A Proof of Concept for a Machine Learning Algorithm to Screen for Adolescent Idiopathic Scoliosis Using Images Captured with Modern Smartphone Technology

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Contents

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List of Acronyms

2-D = Two-dimensional

3-D = Three-dimensional

AI = Artificial intelligence

AIS = Adolescent idiopathic scoliosis

ANN= Artificial neural network

AP = Anterior posterior

AUC = Area under the curve

CHEO = Children's Hospital of Eastern Ontario

CNN = Convolutional neural network

CR = Computed radiography

DL = Deep learning

EOS = X-ray imaging system

FBT = Forward bend test

FC = Fully connected

MAE = Mean absolute error

ML = Machine learning

MP = Megapixel

MSE = Mean square error

NN = Neural network

NPV = Negative predictive values

PA = Posterior anterior

PPV = Positive predictive values

PSF = Posterior spinal fusion

PSIS = Posterior superior iliac spines

R-CNN = Regional-convolutional neural network

RGB = Red-green-blue

RGB-D = Red-green-blue-depth

ST = Surface topography

TOF = Time-of-flight

USPSTF = United States Protective Service Task Force

VGA = Video graphics array

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Abstract

Adolescent idiopathic scoliosis (AIS) is an extremely common three-dimensional (3-D) deformity of the spine, affecting the population between 10 and 18 years of age. Early detection of AIS is critical, as the earlier that the spinal deformity can be identified, the more likely it is that curve progression can be minimized or arrested using conservative treatment options. However, today much of the responsibility for detecting AIS falls on untrained parents. Therefore, the purpose of this thesis project is to use images taken with a smartphone containing a depth sensor to create a simple and effective machine learning (ML) algorithm that can detect the absence or presence of scoliosis. Secondarily, this thesis project aims to 1) provide a proof of concept for a regression-based ML algorithm that can predict the main curvature of the scoliotic spine and 2) to determine if the depth information from the smartphone contains additional features or information that can improve the performance of the ML algorithm when compared to regular red-green-blue (RGB) images. Thirty-three participants (28 AIS; 5 Control) were recruited from the Children's Hospital of Eastern Ontario (CHEO). Images of the unclothed backs of participants were taken with a smartphone (Samsung S20 Ultra 5G) containing a depth sensor, while participants assumed two positions: an upright standing posterior-anterior (PA; mirroring the position participants are in when getting an EOS scan) and a forward bending position. A convolutional-neural-network (CNN)-backed decision tree algorithm was developed and trained using three different data streams: a red-green-blue-depth (RGB-D), a Colourized depth map, and an RGB data stream. It was determined that the model trained with the Colourized forward bending images had the highest overall accuracy. The CNN backed decision tree was able to classify images of participants in a forward bend posture with an accuracy of 93%, specificity of 75%, and a sensitivity of 99%. Additionally, it was found that all algorithms trained with the varying data streams were able to predict the Cobb angle of the spine within 16° of the ground truth Cobb angles. The lowest root mean square error (RMSE) values were obtained from the RGB images when the participants were in the PA position. The PA RGB dataset had RMSE values of 7.17° between the ground truth and predicted Cobb angles. Inter-rater reliability errors typically range between 5-7° for manually measured Cobb angles. Therefore, given the calculated RMSE for the PA RGB dataset were close to this range, there is the potential to use this smartphone technology to screen for scoliosis and predict the curvature of the spine (Morrison et al., 2015). While these results are promising, the dataset is small compared to other studies; therefore, this thesis provides a proof of concept, and more work needs to be done to increase the robustness of the model and to further improve the ability of the model to predict the Cobb angle of the spine.

Chapter 1: Introduction

Adolescent idiopathic scoliosis (AIS) is one of the most common three-dimensional (3-D) deformities of the spine, affecting 2-4% of adolescents between 10 and 18 years of age (Morrison et al., 2015). AIS is characterized by lateral curvatures of the spine, and it is often accompanied by axial rotation of the vertebrae (Minehiro et al., 2019). AIS is diagnosed by measuring an angle greater than 10° between the end-plates of the two most tilted vertebrae of the spine (i.e., Cobb angle; Minehiro et al., 2019; Morrison et al., 2015). General practitioners screen for AIS using methods such as an Adams forward bend test (FBT), Moiré topography and/or by assessing the asymmetry of the trunk using a type of goniometer called a scoliometer (Luk et al., 2010). However, these AIS screening methods are often inaccurate (i.e., high false-negative rate) and are not ideal for the early detection of AIS, as many positive cases are missed (i.e., low sensitivity; Dunn et al., 2018; Karachalios et al., 1999). Previously, school scoliosis screening programs were implemented, where nurses and clinicians provided routine screening to school children. However, these programs have been largely discontinued, as it was found that the benefits did not outweigh the cost, shifting the responsibility of early AIS identification onto untrained parents (Heemskerk et al., 2022).

Further, once AIS has been identified, AIS patients are frequently exposed to imaging radiation, and cumulative radiation exposure is known to increase the risk of developing cancer (Presciutti et al., 2014). Simony et al. (2016) found that AIS patients treated between the years 1983 and 1990 have a five times greater cancer incidence than the age-matched Danish population. Further, it has been well established that patients with more severe spinal curves are required to get more frequent spinal radiographs (Luo et al., 2015). Research shows that AIS patients who receive external bracing as their primary form of treatment receive an average of 3-6 radiographs per year over the course of their treatment (Luo et al., 2015; Presciutti et al., 2014). In comparison, surgical patients have been found to receive an average of 6-12 radiographs per year (Luo et al., 2015; Presciutti et al., 2014). AIS treatment can take 2-5 years, depending on the age of diagnosis and the severity of the curve. This is important as the lack of effective screening procedures and standardized screening programs has resulted in later detection of AIS, which often results in surgical treatment being the only option available. Further, due to the higher number of radiographs that surgical patients receive, this not only increases cancer risk (i.e., due to more frequent spinal radiographs), it also results in psychological distress and anxiety for the patient.

Recently, there has been a push to develop novel methods to screen for scoliosis and to assess the curvature of the spine while limiting the patient's exposure to radiation. Surface topography (ST) has been frequently used with machine learning (ML) methods to classify scoliosis by Lenke type (classification system for AIS; Slattery and Verma, 2018) or by the severity of the curve (Bolzinger et al., 2021; Komeili et al., 2014; Stephan et al., 2020). While the use of ST has the potential to reduce unnecessary radiation exposure, these systems are often not portable and require a skilled technician to use (i.e., cannot be used by non-expert users to screen for AIS). Additionally, researchers that assessed the feasibility of using ST for AIS diagnosis were unable to accurately predict the Cobb angle of the spine with a high degree of accuracy (Fujimori et al., 2014; Giannoglou and Stylianidis, 2016). Therefore, there is a need for an AIS screening or diagnostic tool that does not require complex or expensive equipment and can provide accurate and reliable results.

Yang et al. (2019) trained a deep learning (DL) algorithm to detect AIS, using a variety of cameras to capture two-dimensional (2-D) images of the posterior torso of AIS and control participants. It was found that the developed algorithm outperformed human evaluators and was able to predict the presence of AIS with an accuracy of 75%. Further, Kokabu et al. (2021) used a commercial depth sensor and a ML algorithm to estimate the Cobb angle of the spine and produced predictions that were highly correlated (+0.91) to the ground truth Cobb angles. These studies demonstrate that simple equipment (i.e., an RGB camera, a commercial depth sensor, and a laptop) can be used to screen for AIS and predict the Cobb angle of the spine. While a commercial depth sensor is inexpensive and portable, it is a piece of equipment that is typically only found in clinical or research settings. However, many modern smartphones now contain depth sensors; therefore, this thesis project aims to expand upon this concept to determine if modern smartphones, rather than a commercial depth sensor, can be used to create an AIS screening and diagnostic tool. A ML algorithm trained with images captured with a smartphone could allow for the creation of an application that would enable parents to screen for AIS with the same specificity and sensitivity as an experienced clinician, enabling early AIS identification.

The aim of this present study is to determine if RGB-D images captured from a Samsung S20 Ultra 5G smartphone can be fed into a ML algorithm to classify images based on the presence or absence of AIS. Secondarily, this study aims to 1) provide a proof of concept for a regression-based algorithm that can predict the main curvature of the scoliotic spine and 2) to determine if the depth information from the smartphone improves the performance of the ML algorithm when compared to regular RGB images.

Chapter 2: Literature Review

2.1 Adolescent Idiopathic Scoliosis

AIS is one of the most common spinal deformities affecting 2-4% of people between the ages of 10-18 (Luan et al., 2021). AIS is a 3-D deformity that is characterized by lateral curvatures of the spine and is often accompanied by axial rotation of the vertebrae (Morrison et al., 2015). During adolescence, AIS is often asymptomatic and is generally identified by a parent, coach, or general practitioner. AIS may display as uneven shoulders, rib prominence and/or hip asymmetry (Altaf et al., 2013). If AIS is suspected, the spine is examined through a visual appraisal, a FBT, Moiré topography and/or a by the assessment of trunk asymmetry with a scoliometer (Morrison et al., 2015). If these screening tests are positive, diagnosis is confirmed using full-length PA and lateral spinal radiographs (Figure 2.1; Morrison et al., 2015).

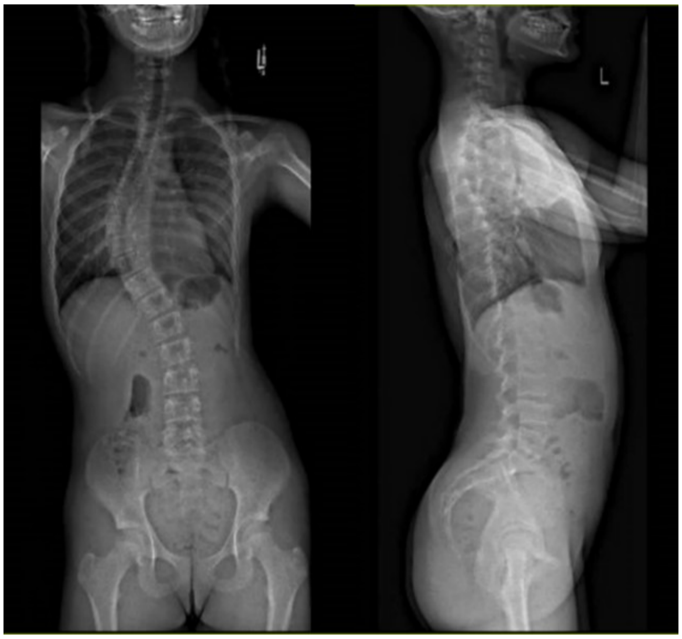

Figure 2.1: Posterior-anterior and lateral full-length spinal radiographs taken from an AIS patient at the Children's Hospital of Eastern Ontario

2.1.1 Cobb angle

The Cobb angle is the current gold standard for diagnosing scoliosis and for assessing the curvature of the spine. Often the Cobb angle is measured manually by identifying the end-plates of the two-most tilted vertebrae of the curve and measuring the angle between them (Figure 2.2; Tu et al., 2019; Zhang et al., 2017).

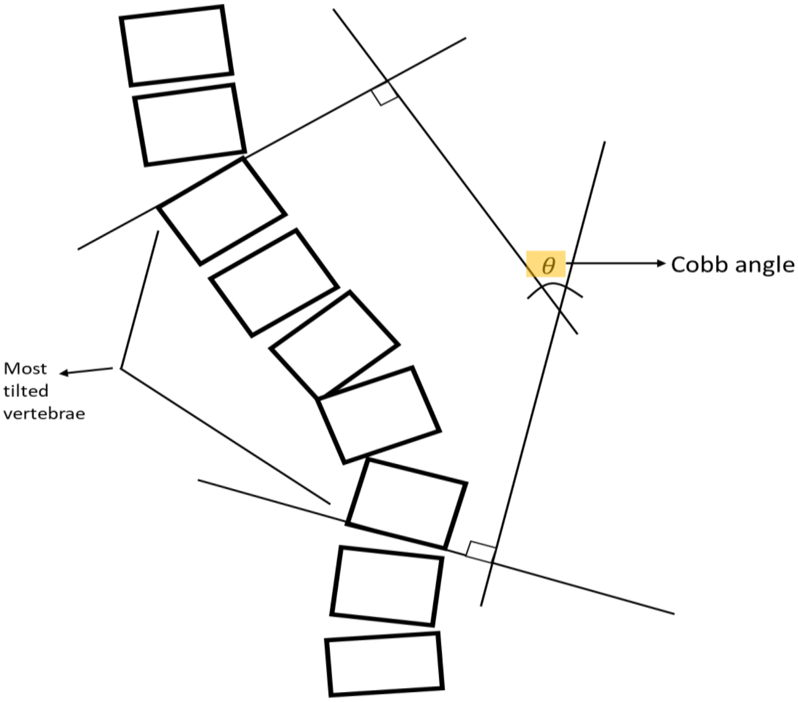

Figure 2.2: Schematic demonstrating how to calculate the Cobb angle of the spine by identifying the end-plates of the two most tilted vertebrae and measuring the angle between them.

