DESIGN AND DEVELOPMENT OF PORTABLE SCOLIOSIS DEVICE FOR CLINICAL TESTING

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ABSTRACT

Scoliosis is a sideways curvature of the spine that occurs more often during the growth spurt just before puberty. The physicians examine the unevenness of the patient's body to suspect scoliosis and conduct x-ray to confirm the severity of scoliosis. The aim of this research is to upgrade the existing ScolioS^2, that can measure Hump Height Difference (HHD) along with Shoulder Height Difference (SHD), Shoulder Lateral Tilting Angle (SLTA) and Angle of Trunk Rotation (ATR). A stable portable device that can avoid human errors during examination and also reduce the harmful effect of x-ray to diagnose and measure the severity of scoliosis. A PCB was also developed to make the device more compact and to reduce data loss. Clinical testing on 17 subjects was conducted to test the reliability and precision of the device. The data obtained were compared against the data obtained from the present gold standards and the results obtained showed high similarity. Hence this device holds a promising potential to be marketed and become a self-diagnosing and monitoring device for scoliosis patients.

ABSTRAK

Scoliosis adalah kelengkungan sisi tulang belakang yang lebih kerap berlaku semasa pertumbuhan pesat sebelum akil baligh. Pakar-pakar perubatan memeriksa keadaan badan pesakit yang tidak sama rata untuk mengesyaki scoliosis dan menjalankan x-ray untuk mengesahkan tahap scoliosis. Tujuan kajian ini adalah untuk meningkatkan ScolioS^2 yang sedia ada, yang boleh mengukur Hump Tinggi Perbezaan (HHD) bersama dengan bahu Tinggi Perbezaan (SHD), bahu Lateral mencondongkan sudut (SLTA) dan Sudut Trunk Rotation (ATR). Peranti mudah alih yang stabil boleh mengelakkan kesilapan manusia semasa pemeriksaan dan juga mengurangkan kesan bahaya x-ray untuk mengenalpasti dan mengukur tahap keterukan scoliosis. PCB juga telah dikembangkan untuk membuat peranti yang lebih padat dan mengurangkan kehilangan data. Di samping itu, ujian klinikal pada 17 subjek telah dijalankan untuk menguji kebolehpercayaan dan ketepatan peranti. Data yang diperolehi telah dibandingkan dengan data yang diperolehi daripada rawatan terkini dan keputusan yang diperolehi menunjukkan persamaan yang tinggi. Oleh itu peranti ini memegang potensi cerah untuk dipasarkan dan menjadi diagnosis-diri dan pemantauan peranti untuk pesakit scoliosis.

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ACKNOWLEDGEMENT

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LIST OF SYMBOLS AND ABBREVIATIONS

µF	microfarad
º	Degrees (plane angle)
3D	Three Dimensional
ATR	Angle of trunk rotation
cm	Centimeter
CT	Computed Tomography
DC	Direct Current
E-book	Electronic book
FDA	Food and Drug Administration
g	Gravity (accelerometer)
HHD	Hump height difference
I/O	Input / Output
I2C	Inter-integrated circuit
IQR	Interquartile Range
kB	Kilobyte
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LoA	Limit of Agreement

mA	milliampere
MHz	Megahertz
MRI	Magnetic resonance imaging
PCB	Printed Circuit Board
POC	Point-of-Care
PPUM	Pusat Perubatan Universiti Malaya
r	Pearson’s Coefficient Correlation
RI	Rib Index
RM	Ringgit Malaysia
SRS	Scoliosis Research Society
SD	Standard Deviation
SHD	Shoulder Height Difference
SLTA	Shoulder Lateral Tilting Angle
SPST	Single pole, single throw
SRU	Spine Research Unit
STL	Standard Triangle Language
UM	University of Malaya
UMMC	University of Malaya Medical Centre
US	United States

V	Volts
X-ray	x-radiation
Ω	Ohms

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1. Overview

Scoliosis Research Society (SRS) has defined scoliosis as a lateral curvature of spine greater than 10º as measured Cobb's Angle on standing radiograph(Deepak et al., 2017). Scoliosis is a complex three-dimensional deformity of the spine, consisting of a lateral curvature with the vertebrae rotated within the curve. There are several classifications of scoliosis patient based on the age of onset, severity, etiology and the type of curve. The two-major classification is Idiopathic and Non-Idiopathic Scoliosis. In most cases of scoliosis, the cause remains unknown where it is classified as Idiopathic Scoliosis; in cases where the cause is identified, it is classified as non-idiopathic scoliosis (Konieczny, Senyurt, & Krauspe, 2013). 80% of scoliosis is idiopathic of which the commonest type is Adolescent Idiopathic Scoliosis constituting 90% of all cases (Deepak et al., 2017). The physicians conduct physical and neurological examination to diagnose scoliosis; once the presence of scoliosis is confirmed, X-ray of the spine is done to check the severity of spinal curvature. Upon suspecting underlying condition that is causing scoliosis, an MRI is conducted to reach the cause of scoliosis. According to National Scoliosis Foundation in Boston, scoliosis affects 2-3% of the US population, approximately six to nine million people. It can develop in infancy or early childhood however prime scoliosis onset age is 10-15 years. It occurs equally in both genders however the severity and progression are eight times higher in females when compared to males [*Source: National Scoliosis Foundation, June 2007]*. Many countries to combat scoliosis in its early stages have introduced scoliosis screening program in its school medical examination schedule. This way they could detect scoliosis in its development stage and have also provided many valuable researches in the field of scoliosis, describing its prevalence over a race, ethnic group, gender, age group, development pattern etc.

In US, 26 states have mandate scoliosis school screening. A population based study of school screening conducted for a period of 5 years, has started monitoring students when the entered grade 5 followed up until the age of 19. Of the 2242 subjects screened 4.1% were referred further evaluation, of which 74% were documented medical or chiropractic evaluation of scoliosis (Yawn, Yawn, Hodge, & et al., 1999). In Singapore, a survey on 72,699 school children in four age groups was conducted to determine the prevalence rate of idiopathic scoliosis. In this study the prevalence of idiopathic scoliosis was found in 0.93% girls and 0.25% in boys of age group 6 to 7 and 9 to 10 years but the prevalence increased rapidly to 1.37% for girls of age group 11 to 12 years and 2.22% of age group 13 to14 years, recommending every year screening of females between the age of 10 to 13 years (Wong, H P Hui, Rajan, & Chia, 2005) (Yong, Wong, & Chow, 2009). In Malaysia, a study was conducted on 8966 school students of age group 13 to 15 years to understand the prevalence rate of adolescent idiopathic scoliosis. 410 students were screened positive of which 156 turned up for radiological assessment. The overall referral rate for female students was higher. The referral rate of female students was 5% and male students was 4.2%. based on the age group 13, 14 and 15, The referral rate for male students rose gradually from 3.5% to 4.2% to 5.0% respectively; whereas for female student's it remained higher and constant throughout the three age groups: 5.0% for 13-year-old, 4.9% for 14-year-old and 5.0% for 15-year-old (Deepak et al., 2017). Hence this study has indicated that prevalence of scoliosis is more dominant and severe in young females when compared with males of the same age group.

1.2. Problem Statement

Present diagnosis of scoliosis is based on doctor's assessment of asymmetries in patient's body and measuring Cobb's angle from radiographs. This technique to diagnose scoliosis is prone to human error and irreproducibility, and puts the patients through the risk of x-ray exposure. This traditional method though widely used, is considered inaccurate, time-consuming and expensive. Though scoliosis has prevailed over the society since early times but still there is no existing POC device that can accurately diagnose scoliosis. Furthermore, the physicians have no tool that can accurately compare the improvements in patient's shoulder balance and hump height after a corrective surgery.

1.3. Report Organization

This report comprises of five chapters, namely: introduction, literature review, methodology, result and discussion and conclusion. Introduction explains scoliosis briefly and the prevalence of scoliosis across different countries. The problem statement and objective of the project is also discussed in this section. Literature review gives a detail background of spine deformities and scoliosis. It also discusses the techniques used in diagnosing scoliosis and drawbacks it experiences. Methodology comprises of development of the new upgraded design, data collection and development of PCB. Result and discussion gives a comprehensive analysis of the data collected and discusses the significance and errors. Conclusion summarizes the overall work that has been put in this project and also briefly discusses the about the future plans involved in this project.

1.4. Objectives

This project is aimed to improve the existing design so that it can provide additional features for detection of scoliosis and measure the unevenness in the patient's body. The objectives of this project are:

1. Design a portable scoliosis measuring device that can measure shoulder height difference (SHD), Shoulder Lateral Tilting Angle (SLTA), Angle of trunk rotation (ATR), and Hump height difference (HHD)
2. Analyze the clinical test results of the portable scoliosis device against the results obtained from the conventional method used to diagnose scoliosis.
3. Print a functional PCB to make the design more compact and reduce errors.

CHAPTER 2: LITERATURE REVIEW

2.1.Spine and its Deformities

The spine of a normal person is made up of 33 vertebral bones stacked vertically one above the other. Each vertebra is separated from the other by the presence of intervertebral discs that cushions the bones from rubbing each other and providing flexibility. The spinal vertebrae are divided into 5 regions, namely: cervical (neck), thoracic (mid-back), lumbar (lower back), sacrum and coccyx. It has gentle curves, which helps in absorbing stress due to body movement and gravity, providing balance to the body and allowing a wide range of motion. A normal spine appears as a gentle 'S' when viewed laterally; the cervical (neck) and lumbar (lower back) regions gives concave curve and the thoracic and sacral region provides convex curve. Spine appears straight when viewed posteriorly but with the occurrence of spinal deformity the natural curvature of the spine is changed.

There are three main types of spine curvature deformity; namely Lordosis, Kyphosis and Scoliosis, as show in Figure 2.1. Lordosis (swayback) is a situation where the lower spine curves inwardly; protruding the buttocks outward. Patients suffering from lordosis have difficulties in moving in certain directions and experience back pain. Second type of spine curvature deformity, known as Kyphosis, is a condition where the upper spine curves by at least 50º, forming a rounded upper back. Kyphosis patients have a prominent hump on the upper back and the head is bent forwards. They generally experience weakness in the back and legs. The third and the most common type of spinal curvature is known as Scoliosis. The person suffering with Scoliosis has their spine curved sideways, often resembling the shape 'C' or 'S'. If the curvature of the back develops one curve, it is C-shaped curve and if the spine develops two curves it is S-shaped curve.

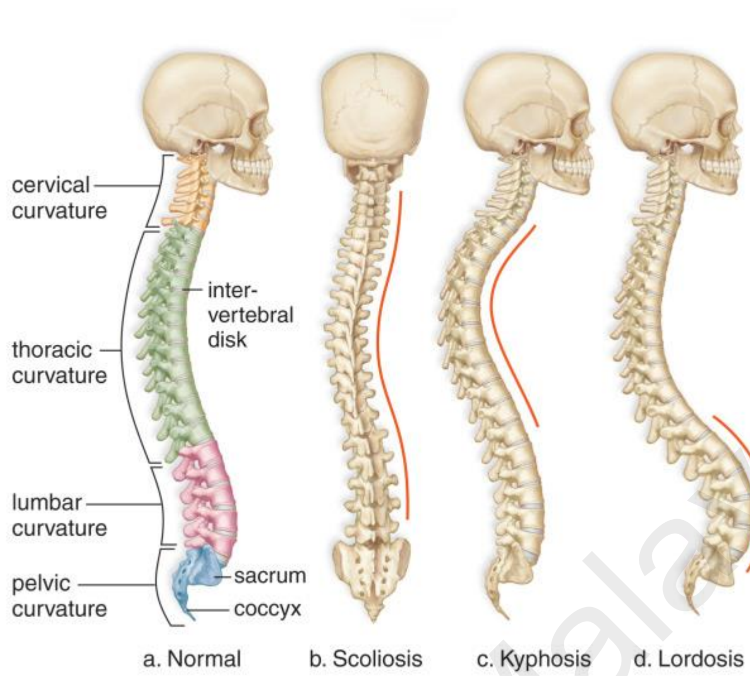


Figure 2. 1: Spine and its deformity

2.2.Scoliosis

Scoliosis was initially defined by Hippocrates as various types of spine curvature that can even be found in healthy population depending on their spine structure and their daily routine or style, also the spine bends as a person ages and also from pain (Goldberg, Moore, Fogarty, & Dowling, 2008). Ever since, many studies and researches have been done on Scoliosis but this statement has remained a vital piece of information since the beginning of research in this field. Presently, scoliosis is defined as a condition involving abnormal sideways curvature of the spine. Scoliosis can be caused by congenital, developmental or degenerative problems, but in most cases the cause remains unknown, this type of scoliosis is known as idiopathic scoliosis. Scoliosis is usually diagnosed when the spine is moderately or severely curved. It is indicated by the unevenness of the shoulder height, shoulder blades, rib cages and hips. As mentioned in Nelson Essential of Pediatrics E-Book (2011) scoliosis can be broadly classified as: Idiopathic, Congenital, and Neuromuscular Scoliosis.

Idiopathic Scoliosis is the most common type of scoliosis occurring in healthy, neurologically normal children having a family history of scoliosis in 20% of the cases. The occurrence is slightly higher in girls than boys; mostly it progresses in females and requires treatment. Idiopathic scoliosis is classified into infantile (age: 0-3 years), Juvenile (age: 4-10 years) and adolescent (age >11years). 70% of the times it is a painless disorder, its treatment depending on the maturity of the curve and whether the curve is progressive or non-progressive. Scoliosis progression is initially observed and monitored through radiographic scans when needed. The probability of curve progression depends on certain factors like gender, curve magnitude and curve progression. In girls it is five times more likely to progress when compared to boys; also, it progresses more in younger patients than the older patients. Normally curves under 25º are periodically observed (Lonstein, 1994). Progressive curves in the range of 20º and 50º in a skeletally immature patient are treated and controlled with bracing (Katz, Herring, Browne, Kelly, & Birch, 2010). Curves above 50º usually require surgical help (Weinstein & Ponseti, 1983).

Congenital Scoliosis is due to abnormal vertebral formation during the first trimester of the pregnancy. It can be classified as Partial or complete failure of vertebral formation (wedge vertebra or hemivertebra), Partial or complete failure of segmentation (unsegmented bars) and Mixed. 75% of patient suffering with congenital scoliosis will show progression till complete skeletal growth; out of which 50% will require some form of treatment. Congenital scoliosis treatment depends on the early diagnosis and identification of progressive curves. Orthotic treatment is not helpful in case of congenital scoliosis, spinal surgery is performed once the curve progression is identified.

Neuromuscular Scoliosis is a progressive type of scoliosis, which occurs with many neuromuscular diseases. It is mostly occurring as a result of weakness or imbalance of trunk musculature. The curves produced as such continues to grow through adulthood. Treatment of neuromuscular scoliosis depends on age of the patient and magnitude of deformity, with progressing curve bracing isn't effective.

