS-22), there are 5 domains involved, including function/activity, pain, self-perceived image, mental health and satisfaction. Table 7.7 lists the scores for the SRS-22 questionnaire. The total score for this questionnaire at the pre-treatment and 3rd month of intervention is 95 (out of a possible 110), which shows that the subjects perceive that their quality of life is satisfactory and has not been affected much by the bracing treatment with the anisotropic textile brace. A similar score was also obtained in Fok (2020).

The score distribution for each domain is also shown in Figure 7.9. After 3 months of bracing, the score in respect of function/ activity and satisfaction shows an obvious improvement whereas worse mental health of subjects has been reported in this study. This might be because they were still anxious about the textile brace and the progression of their spinal curvature even if they felt that the proposed brace treatment could correct the deformity of their spine. The change in the mental health of the subjects is the same as that of the subject who underwent 3 months of bracing with the functional intimate apparel in Fok (2020). However, no significant difference is found in QoL between pre-treatment and 3 months of bracing. Besides, Since only ATB001 completed 6-months of bracing, her scores might also act as a reference or used for simple predictions on the QoL of the other subjects had they completed the entire six months.

Table 7.7 Descriptive statistics of SRS-22 score for 3-6 month clinical trial

	Pre-treatment			**3rd follow-up**		
	Mean	S.D.	Range	Mean	S.D.	Range
TOTAL (22-110)	95.00	4.56	89.00-102.00	95.00	3.95	89.00-101.00
Function/activity	4.67	0.33	4.20-5.00	4.83	0.15	4.80-5.00
Pain	4.73	0.27	4.40-5.00	4.7	0.28	4.40-5.00
Self-perceived image	3.70	0.30	3.20-4.00	3.73	0.33	3.40-4.20
Mental health	4.37	0.39	4.20-5.00	4.03	0.32	3.60-4.60
Satisfaction	3.33	0.41	3.00-4.50	4.25	0.52	3.50-5.00

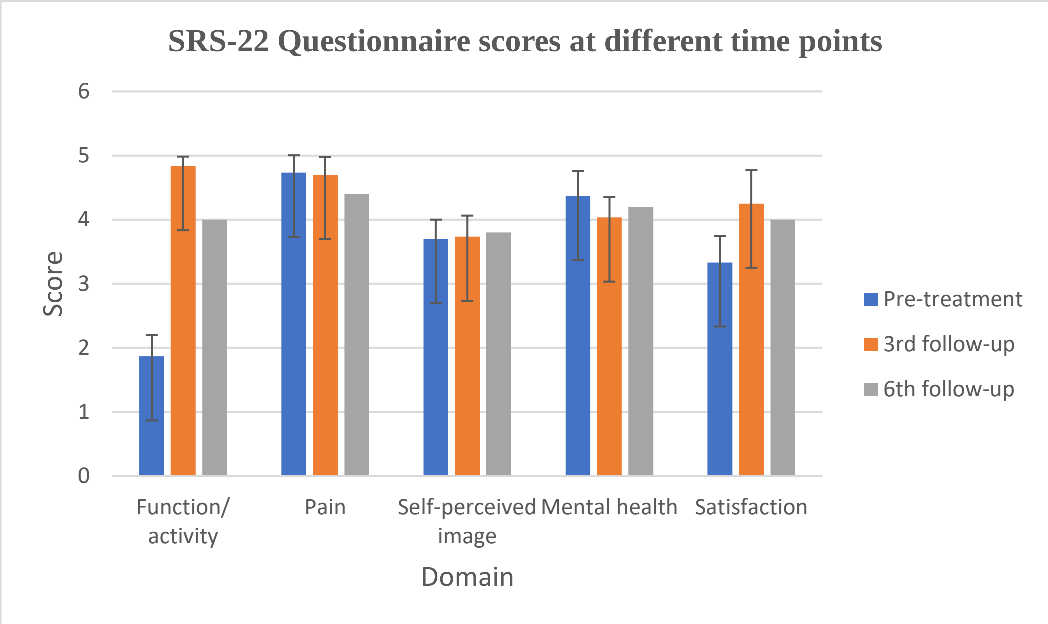


Figure 7.9 SRS-22 questionnaire for 3-6 month clinical trial

7.3.4.2 *Brace Questionnaire*

As for the BrQ, the scores at the preliminary wear trial and 3rd month of intervention were compared with the aim to understand the differences in quality of life during these 3-6 month of bracing treatment, including how the subjects perceived their general health perception, physical functioning, emotional functioning, self-esteem and aesthetics, vitality, effects on school activities, bodily pain, and social functioning. Table 7.8 lists the overall score of the subjects after 3-month bracing is 86.96 and therefore slightly higher than that at the onset of the 3-6 month clinical trial (83.03), and this holds true for 4 domains in particular: physical functioning, self-esteem and aesthetics, vitality, and social functioning, in which a significant difference is found for physical functioning (p=0.031). This difference might show that wearing the proposed anisotropic textile brace does not have much of a negative effect on the quality of life of wearers. However, the brace might even enhance their wear experience, such as donning and doffing the brace independently, as well as enhance positive feelings while wearing the brace. The explanation might be that they become used to wearing the proposed brace which helps them to adapt to the tightness of the brace, as well as having the ability to don and doff the brace without help from others. As such, they would feel less inconvenienced and burdened due to bracing.

Table 7.8 Descriptive statistics of BrQ score for 3-6 month clinical trial

	After preliminary wear trial			**3rd follow-up**		
	Mean	S.D.	Range	Mean	S.D.	Range
Overall score (20-100)	83.03	3.82	75.88-86.47	86.96	4.22	80.59-92.35
General health perception	4.21	0.39	4.00-4.50	3.83	0.26	3.50-4.50
Physical functioning	3.41	0.68	3.15-3.86	4.33	0.60	3.57-5.00
Emotional functioning	4.29	0.45	3.60-5.00	4.00	0.28	3.60-4.40
Self-esteem and aesthetics	2.29	1.07	1.00-3.50	2.67	0.61	2.00-3.50
Vitality	3.29	1.15	1.00-4.50	3.75	0.27	3.50-4.00
School activity	4.71	0.40	3.00-5.00	4.67	0.52	3.67-5.00
Bodily pain	4.83	0.22	4.17-5.00	4.83	0.33	4.17-5.00
Social functioning	4.84	0.32	4.71-5.00	4.86	0.18	4.57-5.00

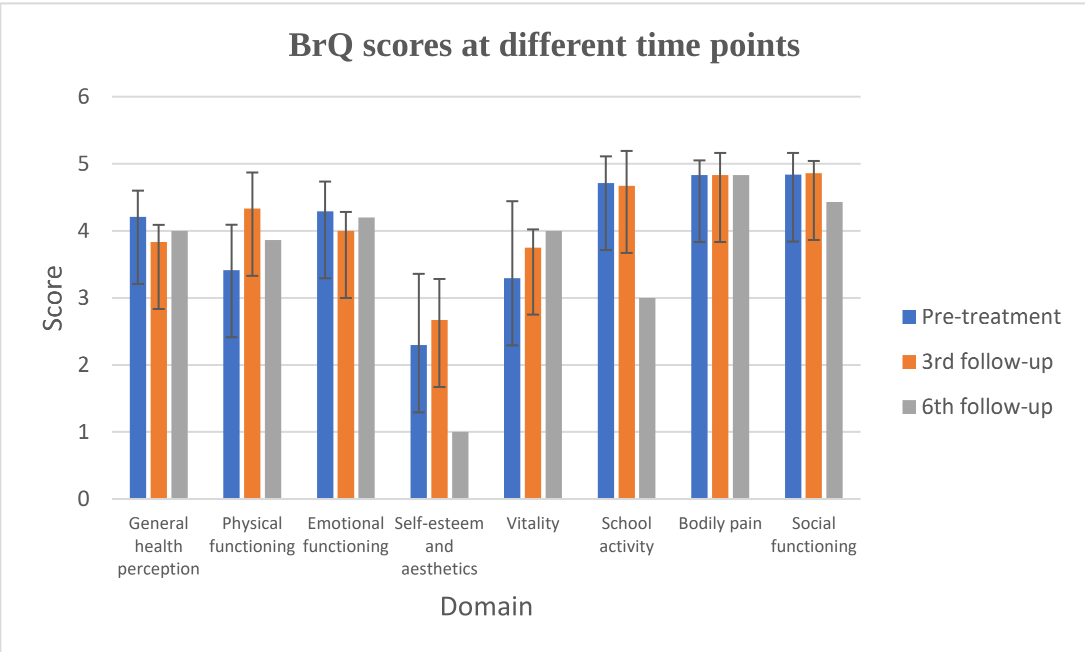


Figure 7.10 BrQ scores for 3-6 month clinical trial

7.3.4.3 *The Trunk Appearance Perception Scale*

Aside from the SRS-22 questionnaire and BrQ, the TAPS questionnaire was allocated to the subjects before they started the 3-6 month clinical trial, and at the 3rd and 6th month follow-up. The total average score before and after the bracing intervention is 3.9 and 3.56, respectively (Table 7.9). They are both similar without a significant difference. A significant difference is also not found for all three questionnaires administered before and after the bracing intervention which implies that the 3-6 month clinical trial has neither improved nor worsened the perception of the subjects of their body contours. As only one questionnaire, the SRS-22, was administered in the 3-month bracing treatment in Fok (2020), no comparison can be made with the proposed brace in this study. The TAPS scores of the Boston brace treatment in Chan, Cheung, Luk, Wong, and Wong (2014) at pre-bracing and after 4-6 months of intervention are also similar, which is in agreement with the results of the wear trial in this study.