However, it has been found that Cobb angle measurements have a low intra- and inter-rater reliability, with some studies reporting error rates of 3-5° and 5-7° for intra- and inter-rater reliability, respectively (Morrison et al., 2015). One of the most common sources of error when calculating the Cobb angle is manual end-plate selection. This may be problematic, as a Cobb angle difference of 5° or more between successive visits is indicative of curve progression, with greater curve progressions correlating to more aggressive treatment suggestions (i.e., observation vs. bracing vs. surgery).

2. 1.2 Digital Cobb Angle Measurement from Spinal radiographs

In recent years, many research projects have attempted to automate the process of AIS diagnosis to reduce intra- and inter-rater reliability issues that arise when calculating the Cobb angle. Numerous research projects have attempted to create iPhone applications to calculate the Cobb angle easily and automatically from spinal radiographs. Two of these applications are the Tiltmeter Pro (Shaw et al., 2012) and the Cobbmeter (Jacquot et al., 2012). To use these applications, the smartphone is aligned to the endplates of the spine on a radiograph. Once the endplates have been identified, the Cobb angle is then automatically calculated using the built-in accelerometer technology (Jacquot et al., 2012; Shaw et al., 2012). A high intraclass correlation coefficient (ICC) has been found between the Cobb angles calculated by the Cobbmeter and the manually measured Cobb angles (ICC = 0.963; Jacquot et al., 2012). This demonstrates that smartphone technology has applications for the diagnosis of AIS. However, considering applications such as the Cobbmeter still require a clinician to manually select the end-plates, the potential for intra- and inter-rater reliability issues still exist, as the largest source of error for Cobb angle measurements are differences in the selection of the two-most tilted vertebrae of the curve (Shaw et al., 2012). Further, as the curve progresses, the same clinician may select different vertebrae for subsequent measurements of the same patient (Shaw et al., 2012).

Suwannarat et al. (2017) examined the intra- and inter-rater reliability of digitally measured Cobb angles that were measured by novice physiotherapists, as physiotherapists are often involved in the treatment program for AIS patients. It was found that when using digital methods for Cobb angle measurement, the novice physiotherapists had excellent reliability (ICC = 0.955 – 0.997) and the Cobb angles measured by the physiotherapists had no significant differences when compared to the Cobb angles calculated by an expert physician (Suwannarat et al., 2017). These findings highlight, that digital methods of Cobb angle measurement can be used accurately across all skill levels.

2.1.3 Lenke Classification

Aside from Cobb angle measurements, AIS can be further classified by identifying the Lenke type of the curve. The Lenke classification system was first proposed in 2001; it is currently the most common classification system used for AIS, by incorporating both sagittal and coronal parameters for classification (Table 2.1; Fujimori et al., 2014). In this classification system, there are six curve types (Table 2.1). The main curve is the largest spinal curve; however, there can be multiple structural curves identified in the spine (Slattery and Verma, 2018). Structural curves are defined as spinal curvatures that are ≥25° or exhibit >20° of kyphosis (Slattery and Verma, 2018). Kyphosis differs from scoliosis, where scoliosis is characterized by side-to-side (lateral) curvatures, while kyphosis is a forward rounding of the spine.

Table 2.1: The classification of AIS using the Lenke classification system. Table adapted from Slattery and Verma (2018).

Type	Curve	Proximal Thoracic	Main Thoracic	Thoracolumbar/Lumbar
1	Main thoracic	Not structural	Structural*	Not structural
2	Double thoracic	Structural	Structural*	Not structural
3	Double major	Not structural	Structural*	Structural
4	Triple major	Structural	Structural*	Structural
5	Thoracolumbar/lumbar	Not structural	Not structural	Structural*
6	Thoracolumbar/lumbar-main thoracic	Not structural	Structural	Structural*
Lumbar Spine Modifiers	CSVL to Lumbar Apex	Thoracic Sagittal Profile	Angle	
A	CSVL between pedicles	- (below normal)	<10°	
B	CSVL touches apical bodies	N (normal)	10-40°	
C	CSVL completely medial	+ (above normal)	>40°	

*Major curve; CSVL = center sacral vertical line

2.2 AIS Treatment

When diagnosing AIS, if the Cobb angle is >10°, a positive diagnosis is confirmed (Figure 2.2). Although both males and females are equally likely to exhibit small curvatures of the spine (~10°), females are ten times more likely to experience curve progression through puberty and receive treatment for AIS (Horne et al., 2014). AIS is often asymptomatic; however, problems can arise later in life if left untreated, such as a visible deformity (this can cause emotional distress and anxiety for the patient; Horne et al., 2014; Li et al., 2021), a decreased range of motion (ROM) and physical discomfort. In more severe cases, where patients experience rib deformities, the curvature can lead to respiratory and/or cardiovascular problems (Horne et al., 2014).

AIS can be grossly categorized into mild (<25°), moderate (25-40°), and severe (>40°) groups based on the Cobb angle of the spine (Stephan et al., 2020). For mild curves, monitoring of the curve is typically recommended by physicians, with frequent follow-ups to ensure the curve is not progressing at an alarming rate. The curve is said to be progressive if the curve has increased by 5° or more between successive bi-annual appointments. As the curve gets larger (>25°), external bracing (e.g., Boston brace) is the preferred treatment option to prevent or minimize curve progression by applying external corrective forces to the spine (Costa et al., 2021). For severe curves, surgical options are explored (i.e., posterior spinal fusion; US Preventive Services Task Force, 2018). Keil et al. (2022) found that at least 47% of AIS patients who received posterior-spinal fusion (PSF) as their surgical intervention experienced at least one post-operative complication (e.g., persistent pain and discomfort). Therefore, surgery should always be a last resort when it comes to AIS management and treatment (Weiss, 2008). For this reason, it is imperative that AIS be detected early so that more conservative treatment options can be implemented (i.e., scoliosis-specific exercises, external bracing; Li et al., 2021) prior to undergoing invasive surgery.

2.2.1 Radiographs and the Associated Risks

Patients diagnosed with AIS will require frequent radiographs to track the progression of the curvature and monitor the effectiveness of the treatment. It is evident that AIS patients are exposed to a much higher lifetime radiation dose than the average healthy person. Research shows that AIS patients who undergo bracing as their primary form of treatment receive an average of 3-6 radiographs per year over the course of their treatment and recovery (Luo et al., 2015; Presciutti et al., 2014). Conversely, surgical patients receive an average of 6-12 radiographs per year (Luo et al., 2015; Presciutti et al., 2014). AIS treatment and recovery can take 2-5 years, depending on the age of diagnosis and the severity of the curve (Luo et al., 2015; Presciutti et al., 2014). The high number of radiation exposures that AIS patients receive results in an increased risk of being diagnosed with cancer later in life (Simony et al., 2016). Simony et al. (2016) found that AIS patients treated between 1983 and 1990 have a 5-times greater cancer incidence than the general Danish population. It is likely that the risks associated with frequent radiographic imaging is lower today than it was in the past, as safer imaging modalities and other safety procedures have been implemented; however, whenever possible the number of radiographs that adolescents are exposed to should be minimized.

In recognition of the volume of radiographs that people with AIS and individuals with other conditions receive on a regular basis, and the potentially harmful effects associated with cumulative radiation exposure, steps have been taken in modern medicine to reduce radiation exposure by creating safer imaging modalities such as EOS scans. EOS is a low-dose imaging system that uses bi-planar slot scanning technology to capture both PA and lateral views of the spine (Pedersen et al., 2018). When applying a micro-dose PA-lateral EOS scan, there is a 5-17-fold reduction in effective radiation dose when compared to a PA and lateral computed radiography (CR) scan (Pedersen et al., 2018). However, EOS scans are typically only available in larger hospitals and city centers in Canada and often cannot be accessed in smaller rural communities. This lack of accessibility means that many adolescents are still frequently receiving CR scans to diagnose and/or treat their AIS. Further, it is evident that given the number of radiographs that AIS patients receive, especially surgical patients, the field would benefit from alternative methods of diagnosing AIS and tracking the progression of the curvature. Additionally, there needs to be an increased effort for early AIS identification to minimize the probability of requiring corrective surgery (Luk et al., 2010).

2.3 Scoliosis Screening

The early detection of AIS is critical. If detected early, AIS can be treated with braces, which can minimize or stop curve progression (Luk et al., 2010). However, in many cases, AIS is not detected until there is a visible deformity, resulting in large spinal curvatures. These large curvatures often have to be treated with invasive surgery, which does have some associated risks, such as postoperative infection and long recovery times (Luk et al., 2010; Rihn et al., 2008). For these reasons, there is a need for safe and accurate scoliosis screening methods that can be used for the early detection of AIS. Previously, school scoliosis screening programs were implemented in an attempt to identify potential cases of scoliosis within the adolescent population (Dunn et al., 2018; Luk et al., 2010). For this program, nurses went to schools and used traditional screening methods to screen for potential cases of AIS (Chen et al., 2020; Karachalios et al., 1999). Scoliosis screening methods that were frequently used included the FBT test, assessment of the angle of trunk rotation with a scoliometer, and Moiré topography (Dunn et al., 2018). If students were identified as potentially having AIS, they were referred to a clinician for follow-up and formal diagnosis.

Moiré topography is a screening method where a pattern of alternating clear and dark stripes are reflected on the surface of a patient's back (Labecka and Plandowska, 2021). The pattern will distort depending on the asymmetry and rotation of the trunk, which is then analyzed to screen for AIS (Labecka and Plandowska, 2021). The FBT is the most common screening procedure and is often used in combination with a scoliometer. When performing a FBT, the clinician examines the trunk by having the patient bend forward until their trunk is parallel to the floor (Dunn et al., 2018). Asymmetries such as differences in the height of the scapula, unlevel hips and/or a rib hump, can all be indicative of underlying AIS (Dunn et al., 2018). However, there is some disagreement in the literature regarding the specificity and the sensitivity of these screening methods (Dunn et al., 2018). Overall, research shows that the FBT has a limited sensitivity and/or specificity and has false-positive rates ranging between 0.8-21.5% (Dunn et al., 2018). These high false positive rates result in some adolescents being unnecessarily referred to a clinician, where they receive a spinal radiograph to confirm diagnosis, which can lead to psychological distress and sometimes unnecessary bracing and radiation exposure (Dunn et al., 2018; Heemskerk et al., 2022). However, research also shows that when the FBT is used alone, many positive cases of AIS are missed (i.e., low sensitivity, Karachalios et al., 1999). For these reasons, large-scale school scoliosis screening programs have been largely discontinued, as it was found that the benefits associated with these programs (i.e., early screening and AIS detection) did not outweigh the costs (i.e., unreliable results, high expenses associated with running these programs; Karachalios et al., 1999). Supporters of the school scoliosis screening programs have argued that the discontinuation of these programs shifts the responsibility of detecting the spinal deformity to untrained parents; as a result, AIS is generally not being detected as early within the adolescent population (Yan et al., 2020). Therefore, it would be beneficial to have a screening method or tool that can be used by parents with the same specificity and sensitivity as when used by experienced practitioners.

2.4 The Use of Machine Learning in the Diagnosis and Treatment of AIS

Artificial intelligence (AI) is becoming increasingly prevalent in our medical system. AI can be divided into virtual (i.e., machine learning) and physical branches (i.e., robots, physical objects). By applying AI to the medical field, it is the hope that sources of human error can be reduced (Takeda et al., 2020). AI also presents an opportunity to use depth information obtained from modern smartphones, or other sources, to screen for scoliosis with a higher accuracy than when using traditional screening methods (i.e., FBT). Eventually, AI may also enable the healthcare system to move away from the use of spinal radiographs for the diagnosis and monitoring of AIS progression.