2.3.Degree of scoliosis

According to South Florida Scoliosis Center, curves between 10º- 25º is considered mild scoliosis; the patient is observed at regular interval to monitor the growth the curve. The curve between 26º- 40º is considered moderate scoliosis, the patients are recommended to be braced and observed for curve progression (Negrini, Negrini, Fusco, & Zaina, 2011). Curves greater than 40º is considered severe scoliosis and mostly undergo corrective surgery (Weinstein & Ponseti, 1983). Figure 2.2 shows different degrees of scoliosis. The risk of progression of the scoliosis curve increases with the degree of scoliosis; for mild scoliosis the risk of progression is 22%, for moderate scoliosis it is 68% and for severe scoliosis the risk of curve progression is up to 90%.

A person suffering from mild scoliosis experiences uneven shoulders or hips, uneven leg length, tilted head, head appears forward of shoulder when viewed from the side, few cases experience pain. Mild scoliosis is curable if detected early and curve is small, but it mostly goes undetected until the curve progresses further. It is mostly diagnosed in young girls but can also be found in boys and adults. Moderate scoliosis affects the physical appearance more severely when compared to mild scoliosis. Along with uneven shoulders or hips, the patients have a shoulder higher than the other creating a rib hump. The patient suffers frequent headaches, fatigue after physical activity and may experience pain between scapulae and at the base of rib cage. Moderate stage scoliosis patients are recommended for bracing as it is necessary to reduce or stop the progression of curve, it is curable in cases of less severe curve. In severe stage scoliosis the shape of spine ('C' or 'S') is visible outwardly, the bellybutton is not in the center, have prominent rib hump, may experience pain in the spine and frequent headaches. In this stage a surgery is usually recommended. Figure 2.3 shows prominent symptoms shown by a scoliosis patient.

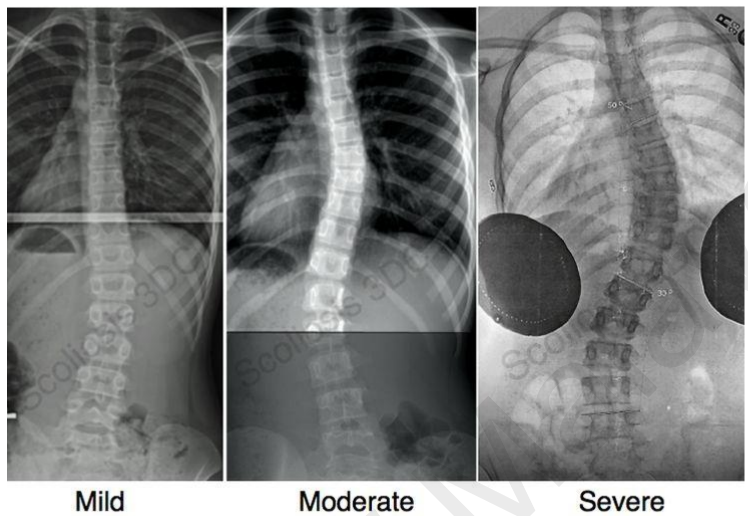


Figure 2. 2: Degrees of scoliosis

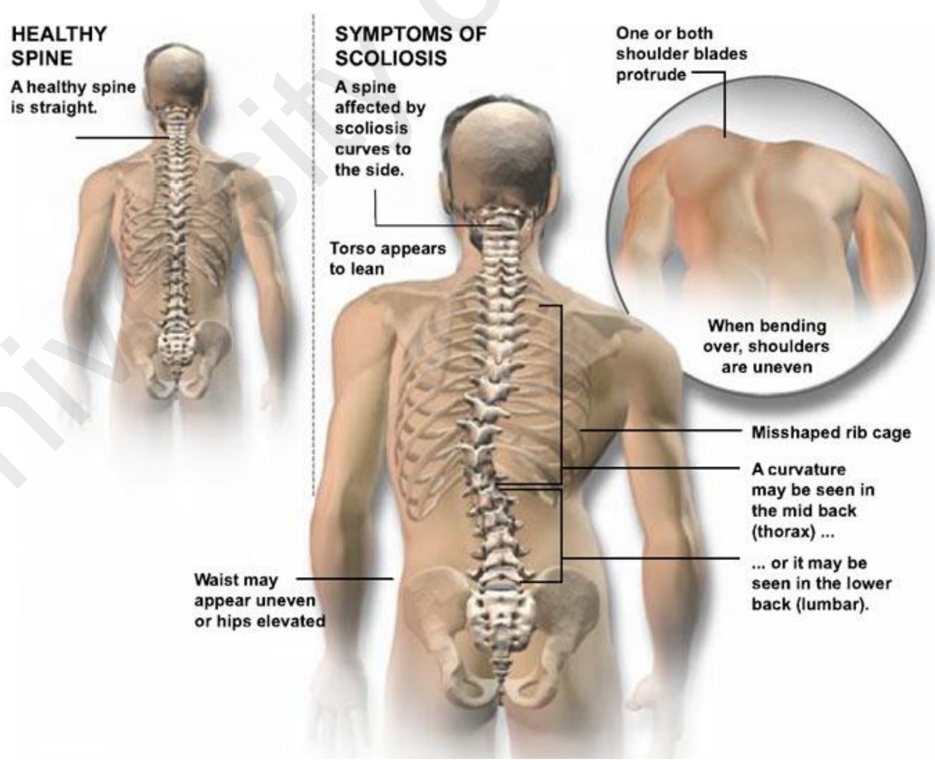


Figure 2. 3: Scoliosis Symptoms (Image adopted from Bernadettewestdc)

2.4. Scoliosis Diagnostic Tests and its Limitation

Scoliosis examination in a medical center usually begins with patient's medical history and physical examination. Medical history mostly includes details of family or relatives suffering with any spinal deformities or scoliosis, allergies, any health disorders or medical conditions, any heart or urinary tract problems at birth, consumption of any medication for any health issues, previous surgeries, etc. Physical examination includes assessment of patients posture and body contour, such as shoulder and hip unevenness, protruding shoulder blades, rib hump, unequal leg length, assessment of physiologic maturity, gait, pain, etc. Few medical devices and tests help in effectively screening scoliosis, it will be discussed in detail in this section.

2.4.1. Adam's Forward Bend Test and ATR Scoliometer

Adam's forward bending test along with an ATR scoliometer has proved to be an effective screening tool for scoliosis. For this test it is preferred for patient's to be bare or have minimum clothing so that the spine can be observed. As shown in Figure 2.4 the patient is asked to bend forward until the back becomes horizontal; with feet together, knee extended, and arms hanging parallel to the legs. The physician observes the patient from behind, eye-level with the patient's horizontal back. They examine patient's spine for any scoliosis indicator such as, asymmetries of vertebral column or scapula, unleveled shoulder or hip, alignment of head with respect to the pelvis or a rib hump. According to a study conducted in Dublin, forward bending test has proved to be 83% sensitive to predict or detect 40º scoliosis, but the sensitivity decreased with lower severe cases of scoliosis (Goldberg, Dowling, Fogarty, & Moore, 1995). According to another study done in a closed island population about a 10-year follow-up evaluation of the effectiveness of school screening for scoliosis, it has shown that Adam's forward bending test is not a safe diagnostic criterion for early detection of scoliosis especially when it is the only screening tool (Karachalios et al., 1999) (Grossman, Mazur, & Cummings, 1995).

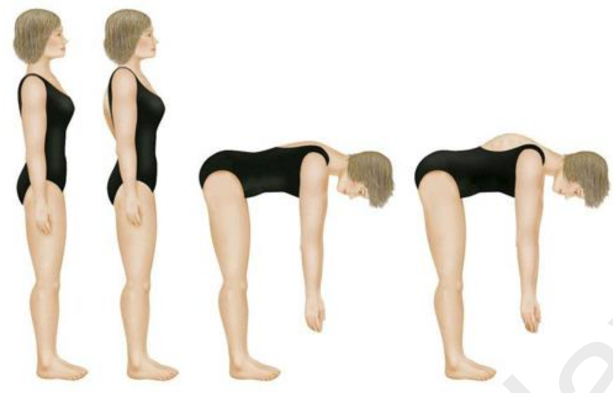


Figure 2. 4: Adam's forward bend test

To get a more affective screening technique, Adam’s forward bend test is combined with ATR scoliometer to diagnose scoliosis, as shown in Figure 2.5. A scoliometer or also known as inclinometer is used to measure the angle of trunk rotation. It is made of anodized aluminum, consisting of a ball placed at the center. The ball moves precisely in the measuring fluid displaying the accurately the inclination of the scoliometer. The information obtained from the scoliometer is used to decide whether the person needs further medical examination.

Figure 2. 5: ATR measurement using ATR scoliometer (adopted from openi.nlm.nih.gov)

To examine the patient using the scoliometer, the patient is asked to bend forward till a curve appears at the patient's thoracic region. The scoliometer is the placed and moved along the spine to measure the highest point of the thoracic curve. Then the patient is asked to bend forward till the lower back (lumbar) curve is visible and again the scoliometer is placed along to spine to measure the highest point of the curve. Bunnell defined the following screening cut-off criteria (Bunnell, 1993):

- $0^{\circ} \leq$ ATR $\leq 3^{\circ}$ Normal
- $4^{\circ} \leq$ ATR $\leq 6^{\circ}$ the trunk rotation is intermediate
- $7^{\circ} \leq$ ATR high possibility of having scoliosis

ATR scoliometer has proved to be reproducible and repeatable examination. In this examination, an ATR of 7º or higher, has shown a sensitivity of 83.3% and specificity of 86.8% (Amendt et al., 1990) (Chowanska, Kotwicki, Rosadzinski, & Sliwinski, 2012). According to other researchers patients with ATR value 5º should be referred for further examination to check for any progression of spinal curve (Coelho, Bonagamba, & Oliveira, 2013) (Stolinski & Kotwicki, 2012). However, scoliometer alone cannot be used to diagnose the presence of scoliosis as studies have proved that when compared with radiographic scans, the scoliometer has shown undesirable result for larger Cobb angles (Huang, 1997). Another study was conducted on scoliosis patients to test the intra-rater and inter-rater reliability of scoliometer. For the lumbar spine and for the upper and lower thorax, the inter-rater reliability is relatively lower than the intra-rater values of the same spinal segments, even with the errors from palpation and instrument positioning eliminated (Bonagamba, Coelho, & Oliveira, 2010). Scoliometer though proved to be a reproducible and repeatable device, it still involves the unreliable events that affects the reliability of the data collected; unreliable events like instrument placement, different bending levels at different measurements and parallax error from the physician.

2.4.2. Imaging Tests

Once a patient is screened positive for scoliosis, he is referred for imaging test to detect the extent of his condition. Currently, radiological scans are the primary technique to diagnose scoliosis, as it is the most cost-effective method. There are other diagnostic methods, such as MRI or CT-scan, but they are more expensive, time-consuming and are more invasive methods Hence x-ray is preferred over other methods. X-ray screening shows all types of spinal deformity, reveals severity of scoliosis, maturity of skeletal growth and can also classify structural and non-structural scoliosis. Young patients or adults with severe progressing scoliosis are recommended x-rays every few months to continuously monitor the spine condition. The x-ray scans show the lateral deviation of spine due to scoliosis. Cobb method is used to measure the lateral deviation of the spine giving Cobb angle. This angle is the angle between the upper boarder of the uppermost vertebra and the lower border of the lower most vertebra in the curve, as shown in Figure 2.6. Though being two-dimensional measurement, it is not accurate to describe a three-dimensional deformity but due to its simplicity to calculate and understand, it has become a standard for scoliosis assessment.

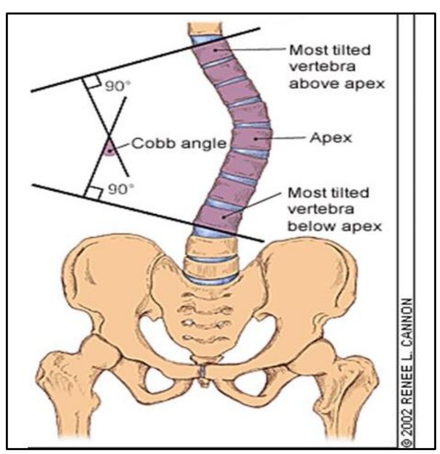


Figure 2. 6: Cobb angle measurement

Cobb angle helps the physicians to determine the type of treatment be given to a specific patient. A Cobb angle greater than 10º indicates the possibility of scoliosis (Choudhry, Ahmad, & Verma, 2016). Cobb angle between from 10º-25º are monitored periodically and are categorized under mild scoliosis. Moderate scoliosis is scoliosis with cobb angle between 26º to 40º and patients suffering with moderate scoliosis are prescribed brace to prevent the curve progression. Cobb angle greater than 40º, falls under the category of severe scoliosis; it usually involves surgical interventions (Weinstein & Ponseti, 1983). Curve progression is monitored by comparing the consecutive graphs taken. If the cobb angle is greater than or equal to 5º, the curve is like progressing (Will, Stokes, Qiu, Walker, & Sanders, 2009). Usually patients with progressing curve are first monitored if bracing helps to stop or reduce curve progression. In cases of severe curve progression where bracing fails, corrective surgery is promoted.

Patients with progressing curve need more frequent x-rays taken when compared to the other cases. Due more frequent exposure of x-ray various protective measures has been adopted to reduce the harmful impact of the radiations. These protective measures include taking patient scans from the back rather than the front which exposes radiation to all soft tissue. Directing the x-ray beams on the back of the patients get absorbed mostly by the spine bones and hence protect the internal soft tissues. Also x-ray filters are used to absorb all the unwanted diverted beams and with the use of fast film the exposure time has reduced by 2-6 times. Lead aprons or shields are used on the parts that does not require the exposure, protecting it from unnecessary exposure (De Smet, Fritz, & Asher, 1981). Even after adopting these protective measures the physicians and experts are still concerned about the frequent exposure and its impact in the long run. Female population are more prone to scoliosis and curve progression, exposing them more to these low-level diagnostic radiations. As per a study done over 1030 women with scoliosis, exposed to an average of 8.7 radiation over a year. 11 cases of breast cancer were reported, mostly report in females who were monitored for more than 30 years. This study revealed exposure risk increased with time since exposure (Hoffman et al., 1989). Apart from breast cancer, continuous exposure to radiation since an early age can induce a radiation induced cancer of the thyroid, brain skin and leukemia (Kleinerman, 2006). Hence the researches are heavily done in this field to develop a reliable tool to reduce the use of radiograph on patients.