Table 7.9 Descriptive statistics of TAPS score for 3-6 month clinical trial

	Pre-treatment			**3rd follow-up**		
	Mean	S.D.	Range	Mean	S.D.	Range
Total score (1-5)	3.90	0.44	2.00-5.00	3.56	0.096	3.50-3.67
TAPS Question 1	3.43	0.98	2.00-5.00	3.5	0.84	2.00-4.00
TAPS Question 2	4.39	0.76	3.00-5.00	3.7	1.03	2.00-5.00
TAPS Question 3	4.00	0.82	3.00-5.00	3.5	1.05	2.00-5.00

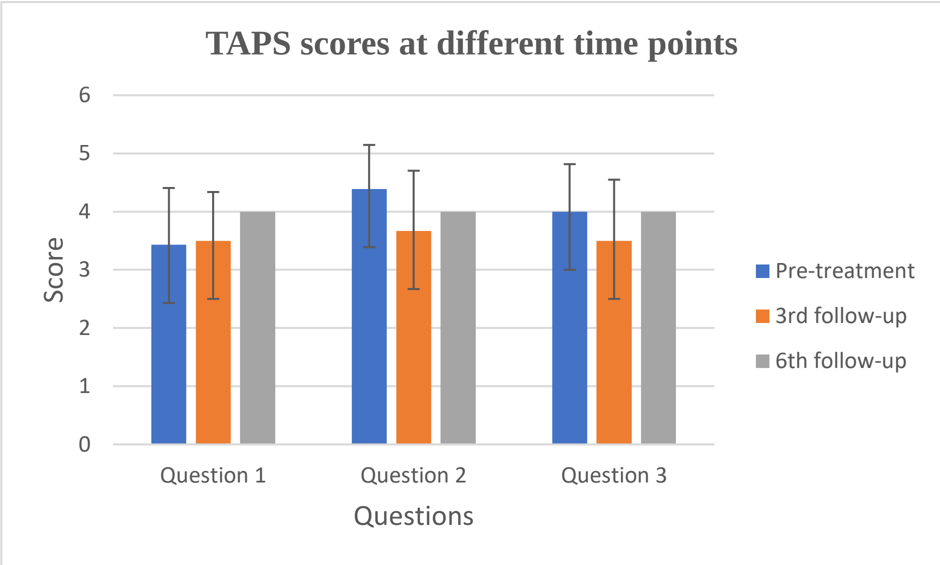


Figure 7.11 TAPS scores during 3-6 month clinical trial

7.3.5 Compliance rate monitoring

To monitor the brace wear time of each subject, the compliance rate of wear with the proposed anisotropic textile brace during the 3-6 month clinical trial was calculated and is plotted in Figure 7.12. The average overall rate of compliance with the proposed brace is 73.8% which shows a higher receptivity of the brace as opposed to the SpineCor (54%) (Hasler et al., 2010), and Chêneau (67.5%) (Helfenstein et al., 2006) braces. In this study, all of the subjects show at least a 69% compliance rate except for ATB007, with only 29.4%. This fluctuation in compliance was also found at the 2nd monthly follow-up, where the lowest compliance rate of 24.7% and the highest rate of 100% are found.

As for ATB007 who did not comply with the bracing requirements, the reason might be attributed to her lack of concern around spinal curvature progression which is demonstrated in her BrQ score. As she does not give much thought to further progression of the spinal deformity, her rate of compliance continuously declined in her 2nd and 3rd months of bracing. Although the others also suddenly reduced their wear time in the 3rd month of bracing, the reasons for doing so might not be the same as those of ATB007. After interviewing the subjects, it was found that they all have different reasons. For example, some of the subjects did not wear the brace during their menstrual period even though the anisotropic textile brace is designed without a crotch. Besides, the subjects were required to take off the brace during exercise so ATB001 often went hiking as this is an acceptable social distancing activity with the COVID-19 pandemic restrictions but did so without wearing the brace. ATB003 did not wear hers when she was preparing for her school exams. These reasons are not related to wear-comfort or limitations of the brace design but their personal preferences. However, ATB005 did not wear her brace during the day since she felt that it would be a waste of time to put on the brace before her lessons with the risk of exposing the brace underneath her school uniform. This is in agreement with a finding in Chan et al. (2014) that the lack of compliance with orthotic treatment could have a psychological element.

The bracing outcomes show that short-term bracing effects are most likely reflected in treatment compliance, which is in agreement with Aulisa et al. (2014), Weinstein, Dolan, Wright, and Dobbs (2013), and Brox, Lange, Gunderson, and Steen (2012). In this study, ATB006 has reduced her spinal curvature the most after 3 months of bracing treatment (32%) whereas ATB007 has the poorest performance and even increased her spinal curvature by 7.3%. The former complied more with the treatment than the latter, at a rate of compliance of 94.8% and 41.7% with an average of 98.3% and 29.4% respectively. Even if the progression of the spinal curvature tends to be slower for subjects who complied more with treatment, it might not be effective for all wearers, notably ATB004. Her average compliance rate is 97.4% but she only showed a reduction of 0.9% in her curvature at the 3 month point which might be due to her relative skeletal maturity (Risser 2). After all, a higher Risser sign means more skeletal maturity with a relatively higher stabilization of the curvature and lower incidence of curve progression (Karol, Virostek, Felton, Jo, & Butler, 2016; JE. Lonstein & JM. Carlson, 1984). Nevertheless, the results of ATB006, ATB004 and ATB007 might even be perfectly explained by their initial in-brace correction level (35.9%, 25.7% and 34.1%, respectively). Landauer, Wimmer, and Behensky (2003) stated that compliant patients with a high initial in-brace correction can reach around a 7° reduction in their Cobb's angle, while compliant patients with low initial in-brace correction might only halt the curve progression after bracing instead of significantly reducing their Cobb's angle. Therefore, patients who do not comply with treatment like ATB007 might find that the curvature of their spine will progress in severity.

Some of the previous studies have highlighted correlations between brace compliance and the QoL of wearers, such as Chan et al. (2014), but no significant difference is found in this aspect here.

The brace compliance of ATB001 is plotted in Figure 7.12. It can be observed that her compliance rate gradually increased to 100% at the 4^{th} to 6^{th} months of intervention. She stated that her compliance increased because she has made it a habit to wear the brace on a daily basis and especially because it was in the fall season. Brace users tend to be more willing to wear their brace in cooler weather because it is less uncomfortable. However, the validity of this trend needs to be further examined.

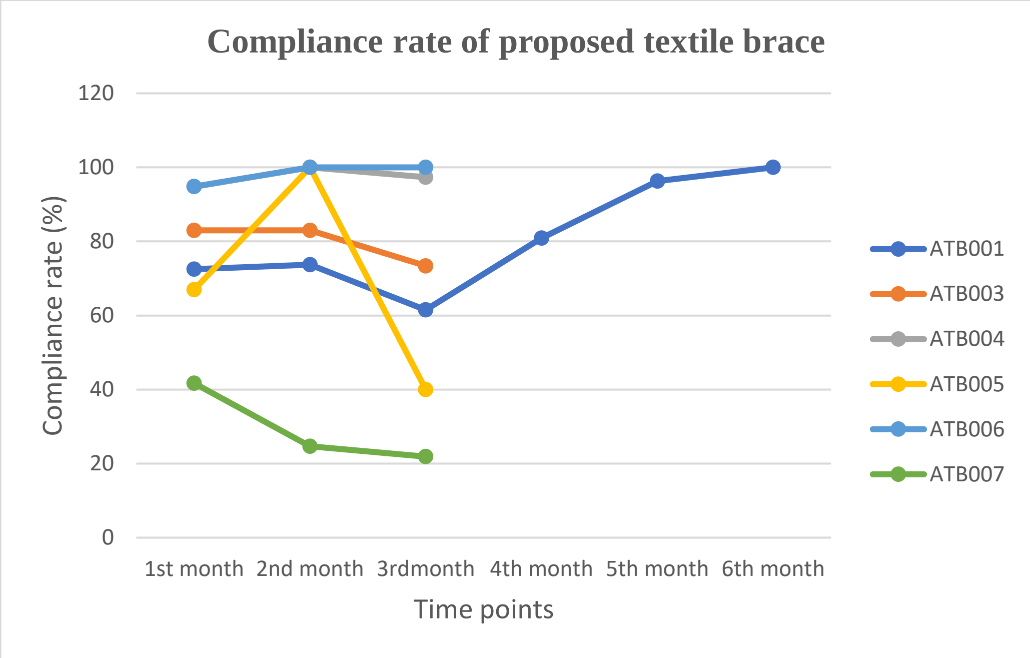


Figure 7.12 Compliance rate of proposed anisotropic textile brace

7.3.6 User feedback of 3-6 month clinical trial

To understand the wear experience of the end-users and the limitations of the proposed brace design, some questions were asked in a short interview at every third month of bracing. At the 3rd month follow-up session, all of the subjects stated that in general, they had no negative feelings during bracing, except:

"The artificial hinged back bone is annoying and weak, so that it makes noise very often and even easily broke after prolonged usage". (ATB001, 004, 005 and 006 said)

As the size of the carbon fibres slightly increased after moisture absorption from the atmosphere, the pin holes of the hinges in the artificial back bone were reduced in size and increased the friction between the pin hole and the slots of the leaf which might produce noise during daily movement. Moreover, the pin inserted in the hinges is made of iron. Therefore, the pin might rust due to the humidity from body sweat which might also result in noise while the subjects are bending. As a result, the noise is annoying and embarrassing to the users.