2.4.1 The Use of Machine Learning in Medical Diagnosis

ML is an area of study that has advanced in recent years. ML is a computer process that can learn and adapt by recognizing patterns and features within the data (Baloglu et al., 2021). ML algorithms can be divided into two gross categories: unsupervised and supervised ML algorithms (Takeda et al., 2020). In unsupervised ML algorithms, the algorithm is unaware of the true labels, and the ML algorithm finds cluster associations within the input data, grouping the data based on these associations (Baloglu et al., 2021). For a supervised ML algorithm, the data is all manually pre-labelled, and the algorithm attempts to identify patterns and group the data based on these provided labels (Baloglu et al., 2021). In this thesis project, a supervised Resnet101 backed decision tree ML algorithm is used. Resnet is a residual neural network that was developed for image recognition tasks (He et al., 2016). Resnet has been successfully used for medical diagnosis of AIS (Yang et al., 2019; Yoo et al., 2021). Yang et al. (2019) used the Resnet101 architecture (where 101 represents the number of layers in the CNN) to create an algorithm to classify RGB images of AIS patients based on the main Cobb angle of the spine. However, CNNs can be difficult to interpret, and it can be difficult to determine how the algorithm made its classification decisions. This is not ideal for medical diagnosis, as transparency is preferred. To address this issue, there is a stream of research where researchers are attempting to create hybrid models by combining CNNs with more traditional image classifiers (Ren et al., 2017). Therefore, this thesis project used a neural network (NN) backed decision tree approach (Wan et al., 2021). Where the final linear layer of a NN is replaced with a decision tree (Wan et al., 2021). This allows for high level feature detection to be maintained while still allowing for the use of an easily interpretable model. A decision tree is a hierarchical ML algorithm that splits at various nodes based on the image features. The decision tree will split in a way that optimizes certain metrics, creating decision paths that classify the images based on a series of learned rules. A metric that is commonly used when creating a classification decision tree is the Gini coefficient. The Gini coefficient is indicative of the purity of the leaf; with a Gini coefficient of 0 indicating an 100% pure leaf (i.e., all the elements or features in that leaf belong to the same class).

In recent years, there has been an increased interest in the use of ML in the medical field and specifically in medical diagnosis, as it has the potential to provide more personalized models of care (Baloglu et al., 2021; Richens et al., 2020). ML has been successfully used for applications such as the diagnosis of diabetic retinopathy (Roychowdhury et al., 2014) and the diagnosis of cancer from radiographs (Hu et al., 2020; Shastri et al., 2020). Further, ML has been used successfully to calculate the Cobb angle of the spine from spinal radiographs (Kim et al., 2020; Tu et al., 2019). There has also been an increased interest in using ML techniques to recognize AIS from RGB images, from depth maps and/or from ST, to reduce the need for spinal radiographs within this population when screening for and/or diagnosing AIS (Kokabu et al., 2021; Yang et al., 2019).

2.4.2 Predicting the Cobb Angle

There have been multiple studies that have applied ML methods to automatically calculate the Cobb angle of the spine from spinal radiographs, without the need for manual end-plate selection, in an attempt to further minimize intra- and inter-rater reliability issues (Fu et al., 2021; Tu et al., 2019). Typically, ML studies that have attempted to automatically calculate the Cobb angle of the spine have used segmentation-based methods, direct estimation-based methods, or a combination of the two (Kim et al., 2020). For segmentation-based methods, the spine/spine region are contoured and a spline is fit to this contour, allowing the Cobb angle to be calculated (Kim et al., 2020). For direct estimation techniques, specific anatomical landmarks are manually labelled, and the algorithm finds associations between these labelled landmarks and the Cobb angle of the spine (Kim et al., 2020).

Tu et al. (2019) developed DU-Net, a ML algorithm that segments the contour of the spine from spinal radiographs. The algorithm then fits a curve to the contour and the Cobb angle is automatically calculated (Tu et al., 2019). The DU-Net algorithm has been found to achieve excellent results, as the error between the Cobb angle measures obtained from the algorithm and the Cobb angles calculated by experienced orthopedists were only 2.9°, which is lower than intra- and inter- rater reliability errors typically found when manually calculating the Cobb angle of the spine (Morrison et al., 2015). Another study was conducted that attempted to assess scoliosis using the identification of the centroid of the vertebrae (Bernstein et al., 2021). In this study, manually labelled vertebrae on spinal radiographs were used to train a NN. After the centroids of the vertebrae were identified, splines were fit to the centroids of the vertebrae. Bernstein et al. (2021) found that the Cobb angles that were calculated with their methodology (spline-based measurements) had higher inter-observer correlations than manually measured Cobb angles.

2.4.3 Classifying Scoliosis Without the Use of Radiographs

There is still a need for scoliosis screening and diagnostic tools that are accurate and do not require spinal radiographs, which is the direction that research is currently heading. Komeili et al. (2014) performed a study where they attempted to use ST, which uses an optical light system, to examine the 3D geometry of the external surface of the back. The methods used in this study allowed researchers to classify torso asymmetry (based on the Lenke classification system) in a completely non-invasive way (Komeili et al., 2014). In contrast, it was found that by using ST asymmetry analysis combined with a decision tree algorithm, researchers were able to classify curve severity (i.e., 10°<Cobb angle <25°, ≥25°) with a sensitivity of 95% and a specificity of 35% (Hong et al., 2016). AIS participants included in this study had spinal curves ranging from 10-45° (mild-moderate; Hong et al., 2016). Further, Stephan et al. (2020) examined the evaluation and classification of scoliotic curvatures using ST and ML. It was found that the algorithm was capable of classifying curve severity (mild, moderate, severe) and progression with a high accuracy (90% accuracy; Stephan et al., 2020).

While ST has been used in numerous studies with varying levels of success, it is still limited, as many of these studies used specialized equipment (i.e., laser scanners) that are not often available in a clinical setting (especially in smaller rural hospitals and clinics), are not portable, and require the expertise of a trained technician (Hong et al., 2016; Komeili et al., 2014). Additionally, while these studies allowed researchers to classify the Lenke type of the curvature of the spine, assess the 3D geometry and predict the severity of scoliosis (i.e., group participants based on mild, moderate, and severe curve types), they were not able to accurately estimate the Cobb angle with enough specificity to have clinical relevance. Therefore, these systems may not have a practical utility, as a clinician may still request a spinal radiograph to confirm the curvature of the spine prior to providing treatment for AIS. Hong et al. (2016) estimated that, assuming mild and non-progressive curves would not require a radiograph of the spine, their ST-based protocol would only eliminate 31% of radiographs within the AIS population. Further, these systems are not suitable for AIS screening outside of a clinic or research setting.

A study was conducted by Yang et al. (2019), where ML algorithms were applied to 2-D images of the back of AIS patients. The ML algorithm classified the images based on the Cobb angle of the spine. It was found that the algorithms were able to predict if the patient had a curvature >10° with an accuracy of 75%, demonstrating that computer vision algorithms can help screen for scoliosis without the need for complex equipment. There are a limited number of studies that have been able to accurately measure the Cobb angle of the spine without using spinal radiographs. Kokabu et al. (2021) used ML to predict the Cobb angle by using a depth sensor and a laptop to collect data while subjects performed an Adams FBT. The relationship between the predicted Cobb angles and the ground truth Cobb angles, which were calculated manually by experienced clinicians, were compared using Pearson's correlation coefficients (Kokabu et al., 2021). It was found that there was a high degree of agreement between the predicted and the manually measured Cobb angles, as the correlation coefficient was 0.91 (Kokabu et al., 2021). Further, the error between the Cobb angle predictions from the algorithm and the manually measured ground truth Cobb angles, were found to be 5.4°.

Although the study conducted by Kokabu et al. (2021) demonstrates that ML methods have the potential to reduce or minimize the number of radiographs required to diagnose and treat AIS, there are still gaps in the literature. The responsibility of screening for AIS falls largely on the untrained guardians of the adolescent. Therefore, there is a need for an AIS screening tool that uses technology that is widely available for everyone to use and that is not limited to a clinical or research setting. Many new consumer-grade smartphones (i.e., Samsung S20 Ultra 5G) now contain an integrated time-of-flight (TOF) camera. This provides useful information, as the TOF sensor emits light that bounces off objects within the frame and calculates the time it takes for the signal to return to the camera, providing depth information. Therefore, these new smartphones can capture an RGB-D image, where a depth map is embedded within the colour (RGB) image. Given that depth information can now be obtained from a smartphone, there is an opportunity to use these devices to obtain data to train a ML algorithm to identify and classify AIS based on the Cobb angle. The use of smartphone technology would be beneficial, as smartphones are a device that many individuals already have available in their home, and they are a device that clinicians could easily integrate into their routine AIS appointments. To the best of the author’s knowledge, this is the first study of its kind to use new smartphone technology (i.e., TOF sensor) to develop a ML algorithm to screen for scoliosis.

Chapter 3: Purpose

The primary objective of this thesis is to use images taken of unclothed AIS and control participants with a smartphone containing TOF technology (Samsung S20 Ultra 5G) to train a CNN-backed decision tree algorithm to identify potential cases of AIS, providing a proof of concept for a simple and accessible AIS screening tool. The secondary objectives of this thesis project are to 1) provide a proof of concept for a regression-based ML algorithm that can predict the Cobb angle of the spine from the images taken with the Samsung S20 Ultra 5G and 2) to determine if the depth information obtained from the smartphone device provides additional features or information that improve the performance of the ML algorithm, compared to regular RGB images. The ML algorithms will be trained with RGB-D, Colourized depth maps and RGB images to achieve this objective.

Chapter 4: Hypothesis

Based on the performance of the ML algorithm developed by Yang et al. (2019), which used RGB images to train ML models to detect AIS, it is hypothesized that the ML algorithm developed for this thesis project will be able to detect a Cobb angle >10° with an accuracy >75% (Yang et al., 2019). Further, it is hypothesized that the regression-based algorithm developed for this thesis project will be able to predict the Cobb angle of the spine within 5-10° of the ground truth Cobb angles (Kokabu et al., 2021; Yang et al., 2019). Additionally, based on the comparison of studies that have used various image sources, such as depth maps and regular RGB images, it is expected that the RGB-D images will have the highest overall accuracy, followed by the Colourized depth maps and the RGB images, respectively.

Chapter 5: Methodology

5.1 Participants

Thirty-three adolescent (10-18 years of age) participants were recruited for this thesis project. The participants were divided into two groups: AIS and control. Of these 33 participants; 28 were diagnosed with AIS, and 5 were 'healthy' controls (i.e., no spinal conditions or deformities). The average patient demographics can be seen in Table 5.1. All participants were recruited from the spine clinic at the Children's Hospital of Eastern Ontario (CHEO) following recommendation from their clinician. The control group consisted of patients that had received treatment or consultation at the spine clinic for another non-scoliosis related issue and/or who had sought early intervention due to fears of AIS developing (e.g., due to family history of scoliosis).

Table 5.1: Average Patient Demographics for both the AIS and control groups

Group	N	Age (years)	Height (cm)	Weight (kg)	Cobb Angle (°)
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
AIS	28	13.5 (2.15)	160.0 (12.1)	47.9 (9.14)	31.5 (16.01)
Control	5	14.00 (2.24)	164.1 (12.2)	48.9 (9.92)	N/A

SD = standard deviation

The AIS group had a Cobb angle greater than 10°, while the control group had no spinal curvatures greater than 10°. Participants in both groups were required to have received a full body PA EOS scan (without a brace) on the same day of data collection to confirm their diagnosis, or lack thereof. Participants in both groups were excluded from study participation if they had previously undergone spinal surgery, had acute spinal trauma, spinal tumours, syndromic scoliosis and/or forms of scoliosis other than AIS, had been diagnosed with a neuromuscular disorder, were unable to stand unassisted, had a leg length discrepancy >2cm, had surface/soft tissue tumors of the torso, and/or a BMI > 30.

5.2 Ethics

Ethical approval was obtained by the ethics committees at both the Children's Hospital of Eastern Ontario (REB file number: 20210247) and the University of Ottawa (REB file number: H-09-21-7348). Copies of the ethics approval forms can be found in Appendix A.

5.3 Assent and Consent

All participants were required to provide their informed consent prior to study participation. Participants under the age of 18 who were unable to fully comprehend the requirements of the study were required to sign an assent form, while their legal guardian was required to sign a consent form on their behalf. The consent form fully and clearly described the procedure, purpose, and risks associated with this study. The assent form contained a synopsis of the same information. Participants in both the AIS and the control group signed the same consent and assent forms. Copies of these forms can be found in Appendix B.