2.5. Pre-and postoperative assessment

In case of severe scoliosis, where the curves continuously get worse and brace fails to control the progression, surgery is considered. The main goals of scoliosis surgery are to stop the progression of curve, deformity reduction and maintain trunk balance. Depending on patient's situation the approach of the surgery differs. Doctors generally classify the curve to identify the curve pattern and determine an appropriate surgical technique to the patient. There are two types of classification technique which the doctors may adopt to identify the curve pattern; namely, King Classification and Lenke Classification. Lenke Classification is more widely used as it takes into consideration more features of the curve, than King Classification, giving more reliable solution. Lenke classification has three components: Curve patterns, Lumbar spine modifiers and Saggital thoracic modifier. Though this classification helps the surgeons in determining the extent of surgical help a patient, it is still in evolving phase to produce better predictions (Choudhry et al., 2016). Once the surgery is determined the surgeons record different asymmetries and irregularities of patient's body and keep it as a reference for post-operative measurement. These data help to determine the success of the surgery. The key aspects to determine the success of the surgery are:

2.5.1. Shoulder Height Difference and Baseline Scoliometer

Right after being diagnosed with scoliosis it is necessary to assess the extent of asymmetry of the spine and other body parts affected because of tilted spine. Shoulder imbalance is one of the common symptoms of scoliosis, surgeons record these differences and compare it with consecutive follow-ups to assess the growth of curve. Shoulder imbalance is commonly identified as shoulder asymmetry. Imbalance in shoulder causes an irregular gait in the patient, and it also plays an important factor in achieving cosmesis after surgery. Cases have been recorded of patient having balanced shoulder with irregular trunk alignment before surgery but post-operative assessment reveal improved trunk but unbalanced shoulder, as shown in Figure 2.7 and Figure 2.8 (Menon, Pillay, M, Tahasildar, & J, 2015).

Figure 2. 7: Pre-and postoperative SHD

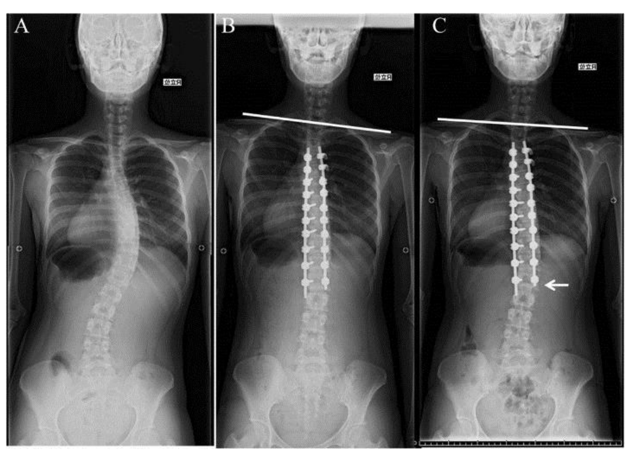


Figure 2. 8: Radiographic image of SHD before and after surgery

To be able to measure these asymmetries in the body a baseline scoliometer is used. Figure 2.9 shows a baseline scoliometer, it is an essential tool in measuring the degree of scoliosis by assessing the asymmetries. It measures six areas to detect scoliosis, provides measurements for unstable lumbosacral curve, the cervical and thoracic curves. It can be calibrated in millimeter, centimeter and degrees based of the requirement of the user. It claims to eliminate the need of x-ray during scoliosis assessment. It consists of centrally placed inclinometer affixed on a transverse rod, distally supporting a pair of movable extension rod that is designed to be placed on patient's acromion. The extension rod is fitted with two sets of adjustable screws. The screws positioned below the transverse rod helps to fix the extension rod in place and the screws positioned on top of transverse rod are designed bring the transverse rod in a horizontal position and the difference between the height of two screws on each side gives the shoulder height difference (SHD) in millimeters. The inclinometer gives the tilting angle when the extension rods are placed on the acromion, displaying the shoulder lateral tilting angle (SLTA) as shown in Figure 2.10.

Figure 2. 9: Baseline Scoliometer

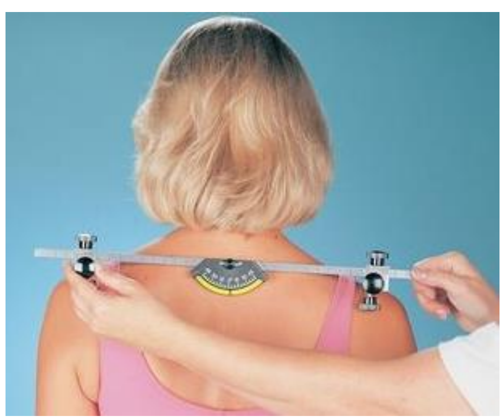


Figure 2. 10: Shoulder imbalance assessment using baseline scoliometer

Baseline scoliometer has the benefit of being lightweight and handy, hence the physicians find it easy to carry. It is a dismountable device, which gives it the benefit of being portable and occupying less storage space. Also, it’s a manual device making it a safe to be operated on patients. However, device requires the user to undergo proper training to use this device. It is a time consuming and tedious process, better performed when the operator has additional help to fix the extension rods in place to measure SHD. The inclinometer affixed on the transverse rod gives analog values with very little precision because of the low accuracy of the inclinometer scale. The inclinometer reading is also subjected to be erroneous depending on the placement of the device and parallax error. The device is expensive as well to be purchased by low to average income population. A reliable method to measure SHD is by manually measuring the SLTA on a radiographic scan, as shown in Figure 2.11, and then calculating the SHD. Though it is a reliable method but due to radiation exposure this method is not appreciated.

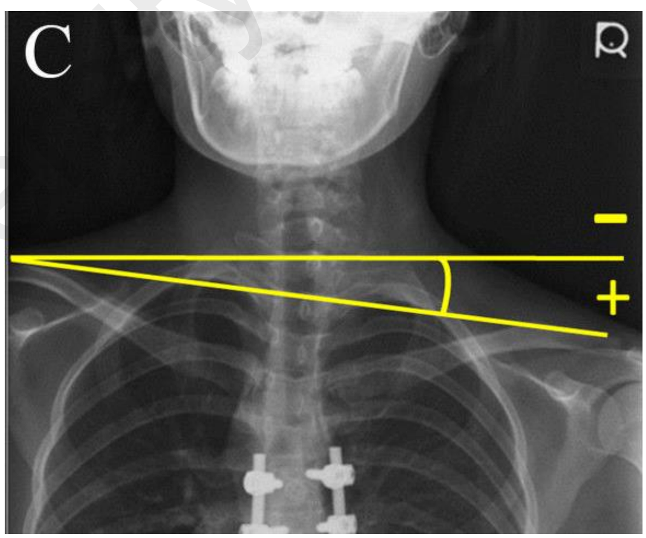


Figure 2. 11: Post-operative radiological shoulder assessment displaying shoulder tilt angle (adopted from (Matsumoto et al., 2014))

2.5.2. Rib Hump

Scoliosis involves lateral curvature of spine, along with vertebral rotation. As the curves progress, the spine rotates towards the concave side of the spine curve, moving the rib cage along with it. As shown in the Figure 2.12, ribs on the concave side are pushed anteriorly while ribs on the opposite side are pushed posteriorly, forming the rib hump that protrudes out in the thoracic region. In most cases no pain is experienced, but in case of pain in rib hump there is a possibility of intraspinal rib displacement at the apex of kyphoscoliotic curve. When the dislocated rib head presses against the spine or thorax, it disturbs the nearby nerve root, producing pain (Gkiokas, Hadzimichalis, Vasiliadis, Katsalouli, & Kannas, 2006).

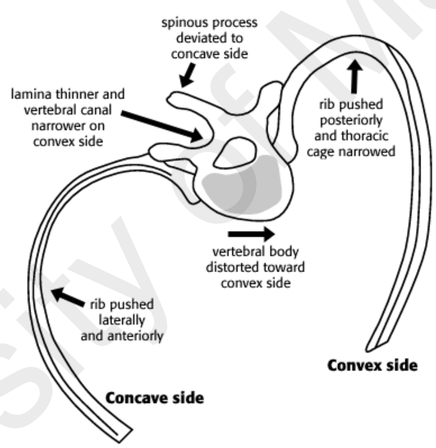


Figure 2. 12: Rib rotation due to scoliosis

Rib hump is not much visible in mild scoliosis but as the curve progresses it becomes more prominent. Physicians have various techniques to measure rib hump, and it is monitored in every patient visit to check for curve progression and trunk rotation. Rib hump can be measured non-invasively using baseline scoliometer or invasively by measuring the Rib Index (RI) on a lateral spinal radiograph. Measurement of rib hump using scoliometer is similar process like SHD measurement, while in this case the patient is asked to bend forward and then physician monitors the thoracic or lumbar hump using baseline scoliometer. To measure the rib hump by calculating rib index, a lateral spinal radiograph is taken. On the image, the distance from the posterior margin of the vertebral body to the most protruding rib is calculated, for the both the convex and concave side. These distances are recorded as d1 and d2 respectively; and then the rib index can be calculated (Equation 2.1).

Equation 2.1 Rib Index Calculation

$$\text{Rib Index (RI)} = \frac{\mathrm{d1}}{\mathrm{d2}}$$

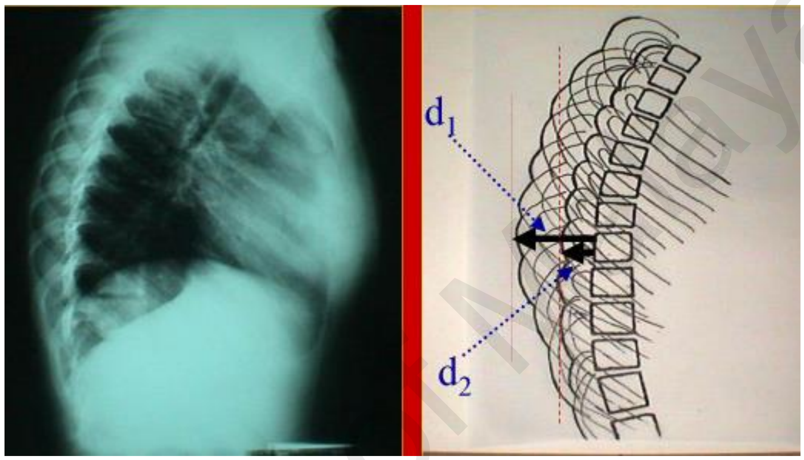


Figure 2. 13: Rib Index (adopted from ResearchGate)

Rib Index is beneficial in treatment of scoliosis in four different ways: Documentation of the deformity, Physiotherapy assessment, Brace treatment assessment and pre-and postoperative assessment. From the time a person is screened for scoliosis, he is frequently monitored for scoliosis progression. RI can be useful in documenting accurate rib hump. In mild to moderate cases of scoliosis the patient's the recommended to undergo physiotherapy to prevent the curve progressing or getting worse. In these cases, RI can used to monitor patient's rib hump and to see how positively the physiotherapy is helping. RI is also useful in monitoring spine improvement in patient's wearing brace. It is also beneficial in assessing pre-and postoperative rib hump (Grivas, 2014). Though RI has proved to be a beneficial method, but it still exposes patients to radiations. Also, this procedure is expensive and more time consuming when compared to baseline scoliometer.

2.6.ScolioS^2

ScolioS^2 was developed by a group of researchers working on developing a digital device that could assist the physicians to measure various parameters involved in scoliosis assessment. This project was initiated in October 2016 by Low June Weng under the supervision of Ir. Dr. Lai Khin Wee. The research group also consisted of Dr. Lee Chee Kean a consultant spine surgeon at UMMC and Prof Dr. Kwan Mun Keong, the chief spine surgeon at UMMC who contributed by sharing their knowledge about the limitations in the existing technology. Development of a portable device ScolioS^2, hence then started with rigorous research and design considerations. The first prototype of ScolioS^2 developed by Low June Weng, could quantitatively measure the SHD, SLTA and ATR. The device was built using different electronic components encased within 3D printed parts.

Figure 2.14 shows the prototype built by Low June Weng. It consists of a 16*2 LCD that displayed the results of parameters measured using this prototype. It consisted of two pushbuttons; one was the power button that works as ON/OFF of the device and the other pushbutton (M) was for selecting the desired mode (SHD and SLTA or ATR). The M pushbutton when in high state used to display ATR in degrees and in low state used to display SHD and SLTA.

Figure 2. 14: ScolioS^2 first prototype developed by Low June Weng

To measure SHD and SLTA the tips of the extension were placed on the patient's acromion and slowly arced up and down till the led in the front lights up. The SHD and SLTA displayed on the LCD is recorded. To measure the ATR, the pushbutton (M) has to be set to high state. The device is then placed on patient's bent back and moved long the visible spine. The LCD displaying the highest ATR is recorded.

This invention was a novelty developed by Low June Weng that has bought him recognition and appreciation. He aims to improve this device up to the present standards of the market and get it FDA approved. To test the accuracy and precision of the device it needed clinical testing. However, when handed over to doctors at PPUM (UMMC) involved in this research, they refused to perform the clinical testing at this stage. They wanted the prototype to measure HHD as well. They also wanted the distance between the two extensions to be reduced as it could not measure the SHD for younger patients.

CHAPTER 3: METHODOLOGY

3.1. Introduction

This chapter discusses the steps involved in upgrading the ScolioS^2 Prototype developed by Low June Weng. It will also discuss the design criteria of the existing device and limitations of the existing methods. This section also discusses the components used, cost estimation, circuit connection, 3D printing of the prototype casing and the PCB development. This prototype, in addition to Shoulder Height Difference (SHD), Angle of Trunk Rotation (ATR), also measures the Hump Height Difference (HHD) as requested by the physicians in PPUM. Once the prototype fabrication was completed it was delivered to PPUM for Clinical testing.

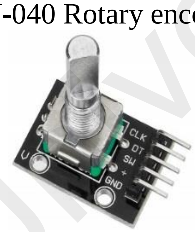
3.2. Design Consideration

A scoliosis patient suffers from shoulder imbalance, rotated spine, rib hump, uneven hips and other imbalances in the body depending from one patient to another. ScolioS^2 was built to measure the shoulder height difference and trunk rotation of the patient. It however failed to measure the rib hump of the patient, which is very prominent for the scoliosis patient when they bend over. It is one important aspect to observe in patients and also beneficial to measure the rib hump after corrective surgery. Hence the doctors of PPUM requested for this additional feature to be added to ScolioS^2. This project hence aimed at adding a new feature to the full functioning ScolioS^2, developing this feature the major concern was to integrate the new features without affecting the precision of the existing features or adding any time delay. Another concern involved in developing this prototype was the weight of this device, it should be light in weight for the ease of use. To reduce the weight of the existing prototype, a PCB was built to eliminate the weight of connectors and also to eliminate the risk of data loss and loose connections.

3.3.Cost Expenditure

The cost expenditure to develop ScolioS^2 is mentioned in Table 3.1 and the cost expenditure to develop the PCB is mentioned in Table 3.2.