Even if hinges of the artificial back bone have an outstanding tensile strength, as stated in Fok (2020), the strength might be reduced due to increasing internal stress caused by moisture absorption. In addition, the hinged back bone is produced by binding polymer with epoxy and using layers of carbon fibres. These layers might increase the formation of weak points as well, especially on the hinges. The hinges could therefore break (see Figure 7.13). According to the feedback of the subjects, breakage occurred with the use of the brace after around 1 to 2 months. When the subjects in this study reported the damage, a new back bone was provided immediately. However, this problem is not acceptable for long-term bracing treatment and further studies are needed to examine the use of stainless steel pins instead of iron pins and even determine if another non-metallic material can be used to replace the carbon fibre.

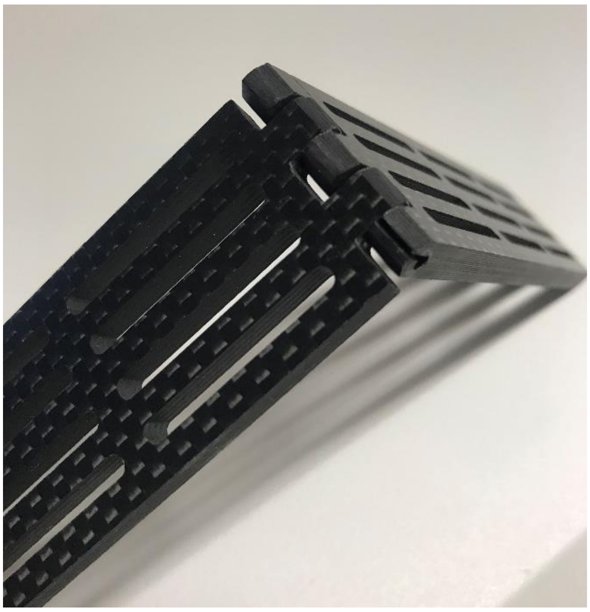


Figure 7.13 Broken hinge

Aside from the durability of the hinges, subjects pointed out that:

"The hinged back bone does not always fit on my back". (ATB001 and 006 said)

In the artificial back bone design, four hinges are connected together, in which the length of each piece ranges from 4.5 to 14.5 cm. Even though these hinges allow the rigid back bone to bend following the body contours of the wearers, the contraption does not always fit well on the centre of their back (Figure 7.14). The subjects might be embarrassed if the upper hinge can be seen underneath their school uniform after they bend over. To cope with this problem, it is recommended that the hinged back bone consists of more pieces so that the contraption can be easily fitted on wearers with different body profiles. Yet, the mechanical properties of this recommended version might not be sufficient enough to withstand the lateral forces that the corrective components are supposed to resist, so that its modification should be investigated in future studies.

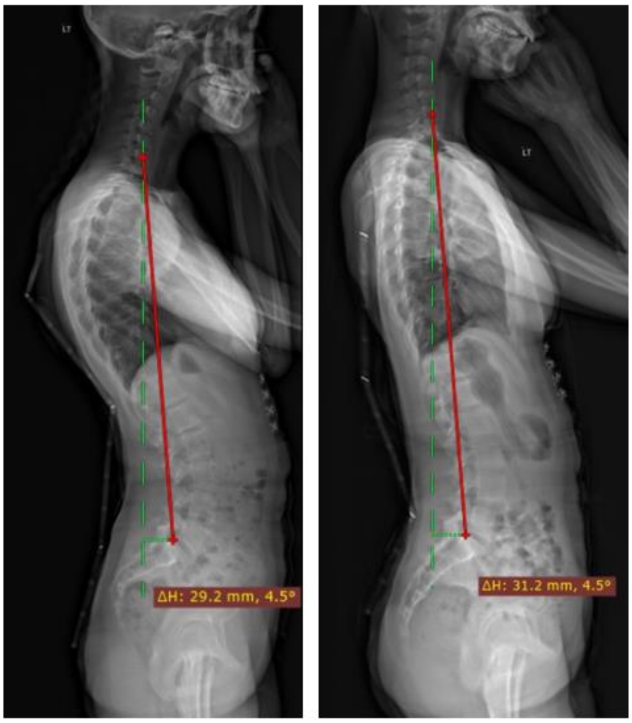


Figure 7.14 Fit problem of hinges on artificial back bone

With respect to the opinions of the peers of the subjects, no negative wear experience is found among the subjects in general. In this study, one of subjects did not wear her brace to school as she was anxious about doing so. Another mentioned that her classmates found out that she was wearing the anisotropic textile brace but she did not feel embarrassed or upset as a result. For the rest of the subjects, their friends did not find out that they were wearing the proposed brace which could be due to the fewer opportunities for gatherings due to social distancing with the COVID-19 pandemic. Also, the brace can be worn underneath school uniforms or other outfits as normal underwear. More importantly, all of the subjects are willing to participate in the 3-6 month clinical trial and psychologically, this contributes to a positive wear experience.

7.4 Chapter summary

Since six of the seven subjects showed an initial in-brace correction of 5 degrees or more in the 2 hour wear trial, they were recruited in the subsequent 6 month clinical trial to evaluate the bracing effect of the newly designed anisotropic textile brace such as changes in the spinal curvature, body contours, and sitting posture, and demonstrated by the quality of life questionnaire responses, compliance rate, and user feedback during the bracing process. Follow-up was carried out as periodical monitoring for each subject once a month. Due to limitations in time and the restrictions of the COVID-19 pandemic during this study, the subjects could only participate in 3 months of bracing with the exception of ATB001 who completed the 6 months of bracing treatment .

The difference in the Cobb's angle shown on a radiograph image of one of the recruited subjects, ATB006, before starting and after undergoing the 3-6 month clinical trial is a reduction of 32%, which is the largest spinal curvature reduction in this study yet it is less than that offered by the functional intimate apparel in Fok (2020) (52.7%). Even if the other subjects do not achieve a 5 degree or more reduction in their Cobb's angle, they halt the curvature from further rapid progression with the use of anisotropic textile brace. By observing the performance of the initial in-brace reduction the of spinal curvature at the preliminary 2-hour wear trial versus the spinal curvature after 3 months of bracing, the former might appear to provide information to predict the bracing outcomes. However, some factors here might also affect the prediction, such as listing to one side and bracing compliance.

After bracing for 3 months, the coronal balance of 4 of the 6 subjects show a mean improvement of 0.38 cm. It is found that there is no corresponding relationship between spinal curvature and coronal balance as the case with the highest reduction in the Cobb's angle showed the worst performance in this aspect. As for sagittal balance, most of the subjects have more sagittal imbalance after 3 months of bracing, except for

ATB005. Even though they tend to show outstanding improvement at the preliminary 2-hour trial, the proposed brace might not be able to correct sagittal imbalance with a short treatment time, especially for cases with inherent lordosis like ATB004.

In terms of changes in body contours, the shoulder obliquity and shoulder rotation are measured but no correlation is found between shoulder orientation and spinal curvature since a more severe imbalance of the shoulders is found in the subject who reduces the curvature of her spine the most after 3 months of bracing, which is similar to a case in Fok (2020). Even if the POTSI values do not reflect the spinal correction as well, it is found that all of the subjects with a single curve have a relatively higher POTSI value and show reduction of asymmetry of their back after wearing the anisotropic textile brace for 3 months. Moreover, the 2 subjects who suffer from double curves do not have an asymmetry problem due to their compensating curve.

With respect to changes in sitting posture, a pilot study was done with 11 subjects without scoliosis and 13 with AIS from the school screening programme. Apart from their Cobb's angle, their age, height, weight and BMI are all similar without a significant difference. According to the pressure distribution obtained from their habitual sitting posture, statistical significant differences are found in the mean peak pressure of the left and right buttock regions and the convexity of their spinal curvature (the AIS patients). Thus, it can be assumed that the mean peak pressure is similar in the two buttock areas when the subjects adopt a more appropriate sitting posture. Following this assumption, the mean peak pressure distribution as well as the convexity of the single and lumbar curves were the focus of a following analysis. Among the subjects in the 3-6 month clinical trial, a significant difference between their convex and concave sides is found prior to the clinical trial ($p=0.014$) and at the 1st follow-up ($p=0.019$). Yet, no further significant differences are found after that, which means that the sitting posture of the subjects is improved after a short period of bracing based on the assumption of the pilot study.