5.4 Study design

Data collection took place at CHEO immediately following the patients' regularly scheduled appointment. After participants received their standard care from their clinician, they were taken to a separate room within the clinic where they were informed of the study's requirements, purpose, and risks, after which their informed consent and/or assent to participate in the study was obtained. This study was considered to be low risk, as the only risks associated with study participation were receiving an EOS scan, which is a part of a regularly scheduled AIS appointment.

First demographic features (i.e., age, height, and weight) were recorded. Ethnicity was recorded if the participant consented to providing this information. A scoliometer was then used to predict torso asymmetry in the thoracic and thoraco-lumbar regions and shoulder elevation was recorded (i.e., was the right or left shoulder more elevated). The demographic sheet used for data collection can be found in Appendix C. The Cobb angles of the upper thoracic, thoracic, and lumbar regions, as well as the Lenke classification and Risser stage (used to grade skeletal maturity) were recorded at a later date by a clinician at the Ottawa General Hospital, who had previous experience calculating the Cobb angle of the spine, from the same day EOS scans.

5.4.1 Participant Preparation and Equipment

Participants were asked to change into an open-backed hospital gown displaying the full surface of the posterior torso and the acromion processes. Participants were asked to remove any undergarments that could obstruct the view of the spine. If they were comfortable, they were also asked to adjust their pants so that the posterior superior iliac spines (PSIS) were visible.

Participants were instructed to face the wall ~1m away from a tripod containing the Samsung S20 Ultra 5G Smartphone. The positioning of the tripod was adjusted slightly for each participant such that the entire torso could be observed when capturing the images. The S20 Ultra 5G contains a quad camera (Figure 5.1). The first camera is 108 MP (wide-angle camera), the second camera is 48 MP (Telephoto), the third camera is 12 MP (ultra-wide, autofocus) and the fourth camera is 0.3 MP VGA (TOF, 3D depth sensing; Figure 5.1). Images were taken while participants were in 3 different poses, from two different camera angles (direct and elevated). The three different poses used in this study were: a regular standing position, a PA position (i.e., mirroring the position during the EOS scan), and a forward bending position.

Figure 5.1: Schematic demonstrating the camera of the Samsung S20 Ultra 5G Smartphone used for data collection.

First, images were taken from a ‘direct’ camera angle: the tripod was adjusted such that the exposed back’s surface was centralized in the camera's view and the top gridlines aligned with the participants shoulders. Images were taken from this camera location while participants were in an upright standing position, a PA position, and a forward bending position (Figure 5.2A-C). For the standing position, participants were instructed to keep their heads facing forward (Figure 5.2A). For the PA position, participants were instructed to bend their elbows and lift their arms, to form a 45° angle with their torso while their palms were facing the wall in front of them (Figure 5.2B). For the forward bend position, participants were instructed to bend forward so that their back was parallel with the floor and to keep their legs straight (Figure 5.2C). The tripod was then moved to be directly behind the participants. The tripod was elevated to ~2 m so that the camera was pointing down at a 30° angle: allowing the acromion’s to be visible while in a forward bend. From the elevated camera angle, images were only taken of participants in a forward bend position (Figure 5.2D). For this thesis project, only the PA (Figure 5.2B) and forward bending images (Figure 5.2D; from an elevated camera angle) were used.

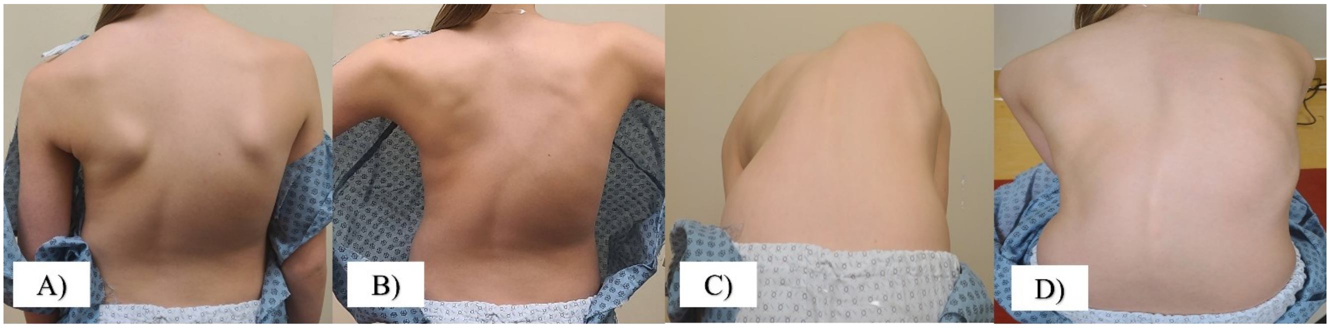

Figure 5.2: Examples of the images taken during data collection at the Children's Hospital of Eastern Ontario. A) Upright standing posture from a direct camera angle B) PA posture from a direct camera angle C) Forward bending posture from a direct camera angle D) Forward bending posture from an overhead camera angle

5.4.2 Dataset

All of the RGB-D images captured by the smartphone were preprocessed by cropping them at the base of the neck (C_3-C_5 vertebrae) to the hips, below the PSIS. Three different data streams were used for this study (i.e., RGB-D, Colourized and RGB, Figure 5.3). The RGB-D images were separated into their individual RGB and depth components. The depth maps were normalized, where the minimum pixel value was mapped to 0, and the maximum pixel value was mapped to 1; all pixel values in between were scaled accordingly. This normalization step was done to enhance the contrast between pixels, making the differences in depth more apparent. The images were then colourized by applying a jet colour map to the normalized depth maps (Figure 5.3A). This created a Colourized data stream. The normalized depth maps were then re-combined with the RGB images to create a 'modified' RGB-D image, where the depth map was overlayed on top of the RGB image, so that it was visible on the posterior surface of the torso. It was necessary to create the 'modified' RGB-D images because the raw RGB-D images from the smartphone lost their depth properties (i.e., could no longer access the depth map from the metadata) when the images were modified in any way (i.e., cropping and/or augmenting the data). The images were all labelled according to diagnosis (i.e., AIS or control) and according to the main curvature of the scoliotic spine using SentiSight AI (Neurotechnology, Lithuania), which is an online ML platform that specializes in image labelling and image recognition tasks. The RGB-D, Colourized, and RGB images were then randomly divided into a train and test dataset with an 80:20 split. All images were augmented (i.e., randomly zooming, horizonal flipping, and rotating the images within 25° in both directions) to increase the robustness of the dataset (i.e., reducing the risk of overfitting). All images were normalized so that they were 400 x 400 pixels in size, with all pixels ranging between 0 and 1.

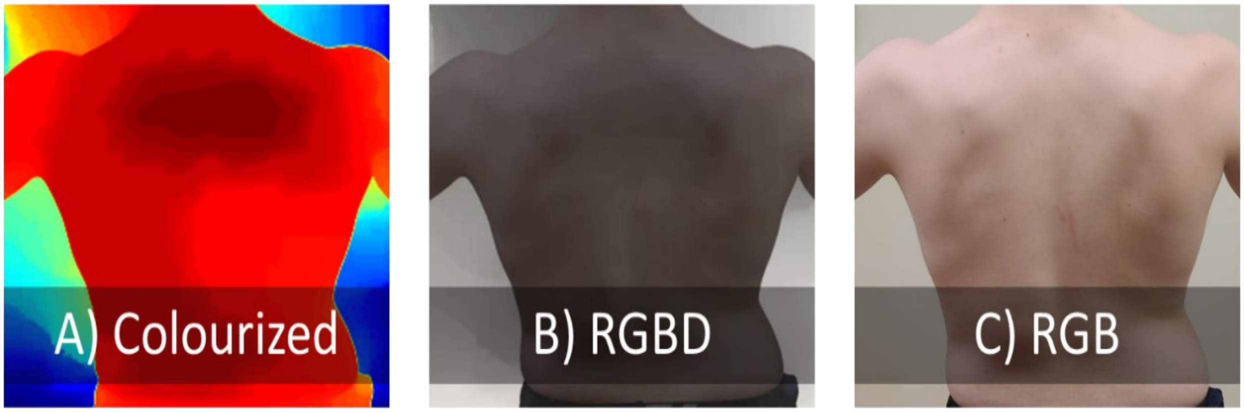

Figure 5.3: A) represents the Colourized data stream used to train the models, B) represents the 'modified' RGB-D data stream and C) represents the RGB data stream

5.5 The CNN-Backed Decision Tree Classifier/Regression Algorithms

Two algorithms were developed for this thesis project. The first algorithm classified images based on the detection of AIS, and the second used a regression-based model to predict the main curvature of the scoliotic spine. Initially, a classification model was trained that attempted to classify the images based on the severity of the curve (i.e., mild, moderate, and severe). However, due to large class imbalances that were present in the training dataset, there was a clear bias when the model was applied to the test dataset; this resulted in low overall performance. For this reason, a regression-based model was chosen to predict the main curvature of the scoliotic spine.

The subsequent models in the following algorithms were all trained with the modified RGB-D, the Colourized depth and the RGB Overhead bending and PA images. This was done to assess whether the image features extracted from one of these image types or positions would result in a better accuracy when used to train the ML algorithm. The workflow for the developed ML algorithm can be seen in Figure 5.4.

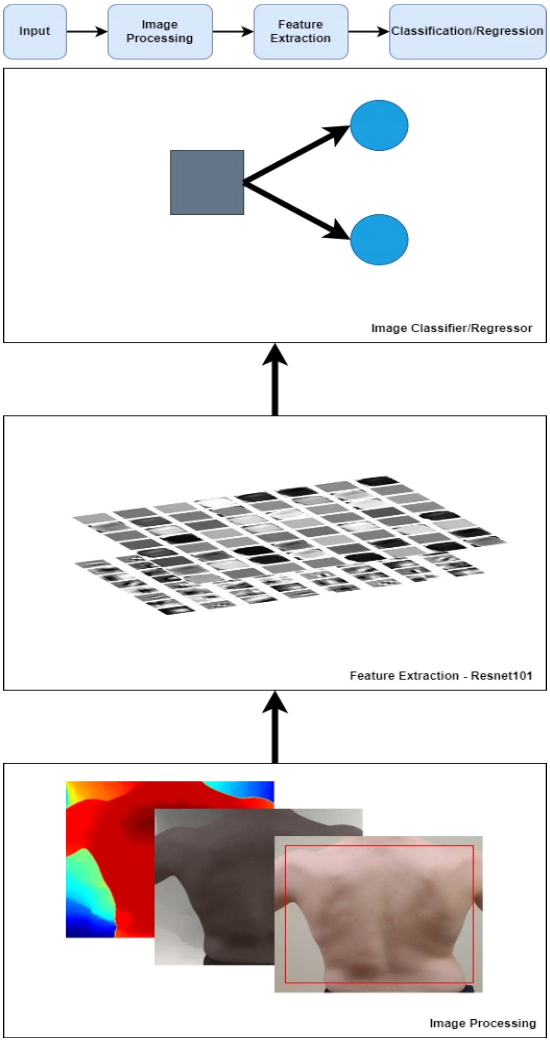

Figure 5.4: Workflow of the ML algorithm

5.5.1 Classification Based on General Diagnosis

The first algorithm classified images based on the general diagnosis (i.e., AIS or control). The images were first fed through a Resnet101 CNN block (Figure 5.5), which was done to extract high level features from the images (Paszke et al., 2019). The features were then standardized and scaled before being passed down into a random forest classifier, which replaced the last fully connected (FC) layer of the CNN.

Prior to using a CNN-backed decision tree approach, the classification tasks were attempted using a Resnet101 CNN classifier; however, it was found that the model was not performing well (i.e., low accuracy and high loss function). It is thought that the CNN did not perform well for this classification task due to the size of the dataset and data imbalances. Therefore, a decision tree-based model was tested, as decision trees provide more options to account for these class imbalances (i.e., artificially adjusting the weights of the classes, oversampling, undersampling). Further, decision trees have been previously used to classify AIS patients based on the severity of the curve from ST inputs (Hong et al., 2016). It is important to note that decision trees tend to have a lower accuracy than many modern CNNs (i.e. Resnet). With that being considered, research has shown that using a NN-backed decision tree can improve the accuracy of traditional decision tree classifiers, while maintaining some of the transparency in terms of classification decisions (Wan et al., 2021). Therefore, for this thesis project, a CNN was combined with a traditional random forest classifier (Figure 5.5).

