The Exploration of Sagittal Spine Curvature

Validating a surface topography method & relating curvature to physical function

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Abstract

Abnormal or altered sagittal spine curvature is associated with poor health-related outcomes including pain, impaired physical function and mobility, decreased quality of life, and increased mortality. Therefore, it is important to both understand its consequences as well as accurately measure and monitor curvature. The overarching aim of this thesis was to explore sagittal spine curvature by validating a new surface measurement tool and implementing it in a clinical setting in order to understand and relate it to physical function outcomes. The findings from the first stage of this thesis came from an exploratory analysis of a large physiotherapy randomised controlled trial; it showed that there was an apparent, but weak, correlation between thoracic kyphosis and aspects of balance, walking capacity and physical performance in people with osteoporotic vertebral fracture (OVF). Since this analysis took into account only the thoracic spine region, there was a need to explore the relationship further, but with a surface measurement tool that had a higher potential for a robust description of sagittal spine curvature. The second stage of the thesis focused on the protocol development and testing of the Microsoft Kinect sensor, a new technology for surface topography measurement. The Kinect sensor demonstrated high reliability and aspects of validity in thoracolumbar measurement. In the last stage, the Kinect sensor was used as an outcome measure in a cohort study aimed at relating sagittal spine curvature with walking and balance related outcome measures in people with symptomatic degenerative spinal conditions. In its implementation, the Kinect sensor demonstrated good utility and acceptability as a measurement tool, but the findings between curvature and physical function showed weak correlational and predictive relationships, likely due to the confounding spinal presentations and the small sample size. The novel contributions of this thesis included understanding the response to physiotherapy in people with severe hyperkyphosis and OVF, the method development and testing of an new surface topography measurement tool, and the successful implementation of the tool and method in a relevant clinical cohort.

To Mauro and Gemma.

Publications and Presentations

Publications

- Hannink E, Shannon T, Barker KL, Dawes H. The reliability and reproducibility of sagittal spinal curvature measurement using the Microsoft Kinect V2. *J Back Musculoskelet Rehabil*. 2020;33(2):295-301. doi: 10.3233/BMR-191554.

- Hannink E, Newman M, Barker KL. Does thoracic kyphosis severity predict response to physiotherapy rehabilitation in patients with osteoporotic vertebral fracture? A secondary analysis of the PROVE RCT trial. Under review in *Physiotherapy*.

- Hannink E, Dawes H, Shannon TL, Barker KL. Validity of sagittal thoracolumbar curvature measurement using a surface topography method: the Kinect sensor. Under review in *Archives of Physiotherapy*.

Presentations

- Annual Meeting of the European Society of Movement Analysis in Adults and Children. Prague, Czech Republic, 27-29 September 2018. Oral presentation: *"The intra-rater and inter-rater reliability of a method measuring the sagittal curvature of the spine using surface topography."*

- Physiotherapy UK 2018 Conference. Birmingham, UK, 19-20 October 2018. Poster presentation: *"The intra-rater and inter-rater reliability of a method measuring the sagittal curvature of the spine using surface topography."*

- Oxford Brookes University Postgraduate Research Student Symposium 2019. Oxford, UK, 10 January 2019. Poster presentation: *"The exploration of sagittal plane deformity in the spine."*

- Physiotherapy UK 2019 Conference. Birmingham, UK, 1-2 November 2019. Platform presentation: *"Measurement of sagittal spine curvature: comparing the Kinect depth camera to the flexicurve and digital inclinometers in a clinical population."* Rapid 5 and poster presentation: *"The validity of the Kinect sensor for the measurement of sagittal spine curvature against the gold standard lateral spinal radiograph."*

- Oxford Brookes University Postgraduate Research Student Symposium 2020. Oxford, UK, 17 January 2020. Oral presentation: *"The exploration of sagittal spine curvature: validating a surface topography method & relating spinal curvature to physical function."* Awarded Best Oral Presentation.

- Royal Osteoporosis Society Conference 2020, 'Osteoporosis Online.' 1 December 2020. Oral presentation and poster: *"Does thoracic kyphosis severity predict response to physiotherapy rehabilitation in patients with osteoporotic vertebral fracture?"*. Awarded outstanding abstract.

Declaration

I certify that the work presented in this thesis is the result of my own original research and, unless otherwise stated, is written and produced entirely by myself.