Table 3. 1: Total Cost in Building ScolioS2

Component	Specification	Quantity	Unit Price (RM)	Subtotal (RM)
Arduino Nano V3.0 	• Microcontroller: ATmega328 • Operating Voltage (logic level): 5 V • Input Voltage (recommended): 7 – 12V • Input Voltage (limits): 6 – 20V • DC Current per I/O Pin:40 mA • EEPROM: 1kB • Clock Speed: 16 MHz	1	30.00	30.00
GY-291 ADXL345 Triple Axis Accelerometer Module 	• Operating voltage: 2.0 – 3.6 V • I/O Voltage Range: 1.7V - 3.6V • SPI (3- and 4-wire) and I2C digital interfaces • Acceleration range: ±2, ±4 ±8, ±16g • Sensitivity: 660mV/g at ±2g; 330mV/g at ±4g; 165mV/g at ±8g; 82.5mV/g at ±16g	1	15.00	15.00
KY-040 Rotary encoder 	• Operating voltage: 5V DC • Resolution: 20 pulses/360º per phase • With push button • Most commonly used with Arduino	1	7.00	7.00
LCD 	• Operating voltage: 5VDC • Display format: 16 characters × 2 lines • Display dimension: 66 × 16mm • Display Font: 5 × 8 dots • LED backlight: white • Adjustable contrast with I2C potentiometer	1	22.00	22.00

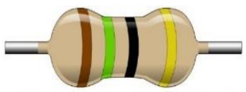
Pushbutton 	• Thread Black & Red Cap SPST Latching Type Push Button Switch OFF-ON	4	2.00	8.00
LED 	• Red light emitting diode	1	0.15	0.15
Resistor 	• Linear Fixed Resistor • Resistance: 15 Ω • Tolerance: 5%	1	0.05	0.05
Capacitor 	• Ceramic capacitor • Capacitance: 1μF	1	0.15	0.15
Jumper Wire 	• Solid conducting wires • Female to female • Length 10cm	10	0.50	5.00
9V Battery 	• GP 1604A PP3 6LF22 6LR61 1604G 6F22 9V Alkaline Battery Gold	1	10.00	10.00
Battery Snap 	• 9V Battery Holder Clip Contor Hard Shell 10cm Cable Lead	1	0.40	0.40
Screw 	Oval head lag screw course thread	4	0.13	0.50
Total (RM)				98.25

Table 3. 2: Total Cost in developing the PCB

Component	Quantity	Price per unit (RM)	Subtotal (RM)
PCB Printing	1	180.00	180.00
Arduino Nano V3.0	1	30.00	30.00
GY-291 ADXL345 Triple Axis Accelerometer Module	1	15.00	15.00
KY-040 Rotary encoder	1	7.00	7.00
LCD	1	22.00	22.00
Pushbutton	4	1.50	6.00
LED	1	0.15	0.15
Resistor	1	0.05	0.05
Capacitor	1	0.15	0.15
Male/Female Headers	-	-	16.00
9V Battery	1	10.00	10.00
Battery Snap	1	0.40	0.40
Total			286.75

3.4.Hump Height Difference:

The existing prototype ScolioS^2 could precisely measure SHD and ATR, but a scoliosis patient suffers from many other asymmetries in the body that needs to be measured in the diagnosis and monitoring the severity of scoliosis. Among the various asymmetries, the scoliosis patients suffering from spinal deformity has asymmetrical hump height. The doctors at Spine Research Unit of PPUM wanted the existing prototype to measure HHD along with SHD and ATR. Hence the first step of this project was to add an additional feature as requested by the doctors of PPUM. The previous prototype operated on two pushbuttons, one was connected to the 9V battery that switched on and off the prototype. The second was connected to the two modes, displaying the SHD in the low state and ATR in the high state.

Whereas, the present prototype has separate pushbuttons for all the three modes and a power button to switch on and off the prototype. The main challenge in developing this third mode was to integrate it with the existing two modes without affecting the precision of the two modes or introducing any time lapse in the system. The whole system has to give a real-time output without any delay.

The working principle of the present prototype is similar to that of ScolioS^2. The KY040 rotary encoder and ADXL345 accelerometer acts as the sensing input, the Arduino Nano is the processing unit and the LCD and LED are the output units. As shown in Figure 3.1, a 9V Alkaline Battery powers the prototype. It is connected to a pushbutton which is then connected to the Vin of the Arduino Nano, hence acts as the power button. The prototype turns on when this push button is in high state and the system shuts down at low state of the push button. Other three pushbuttons are connected to D5, D6 and D7 pins of Arduino Nano to measure the SHD, ATR and HHD respectively. The LED is connected to D4 pin of the Arduino Nano. It lights up when the y-tilting angle of the accelerometer falls in the range of -1.0º and 1.0º, while measuring the SHD and HHD, which in turn freezes the LCD screen for a short duration so that the readings could be recorded. It also lights up while measuring ATR if the angle falls out of the range of -7.0º and 7.0º indicating the presence of mild scoliosis.

The KY040 rotary encoder is connected to the 5V pin of the Arduino and the common ground. The CLK and DT pins acts as the output of the rotary encoder, which sends digital signal to the Arduino indicating the magnitude and direction of shaft rotation. The CLK and DT pin of rotary encoder are connected to the D2 and D3 pins of Arduino respectively. The ADXL345 measures the tilting angle of the prototype in the x and y-direction. It communicates with Arduino through its inbuilt inter-integrated (I2C) communication protocol. The two I2C interface pins of accelerometer, SDA and SCL are connected to the

A4 and A5 pins of Arduino respectively. The ADXL345 need 2.0V to 3.6V of voltage supply to operate. Hence it is connected to the 3V3 pin of Arduino board which supplies 3.3V to the accelerometer. The I2C compatible LCD module used in this project, like ADXL345, consist of a SDA connected to pin A4 and SCL connected to pin A5 of Arduino. A 5V supply is provided from the board to the LCD and the ground is connected to the common ground.

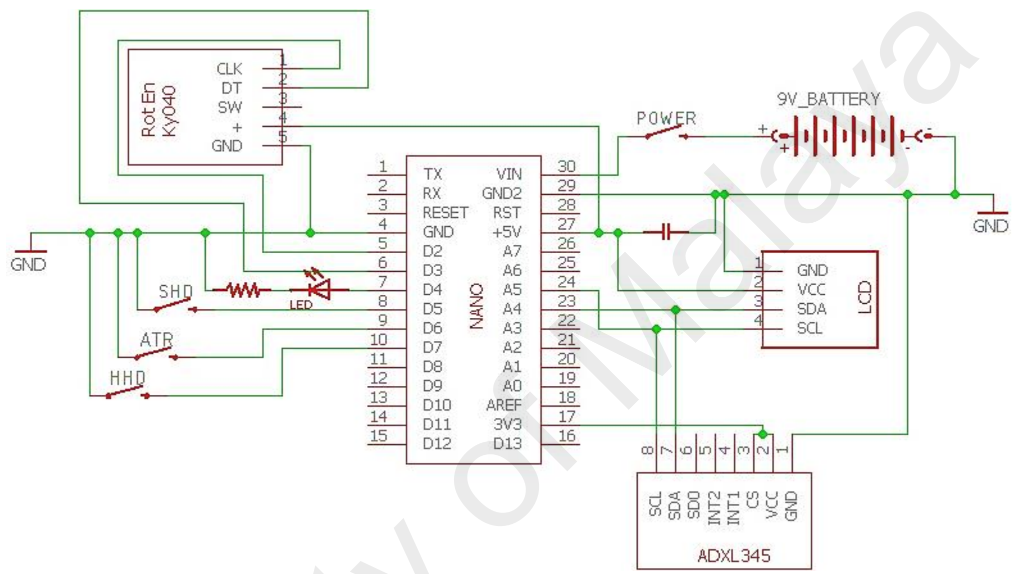


Figure 3.1: Schematic of the connection

3.5.Prototype Design

Doctor’s preferences were taken into consideration while designing the new casing, which included the prototype being user-friendly, compact size, light in weight as it is a handheld device it would be comfortable for the physician to use it for a longer duration. The doctors also wanted the distance between the two extensions to be reduced to 10cm so that it is convenient to measure for young patients. With the added circuitry of the third mode to the previous prototype, reducing the size of the prototype was difficult. Hence the casing of previous prototype developed using SOLIDWORKS was modified, so that the new casing could accommodate four pushbuttons instead of two. Also, the shapes of racks where modified to reduce the distance between the extensions to at least 13cm, which was later accepted by the doctors as well. Once the modifications were made on SOLIDWORKS, the 3D model files were converted to Standard Triangle Language (STL) files that is accepted by the 3D printers. The parts were printed using Stratasys Mojo printer and Poseidon X 3D printer. Similar to ScolioS^2 the LCD and LED were installed on the front cover, the 9V battery was put in the battery compartment designed on the top-left of the central enclosure, the pushbuttons were mounted on top-right of the central enclosure, the accelerometer occupied right floor end of the central enclosure, Arduino was placed on the bottom left of the central enclosure and the rotary encoder was placed on the back wall of the central enclosure. The gear is mounted on the shaft of rotary encoder. The two racks are connected together through the gear. Figure 3.2-11 show different parts on ScolioS^2 designed on SOLIDWORKS, Figure 3.12 shows the whole assembly and Figure 3.13-15 shows the assembled ScolioS^2.

Figure 3. 2: Front Cover

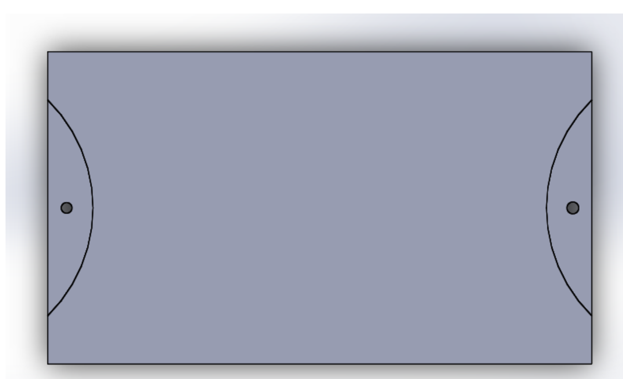


Figure 3. 3: Back Cover

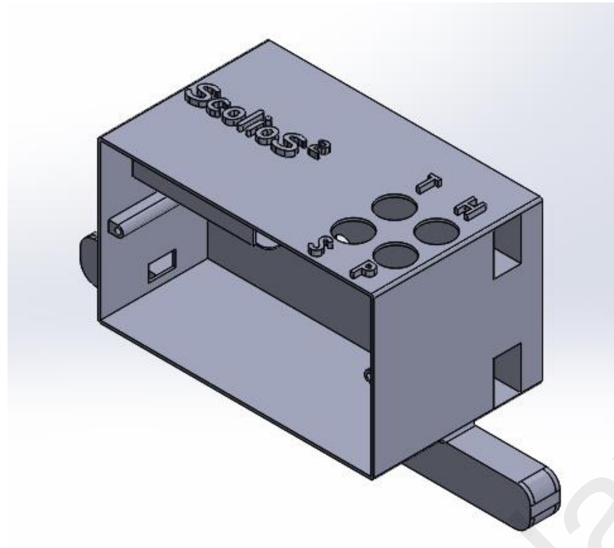


Figure 3. 4: Center Enclosure

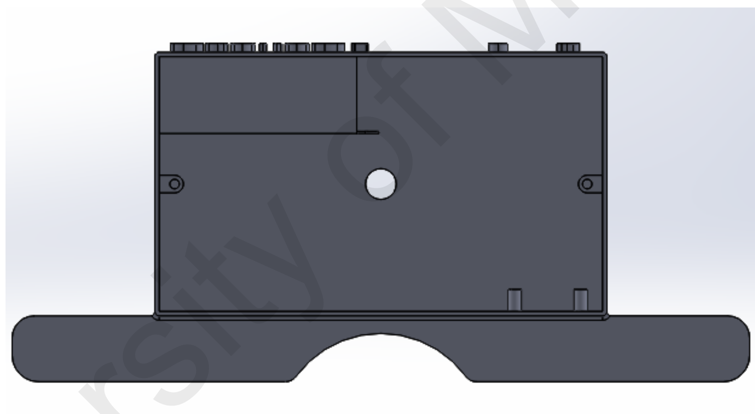


Figure 3. 5: Center enclosure (front view)

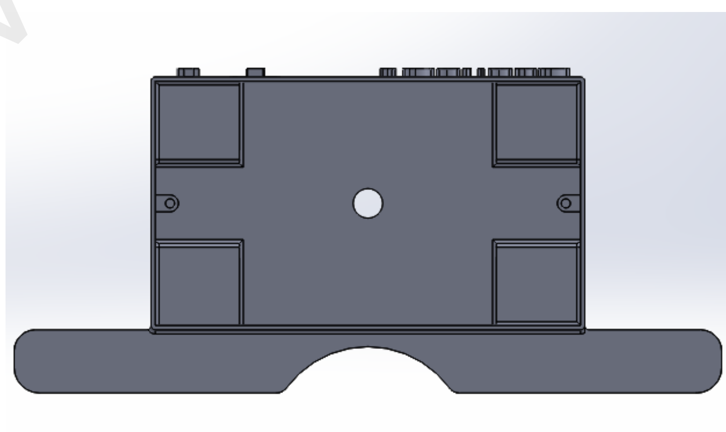


Figure 3. 6: Center enclosure (back view)