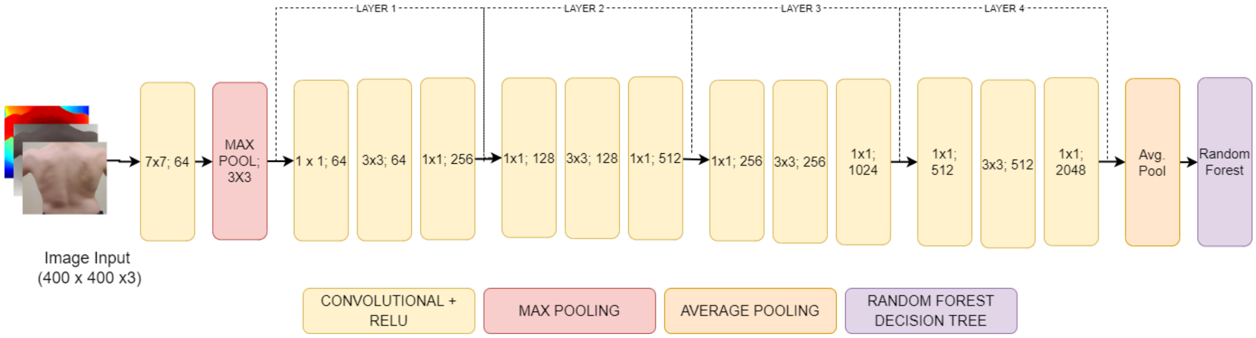

Figure 5.5: Schematic demonstrating the architecture used for the developed algorithm

The Random Forest classifier fit multiple decision tree classifiers to sub-samples of the dataset. The average of these classifiers was used to help minimize the risk of over-fitting. The model classified the images based on whether they were labelled as AIS or control. The Gini coefficient was used to determine when the decision tree should split. The equation for the Gini coefficient can be seen in Eq. 5.1, where p_i represents the probability of a feature being classified as a particular class. The decision tree attempted to split in a way that minimizes the Gini coefficient, as a Gini coefficient of 0 is indicative of an 100% pure leaf. Additionally, to help mitigate the effects of overfitting, the decision trees were pre-pruned, meaning a maximum depth and a maximum number of leaf nodes were set prior to training. Further, a large class imbalance was present in the dataset. It was easier to recruit participants who had been diagnosed with AIS, as one of the requirements for study participation was a same-day EOS scan. Therefore, the weights assigned to each class had to be artificially balanced. A larger weight was assigned to the images that were labelled as control. This ensured that when applying the trained model to the test images, it was not as biased towards classifying as AIS.

$$Gini = 1 - \sum_{i=1}^{n} (p_i)^2 \qquad \textbf{(Eq. 5.1)}$$

5.5.2 Regression Algorithm

To predict the Cobb angle of the spine, a regression-based algorithm was used. The control images were removed from the dataset; only AIS positive images were used to train the regression model. The images were again passed through a Resnet101 feature extractor to extract high level features from the images (Figure 5.5). The features obtained from the Resnet101 feature extractor were then inserted into a random forest regressor, using the squared error as a criterion for when to split the decision tree into separate nodes. The goal of the decision tree was to split in a way that reduced the value of the squared error. This decision tree was pre-pruned by adjusting the following hyperparameters: maximum depth, minimum samples per split, and maximum number of nodes. This ensured that the decision tree did not get too deep and/or too fitted to the images within the training dataset.

After the models had been trained using the developed algorithms, the trained models were applied to images in the test dataset to assess the accuracy of the models on 'unseen' participants (i.e., test dataset). None of the participants included in the training dataset appeared in the test dataset, and vice versa.

5.6 Statistics

All statistical analyses were performed using statistic packages from scikit learn (Pedregosa et al., 2011). The performance of the classification algorithm was assessed using an accuracy metric along with the macro-F1 score, to compute the subset accuracy. Further, the positive and negative predictive values (PPV, NPV, respectively) and the sensitivity and specificity were assessed for all models. This was done to provide further insight into the ability of the trained models to classify the images correctly. The equations for the PPV and NPV can be seen in Eq. 5.2 and 5.3, respectively. Where TP represents the number of true positives, TN represents the true negatives, FP represents the false positives, and FN represents the number of false negatives. The predictive values are an indication of the probability of an image that is classified into a particular class actually belonging to that class. The equations for sensitivity and specificity can be seen in Eq. 5.4 and 5.5, respectively. For this classification task, the sensitivity is the proportion of people with AIS who are correctly classified as having AIS. Specificity is the proportion of people who do not have AIS, who are correctly classified as controls. The performance of the regression-based model at predicting the Cobb angle of the spine was analyzed by calculating the root mean square error (RMSE). The equation for the RMSE can be seen in Eq. 5.4, where x_i is the ground truth Cobb angle and $\hat{x}$ is the predicted Cobb angle.

$$\frac{TP}{TP+FP} \qquad \textbf{(Eq. 5.2)}$$

$$\frac{TN}{TN+FN} \qquad \textbf{(Eq. 5.3)}$$

$$\frac{TP}{TP+FN} \qquad \textbf{(Eq. 5.4)}$$

$$\frac{TN}{TN+FP} \qquad \textbf{(Eq. 5. 5)}$$

$$\sqrt{\frac{\sum_{i=1}^{N}(x_i - \bar{\hat{x}})^2}{N}} \qquad \textbf{(Eq. 5. 6)}$$

Chapter 6: Results

6.1 AIS Classification Model Training

It was found that when training the decision tree model to classify the images as AIS or control, the algorithm was successfully able to identify key features to group the images based on their diagnosis for all image types (i.e., RGB-D, Colourized, RGB) and participant positions (i.e., Overhead bending, PA standing; Table 6.1). In total six models were trained with three different image types and two different participant positions. When training these models, an overall training accuracy of >88 % was achieved for each model (Table 6.2).

Table 6.1: The performance metrics of the ML algorithm on the training dataset.

Image Type	Negative Predictive Value	Positive Predictive Value	Specificity	Sensitivity
Overhead Colourized	0.44	1.00	1.00	0.87
PA Colourized	0.58	1.00	1.00	0.92
Overhead RGB-D	0.70	1.00	1.00	0.95
PA RGB-D	0.47	1.00	1.00	0.88
Overhead RGB	0.43	1.00	1.00	0.86
PA RGB	0.44	1.00	1.00	0.86

Class 0 = Control; Class 1 = AIS; RGB = red-green-blue; RGB-D = red-green-blue-depth

Table 6.2: Accuracy of the ML models on the training dataset

Image Type	Accuracy (%)	Macro-F1 (%)
Overhead Colourized	88	77
PA Colourized	93	85
Overhead RGB-D	96	90
PA RGB-D	89	79
Overhead RGB	88	76
PA RGB	88	77

RGB = red-green-blue; RGB-D = red-green-blue-depth

6.2 AIS Classification Model Testing

6.2.1 Colourized Depth Images

The model that was trained with the Overhead Colourized depth images had the highest accuracy when applied to the images in the test dataset. The model's accuracy on the train and test datasets was 88% and 93%, respectively. Further, the F1-score for the test dataset was found to be 89%. The NPV and the PPV were found to be 96% and 91%. This indicates that 96% of the images classified as control were classified appropriately, whereas 91% of the images classified as AIS were classified accurately. The specificity and the sensitivity of this model were found to be 75% and 99%, respectively (Table 6.3). Therefore, control participants were accurately classified as control 75% of the time and AIS participants were classified correctly 99% of the time. For this model, there was a higher proportion of false positives classified into the AIS group than false negatives (Figure 6.1).

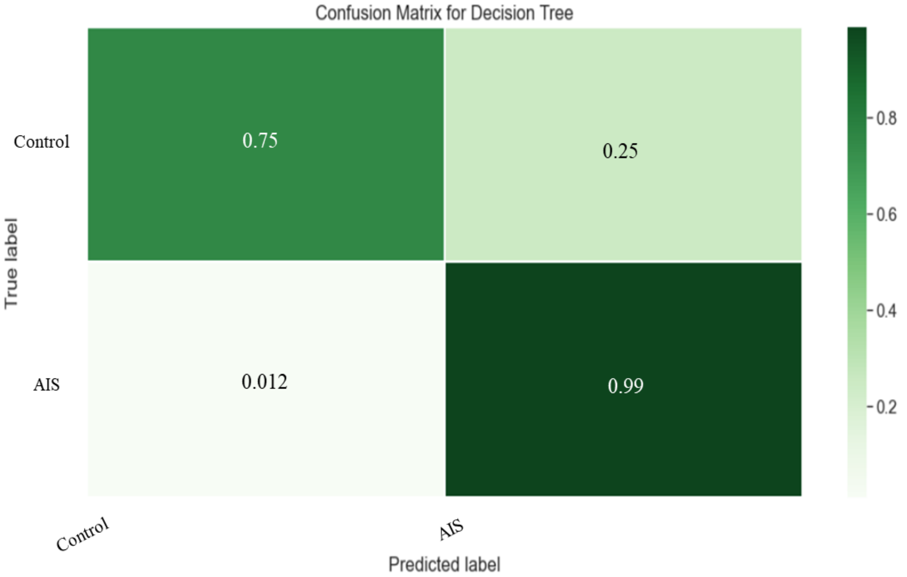

Figure 6.2: Confusion Matrix demonstrating the performance of the machine learning model, based on the proportion of correctly classified images. This model was trained with Overhead Colourized images and was applied to the test dataset

For the Colourized images, the model performance decreased when using images of participants in the PA position. For the test dataset of PA Colourized images, the overall accuracy of the model was only 70% and the F1-score was 63% (Table 6.3). The NPV and PPV were found to be 47% and 78%, respectively. In contrast, the sensitivity of this model was found to be 80% and the specificity was 44%. This indicates that there were a large proportion of healthy controls who were classified incorrectly by the model. There was a high false positive rate in terms of control images being mislabelled as AIS. It was found that 56% of the images with a true label of control were classified as AIS when applying the trained model.

6.2.2 RGB-D Images

The model that was trained with the Overhead RGB-D images had a satisfactory performance on the test dataset, with an accuracy of 72%. However, the accuracy was lower than the accuracy achieved with the Overhead Colourized model. It was found that 76% of the AIS images were correctly classified, and only 60% of the control images were classified accurately (Table 6.3).

For the PA RGB-D model, the overall performance was improved compared to the Overhead RGB-D model (75% accuracy). However, there was a higher proportion of images that were incorrectly classified as being AIS positive. The specificity and sensitivity of this model was 49% and 89%, respectively (Table 6.3).

6.2.3 RGB Images

The models that were trained using Overhead RGB images were found to have an overall accuracy of 76%. It was found that this model had the highest accuracy when classifying control images, as 84% of the images with a true label of control were classified correctly. In contrast, 73% of the AIS images were classified correctly. On the test dataset, the F1-score was found to be 75%.

The overall accuracy of the RGB model was improved when using PA images, as the overall accuracy was found to be 84% (Table 6.4). However, the ability of the model to correctly distinguish between AIS and control images decreased. It was found that the F1-score was 77% and both the PPV and NPV were found to be 84%. The sensitivity and specificity of the model trained using PA RGB images was found to be 96% and 53%, respectively. Therefore, while the majority of control images were classified correctly, there was still a high proportion of false positives in the AIS group.

Table 6.3: The performance of the ML algorithm on the test dataset

Image Type	Negative Predictive Value	Positive Predictive Value	Specificity	Sensitivity
Overhead Colourized	0.96	0.91	0.75	0.99
PA Colourized	0.47	0.78	0.44	0.80
Overhead RGB-D	0.50	0.83	0.60	0.76
PA RGB-D	0.57	0.81	0.49	0.85
Overhead RGB	0.56	0.92	0.84	0.73
PA RGB	0.84	0.84	0.53	0.96

Class 0 = Control; Class 1 = AIS; RGB = red-green-blue; RGB-D = red-green-blue-depth

Table 6.3: The Overall Performance of the ML algorithm on the test dataset

Image Type	Accuracy (%)	Macro-F1 Score
Overhead Colourized	93	89
PA Colourized	70	63
Overhead RGB-D	72	67
PA RGB-D	75	68
Overhead RGB	76	75
PA RGB	84	77

RGB = red-green-blue; RGB-D = red-green-blue-depth

6.3 Prediction of the Cobb angle of the Spine

When the performance of the regression-based ML algorithm was assessed, it was found that when the model was applied to a random subset of unseen test participants, the RMSE between the actual and predicted Cobb angles ranged between 7 and 16° (Table 6.5). Based on the results that can be seen in Table 6.5, the performance was the best for the model trained with PA RGB images, as the RMSE between the actual and predicted Cobb angles were 7.17°. The second-best performance was observed when the model that was trained with Overhead Colourized images was applied to the test dataset, as the RMSE values were found to be 8.28°. The lowest performance was observed with the model that was trained with PA Colourized images, as RMSE values of 15.4° were observed (Table 6. 5).