As for changes in the quality of life, all three questionnaires administered in the clinical trial show similar results prior to the clinical trial and in the 3rd month of intervention which indicates that the quality of life has not been affected due to donning the proposed brace for a few months. Also, a significant difference is found in changes for physical functioning in the BrQ ($p=0.031$). The subjects might have become used to wearing the proposed brace and feel less inconvenienced and burdened due to bracing.

With reference to brace compliance, all of the subjects demonstrate good compliance (69%- 98.3%) overall, except for ATB007, with only a compliance rate of 29.4%. As such, ATB007 increased the severity of her spinal curvature progression by 7.3% after 3 months of bracing which shows the importance of compliance in bracing treatment.

Besides, some of the subjects also offered input in a short interview, including on the durability and fit problems of the hinged back bone and their wear experience. All in all, they are satisfied with the proposed brace treatment which implies that the proposed brace might successfully provide them a comfortable and satisfying wear experience.

To summarize, the proposed anisotropic textile brace can provide wearers with good stabilization of the spinal curvature and even reduce the curve by up to 32% after 3 months of bracing. However, its effectiveness relies on brace compliance and the initial in-brace correction. Although not all of the participants with a high compliance rate have reduced their spinal curvature significantly and successfully after the 3-6 month bracing treatment, the spinal curvature corrective effects might be potentially comparable to t some of the existing braces in the market as long as a high bracing compliance is realized. Nevertheless, further studies are needed to evaluate its bracing effectiveness for long periods of wear.

CHAPTER 8 – CONCLUSIONS AND SUGGESTIONS FOR FUTURE RESEARCH

8.1 Conclusion

AIS is the most common form of 3D spinal deformity which affects children during puberty. The abnormal shape of the spine, uneven shoulders, scapular asymmetry and pelvis obliquity are all symptoms of AIS. To prevent any further rapid progression of the spinal deformity, periodical monitoring and controlling the spinal curvature of AIS patients are essential tasks. To date, observation, bracing, exercise and surgical correction are considered to be the primary means to treat AIS based on the extent of the curvature, among which bracing is the most prevalent treatment option.

There are various types of braces designed for AIS. Briefly, they can be classified into 3 main types in terms of the materials used, which are rigid, semi-rigid and flexible braces. Even if the corrective performance of rigid braces has been proven, the physical and psychological consequences to users such as low self-esteem cannot be neglected as they may result in low compliance and failure of bracing treatment. To overcome these limitations, semi-rigid and soft braces, such as SpineCor (Wong et al., 2008) and a functional intimate apparel (Fok, 2020), have been developed. However, they can only resolve some of the problems found with rigid braces. There are also other problems; for instance, insufficient corrective forces, skin irritation and inconvenience when using the toilet. The variability of non-invasive treatment, lack of consensus on bracing options and uncertainty of the efficacy around exercises for AIS have been identified through a literature review and using a CNA.

Thus, a semi-rigid brace in this study called the “anisotropic textile brace” has been developed for AIS with the aim to provide an alternative choice or even a more comfortable and better option for bracing treatment to control the progression of spinal deformity and correct posture and body shape. The objectives of this study are to 1) provide background information of AIS and the current treatment methods, and a conduct systematic review on the various mechanisms of scoliosis braces; 2) To design and develop an anisotropic textile brace for adolescents with idiopathic scoliosis on the basis of clinical applications and materials science as well as garment technology with the aim to correct the spinal deformity, reduce the possibility of spinal curve progression, and address the needs of the patients as well as take their psychological concerns into consideration; 3) To conduct physical and mechanical tests in order to select the appropriate materials to fabricate the anisotropic textile brace; and 4) To conduct a clinical study to evaluate the efficacy of the anisotropic textile brace by examining the spinal deformity and body shape through non-invasive methods as well as collecting user feedback on their health-related quality of life (HRQOL). These objectives have been addressed and the results of the research work are summarized as follows.

1) After the literature review was carried out, the background information of AIS, current treatment options, corrective mechanisms and limitations of different types of braces, as well as identification of the potential trends in research or research areas by using a CNA have been discussed. Furthermore, a design framework, modified FEA model for designing a medical textile or scoliosis brace, has been developed and applied in this study.

2) A new non-rigid brace called the anisotropic textile brace has been designed. The functional intimate apparel in Fok (2020) inspired this brace. After continuous

design modifications, the optimum brace design is obtained. Unlike previous brace designs, this is a cupless one-piece garment that is composed of a hinged artificial back bone, corrective bands with paddings, and pelvis belts. The aim of this proposed brace is to maintain the corrective performance of the functional intimate apparel in Fok (2020) while minimizing the negative impacts of its design and bracing treatment, such as discomfort and fitting problems.

3) To fabricate the proposed brace for further assessments and a clinical trial, material selection and a series of laboratory tests have been conducted. After that, three sizes (S, M and L) of the proposed brace, hinged back bone and silicone apical pad are developed.

4) The first phase of the wear trial, which is a preliminary 2-hour wear trial, has been conducted to investigate the initial bracing outcomes of the newly designed brace, including the in-brace reduction of the spinal curvature, and changes in body contours and quality of life, as well as user feedback on wear experience. This 2-hour wear trial shows that the anisotropic textile brace provides a similar degree of interface pressure as that of the functional intimate apparel, and even achieves an initial in-brace correction of the spinal curvature in almost all of the cases in this study. The average in-brace reduction in the spinal curvature is also comparable to some of the existing braces in the market. Besides, the satisfaction of the wearers is reflected by their ratings of the wear comfort of the anisotropic textile brace, which are significantly higher than the brace in Fok (2020). As for the subsequent wear trial, 3-6 month wear trial with monthly follow-ups and then low-dose radiographic imaging after 3 and 6 months of wear has been carried out to further determine the effectiveness of the anisotropic textile brace after a short period of use. After 3

months, the importance of bracing compliance is evident. The spinal deformity of all of the subjects is controlled but one of compliant subjects reduced her curvature by 7.4°. This curve stabilization is also found in the subject who completed the 6-month bracing treatment (the only subject to do so). More importantly, all of the subjects are satisfied with the proposed brace treatment which points to the possibility of using the proposed brace to treat AIS.

8.2 Limitations of the study

Like all research work, there are limitations in this study which are discussed as follows.

1. With respect to the review of the non-invasive treatment of AIS by using a CNA, some of the more recently published articles have yet to appear on the academic radar due to low citation impact. After all, time is needed for a citation to have impact. Besides, only one database, the Web of Science, and English articles are taken into consideration for the sample. Therefore, relevant papers might have been omitted from this review study, which may have affected the results. Moreover, there could have been negative citations (i.e., citing others to criticize them), which causes citation polarity and biases the results, although this is not a substantial problem in most cases.

2. As for the development of the proposed anisotropic textile brace, it is assumed that the silicone used in the functional intimate apparel in Fok (2020) is the ideal choice. Even though the original material could not be purchased for this study, only one type of silicone with similar material properties is sourced from the market due to limited resources. There is still room to determine whether greater in-brace spinal correction could be obtained by using other types of silicone with different material

properties. Moreover, the pilot done in this study that observes the sitting posture via pressure distribution only provides a preliminary direction for evaluation because of limited resources and sample size. The correlation among the pressure distribution in the buttock regions, habitual sitting posture and the extent of spinal deformity have not been further taken into consideration.

3. In terms of the preliminary wear trial and 3-6 month clinical study of the proposed brace, none of the subjects in this study have undergone supine radiograph imaging due to radiation exposure concerns. Unlike the EOS^{TM} imaging system, this is not a low-dosage x-ray process. The supine measurement of the Cobb's angle has a significant correlation with the initial in-brace Cobb's angle, so lack of the details of the inherent flexibility of subjects might not allow for an accurate analysis of the effectiveness of the anisotropic textile brace. Furthermore, the sample size in this study is very small. Also, no control group is used in both 2-hour and 3-6 month clinical studies. The information on the rate of spinal curvature progression in a control group is thus neglected and no comparison can be conducted in this aspect.

4. With regard to the durability of the proposed brace, the fit and durability problems of the hinged artificial back bone might affect the bracing compliance in this study, the possibility of usage of the proposed brace for long term bracing, and even the bracing effectiveness of the anisotropic textile brace. Moreover, there is room for improvement of the brace in terms of the pilling and fuzzing problems of the V-fold elastic that is used, although no recruited subject mentioned this problem. Yet, due to the friction caused by the hooks of the velcro used, these problems are unavoidable with the stretchable materials used due to their knit structure and composition and might affect the appearance of brace.

8.3 Recommendations for future work

In light of the research findings, the following are some recommendations for future related work.

1. To reduce the likelihood of omitted articles, more databases should be consulted instead of just a single database if a CNA is used, such as Scopus and PubMed. As such, a more comprehensive background review can be provided to better identify the limitations in the field and potential research directions.

2. In order to determine the most suitable apical pad, the difference in the amount of spinal correction with the use of different types of silicone pads can be systematically investigated. Also, a larger sample size is recommended for the pilot study for posture checking during sitting. The centre of pressure (COP), pressure distribution of the suggested sitting posture and motion capture can also be taken into consideration and compared to further determine the likelihood of using this kind of pressure distribution as a reference to examine the sitting posture.