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List of Abbreviations

-2LL	-2 Log Likelihood
2MWT	Two-minute walk test
3D	Three-dimensional
6MWT	Six-minute walk test
ABC scale	Activities-specific balance confidence scale
ADL	Activity of daily living
AIC	Akaike Information Criterion
AIS	Adolescent idiopathic scoliosis
AMED	Allied and Complementary Medicine Database
ANOVA	Analysis of variance
BIC	Schwarz's Bayesian Criterion
BMI	Body mass index
C7	7th cervical vertebrae
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COM	Centre of mass
CONSORT	Consolidated Standards of Reporting Trials
COSMIN	COnsensus-based Standards for the selection of health Measurement Instruments
CoV	Coefficient of variance
DEXA	Dual X-Ray Absorptiometry
EMM	Estimated marginal means
FR	Functional reach
FSST	Four square step test
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
GRRAS	Guidelines for Reporting Reliability and Agreement Studies
ICC	Interclass correlation coefficient
IMU	Inertial measurement unit
ISRCTN	International Standard Randomised Controlled Trial Number
KI	Kyphosis index
L1	1st lumbar vertebrae
LI	Lumbar index
M-L	Medial-lateral
MAPS	Measuring Alignment and Posture of the Spine
MCS	Mental component scale
MDD	Minimal detectible difference
MEDLINE	Medical Literature Analysis and Retrieval System Online
mGES	Modified Gait Efficacy Scale
OVF	Osteoporotic vertebral fracture
PCS	Physical component scale
PROVE	Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture
PSIS	Posterior superior iliac spine

QoL	Quality of life
QUALEFFO-41	Quality of Life Questionnaire of the European Foundation for Osteoporosis
RCT	Randomised controlled trial
ROBIS	Risk of Bias in Systematic Reviews
S1	1st sacral vertebrae
S2	2nd sacral vertebrae
SD	Standard deviation
SEM	Standard error of measurement
SF-36	36-item Short Form Health Survey
SPPB	Short performance physical battery
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
T/L ratio	Thoracic/lumbar ratio
T12	12th thoracic vertebrae
TLS	Timed loaded standing
ToF	Time-of-flight
TWD	Tragus-to-wall distance
V2	Version 2
VAS	Visual analogue scale
WiSPA	Walking and balance related to sagittal Spinal Posture and Alignment

Contents

List of Figures

List of Tables

Chapter 1

Introduction

1.1 Summary of contents

This chapter lays out the background of the anatomical structure of the spine, in particular the sagittal plane. It describes how the spine is measured and a review of the literature outlines the current tools and methods used to measure sagittal spine curvature. Lastly, the chapter describes the motivations and objectives of this thesis.

1.2 Background

In order to recognise the importance and implications of sagittal spine curvature and alignment, it is first essential to understand the fundamentals of the spine and the differences between normal and abnormal curvature. Abnormal sagittal spine curvature is a clinical characteristic stemming from various conditions, from congenital to degenerative, with impact reaching multiple aspects of a person's life. There are meaningful impairment, activity and participation-level consequences associated sagittal spine alignment which are important to understand in order to get a full clinical picture. Additionally, without a reliable and accurate way to measure abnormal spinal alignment, a researcher or clinician cannot take this next step to understand the impact of altered or unbalanced alignment. Therefore knowledge of the various methods and tools of measurement, and the evidence base behind them, is crucial.

1.2.1 Anatomy of the spine

The spine is essential in protecting the spinal cord and providing structural support to maintain upright posture. Vertebrae make up the spine and act as composite building blocks that form the spinal column. The spine is made up of five regions: the cervical region with seven vertebrae, the thoracic region with 12 vertebrae, the lumbar region with five vertebrae, the sacrum with five fused vertebrae, and the coccyx with three to five small fused vertebrae[3]. While the spine as a whole provides overall structural support, each region serves a different purpose and are thus shaped differently[4]. For example, cervical vertebrae are smaller and allow for more range of motion, thoracic vertebrae are shaped for rib attachment, and lumbar vertebrae are larger and allow for more weight bearing[3]. In between each vertebrae of the cervical, thoracic and lumbar regions are intervertebral discs. The discs serve as both barriers between boney structures and cushions to absorb shock. Overlaying the vertebral column are numerous ligamentous attachments that provide another layer of structural support to the spine[3]. These are strong passive structures that connect vertebrae to each other and to neighbouring structures, e.g. ribs and occiput. There are also tendon attachments to the vertebrae which create an active supportive layer of spinal musculature. Similar to ligaments, they attach between vertebrae at various levels and connect to neighbouring extremities.