Table 6.4: Performance of the ML regression-based algorithm trained with different data streams at predicting the Cobb angle of the spine on the unseen test data

Image Type	RMSE (°)	MSE (°)	MAE (°)
Overhead Colourized	8.28	68.5	5.98
PA Colourized	15.4	235.0	10.8
Overhead RGB-D	9.61	92.4	6.86
PA RGB-D	9.69	93.8	6.78
Overhead RGB	10.6	113.0	7.46
PA RGB	7.17	51.4	5.35

RMSE = root mean square error; MSE = mean square error; MAE = mean absolute error; RGB = red-green-blue; RGB-D = red-green-blue-depth

Chapter 7: Discussion

This thesis project aimed to determine if images captured with a smartphone containing a TOF camera (Samsung S20 Ultra 5G) could be used to create and train a CNN-backed decision tree model to recognize the absence or presence of AIS. This method could be used to create a screening tool that is inexpensive, accessible, and effective. The secondary objectives of this thesis project were to 1) provide a proof of concept for the use of the developed ML algorithm to predict the major Cobb angle of the spine and 2) to determine if the depth information obtained from the Samsung S20 Ultra 5G could improve the performance of the ML algorithm when compared to regular RGB images.

It was found that the CNN- backed decision tree was able to accurately classify the images based on diagnosis (i.e., AIS vs. control). In support of the initial hypothesis, an accuracy higher than 75% was achieved for the Overhead Colourized, PA RGB-D, Overhead RGB, and PA RGB models. When the Overhead Colourized model was applied to the test dataset, an overall accuracy of 93% was achieved. This model had an excellent sensitivity: 99% of the AIS images were classified correctly. Although, the specificity was lower, where only 75% of the control images were classified correctly. This indicates that there were a higher number of false positives (25%) than false negatives (1.2%). However, the model was still able to correctly classify the majority of the control images. If used in its current state, the developed algorithm would mislabel 25% of non-AIS adolescents, while achieving the goal of early AIS identification, with very few AIS positive cases being mislabelled. Based on the negative implications associated with late diagnosis of AIS, it might be preferred that there are more false positives than false negatives, as it ensures that positive cases of AIS are detected early, resulting in less severe spinal curvatures upon first referral to a clinician. However, it is important to note that there were a limited number of control participants included in the dataset; therefore, as the dataset continues to grow, the ability of the model to correctly label the control participants will improve.

The model that was trained and tested with the Overhead Colourized data stream had the highest overall accuracy (93% accuracy) when compared to the other models. This demonstrates that the depth information from the Samsung S20 Ultra 5G contains additional features/information that improves the performance of the AIS screening ML algorithm when compared to regular RGB images. However, contrary to the initial hypothesis, the accuracy of the models trained with the RGB-D data streams were only satisfactory (75%-76%) and the accuracy of the RGB models ranged from satisfactory to good (76%-84%). Interestingly, the lowest accuracy was seen with the PA Colourized data stream (70% accuracy). It is thought that the PA Colourized model achieved the lowest accuracy, as, upon visual inspection of the depth maps, it is likely that the features extracted from the Resnet101 feature extractor came primarily from the scapular region. However, many of the participants in the control group had sought treatment or early intervention/diagnosis for suspected cases of AIS (upon review of the spinal radiograph, no curves >10° were observed). Therefore, some of the control participants exhibited slight asymmetries in the scapular region, making it difficult for the PA Colourized model to distinguish between AIS and control participants.

The accuracy of the screening method that was developed for this thesis project was found to be comparable to traditional AIS screening techniques and procedures (Dunn et al., 2018; Karachalios et al., 1999). The US protective service task force (USPSTF) determined that when using three different screening methods in conjunction (i.e., Adams FBT, scoliometer measurements, Moiré topography), there is a sensitivity and a specificity of 93.8% and 99.2 %, respectively (Dunn et al., 2018). When the FBT is used alone, this screening method has a sensitivity of 84.4% and a specificity of 95.2%. When the FBT is used in combination with scoliometer measurements, this screening method has a sensitivity of 71.1% and a specificity of 97.1%. The Overhead Colourized and the PA RGB models trained for this thesis project had a higher sensitivity than the FBT, when used alone and in combination with the scoliometer. Further, research has shown that Moiré topography has a sensitivity and specificity of 100% and 85.4%, respectively (Dunn et al., 2018; Karachalios et al., 1999). The sensitivity of the Overhead Colourized model was found to be 99%, which is similar to the sensitivity of the Moiré topography technique. However, the specificity of this model was found to be lower (75%) than the specificity of these traditionally used screening techniques. In contrast, other research that applied a digital Moiré technique only found a specificity of 53%, which is lower than the specificity of the models trained with the Overhead Colourized, Overhead RGB-D, and Overhead RGB images (Sato et al., 2020). It is worth noting that due to ethical considerations, and the potential harm caused by excess radiation exposure, controls could only be recruited from the spine clinic and/or other clinics within CHEO, where the participants received a spinal radiograph for other ailments or concerns. Therefore, only five controls were included in the dataset (three controls in the training and two in the test datasets). With that being considered, it is likely that the model was demonstrating overfitting towards the control images within the training dataset, as the model was not exposed to much variability in terms of controls. This is an ongoing research project; therefore, as the dataset continues to grow, the specificity of the model will likely continue to improve.

One potential benefit of this proposed AIS screening protocol compared to other more traditional screening methods is that it is not dependent on the skill of the evaluator. With the discontinuation of school scoliosis screening programs, the responsibility of recognizing AIS has shifted from nurses and experienced practitioners towards untrained parents (Heemskerk et al., 2022). While the FBT and other screening methods have a high specificity and/or sensitivity, they cannot be used by individuals across all-skill levels with the same results. For this reason, AIS is not being detected as early, which results in patients seeking treatment with larger curves, thus requiring more aggressive intervention (i.e., surgery; Chen et al., 2020; Yan et al., 2020). Eventually, a smartphone application could be developed from this thesis project or future related work, which would allow untrained parents to screen for AIS with the same sensitivity and specificity as a health care professional. Heemskerk et al. (2022) performed a study where they compared the ability of healthcare professionals and untrained parents to identify AIS from images of the exposed posterior torso of adolescents in an upright standing posture and in a forward bend. It was found that the healthcare professionals and the untrained parents had similar specificity when classifying the images (65.3% and 63.6% for healthcare professionals and untrained parents, respectively; Heemskerk et al., 2022). However, as was expected, the healthcare professional group was better able to identify positive cases of AIS (73.4%) compared to the untrained parent group (63.8%; Heemskerk et al., 2022). Most of the models in this present study outperformed both the healthcare professionals and the untrained parents. This is important as a ML-based screening method enables anyone to screen for scoliosis without any prior experience or training. A ML-based protocol can potentially allow for earlier detection of AIS and, therefore, earlier treatment, resulting in less aggressive and less invasive treatment options (Li et al., 2021).

There have been other ML algorithms developed that have attempted to find a means of screening for and diagnosing AIS without the use of spinal radiographs with varying levels of success (Cho et al., 2018; Kokabu et al., 2021; Komeili et al., 2014; Stephan et al., 2020; Yang et al., 2019). Yang et al. (2019) created a ML algorithm to automate scoliosis screening. Much like this current thesis project, this model was trained with unclothed images of the posterior surface of the torso, of both AIS and control participants, in an upright standing posture. It was reported that the accuracy of the algorithm for detecting spinal curves >10° and >20° was 75% and 87%, respectively (Yang et al., 2019). In this present thesis, the model trained with PA RGB images was able to differentiate between control (spinal curve <10°) and AIS (>10°) participants with an accuracy of 84%, and the model that was trained with Overhead RGB images was able to classify the images with an overall accuracy of 76%. These accuracy results are comparable to the results obtained by Yang et al. (2019). However, Yang et al. (2019) had 2495 AIS patients and 745 controls enrolled in their study. Therefore, it is possible that with an increased dataset, the models in this present thesis project could have improved results. In contrast, the model that was trained with the Overhead Colourized images outperformed Yang et al. (2019) in terms of the overall accuracy of the model, as the Overhead Colourized model achieved an accuracy of 93% on the test dataset. A recent study by Kokabu et al. (2021) achieved similar results, as they found that their ML algorithm was able to identify a Cobb angle >10° with an accuracy of 94%. Kokabu et al. (2021) used a commercial depth sensor to train their ML model (Xtion Pro Live, ASUSTeK Computer Inc. Taipei, Taiwan). While the depth sensor used by Kokabu et al. (2021) is not overly expensive, it is still a piece of equipment that the average person would not have readily available. This present thesis project demonstrates that using a depth sensor from a smartphone can achieve similar results.

A secondary objective of this thesis project was to determine if the images could be used to predict the main curvature of the scoliotic spine. The RMSE values calculated from the regression model were higher than what was initially expected. It was found that when the trained regression-based model was applied to the test dataset, RMSE values of 7°-16° were achieved.

Kokabu et al. (2021) performed a similar study, where they calculated an asymmetry index from the surface of the posterior torso of AIS patients. The asymmetry index was calculated as the mean deviation between the point cloud of the surface of the posterior torso (obtained from a depth map) and the best fit reflected point cloud. This asymmetry index was fed into a regression algorithm to predict the Cobb angle of the spine. It was found that the RMSE between the actual and predicted Cobb angles were 5.4° (Kokabu et al., 2021). While these results are better than the results of the present thesis work, Kokabu et al. (2021) had 160 participants enrolled in their study, compared to the 28 whose Cobb angle were calculated for this thesis. Additionally, the methods introduced by Kokabu et al. (2021) are computationally expensive and require more preprocessing steps before the input data can be fed into the CNN to get the Cobb angle predictions. Therefore, their approach may not be ideal for the creation of a smartphone application. Additionally, the PA RGB data stream in this thesis project had a RMSE of 7.17°, between the predicted and ground truth Cobb angles, which still has some clinical relevance and could provide insight into the severity of the curve and the potential treatment options. When the Cobb angle is calculated manually, there are inter-rater reliability errors ranging from 5-7° (Morrison et al., 2015). Therefore, if the ML model can achieve RMSE values within that range, it has clinical significance.

While other studies have attempted to tackle this problem, this project is unique in that it uses modern smartphone technology that is widely available and is relatively inexpensive and accessible. This project is the first step in the creation of an AIS screening and diagnostic tool that could potentially be made available to the public through a smartphone application, allowing everyone to screen for AIS easily and effectively.

Chapter 8: Limitations

There are some limitations that need to be mentioned in relation to this thesis project. It was difficult to recruit healthy controls for this study because participants must have had a spinal radiograph on the same day of data collection to be included in the study. This was to ensure that nobody in the control group had an underlying condition/AIS that may affect the symmetry of their back's surface. It has been well established that there are harmful effects associated with frequent and unnecessary radiation exposure (Knott et al., 2014; Presciutti et al., 2014; Simony et al., 2016). Therefore, only controls who had been referred to CHEO for other ailments or conditions (i.e., low back pain) were recruited. Often the control group consisted of participants who had a sibling or parent who had previously been diagnosed with AIS and had therefore sought an early spinal radiograph to ensure that they did not develop the deformity. For this reason, we were unable to recruit as many control participants as AIS participants. One of the benefits of using a decision tree-based algorithm is that it was easy to artificially adjust for weight imbalances when training the model. Therefore, this class imbalance was accounted for. However, given the size of the data imbalance, it must be assumed that the model exhibits some bias towards predicting images as being AIS positive. Future research should address this data imbalance, to minimize the number of false-positive results.