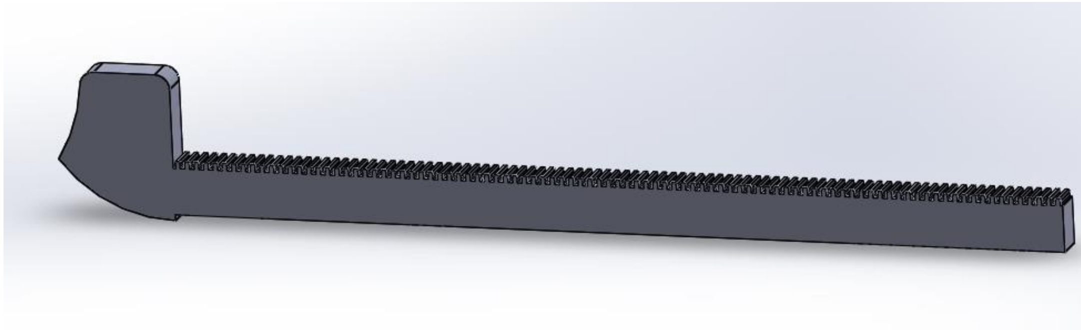


Figure 3. 7: Rack 1

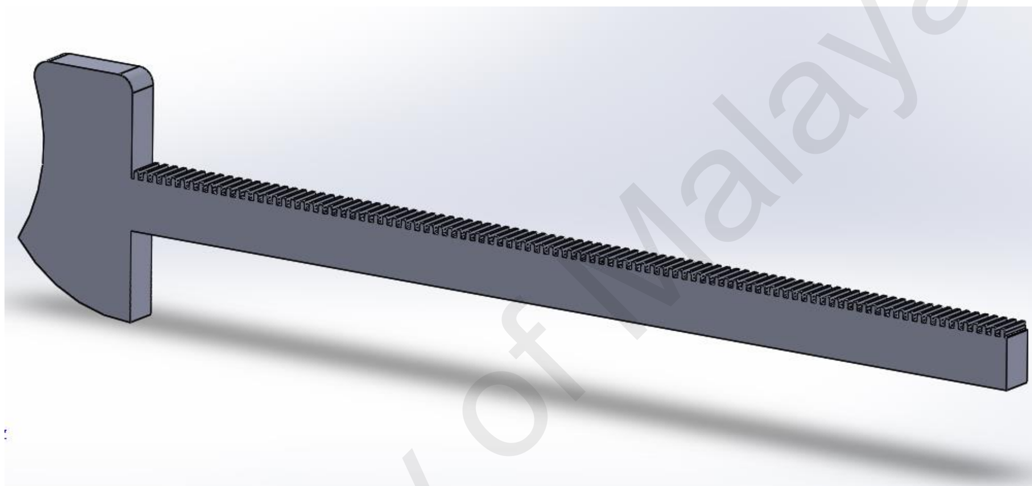


Figure 3. 8: Rack 2

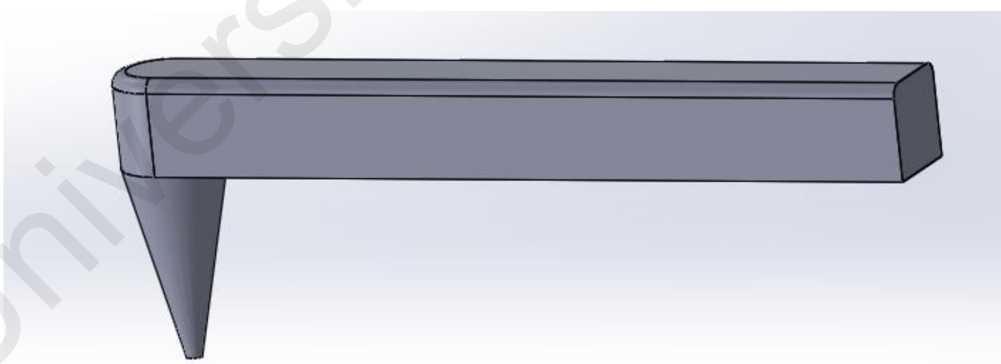


Figure 3. 9: Extension

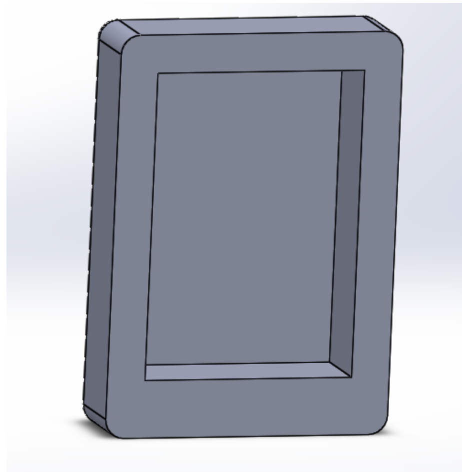


Figure 3. 10: Stopper

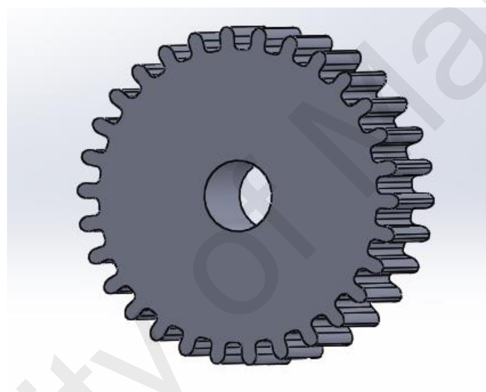


Figure 3. 11: Pinion

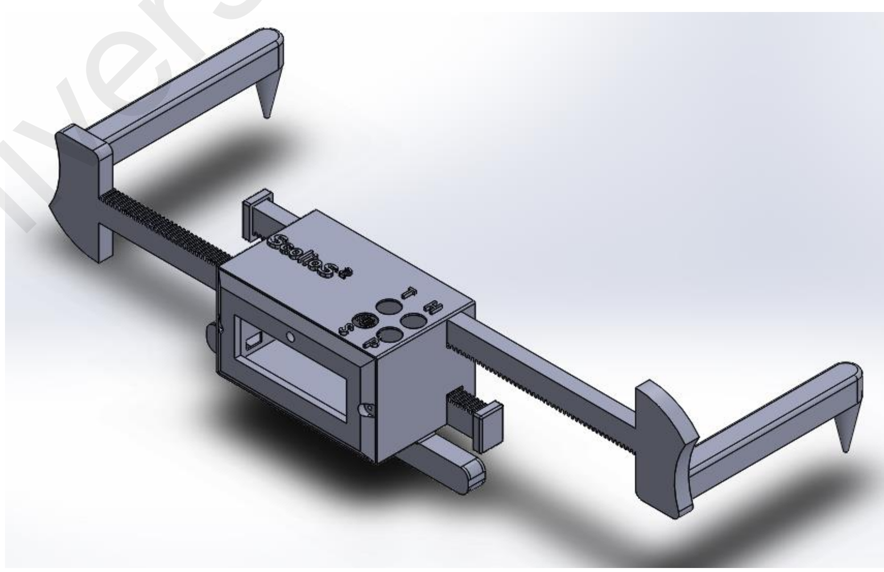


Figure 3. 12: Full assembly

Figure 3. 13: ScolioS^{2} Prototype (top view)


Figure 3. 14: ScolioS^{2} Prototype (front view)

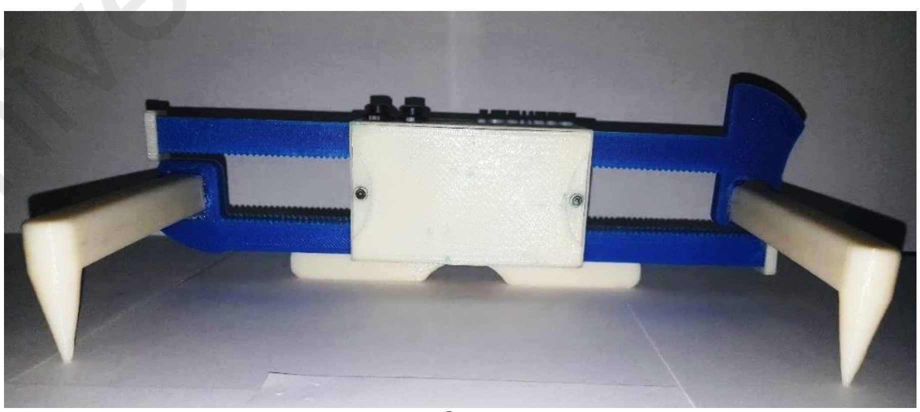


Figure 3. 15: ScolioS^{2} Prototype (back view)

3.6.Working Principle of the Prototype

The prototype consists of a sensitive accelerometer that measures the tilting angle of the device and a rotary encoder detects the translational motion of the racks through rotating gear that is mounted on the shaft of the rotary encoder and then detects the linear displacement of the racks. The linear displacement measured by the rotary encoder is the distance between the two tips of the extension. Using trigonometric equations, tilting angle and distance between the two tips we can calculate the height difference between the two tips. To measure Shoulder Height Difference (SHD) and Shoulder Lateral Tilting Angle (SLTA) of a patient, the patient is asked to stand straight and both the distal ends of the extension of the prototype is placed on patient's acromion (scapula's protruding bony process). The prototype then needs to be slowly moved up and down until the LED turns on. Turning on of the LED freezes the reading of SHD and SLTA for a few seconds so that the physicians can record it, before it resumes to give real-time readings.

To measure ATR, the patient is requested to remove or wear minimum clothing to perform Adam's Forward Bend Test. Placing the bottom of the prototype on patient's spine at right angle and slowly move it from the cervical region to the lumbar region to test for any spinal deformity. With the help of the accelerometer mounted inside the prototype, the device continuously displays the tilting angle. For Patients with ATR of 7º or higher, are susceptible to spinal curvature or Cobb angle of at least 25º, which indicate the presence of scoliosis in patients (Samuelsson & Noren, 1997). To measure the HHD the patient is told to bend as done in forward bending. The tip of the extension is then placed of the two-visible rib hump of the patient and the device is moved slightly up and down till the LED lights up. The LCD displays locks allowing physicians to record the reading before it resumes displaying real-time values.

3.7. Testing of ScolioS^2

Clinical testing of ScolioS^2 was conducted on patients with different degree of scoliosis to verify its accuracy. A total of 17 subjects were assembled to test the validity of ScolioS^2. The subjects were firstly examined for SHD and SLTA using baseline scoliometer and then were asked to bent forward to measure the ATR using ATR scoliometer and HHD using baseline scoliometer. The subject then went through the same procedure of examination once again but using ScolioS^2. These examinations were done for all the patients in order to test the accuracy of ScolioS^2 with respect to the conventional scoliometer.

3.8. Data Analysis

The clinical data obtained from UMMC is displayed in the Appendix C of this report. The data consists of results obtained for SHD, SLTA, ATR and HHD from conventional method (baseline scoliometer and ATR scoliometer) and from ScolioS^2. It also consists time taken by each method to record the data. The data obtained is analyzed using the excel statistical analysis tools and MedCalc software. MedCalc is a software widely used in analyzing clinical data. A very systematic handy tool while dealing a wide range of data.

Box plot is constructed to evaluate the time take by each method, bar charts are plotted to compare the results of the two methods, correlation graphs are plotted to understand the relation between the two methods and Bland Altman analysis is done to analyze the agreement between the two methods.

3.9. PCB Development

PCB has become the integral part of all electronic devices in the present time. It helps to reduce electronic noise, diagnostic and repair simplicity in case of breakdown, provides a compact size and freedom to move the device without affecting the internal components. A PCB was built for ScolioS^2 using Eagle 8.3.2 premium provided by AUTODESK. After designing and modifying the PCB Layout based on the requirement of PCB Lab at the Electrical Engineering Faculty at UM, it was passed to the lab for printing. Undergoing a series of processes in the lab, a Single Sided PCB was fabricated and passed back in three working days. Steps to fabricate Single-Sided PCB is shown in Figure 3.16. Figure 3.17-21 shows fabrication and development of a functional PCB.