3. To obtain a better understanding of the effectiveness of the brace in reducing the spinal curvature, the inherent flexibility of the spine can be measured with the application of supine lateral bending radiographs. The brace design can thus be modified accordingly. Besides, a randomized control trial with a large sample size should be carried out to investigate and compare the in-brace correction between the anisotropic textile brace and rigid brace. Their bracing outcomes can then be determined in a more accurate and reliable way.

4. The hinge which is used for the artificial back bone in this study is made of carbon fibre which does not obscure imaging. Therefore, it is a convenient material to use when there is the need to undergo in-brace radiographs. The new version of the hinge for the artificial back bone should also have this property but with better textile strength. Therefore, different non-metallic materials and different shapes of the hinges can be examined and compared with the aim to address the current limitations of durability and fitting. Moreover, pilling tests should be conducted for all accessories including the V-fold elastics before brace fabrication. The V-fold elastics used in the proposed brace should be replaced by another type of binding tape with a certain amount of stretchability and resistance to pilling.

Appendix I. Information sheet for participant in clinical study

(English version)

INFORMATION SHEET

Design and Development of Anisotropic Textile Brace for Adolescent Idiopathic Scoliosis (AIS)

This research study is supervised by Dr. Joanne Yip of Institute of Textiles and Clothing, The Hong Kong Polytechnic University, and her team members. Please take time to read the following information carefully and discuss it with your family members, relatives and your family doctor if you want. You are welcome to ask us if there is anything that is not clear or if you would like to have more information. Take time to decide whether or not you wish to take part in this research programme.

Purpose of the study

This study aims to design and develop an anisotropic textile brace with different corrective forces with rigid, semi-rigid and flexible materials for AIS patients. Through this newly designed brace, it hopes to provide an alternative choice as well as even more comfortable and satisfactory option of brace treatment for patients, which can relieve their progression of spinal deformity and improve their aesthetic body image. Their spinal situation, body measurement, the data of their sitting posture, their asymmetric body image, and daily wearing record will be collected for academic analysis.

Who will be invited to participate in this study?

Female subjects diagnosed with moderate adolescent idiopathic scoliosis who have a Cobb's angles greater than 18 degrees will be recruited. The inclusion criteria for subject recruitment are the age that should range between 10 and 13 and have not received or scheduled surgical treatment. You will be invited to take part in a series of assessments if you fulfill the criteria of this study.

What will happen if you decide to take part?

First, you will be invited to the medical centre to take an EOS Low Dose Imaging Diagnosis to further understand the curvature of your spine. EOS is a relatively new X-ray imaging device and it can acquire frontal and lateral images simultaneously with significant dose reduction compared to conventional radiography for about 50% to 85% so that it helps to minimize the unnecessary radiation used and radiation hazard from human body.

After understanding your spinal curvature, you will be arranged to participate the preliminary wear trial for few hours. We will collect your three-dimensional body image, data of sitting posture, and the post-radiography for analysis. You will be further arranged to join the clinical trial for 3-6 months once the spinal correction obtained from preliminary wear trial is satisfactory.

What is 3-6 months clinical trial?

It is a periodical monitoring. Participants will be asked to wear the textile brace everyday and attend the periodical follow-up in The Hong Kong Polytechnic University every month. For the AIS patients, periodical monitoring is very important, which aims to closely monitor and record the situation of all participants during the trial, including the change of their sitting posture, asymmetric body image, the challenge they are facing in daily life, as well as the compliance rate monitoring. To ensure the designed brace fitting well, we will help to fix the fitting problems during the follow-up if needed. For instance, the problem of loose shoulder tapes due to long usage.

At the end of the clinical trial (ie. The last follow-up of the trial), all participants will be required to fill in the health-related quality-of-life (HRQOL) questionnaire and take one more low dose radiography that aims to obtain your latest spinal situation. The effectiveness of the anisotropic textile brace will be evaluated by comparing the results of the different tests before and after the 3-6 months clinical trial, whereas the three-dimensional body scanning and sitting posture results will be used to examine the posture and the change of the aesthetic body image of participants. Besides, the pre and post results of the HRQOL questionnaire will also be compared to assess the psychological change of wearers.

What are the benefits of taking part?

The brace design of this study was modified by the brace of previous research stage which has been proven its effectiveness and the corrective mechanism. This research study can offer patients a series of checking and periodical monitoring systematically, and even an alternative option of bracing treatment so as to reduce the risk of the spinal deformity.

Do you have to take part?

This programme is voluntary, you can decide if you take part. If you do decide to take part in this study, please keep this information sheet and sign a consent form. During the study, you still have right to withdraw at any time without giving a reason. No matter what decision you make, it would not affect the standard of care you receive in the clinic. If you are failed to turn up at appointments, your participation eligibility will be terminated without further notice.

Are there any disadvantages and risks of taking part?

Three-dimensional body scanning, sitting posture checking, and compliance rate monitoring have no harm for human being. The frequency of taking low dose X-ray scans will be adopted following the instruction and advice of professionals. It is believed that it only carries mild dose of radiation.

For the few hours preliminary wear trial, it will not further deform the spine of participants. Even if the corrective effect is not satisfactory, their spinal situation will be returned to their own original appearance naturally after doffing the brace. Although 3-6 months clinical trial will only be arranged for participants who have already achieved the curvature improvement in the preliminary wear trial, it cannot be guaranteed their spinal curvature must be improved after bracing. Further spinal deformity may also be found. Thus, you are asked to take the risks into your consideration before deciding the participation.

What if something goes wrong?

There are no special compensation arrangements in this study. If you wish to complain about any aspect of the way you have been approached or treated during this study, you can also contact The Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o M1303, Human Resources Office of the University).

Will the personal information in this study be opened to public?

No. If you decide to take part in this study, all personal information and research data collected from participants will only be used by research team as research aspect. All information collected will be kept confidential.

How do we deal with the collected results?

The results will be published in referred journal.

Who is organizing and funding the research?

The research is organized by Institute of Textiles and Clothing, The Hong Kong Polytechnic University. The work is supported by funding from the RGC General Research Funds [PolyU 152101/16E] entitled "Anisotropic Textile Braces for Adolescent Idiopathic Scoliosis" and a research student granted from the Hong Kong Polytechnic University.

Who has reviewed the study?

The study has been reviewed by Departmental Research Committee of Institute of Textiles and Clothing, The Hong Kong Polytechnic University.

Please keep this information sheet for your reference, together with a signed consent form. Should you have any queries, please do not hesitate to contact Dr. Joanne Yip at 2766 4848. Thank you very much in helping us to improve our patients' care. Updates of this study will only be informed, if necessary.

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(Chinese version)

資料單張

為患脊柱側彎青少年研發的非等向性矯型衣

這項研究計劃是由香港理工大學紡織及製衣學系葉曉雲博士以及她的研究團隊所負責。請細閱以下有關本次研究之資料，如有需要請咨詢家人或家庭醫生的意見。若閣下對本次研究內容有任何問題或想進一步了解更多資訊，歡迎向任何一位研究人員提出，我們非常樂意為您解答。請閣下仔細考慮是否參與是次研究。

研究目的

是次研究目的是為患脊柱側彎青少年設計一件非等向性的矯型衣，利用不同堅硬度的物料，控制其脊柱側彎惡化的情況及改善其身型的外觀。同時，望提供多一個可能的選擇，甚至更舒適和滿意的矯型衣治療予患者。參加者的脊柱情況、身體尺寸、坐姿數據、身體不對稱情況以及日常穿著情況會被紀錄並用作學術分析。

誰會被邀請參與本次研究？

此研究會招募任何診斷患有中期脊柱側彎（脊柱側彎角度約 18 度或以上）的青少年。參加者年齡需介乎１０至１３歲，而且從未接受或安排任何手術治療。合乎資格者將被邀請參與本次研究。

如您決定參加，評估內容是什麼？

首先，您會被邀請到醫療中心進行低輻射劑量站立式 X 光影像檢查（EOS Imaging）進一步確認您的脊柱側彎的彎曲情況。相對於傳統 X 光，此仍較新式的 X 光儀器，其輻射劑量比傳統 X 光低約 50 – 85%，可盡量減少因重複拍攝而接受額外的輻射劑量，減少對人體的傷害。

了解您脊柱的彎曲情況後，您會被安排參與為期數小時的初期穿著試驗期，我們會收集您的三維人體掃瞄影像、坐姿數據以及試驗期後的 X 光資料作分析研究。如參與者的脊柱側彎的改善情況理想，您會進一步被安排參加三至六個月的穿著試驗期。

為期三至六個月的穿着試驗是什麼？

這是一個定期監測。參與者需每天穿著矯型衣，並每隔一個月前往香港理工大學

作跟進檢查。對患有脊柱側彎的青少年而言，定期監測是非常重要的，目的是密切監察和記錄參與者在穿着試驗期間的情況，包括其坐姿改變、身體不對稱情況、日常穿著所遇到的問題及穿著頻率。如有需要，我們會為參與者輕微調整矯型衣的配件，例如：因長期穿著而造成的肩帶寬鬆問題，以確保矯型衣合身。