Another limitation is the size of the dataset. With many ML models, the more data the better. Many comparable studies had at least twice the number of participants. This is the first phase of an ongoing project, where data collection is still occurring at the writing of this thesis. Therefore, it is expected that as more data becomes available and are added to the dataset, the performance of the ML algorithm will continue to improve.

It is also worth noting that all of the images that were taken for this thesis project were taken while the smartphone was attached to a tripod. This was done to improve the quality of the images and to standardize the way that the images were captured between participants. However, if a smartphone application were to be created from this thesis project or related work, most users would not be using a tripod. This is a limitation that was accepted for this present thesis project.

Another limitation is that there are high intra- and inter-rater reliability issues in terms of Cobb angles measurements (Morrison et al., 2015). With this being considered, the Cobb angles that were calculated for the participants enrolled in this thesis project were obtained and calculated by a single clinician working out of the Ottawa General Hospital. This is a limitation that should be addressed prior to any papers being published from this current thesis project.

Chapter 9: Conclusion

This thesis project was the first of its kind to use modern smartphone technology to create a CNN-backed decision tree algorithm to screen for AIS. It was found that the Overhead Colourized data stream, which consisted of depth maps with a jet colour map applied, had the highest accuracy at classifying control and AIS participants (93% accuracy). The RGB-D data streams had the lowest overall accuracy, followed by the RGB data streams. Further, it was found that the ML algorithm developed for this thesis project performed similarly to many other traditional screening methods currently used in standard practice, such as a FBT or a FBT with scoliometer measurements. The results of this thesis project are promising, as they display that a ML model trained with images captured by a smartphone containing a TOF camera can be used to predict the main curvature of the scoliotic spine. The RMSE values between the predicted and ground truth Cobb angles were found to be higher than what was initially expected. However, the RMSE values calculated from the model trained with PA RGB images appear to have some clinical relevance. Further, as the dataset continues to grow, it is expected that these results will continue to improve. Therefore, this thesis demonstrates the feasibility of creating an application using these ML algorithms to allow for AIS to be screened by parents, coaches and/or general practitioners from their smartphones. Providing a safe, accessible, inexpensive, and effective diagnostic aid or tool.

Chapter 10: Future Directions

There were large class imbalances present in the dataset due to one of the requirements for study participation being a same day EOS scan. Moving forward the requirement of a same day EOS scan for the control participants will be eliminated to improve participant recruitment. Instead, the control participants will be screened with a FBT and with scoliometer measurements and they will be excluded from study participation if they have a familial history of scoliosis. A clinician will then independently review all of the images for control participants and will flag any participants who appears to exhibit visual signs of the deformity.

A priority should also be to continue to expand the dataset to improve the ability of the algorithm to predict the main Cobb angle of the spine. Additionally, future research should investigate the impact of parameterizing the images, such as finding an asymmetry index similar to Kokabu et al. (2021), as this might improve the predictions made by the algorithm when using a regression-based model.

As the dataset grows, the models could be trained to recognize additional spinal metrics, such as the directionality of the curve and the degree of spinal curvature at various spinal levels (i.e., upper thoracic, thoracic, and lumbar regions). In the future, the algorithms should also be trained to classify the images based on the Lenke type to provide more information on the 3D geometry of the back's surface. The Overhead and PA images should also be combined for each participant to determine if this improves the performance of the ML algorithm. Further, it might be worthwhile to assess the generalizability of the model when applied to images taken from a handheld smartphone (i.e., images taken without a tripod).

When training the models for this thesis project, various classification tasks were tested that used various architectures. As the dataset continues to grow and becomes more balanced, it might be worthwhile to re-train these models and/or test other architectures. Initially, it was expected that using a CNN or a regional-CNN (R-CNN) would achieve better results than using a traditional ML algorithm (i.e., decision trees). However, given the distribution of the data, it was found that the CNN-backed decision tree model performed the best, and was thus selected for this thesis project. With a large and balanced dataset available for training, it is expected that a CNN or R-CNN classifier would perform better than the current algorithm.

Initially, it was the goal to have three different clinicians calculate the participant Cobb angles independent from each other. The average of these three values was then going to serve as the ground truth, to account for inter-rater reliability errors that exist when manually calculating the Cobb angle. However, given time constraints, this was not possible for this current thesis project. With that being considered, prior to any papers being published from this piece of work, two additional clinicians will review the Cobb angles, and the models will be retrained with these values to ensure the most accurate results.

The long-term goal is to eventually have a model that can predict the presence or absence of AIS and the degree of spinal curvature with a high level of confidence. Eventually a smartphone application could be created from this thesis project or related work; providing a diagnostic aid or tool that can minimize the number of radiographs required to adequately diagnose and treat AIS.

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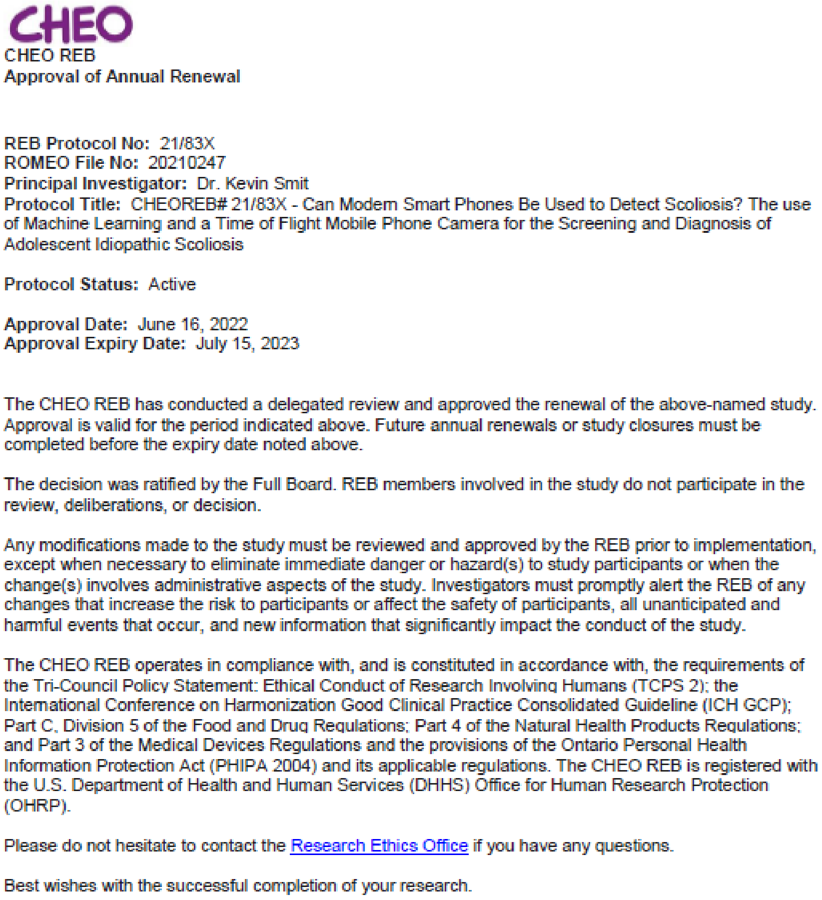
Appendix A



CHEO REB
Approval of Annual Renewal

REB Protocol No: 21/83X
ROMEO File No: 20210247
Principal Investigator: Dr. Kevin Smit
Protocol Title: CHEOREB# 21/83X - Can Modern Smart Phones Be Used to Detect Scoliosis? The use of Machine Learning and a Time of Flight Mobile Phone Camera for the Screening and Diagnosis of Adolescent Idiopathic Scoliosis

Protocol Status: Active

Approval Date: June 16, 2022
Approval Expiry Date: July 15, 2023

The CHEO REB has conducted a delegated review and approved the renewal of the above-named study. Approval is valid for the period indicated above. Future annual renewals or study closures must be completed before the expiry date noted above.

The decision was ratified by the Full Board. REB members involved in the study do not participate in the review, deliberations, or decision.

Any modifications made to the study must be reviewed and approved by the REB prior to implementation, except when necessary to eliminate immediate danger or hazard(s) to study participants or when the change(s) involves administrative aspects of the study. Investigators must promptly alert the REB of any changes that increase the risk to participants or affect the safety of participants, all unanticipated and harmful events that occur, and new information that significantly impact the conduct of the study.

The CHEO REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2); the International Conference on Harmonization Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; and Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The CHEO REB is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

Please do not hesitate to contact the Research Ethics Office if you have any questions.

Best wishes with the successful completion of your research.

21/06/2022

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Lettre d'approbation administrative | Letter of administrative approval

Numéro de dossier / Ethics File Number	H-09-21-7348
Titre du projet / Project Title	Can Modern Smart Phones Be Used to Detect Scoliosis? The use of Machine Learning and a Time of Flight Mobile Phone Camera for the Screening and Diagnosis of Adolescent Idiopathic Scoliosis
Type de projet / Project Type	Recherche de clinicien / Clinician's research project
CÉR primaire / Primary REB	CHEO / CHEO
Statut du projet / Project Status	Renouvelé / Renewed
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	10/09/2021
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	15/07/2023

Équipe de recherche / Research Team

Chercheur / Researcher	Affiliation	Role
Ryan GRAHAM	École des sciences de l'activité physique / School of Human Kinetics	Chercheur Principal / Principal Investigator
Jessica WENGHOFER	École des sciences de l'activité physique / School of Human Kinetics	Étudiant-chercheur / Student-researcher

Conditions spéciales ou commentaires / Special conditions or comments:

The uOttawa expiry date is set in accordance with the one from the CHEO-REB.

Appendix B

Information & consent form

Protocol Title: **Use of Machine Learning and a Time of Flight Mobile Phone Camera for the Screening and Diagnosis of Adolescent Idiopathic Scoliosis: A Novel Non-Invasive Tool**

Investigator: Dr. Kevin Smit, MD.

Co-Investigators: Dr. Andrew Tice, MD.; Dr. Ryan Graham, PhD.; Dr. Luke Beaton, MD, Jessica Wenghofer, MSc. Candidate

Address:
CHEO, Department of Orthopedics,
401 Smyth Road, Ottawa, ON K1H 8L1

Telephone Number: **(613) 737-7600 Ext 2998**

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

You are being invited to join in a research study non-invasive diagnosis and monitoring of adolescent idiopathic scoliosis (AIS). Adolescent idiopathic scoliosis is when you have a condition where there is a curve in your spine. This usually occurs when you are between the ages of 10 and 18. You are being invited to join this study because you are being followed by a clinician at the Children's Hospital of Eastern Ontario (CHEO) for your diagnosis of AIS, or for an evaluation of you back pain. Before agreeing to take part in this study, it is important that you read and understand this document.

Taking part in this study is voluntary. Your decision to participate, or not participate in this study will not affect the care you receive at CHEO. You are free to withdraw from the study at any time and there will be no penalty to you.

Why is this study being done?
The purpose of this study is to develop software that uses pictures taken with a mobile phone to assist clinicians in the diagnosis and monitoring of patients with AIS, without the need for x-ray imaging. The study will recruit participants into the following groups:

1. Control (no scoliosis) – healthy volunteers being assessed for back pain
2. Scoliosis (pre-operative) - patients with untreated AIS

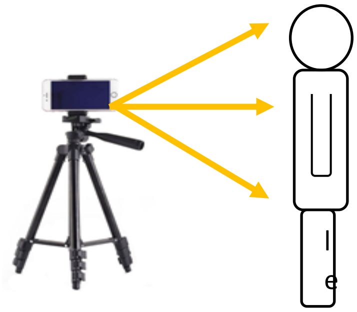
This research may help doctors diagnose patients with AIS as well as follow their clinical course without repeated exposure to x-ray imaging, as well as allow clinicians without expert training in pediatric orthopedics or AIS to screen patients in remote settings where access to specialized care might be limited.

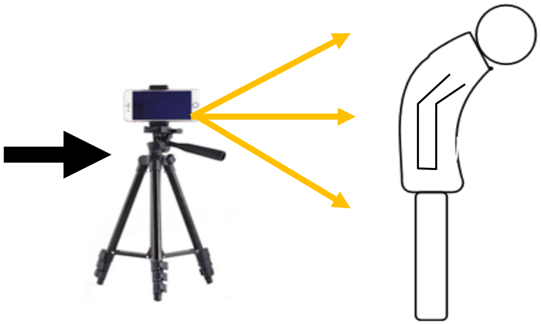
How many people will participate?
We expect to have 150-200 people participate, with 75-100 participants in each of the two groups recruited from CHEO. The study is expected to be recruiting for 8-10 months.