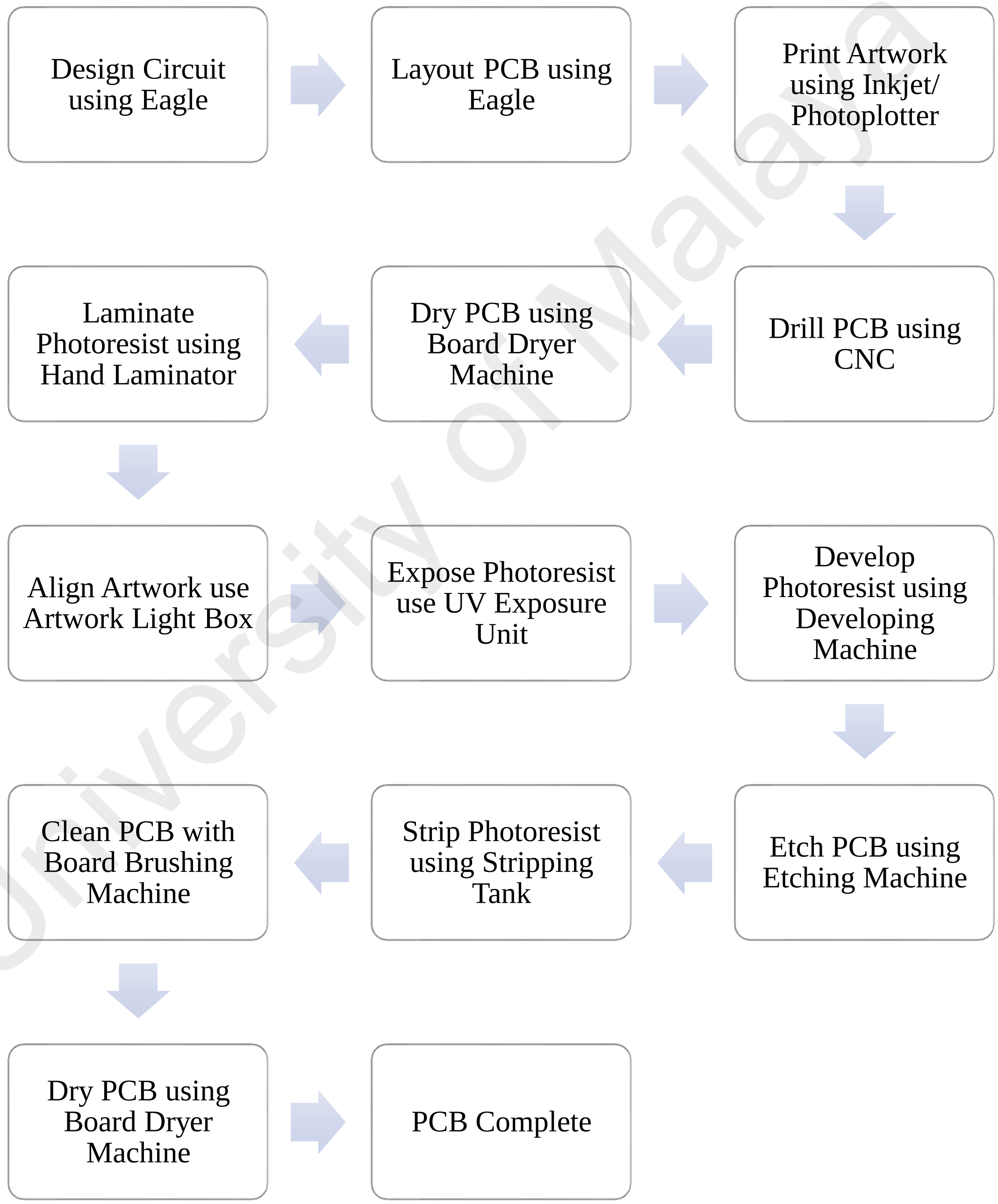


Figure 3. 16: PCB Development Process

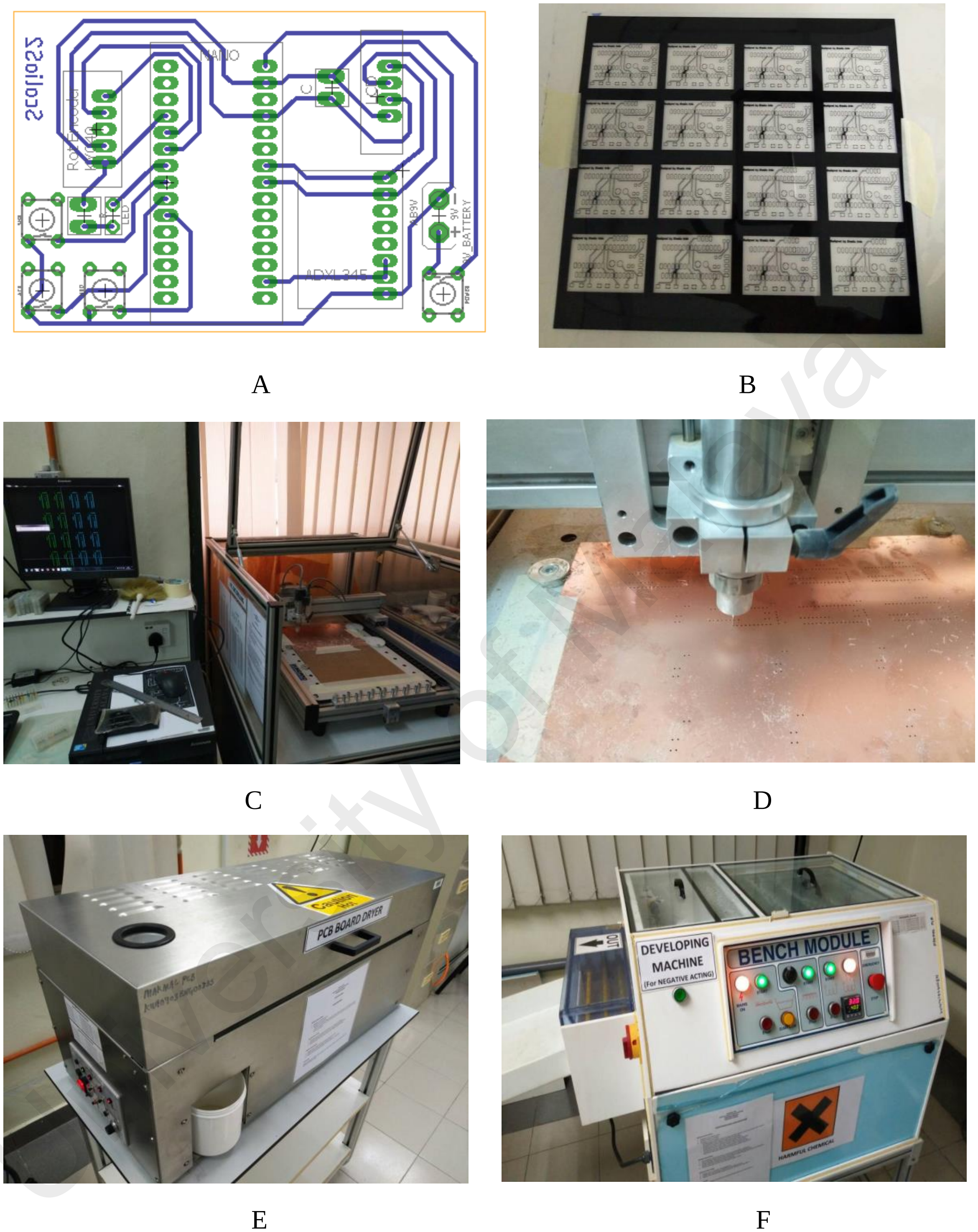


Figure 3. 17: PCB printing process A) PCB Layout; B) Artwork printed using Photoplotter; C) CNC Drilling Machine; D) Drilling PCB E) PCB Board Dryer used to dry the PCB after cleaning; F) Developing Machine to develop Photoresist

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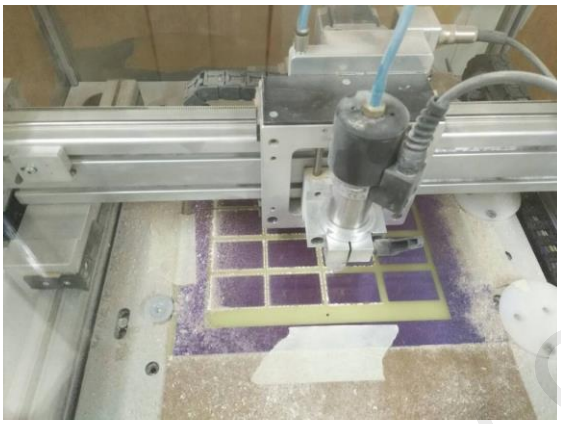

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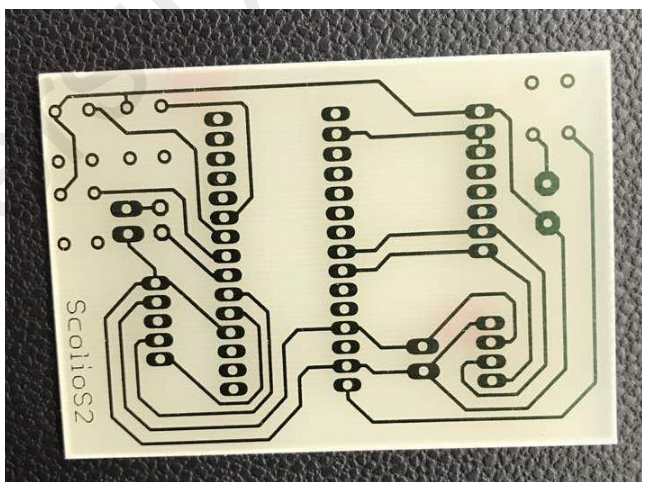

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Figure 3. 18: PCB printing process continued; G) Etching Machine to Etch PCB; H) Water Treatment System and Stripping Tank; I) Separating the PCB boards; J) Brushing Machine to clean the PCB; K) Complete PCB

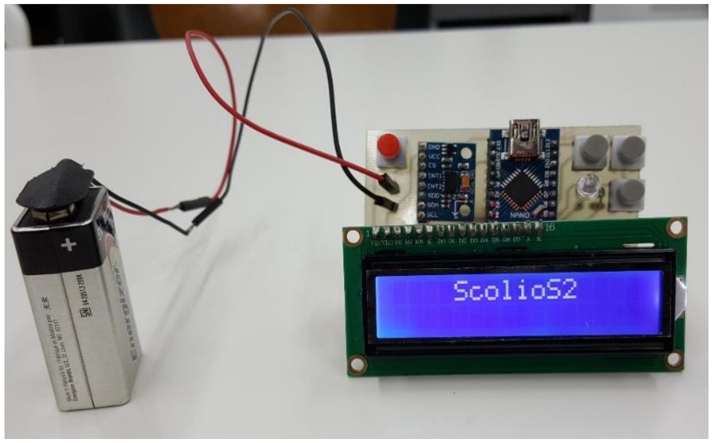

Figure 3. 19: PCB front view

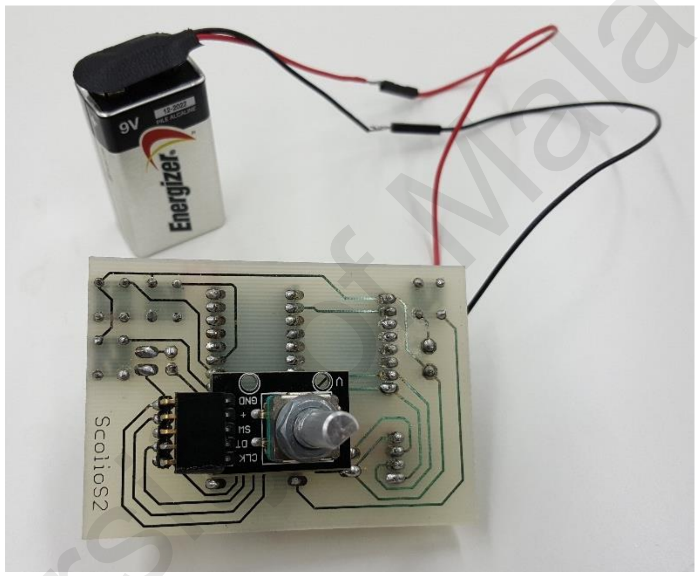

Figure 3. 20: PCB back view

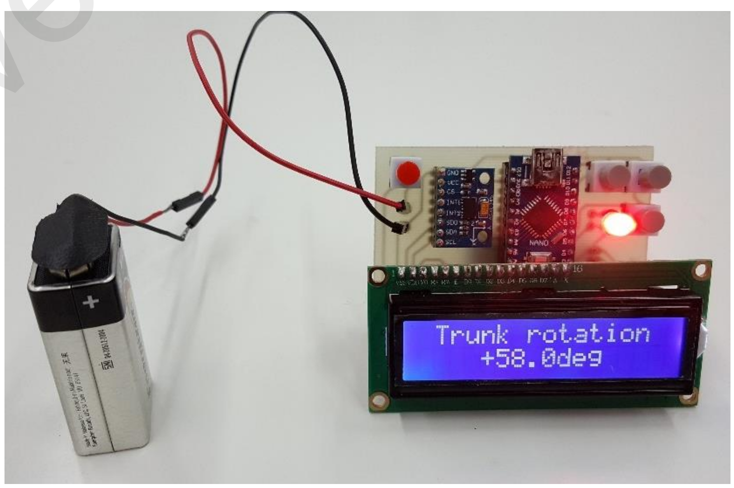

Figure 3. 21: PCB displaying ATR

CHAPTER 4: RESULT AND DISCUSSION

Refer Appendix C for the clinical data obtained from UMMC.

4.1.Shoulder Height Difference (SHD)

For this study, the method to measure SHD was firstly by using a baseline scoliometer, and then using ScolioS^2. In Figure 4.1, Time_CSHD represents the time taken by baseline scoliometer and Time_PSHD is the time take by ScolioS^2. In the figure below, it can be seen that the median of both the graph is same, but the IQR and range of baseline scoliometer is wider than that of ScolioS^2. We can hence deduce that the time taken to record data from baseline scoliometer is more varied and longer than that of ScolioS^2. There are some outliers in the box plot which was caused by the difficulty is obtaining the data due to improper device handling and difficulty in finding the right placement position on subject's shoulder.

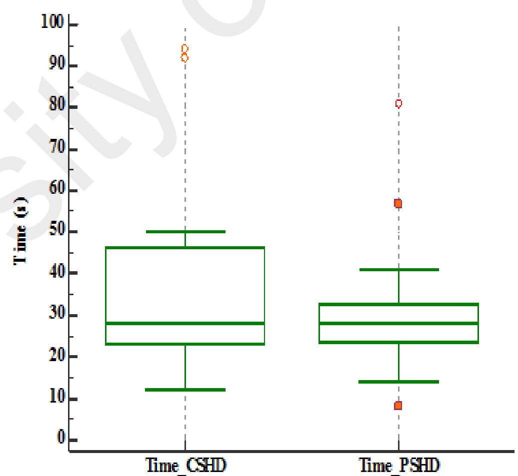

Figure 4. 1:Time Comparison box plot illustrating the time taken by the two methods

The Figure 4.2 gives a comparison of SHD measured with baseline scoliometer and ScolioS^2; C_SHD representing the values of SHD measured from baseline scoliometer and P_SHD from ScolioS^2. The positive values in the graph indicate right shoulder being higher than the left shoulder while negative values indicate left shoulder higher than the right. As observed in the graph below subject 7, 8, 12 14, and 17 show larger difference. The difference could be because of wrong placement of the ScolioS^2 or baseline scoliometer, this could be verified when compared against the radiographic SHD.

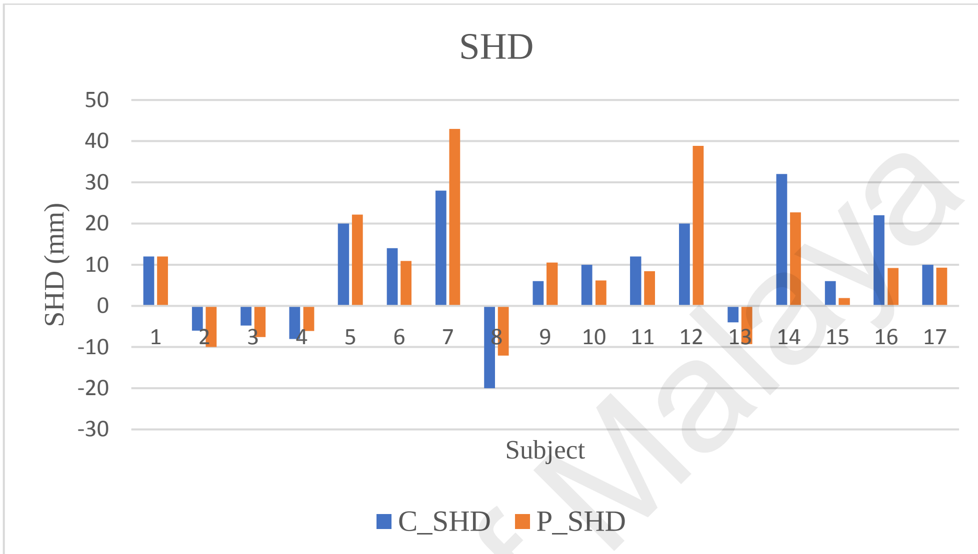

Figure 4.2: Comparison Bar Chart of SHD measured with ScolioS^2 and Baseline Scoliometer

Figure 4.3 illustrates the correlation between the techniques used to measure SHD. C_SHD representing the baseline scoliometer and P_SHD representing the ScolioS^2. This statistical analysis has a significance level of P=0.0015 that is $p < 0.05$. Also, has a coefficient correlation of 0.7 and, indicating a strong correlation between the two data.

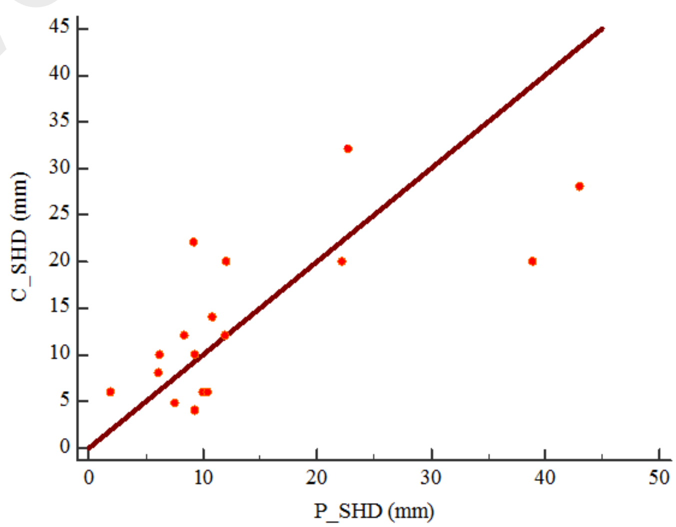

Figure 4. 3: Correlation between the two methods

Table 4. 1: SHD Scatter Diagram description

Sample size	17
Correlation coefficient r	0.7084
Significance level	P=0.0015
95% Confidence interval for r	0.3454 to 0.8870

In Figure 4.4 show the Bland-Altman analysis. C_SHD representing the baseline scoliometer and P_SHD representing the ScolioS2. In the graph below, we can clearly see that majority of the readings data within LoA, as proposed by Bland and Altman. Also, the average of the differences is -0.1. With mean or bias is not equal to zero, we can say that on average ScolioS^2 measures 0.1 units more or less than the baseline scoliometer. Since the subject are limited, the graph pattern can change for larger population.