在穿着試驗期結束時（即是最後一次的跟進檢查），參與者需再次填寫健康相關生命質量(HRQOL)問卷，以及再一次接受安排進行低輻射劑量 X 光影像檢查，以了解您最新的脊柱側彎情況。非等向性矯型衣的有效性將透過其三至六個月穿著試驗前後的測試比較作評估。三維人體掃瞄和坐姿檢查數據則用作測量臨床試驗前後參與者的姿勢和身型外觀上的改變。除此之外，參與者於臨床試驗前後填寫的生命健康狀況問卷亦會用作評估其在相關方面的變化。

參加是次計劃有什麼好處？

本計劃的矯型衣設計是根據已於早前研究的束身衣改良而成的，其力學原理已獲得初步認可。參與此研究計劃可提供一系列有系統的檢查和定期監察，新設計較舒適和容易接納，希望藉此減低您們脊柱側彎惡化的機會。

您必須參與此研究計劃嗎？

本計劃全屬自願性質，您可自行選擇是否參加。如果您決定參加，請保存這張詳細資料單張及簽署同意書。在研究過程中，您有權隨時無條件退出本研究計劃。不論任何決定皆不會影響您在診所接受的服務質素。若您在研究期間無故缺席相關的跟進檢查，您的參加資格將被取消，恕不另行通知。

參與此研究存在風險嗎？

三維人體掃瞄、坐姿檢查、日常穿著頻率監測並不存在任何對人體有害的風險。低輻射劑量 X 光拍攝頻率將參考相關專業人士的建議，相信只會對人體造成輕微的輻射影響。

為期數小時的初期穿著試驗期並不會令參與者的脊骨情況惡化，即使矯正效果未如理想，其脊骨情況亦會在穿著試驗期後自然回復原來的模樣。雖然只有在初期穿著試驗期獲得脊骨改善的參與者才會被邀請參加為期三至六個月的穿着試驗，此三至六個月的穿着試驗期或有機會未能成功改善患者的脊柱側彎情況，或有可能出現惡化的機會。閣下需在參與本計劃前仔細考慮並平衡當中涉及的利益及風

險項目。

如果出現任何事故怎麼辦?

本研究計劃並沒有設特殊的補償安排。若您欲就本研究提出任何投訴，您可親自或以書面形式聯繫香港理工大學道德評議會秘書 (c/o M1303, 大學人力資源辦公室)。

於是次研究計劃提供的個人資料會被公開嗎？

不會。如您決定參與此計劃，當中獲得的參與者個人資料及研究數據只會用作研究用途，並由今次的研究人員全權收集及分析，所得的一切資料一概保密。

我們會如何處理所得的研究結果?

研究結果將會發佈在醫學矯形和紡織設計刊物內。

誰統籌及資助此項研究計劃？

這項研究計劃由香港理工大學紡織及製衣學系統籌，並獲香港研究資助局（研資局）的優配研究金 [PolyU 152101/16E]，以及香港理工大學資助。

由誰審批是項研究？

是項研究經由香港理工大學紡織及製衣學系研究委員會審批。

請小心保存這份資料和同意書作日後參考。

如有疑問，請致電 2766 4848 向葉曉雲博士查詢。特此再次感謝您的參與，閣下的支持定能對將來改善醫院病人的服務有很大的幫助。

有關此研究的更新資料或資訊，有需要時，將會個別另行通知。

葉曉雲博士

研究組組長

Tel: +852-27664848

Email: joanne.yip@

Appendix II. Consent form for participant in clinical study

(English version)

PARTICIPANT CONSENT FORM

Title of Project: Design and Development of Anisotropic Textile Brace for Adolescent Idiopathic Scoliosis (AIS)

Name of Researchers: Dr. YIP Yiu Wan, Dr. KICK Kit-lun, Dr. NG Sun-pui

1. I confirmed that I have had the opportunity to ask questions.
2. I understand that my child's participation is voluntary and that I am free to withdraw at any time, without giving any reasons, without my legal rights being affected.
3. I understand that sections of any of my child's medical notes may be looked at by responsible individuals from the researcher's team or from regulatory authorities where it is relevant to my takig part in research. I give permission for these individuals to have access to my records.
4. The results will be published in referred journal. All information collected will be kept confidential.
5. I agree to take part in the above study.

Name of parent/ Legal guardian	Date	Signature
Name of witness (if applicable)	Date	Signature
Researcher	Date	Signature

(Chinese Version)

參與研究項目同意書

研究主題：為患脊柱側彎青少年研發的非等向性矯型衣

研究人員名稱：葉曉雲博士，易潔倫博士，吳新培博士

1. 本人已有足夠時間發問問題。
2. 本人明白是次參與全是自願性質，本人有權隨時退出而不必提出任何理由，而本人法律權利不會有改變。
3. 本人明白及同意本人子女之病歷記錄需要時給與研究員和有關人事作參考。
4. 研究結果將會發報在醫學矯形和紡織設計刊物內。其他收集的資料一概保密。
5. 本人同意參與此項研究。

______________________	________________	____________________
參加者家屬/監護人姓名	日期	簽名
______________________	________________	____________________
見証人(如適用)	日期	簽名
______________________	________________	____________________
研究員	日期	簽名

Appendix III. Subject list for preliminary wear trial and clinical trial

Subject List- Wear Trial & Clinical Trial

#	Surname	Scoliotic Type	Cobb's Angle	Risser Sign	Remarks

Appendix IV. Record sheet for preliminary wear trial and clinical trial

Record Sheet- Wear Trial & Clinical Trial

Subject Name:___________________ Code： _____________________

Gender/Age: __________

	Scolioscan (if available)	Out-brace X-ray	Preliminary wear trial
Date			

	Date
Pre-treatment	
1st Follow-up (1month)	
2nd Follow-up (2 months)	
3rd Follow-up (3 months)	
4th Follow-up (4 months)	
5th Follow-up (5 months)	
Post-treatment (6 months)	

Remarks:

Height:___________ Weight:______________

Cobb's angle: (Out brace X-ray):_______________

Scoliosis: ________________________ Convexity: ________

Skeletal maturity: Risser _____

Preliminary 2-hour Wear Trial

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

☐ Consent form

☐ Sitting posture checking (Pressure mat)

☐ Out-brace 3D body scan

☐ Brace fitting (Both functional intimate apparel & Anisotropic textile brace)

☐ In-brace 3D body scan

☐ Point pressure (instant)

☐ Feedback

☐ Questionnaire – TAPS

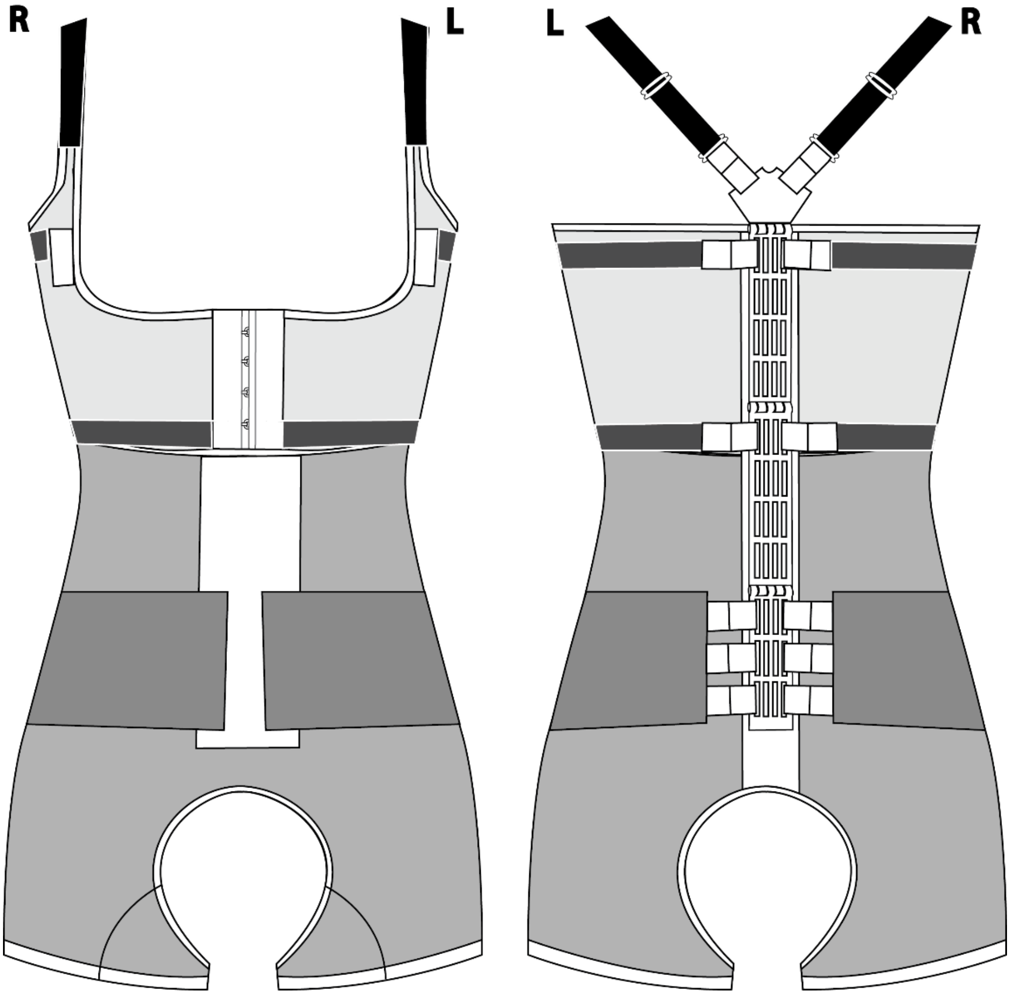
☐ 2 hours bracing

☐ Interface pressure measurement(after 2 hours)