What will I have to do?
Participants enrolled in the study will follow regular standard of care for AIS or evaluated for back pain. Researchers will collect these images from your medical records Visit will take place at the CHEO Orthopedic Clinic. At each visit, various demographic data (age, weight and height, menarchal status, etc.) will be collected, as well as a number of characteristics related to your spinal geometry (curve pattern, Cobb angle, leg length discrepancy, etc.). Additionally, you will be asked whether you give consent to provide information about your ethnicity to the research team, for the research purposes only.

At each visit, in addition to a standard of care PA/Lateral EOS spine radiograph for participants diagnosed with scoliosis, each study participant, both the healthy and scoliosis participants, will have images captured with a distance-sensing mobile phone camera. These will take a video of the surface of the back whilst wearing an open-backed gown, moving from a standing erect position into a forward bend. The camera position in terms of distance, height, and angle in relation to the participant will be standardized using a tripod (or similar).
arrow


a) Example Image


b) Erect posture


c) Forward bend posture

How long will participants be in the study?
Your participation on this study will last until you are discharged from your surgeon's care.

Are there any risks to participating?

Physical Risks:

Back movements involving a forward bend may pose a miniscule risk of injury to the spine, so these movements can only be completed once you have been cleared by a medical doctor.

Are there any benefits to participating?
If you decide to participate, you may or may not benefit from participating in this study; however, we hope to take better care of patients in the future with the results from this study.

Will I be paid to participate?
There is no financial compensation for your participation in this study.

What is the cost to participants?
Participation in this study will not involve any additional costs to you or your private health care insurance.

What are the rights of participants in a research study?
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the researcher, or involved institutions for compensation, nor does this form relieve the researcher or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

Can I Withdraw?
You can withdraw from the study at any time without any impact to your current or future care at CHEO. Please discuss with your investigator if you would like to withdraw. If you withdraw your consent, the investigator will no longer collect, and disclose your health information for the purpose of this study. Information that was already collected may still be used by the Investigator if provided consent by the participant.

What if I get injured?
In the unlikely event that you or your child suffers injury as a direct result of participating in this study, normal legal rules on compensation will apply. Medical care will be provided to you or your child. By signing this consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Will I be told about new information?
We will inform you of any new information that might change your decision to continue to participate in this research project. We will ask you again if you still want to be in the study.

You can receive a copy of the study results at the end of the study. We can also provide a participant summary report if you are interested. Please let the study team know if you would like to receive a copy.

What about confidentiality and privacy?
Your personal information will be kept strictly confidential except as required or permitted by law. Any information that would indicate that a child was being harmed or at risk of such harm, would not be kept confidential and instead be disclosed as appropriate to the appropriate authorities.

For this study we will be collecting these personal identifiers: name, gender, and date of birth, email address for the research purposes described in this consent form. Your personal identifiers will be kept in a document that links this information with a study ID, called a master list. The study ID will be used in all of the research documents instead of your personal identifiers to protect your privacy. The master list will be stored separately from the research data. It will be password protected and stored in a secure location at CHEO with access restricted to the research team.

This research study is collecting information on ethnicity as well as other characteristics of individuals because these characteristics may affect the images taken by the distance-sensing mobile phone camera. Providing information on your ethnic origin is voluntary.

Representatives from the CHEO research Ethics Board and a quality reviewer from CHEO research institute may look at your records at the site where these records are held, to check that the study is following the proper laws and guidelines.

The research data produced from this study will be stored on a CHEO RedCap database. Only members of the research team and the individuals described above will have access to the data. Following completion of the study the research data and master list will be kept for 7 years after the last publication of this study. They will then be destroyed.

You will not be identified in any publication or presentation of this study. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

The data collected in this study will require post-processing with computer hardware not present at CHEO, which means the research data will be shared outside of the hospital. Representatives from The University of Ottawa Biomechanics Lab will receive anonymized research data including your study ID, gender and date of birth for data analysis and/or quality assurance. Any other personal information about you that leaves the hospital will be coded with a study ID so that you cannot be identified by name. This is called de-identified data. The de-identified research data will inputed into a secure RedCap database with access to the research team from CHEO and The University of Ottawa Biomechancs lab.

A copy of the signed consent form will be provided to you.

Is the research team benefiting from the study?

Funding applications are ongoing for this study. It is possible we will receive funding for a medical student, master's student and research coordinator to contribute to running this study. The PI and any other team members are not currently benefiting from this study personally, financially or any other way. It is possible that a commercialized application for mobile devices may be developed in the future, which may or may not be freely available.

What if I have questions?

If you have any questions concerning participation in this study, please contact:
Dr. Kevin Smit 613- 737-7600 Ext.2998

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

CHEO Research Ethics Board	613-737-7600 ext. 3272

Consent form Signatures

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Data collection for this research may be used in future related research projects that are either and extension of the original project or in the same general area of research. Any personal identifying information will be removed from the data and cannot be linked back to you. Researchers outside of this specific study may request access to the data for new research purposed. Participants will not be asked to provide additional informed consent for the use of your de-identified data for future research.

I agree to the secondary use of my data to answer future related research questions:

☐ Yes☐ No

Signatures

____________________	________________	____________
Signature of Participant/ Substitute Decision-Maker	PRINTED NAME	Date

If consent is provided
by Substitute Decision Maker: ____________________
PRINTED NAME of Participant

____________________	________________	____________
Printed Name of Person who Conducted the Discussion	Signature	Date

Use this section if a translator or impartial witness is required.

If the consent discussion has been conducted in a language other than English, and an impartial qualified translator is required.

____________________	________________	____________
Printed Name of Translator	Translator Signature	Date

The "Signature of the Witness" line is intended for an impartial witness which is necessary when either the subject or the subject's legally authorized representative (LAR) speaks and understands English, but cannot read and write or is visually impaired

____________________	________________	____________
Printed Witness Name	Signature of Witness	Date

Assent Form

Protocol Title: **Use of Machine Learning and a Time of Flight Mobile Phone Camera for the Screening and Diagnosis of Adolescent Idiopathic Scoliosis: A Novel Non-Invasive Tool**

Investigator: Dr. Kevin Smit, MD.

Co-Investigators: Dr. Andrew Tice, MD.; Dr. Ryan Graham, PhD.; Dr. Luke Beaton, MD.; Jessica Wenghofer, MSc. Candidate

Address: CHEO, Department of Orthopedics,
401 Smyth Road, Ottawa, ON K1H 8L1

Telephone Number: **(613) 737-7600 Ext 2998**

Why is this study being done?

We would like to invite you to be part of a research study. Research is a way to test new ideas to see if we can do things better.

In our study, we want to see if a computer program can determine whether someone has adolescent idiopathic scoliosis (AIS), and what the shape of their spine is, based on pictures of their back taken with a mobile phone. Adolescent idiopathic scoliosis is when you are between the ages of 10 and 18 and have a curve in your spine.

Who will take part?

Children seen at CHEO for scoliosis are being asked to join this study. Also, children who do not have scoliosis (healthy volunteers) who come to CHEO for back pain, will be asked to join this study. We expect to have 200 children, join the study over the next 8-10 months.
The study will include 2 different groups:

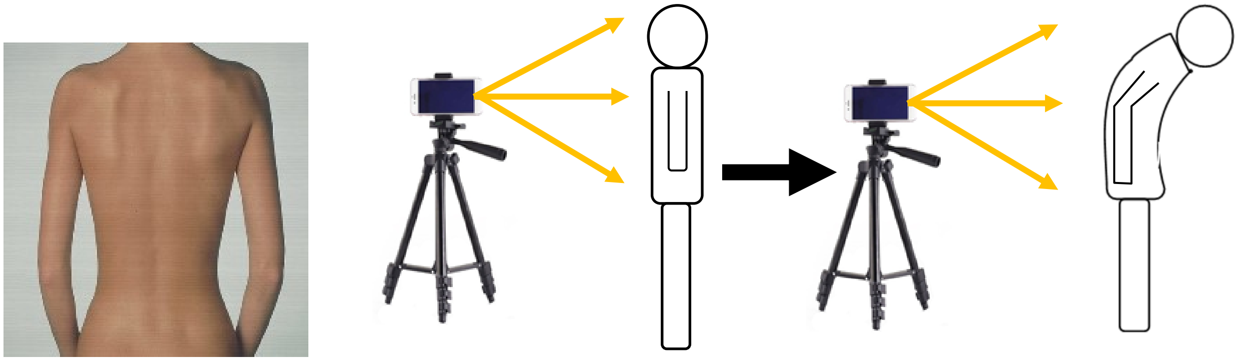
1. Healthy volunteers without scoliosis who are being assessed for back pain
2. Patients with Scoliosis who have not yet had surgery

What will happen during the study?

You will have your regular clinic visits to follow your AIS or back pain respectively during this study.

At each visit, you will go to the CHEO Orthopedic Clinic where we will collect information about you (such as how tall you are and how much you weigh). We will also collect information about your scoliosis/back pain and have you answer some questions about how you feel. Additionally, you will be asked to permission to give the research team information about your ethnicity.

At each visit we will take the usual x-ray that you would normally get to track any changes in your spine. If you agree to participate in this study, we will also take pictures of your back with a mobile phone camera. You will be wearing a gown with the back open above your waist. You will be asked to have a short video of your back taken, moving from standing straight up to bending forward.



a) Example Picture b) Standing posture c) Forward Bend Posture

Are there good things that can happen from this study?
Sometimes good things can happen to people when they are in a study. These good things are called "benefits." This study will help us better understand children like you who may have scoliosis. It will help us develop a tool that may allow doctors to understand your spine shape without having to take an x-ray. That is a benefit. There are no other benefits that we think will happen to you if you decide to join this study.

Are there bad things that can happen from this study?
There is a very small chance your back might hurt after doing the forward bend movement in this study. You will only be allowed to do these movements if your doctor says you can do them. You can also choose whether you want to do this movement. If you do not want to, you do not have to.

What if something bad happens?
If something does go wrong, we will immediately contact your doctor to take care of you.

What if there is new information?
Sometimes during a study, we learn new information. We will talk to your doctors about any new information that might be important to you.

Is this private?
We will keep your information private whether you decide to join this study or not.

The data collected in this study will require computer analysis that can't be done at CHEO. Therefore, your research data that contains only your study ID, gender and date of birth will be sent to the University of Ottawa Biomechanics Lab. The data we are sending cannot be traced back to you.

Will I be paid to participate?
You will not be paid to participate in this study.

Can I say no?
You can choose to be a part of this study or not. You can also decide to stop being in this study at any time once you start. Talk to your parents or your doctor if you want to stop being in the study, and they will tell the researchers. No one will be mad at you if you choose not to take part

What if I have questions?
Please ask us and we will do anything we can to answer your questions.

Assent form Signatures
If you agree to participate in this research study, please sign the form. I understand the information that was explained to me, and I can ask any question that I like about the study.

______________________________	________________________	__________________
Signature of Participant	Name of Participant	Date
______________________________	________________________	__________________
Printed Name of Person who Conducted the Discussion	Signature	Date

Appendix C

Patient Characteristics:

Inclusion Criteria:

- ☐ Adolescent Idiopathic Scoliosis
- ☐ Ages 10-18
- ☐ EOS scan PA/lateral and camera images both performed today
- ☐ OR (control) back pain/normal without other diagnosis

Exclusion Criteria:

- ☐ Previous spinal surgery
- ☐ Acute spinal trauma
- ☐ Spinal tumors
- ☐ Syndromic scoliosis
- ☐ Neuromuscular disorder
- ☐ BMI >30
- ☐ Inability to stand unassisted on their own OR inability to perform an Adams forward bending task
- ☐ Leg length discrepancy > 2cm
- ☐ Surface/soft tissue tumors of the torso

Demographics:	
Age	
Sex	
Ethnicity	
Height (cm)	
Weight (kg)	
Menarchal Status	Pre Post N/A (male)

Physical Exam:	
Shoulder Elevation:	Left Right Level
Scoliometer Reading (deg)	Thoracic: Lumbar:

Ethnicity List (as per Census Canada 2020):

White – ex) German, Irish, English, Italian, Egyptian, etc.

Black or African American – ex) African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali etc.

Indigenous – print name of enrolled participants tribe (s)

Chinese

Filipino

Asian Indian

Vietnamese

Korean

Japanese

Native Hawaiian

Samoan

Chamorro

Pacific Islander

Other