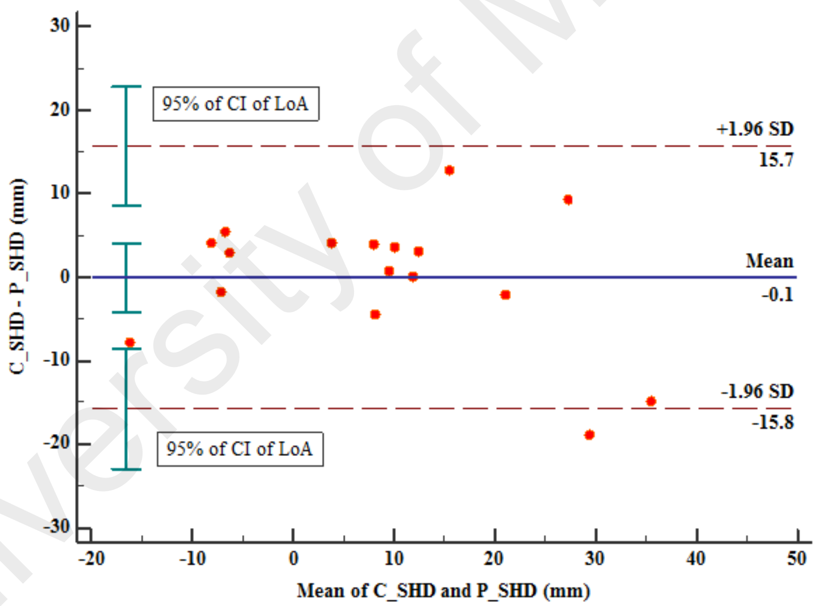

Figure 4. 4: Bland-Altman Analysis of SHD

4.2.Shoulder Lateral Tilting Angle (SLTA)

In Figure 4.5, the methods to measure SLTA was firstly by using a baseline scoliometer, and then using ScolioS^2. Time_CSLTA represents the time taken by baseline scoliometer to measure the tilting angle and Time_PSLTA is the time take by ScolioS^2. In the figure below, it can be seen that the median of baseline scoliometer is higher than that of ScolioS^2, but the

IQR of baseline scoliometer is wider than that of ScolioS^2. Also, in the graph below subject 4 and 2 are assumed outlier when ScolioS^2 time is taken into consideration, but when compared with baseline scoliometer those values are similar to maximum value of baseline scoliometer. We can hence again deduce that the time taken to record data from baseline scoliometer is more varied and longer than that of ScolioS^2.

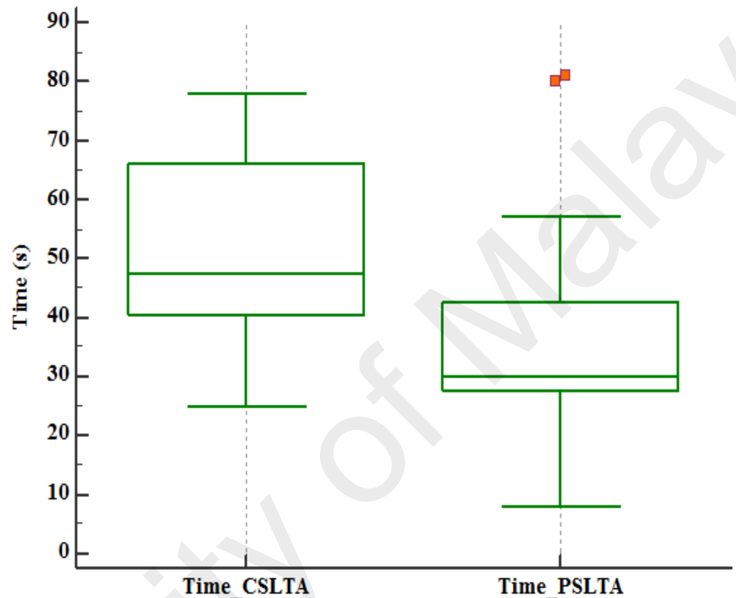

Figure 4. 5:Time Comparison box plot illustrating the time taken by the two methods

The Figure 4.6 gives a comparison of SLTA measured with baseline scoliometer and ScolioS^2; C_SLTA representing the values of SLTA measured from baseline scoliometer and P_SLTA from ScolioS^2. The positive values in the graph indicate right shoulder being higher than the left shoulder while negative values indicate left shoulder higher than the right. As mentioned earlier, SLTA is the tilting angle that is used to measure SHD. In the graph below a lot of variation can be seen between both the readings. We can deduce that one of the measuring method is creating the majority error. ScolioS^2 uses ADXL345 to measure the angle and then algorithmically calculates the value of SHD, indicating an error in SLTA recording will cause an error in SHD calculation. Whereas a baseline scoliometer has an analog inclinometer with large (or huge) scale division, which can be subjected to parallax error or mishandling human error. As a result, we can say the SLTA measured using scoliometer cannot be considered accurate and more clarity can be brought into this case when these results will be compared with radiographic data.

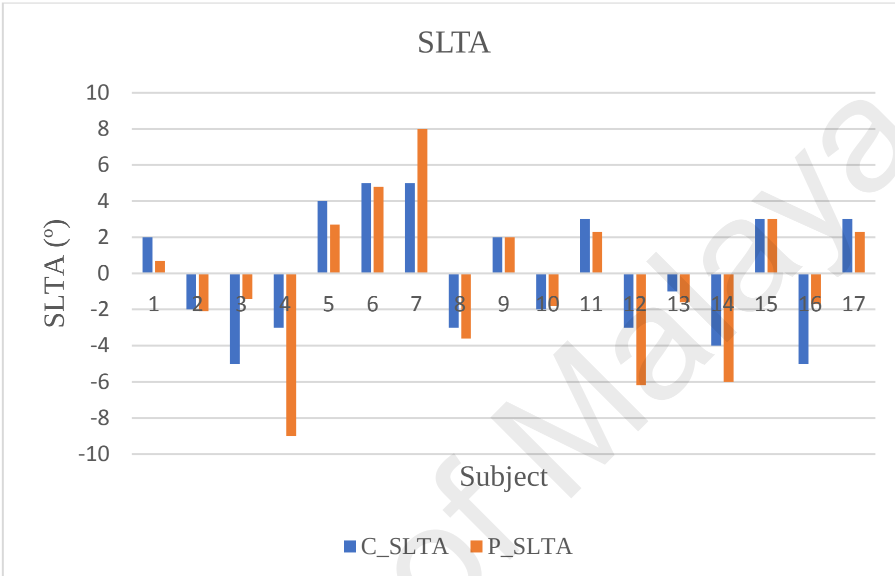

Figure 4. 6: Comparison Bar Chart of SLTA measured with ScolioS2 and Baseline Scoliometer

Figure 4.7 illustrates the correlation between the techniques used to measure SLTA. C_SLTA representing the values of SLTA measured from baseline scoliometer and P_SLTA from ScolioS^2. This statistical analysis has a significance level of P=0.1785 that is $p > 0.05$, as seen in Table 4.2. Also, the result indicates a coefficient correlation of 0.3, indicating a weak correlation between the two data. The low value of correlation coefficient is due to imprecise data recorded from the inclinometer of the baseline scoliometer as mentioned earlier in the report.

Table 4. 2: SLTA Scatter Diagram description

Sample size	17
Correlation coefficient r	0.3425
Significance level	P=0.1785
95% Confidence interval for r	-0.1654 to 0.7068

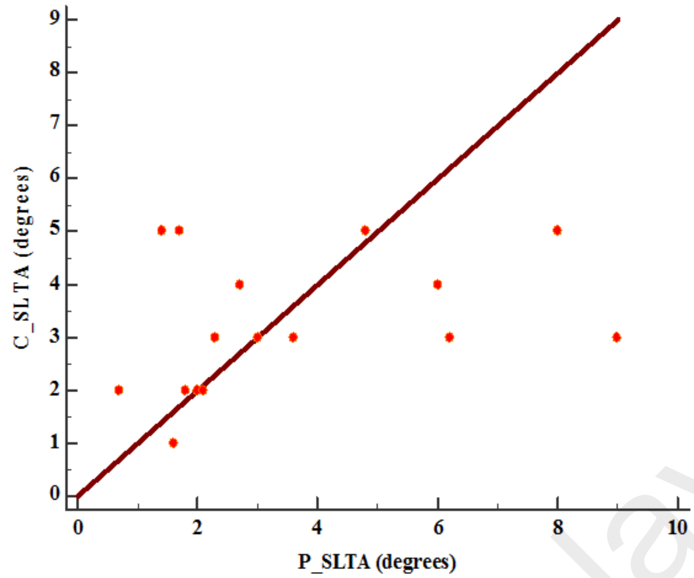

Figure 4. 7: Correlation between the two methods

In Figure 4.8 show the Bland-Altman analysis. For the graph below, we can clearly see that majority of the data is within LoA, as proposed by Bland and Altman. Also, the average of the differences is 0.4 With mean or bias is not equal to zero, we can say that on average ScolioS^2 measures 0.4 units more or less than the baseline scoliometer.

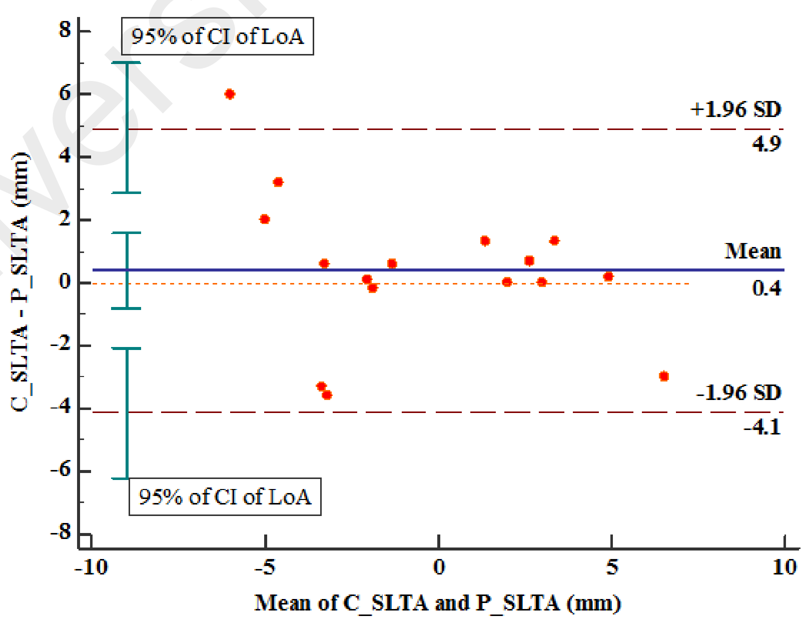

Figure 4. 8: Bland-Altman Analysis of SLTA

4.3.Angle of Trunk Rotation (ATR)

In Figure 4.9, the methods to measure ATR was firstly by using a ATR scoliometer, and then using $ScolioS^2$. Time_CATR represents the time taken by ATR scoliometer to measure the trunk rotation and Time_PATR is the time take by $ScolioS^2$. In the figure below, it can be seen that the median of ATR scoliometer is lower than that of $ScolioS^2$, but the IQR and range of ATR scoliometer is wider than that of $ScolioS^2$. We can hence again deduce that, predominantly the time taken to record data from baseline scoliometer is more varied and longer than that of $ScolioS^2$.

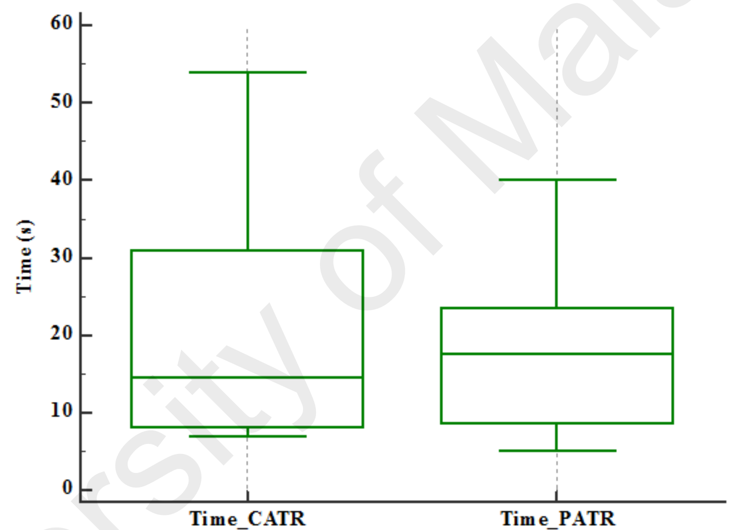

Figure 4. 9: Time comparison box plot illustrating the time taken by the two methods

The Figure 4.10 gives a comparison of ATR measured with ATR scoliometer and $ScolioS^2$; C_ATR representing the values of ATR measured from baseline scoliometer and P_ATR from $ScolioS^2$. The positive values in the graph indicate right thoracic curve while negative values indicate left thoracic curve. Almost similar value has been recorded by both the methods.

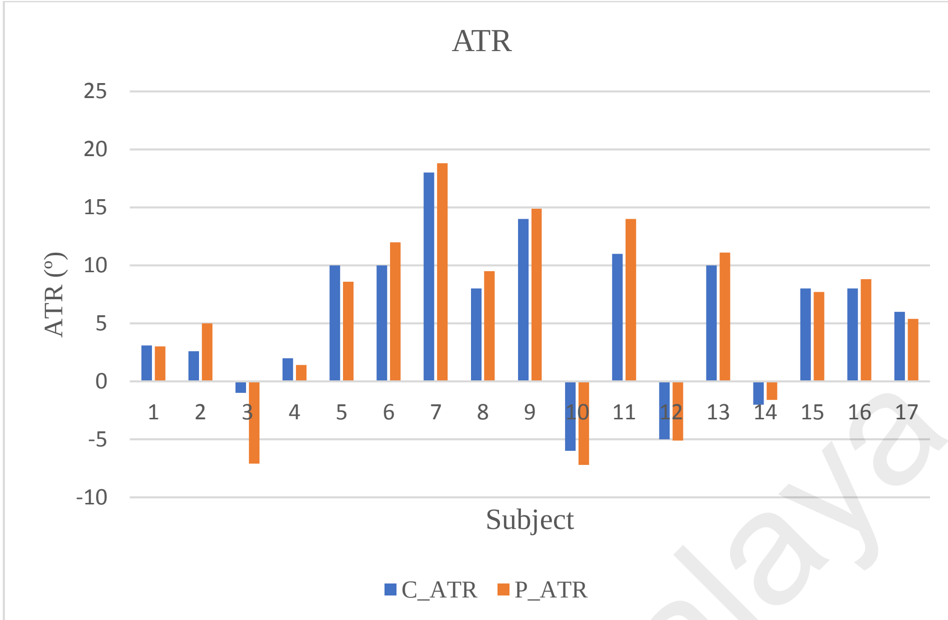

Figure 4. 10: Comparison Bar Chart of ATR measured with ScolioS2 and ATR Scoliometer

Figure 4.11 illustrates the correlation between the techniques used to measure ATR. This statistical analysis has a significance level of $P < 0.0001$ with coefficient correlation of 0.9, indicating a strong positive correlation between the two data. It depicts any fluctuation in data measured by one method will definitely affect the other as well.