☐ Questionnaire – Brace Questionnaire (BrQ)

Remarks:

Brace Fitting- padding & point pressure



Instant interface pressure measurement

Interface pressure (kPa)	Brace A Functional intimate apparel	Brace B Anisotropic Textile brace
L3		
R3		
L2		
R2		
L1		
R1		

Pre-treatment

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

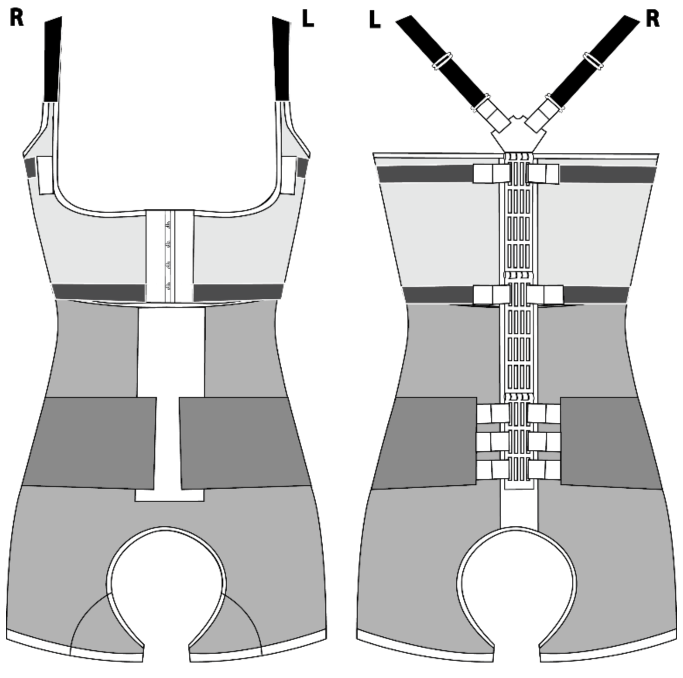
Quantity of brace:________

Temperature loggers:_____________________

☐ Information sheet & Consent form ☐ Interface pressure

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22/TAPS

☐ 3D Body scanning (out & in-brace)



_____Follow-up

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:_____________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

_____Follow-up

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:_____________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

_____Follow-up

Date:___________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:______________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

_____Follow-up

Date:___________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:______________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

_____Follow-up

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:_____________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

Post- treatment (6th month)

Date:__________________ Brace Size: S/ M/ L/ Special size:_______

Quantity of brace (total):________

Temperature loggers:_____________________

☐ Sitting Posture Checking ☐ Questionnaire- SRS-22 (3M,6M)

☐ 3D Body scanning (out & in-brace) ☐ Questionnaire- TAPS (3M,6M)

☐ Interface pressure ☐ Questionnaire- BrQ (3M,6M)

☐ Compliance rate record ☐ Simple interview (3M,6M)

Remarks:

Radiographic Measurement

	Cobb's Angle (°)	Coronal Balance (mm)	SVA (mm)
Pre-treatment			
2 hours trial (in-brace)			
3rd Follow-up (out-brace)			
3rd Follow-up (in-brace)			
6th Follow-up (out-brace)			
6th Follow-up (in-brace)			

Appendix V. SRS-22 Questionnaire

(Chinese version)

SRS-22 問卷

指示: 我們正在小心評估你背部的情況，因此問卷上的每一條問題必須由你親自回答。請在每一條問題所提供的選擇中，小心圈出你認為最正確的一個答案。

1. 以下哪一項最能夠準確描述你在過去六個月所感受到痛楚的程度？

無痛楚　輕微　中等　中等至嚴重　嚴重

2. 以下哪一項最能夠準確描述你在過去一個月所感受到痛楚的程度？

無痛楚　輕微　中等　中等至嚴重　嚴重

3. 整體來說，在過去六個月期間你有感到十分焦慮嗎？

完全沒有　小部份時間　有時　大部份時間　全部時間

4. 如果你必須在背部維持現狀不變的情況下繼續生活，你會有甚麼感受？

十分愉快　某程度上愉快　沒有愉快/不愉快　某程度上不愉快　十分不愉快

5. 你現時的活動能力如何？

只限於床上　基本上不能活動　些微的運動及勞動　有限度的運動及勞動　活動不受限制

6. 你在穿上衣服後的外觀如何？

很好　好　可以接受　差勁　十分差勁

7. 在過去六個月期間你曾感到十分沮喪以至於任何事物也不能讓你開懷嗎？

經常　大多數時間　有時　很少數時間　全部沒有

8. 你在休息時背部有感到疼痛嗎？

經常　大多數時間　有時　很少數時間　全部沒有

9. 你現時在工作/學校的活動能力為多少？

正常的 100%　正常的 75%　正常的 50%　正常的 25%　正常的 0%

10. 以下哪一項最能夠描述你軀幹的外觀？
(軀幹的定義為人的身體除去頭部及四肢)

很好　好　可以接受　差勁　十分差勁

11. 下例哪一項最能準確地描述你因背部疼痛而所需要服用的藥物？

無

一般止痛藥 (每星期服用一次或更少)

一般止痛藥 (天天服用)

特效止痛藥 (每星期服用一次或更少)

特效止痛藥 (天天服用)

其他：藥物名稱_________ 使用程度 (每星期或攻少或天天)___________

12. 你的背部疼痛有否影響你做家務的能力？

沒有　少許　某程度上有　很大程度有　經常有

13. 整體來說，你在過去六個月期間有感到安寧和平靜嗎？

經常　大多數時間　有時　很少數時間　全部沒有

14. 你有否感到你背部的狀況對你的人際關係構成影響？

沒有　少許　某程度上有　很大程度有　經常有

15. 你以及/或你的家人有否因為你背部的問題而在經濟方面遇到困難？

經常　大多數時間　有時　很少數時間　全部沒有

16. 整體來說，在過去六個月期間你有否感到失落和灰心？

完全沒有　很少數時間　有時　很大數時間　經常

17. 在過去三個月期間你有否因背痛而向學校/公司請假？如有，共有多少天？

零天　一天　兩天　三天　四天或以上

18. 你背部的狀況有否阻礙你和家人/朋友外出？

完全沒有　很少數時間　有時　很大數時間　經常

19. 你現時背部的狀況會否讓你覺得自己仍有吸引力？

會，很有吸引力　　會，某程度上有吸引力　　無影響

否，沒有甚麼吸引力　　否，完全沒有吸引力

20. 整體來說，你在過去的六個月裏感到愉快嗎？

完全沒有　　很少數時間　　有時　　很大數時間　　經常

21. 你對你背部治療的成效感到滿意嗎？

十分滿意　　滿意　　不是滿意也不是不滿意　　不滿意　　非常不滿意

22. 如果你的背部再次遇到同類的情況你會否接受同樣的治理？

一定會　　可能會　　不清楚　　可能不會　　一定不會

-問卷完-

Appendix VI. Brace Questionnaire (BrQ)

(Chinese version)

Brace Questionnaire (BrQ)

支架問卷

姓名：____________________　　　　　　　日期：

____

本問卷旨於了解你在佩戴支架時，對自己健康的看法。本問卷並非測驗，答案並無對錯之分。請仔細閱讀每條題目，自行選取你認為最適當的答案，並以 X 標示。

例子	從不	幾乎不會	有時	大部份時間	經常
在過去一星期，你有良好的學習情緒	□	□	□	X	□

<u>個人資料</u>

請填寫你的背景資料。

年齡：_______

你從________________開始佩戴支架

你每天佩戴支架________小時

在過去 3 個月…	從不	幾乎不會	有時	大部份時間	經常
1. 支架令你有生病的感覺	□	□	□	□	□
2. 你害怕背部情況會惡化	□	□	□	□	□

在過去 3 個月，你佩戴支架時…	從不	幾乎不會	有時	大部份時間	經常
3. 你走路時感到疲倦	□	□	□	□	□
4. 你能跑步	□	□	□	□	□
5. 你能在沒有任何協助下佩戴支架	□	□	□	□	□
6. 你能在沒有任何協助下除下支架	□	□	□	□	□
7. 你的胃口不佳	□	□	□	□	□
8. 你睡得不好	□	□	□	□	□
9. 你呼吸不暢順	□	□	□	□	□

在過去 3 個月…	從不	幾乎不會	有時	大部份時間	經常
10. 你因支架而感到緊張	□	□	□	□	□
11. 你因支架已感到擔心	□	□	□	□	□
12. 你感到快樂	□	□	□	□	□
13. 你相信如果不用佩戴支架的話你會生活得更好	□	□	□	□	□