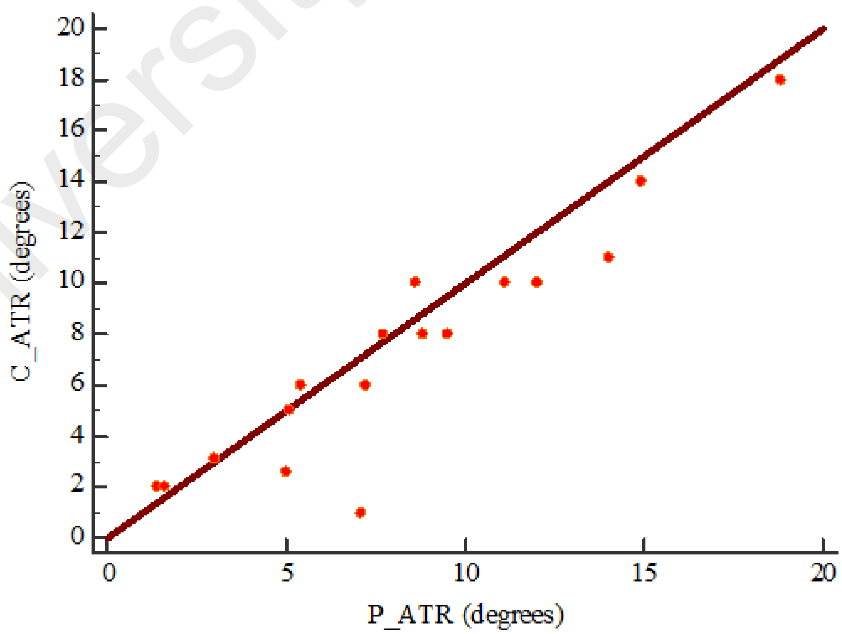

Figure 4. 11 Correlation between the two methods

Table 4. 3: ATR Scatter Diagram description

Sample size	17
Correlation coefficient r	0.9295
Significance level	P<0.0001
95% Confidence interval for r	0.8114 to 0.9747

In Figure 4.12 show the Bland-Altman analysis. For the graph below, we can clearly see that majority of the data is within LoA, as proposed by Bland and Altman. Also, the average of the differences is -0.1 With mean or bias is not equal to zero, we can say that on average ScolioS^2 measures 0.1 units more or less than the ATR scoliometer.

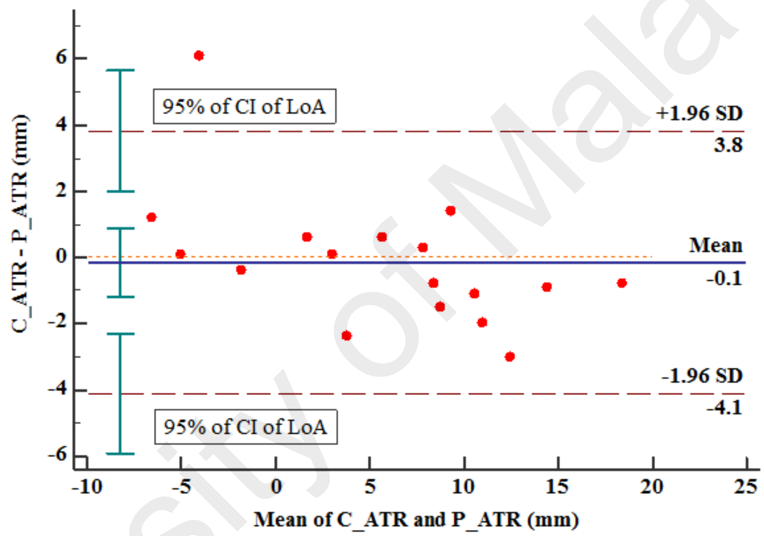

Figure 4. 12: Bland-Altman Analysis of ATR

4.4.Hump Height Difference (HHD)

In Figure 4.13, for recording the values of HHD, first baseline scoliometer was used and then the ScolioS^2 used. Time_CHH represents the time taken by baseline scoliometer to measure the hump height difference and Time_PHH is the time take by ScolioS^2. In the figure below, it can be seen that the median of baseline scoliometer is higher than that of ScolioS^2, and the IQR and range of baseline scoliometer is wider than that of ScolioS^2. We can hence again deduce that the time taken to record data from baseline scoliometer is more varied and longer than that of ScolioS^2.

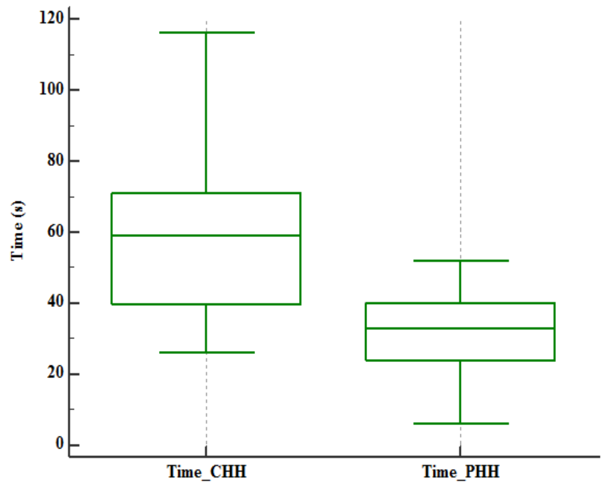

Figure 4. 13:Time comparison box plot illustrating the time taken by the two methods

The Figure 4.14 gives a comparison of HHD measured with baseline scoliometer and ScolioS^2; C_HH representing the values of HHD measured from baseline scoliometer and P_HH from ScolioS^2. The positive values in the graph indicate right side of the ribcage being higher than the left while negative values indicate left side of the ribcage higher than the right. Variations observed in the two methods are due to various reasons like subject experiencing discomfort on bending or getting tired for being bent for long, subject with unequal leg length, error in locating rib hump, human error etc.

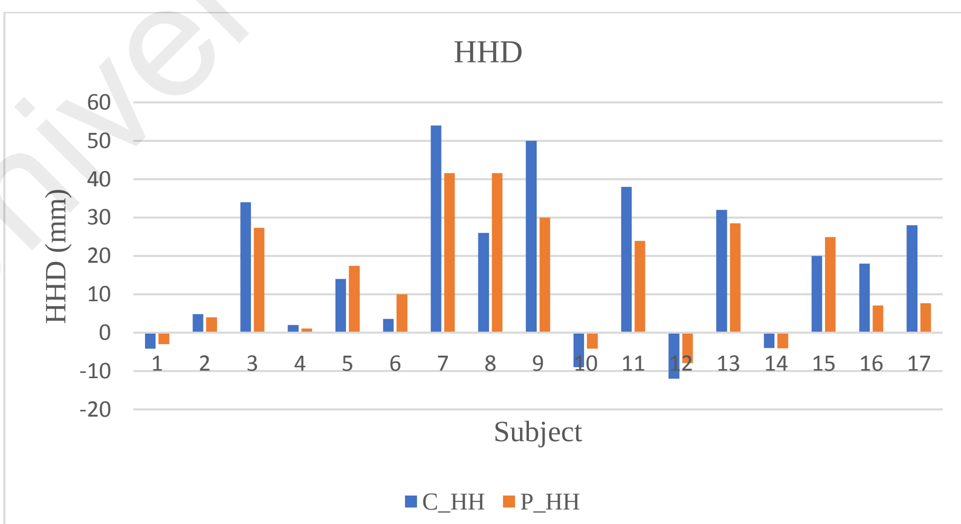

Figure 4. 14: Comparison Bar Chart of HHD measured with ScolioS2 and ATR Scoliometer

Figure 4.15 illustrates the correlation between the techniques used to measure HHD. This statistical analysis has a significance level of $P < 0.0001$. Also, the result indicates a coefficient correlation of 0.8, indicating a strong correlation between the two data. It depicts any fluctuation in data measured by one method will mostly affect the other as well.

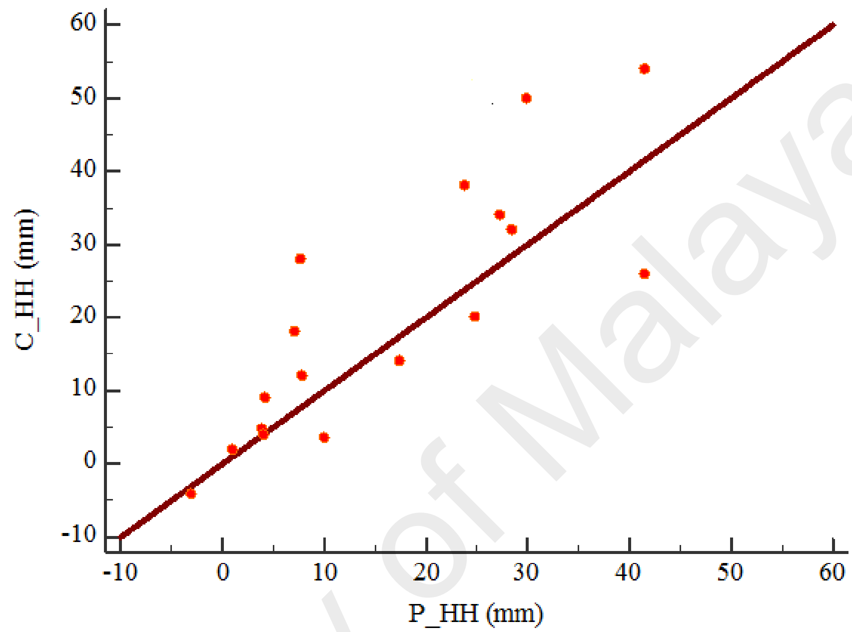

Figure 4. 15: Correlation between the two methods

Table 4. 4: HHD Scatter Diagram description

Sample size	17
Correlation coefficient r	0.8333
Significance level	P<0.0001
95% Confidence interval for r	0.5882 to 0.9382

In Figure 4.16, show the Bland-Altman analysis. For the graph below, we can clearly see that majority of the data is within LoA, as proposed by Bland and Altman. Also, the average of the differences is 2.9 With mean or bias is not equal to zero, we can say that on average ScolioS^2 measures 2.9 units more or less than the baseline scoliometer.

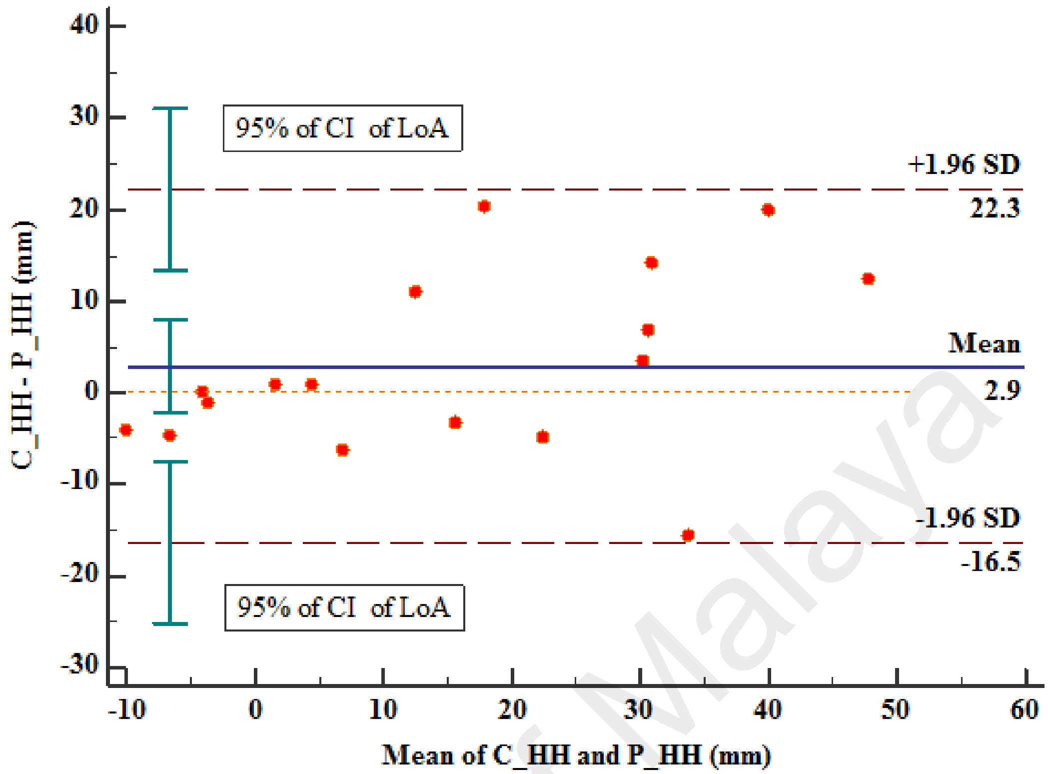

Figure 4. 16: Bland-Altman Analysis of HHD

CHAPTER 5: CONCLUSION

The incorporation of hump height difference in the existing device was successfully achieved without altering the functionality of the previously built device. The prototype was given to the Spine Research Unit of University Malaya Medical Center for clinical testing and data of 17 subjects was recorded in UMMC. The results obtained from ScolioS^2 has high similarity with the conventional devices (baseline scoliometer and ATR scoliometer). The statistical analyses done on obtained data has given us an idea of how the device is performing so far. On collection of larger data, more tests would be implemented to evaluate the accuracy reliability and reproducibility of the device. At this stage the data from ScolioS^2 was compared to the data obtained from baseline scoliometer and ATR scoliometer. Our further aim is to compare these results also with the data obtained from radiological scans.

A functional PCB has been developed over the course of this project. With internal connections more compact and stable, the external casing needs to be modified for housing the PCB and testing its performance. The casing could be made lighter and more durable by changing the casing material to carbon fiber, aluminium or light-weight steel. Once passing these initial testing and modification phase, the aim is to get FDA approval so this novel project could enter the markets, locally and globally, and be helpful tool for the doctors and the common people to detect scoliosis and its progression at early stage and take proper action at the right time.

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