14. 你相信支架治療是有益處的	☐	☐	☐	☐	☐

在過去 1 個月…	從不	幾乎不會	有時	大部份時間	經常
15. 你感到自豪	☐	☐	☐	☐	☐
16. 你為自己的身體感到滿意	☐	☐	☐	☐	☐

在過去 1 個月…	從不	幾乎不會	有時	大部份時間	經常
17. 你感到強壯和充滿力量	☐	☐	☐	☐	☐
18. 你因支架而感到疲倦乏力	☐	☐	☐	☐	☐

在過去 1 個月，因為支架…	從不	幾乎不會	有時	大部份時間	經常
19. 你上課時遇到困難	☐	☐	☐	☐	☐
20. 你曾經缺課	☐	☐	☐	☐	☐
21. 你發覺上課時難以集中精神	☐	☐	☐	☐	☐

在過去 1 個月，你佩戴支架時…	從不	幾乎不會	有時	大部份時間	經常
22. 你需服藥止痛	☐	☐	☐	☐	☐
23. 你晚上有痛楚	☐	☐	☐	☐	☐

24. 你走路時有痛楚	□	□	□	□	□
25. 你坐着是有痛楚	□	□	□	□	□
26. 你上落樓梯時又痛楚	□	□	□	□	□
27. 你的手臂或大腿有針刺般的感覺	□	□	□	□	□

在過去 1 個月，因為支架…	從不	幾乎不會	有時	大部份時間	經常
28. 你不能跟朋友外出	□	□	□	□	□
29. 朋友同情你	□	□	□	□	□
30. 你覺得自己有別於同儕（朋友）	□	□	□	□	□
31. 跟家人相處有問題	□	□	□	□	□
32. 你相信如果不用佩戴支架的話，你跟家人或朋友的關係會更好	□	□	□	□	□
33. 因感到羞愧而留在家中	□	□	□	□	□
34. 你穿着特別的衣服	□	□	□	□	□

謝謝！

問卷完

Appendix VII. The Trunk Appearance Perception Scale (TAPS)

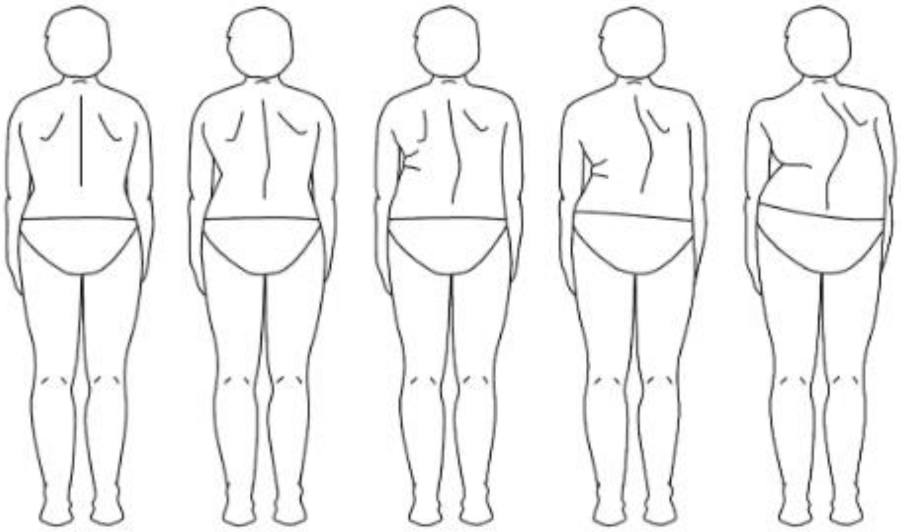
(Chinese version)

Trunk Appearance Perception Scale (TAPS)

軀幹外觀認知問卷

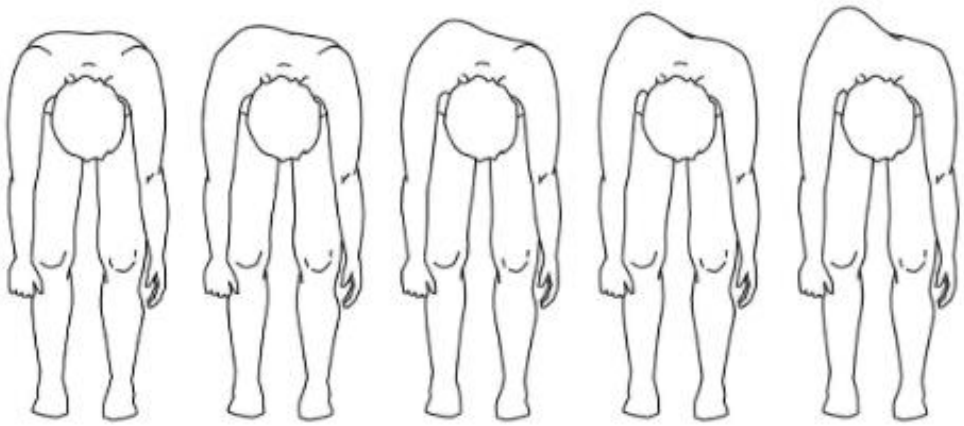
請在以下五幅示意圖中選取一幅你認為最能代表你現時的軀幹外觀。

<u>問題 1</u>



□ □ □ □ □

<u>問題 2</u>



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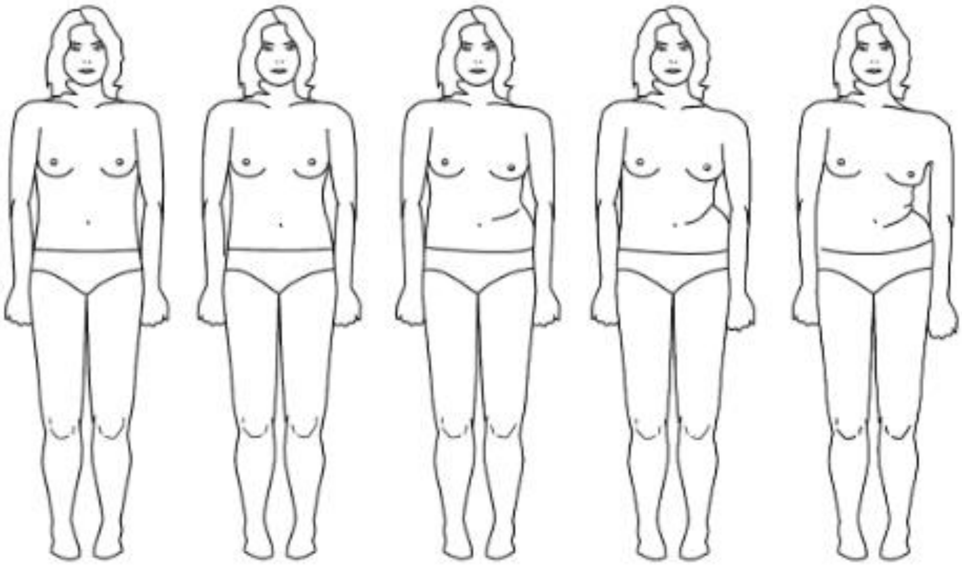
<u>問題 3</u>



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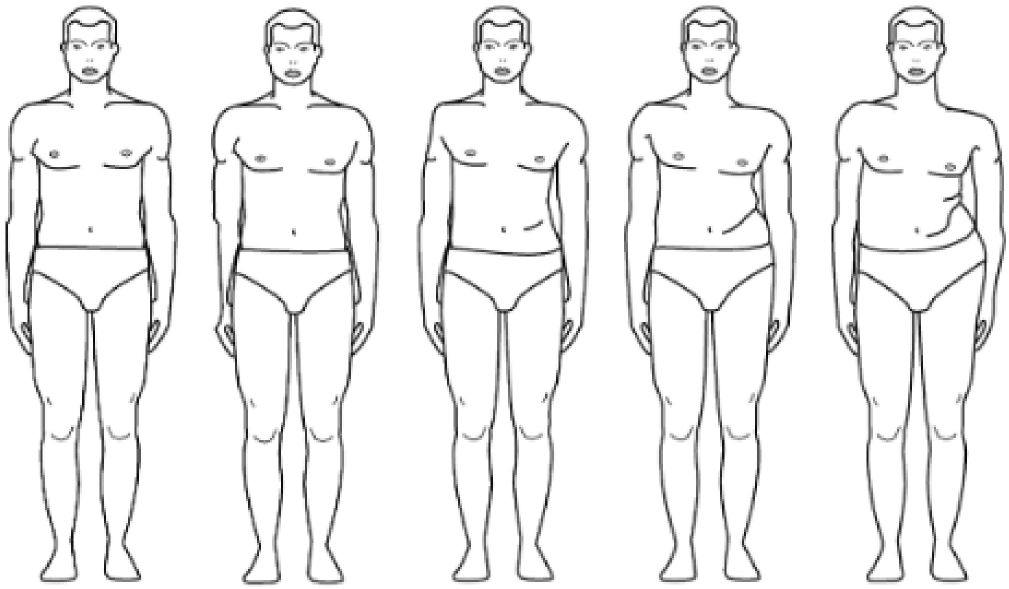

□ □ □ □ □

-問卷完-

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