These vertebral ligaments and musculature allow the spine to be both rigid and flexible in order to perform normal functional movement[3,5]. Optimal alignment of the spine allows for efficient function of the musculoskeletal system and minimises energy expenditure during upright posture[5]. When moving out of optimal alignment, the musculoskeletal system must support the spine to move in three anatomical planes: transverse, frontal and sagittal (Figure 1.1). The transverse plane allows for rotational or twisting movement; the coronal plane allows for lateral flexion or side bending movement; and the sagittal plane allows for flexion and extension or forward and backward movement. While all planes of motion are vital and none work in isolation, the focus of this thesis will be on the sagittal plane.

1.2.2 Sagittal spine curvature

The sagittal plane is unique to the other planes in that its definition of "normal" is more loosely described since there is more inherent, natural variation in the sagittal alignment of the spine.

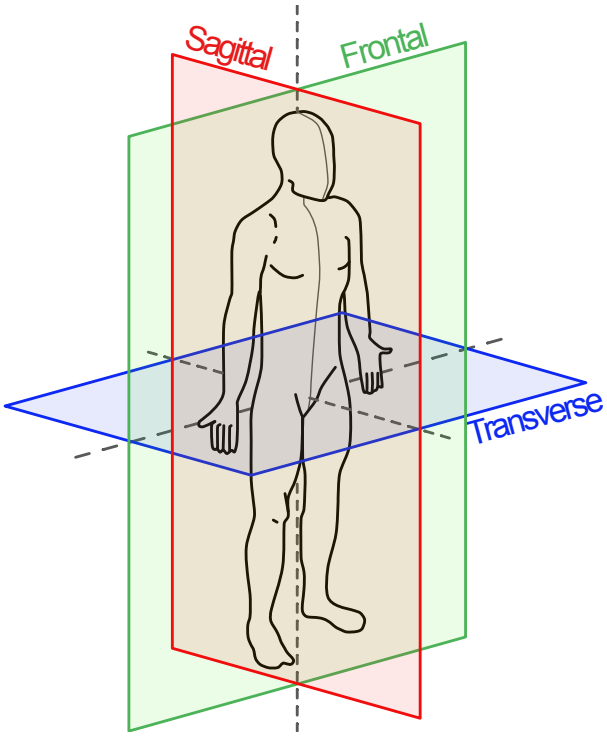


Figure 1.1: Anatomical planes. Sagittal, frontal and transverse planes represented in the human anatomical position.

Ideal spinal alignment in the other anatomical planes has been established and is defined by <10° curvature in the coronal plane, with deviations beyond the threshold labelled as scoliosis deformity[5]. However, each region of the in the sagittal plane of the spine has a different requirement for "normal" range. The cervical region has a lordotic curve, the thoracic region has a kyphotic curve and the lumbar region transitions again to a lordotic curve (Figure 1.2). The sacrum and coccyx are fused and do not take on a specific curvature, yet the degree of tilt defines the pelvic alignment[4]. Due to the complicated shape of the spine in the sagittal plane and the additive degree of variability linking 25 movable vertebral interfaces, there is a less clear definition of normal versus abnormal alignment. Generally, the accepted normal cervical lordosis angle is 40° (± 9.7°), thoracic kyphosis is 20°-40° and lumbar lordosis is 43°-44° (± 4.5°-11.2°)[6–10]. Using angles to measure sagittal spine curvature is based off of the widely-accepted Cobb method[11], which is illustrated in Figure 1.2 and described in more detail in the latter half of this chapter.

The focus of this thesis will be on the curvature and balance of the thoracolumbar spine as it has the most substantial relationship with lower extremity physical function activities, such as gait and balance. While all body regions are interconnected and the cervical spine can

have an indirect effect on gait and balance, its primary impact is on the function of the upper extremities. The influence of the cervical spine can be partially captured in the measurement of the thoracolumbar spine due to the predictive association between cervical lordosis and the alignment of T1[12], therefore the specific focus on the thoracolumbar spine is the most relevant choice for this body of research.

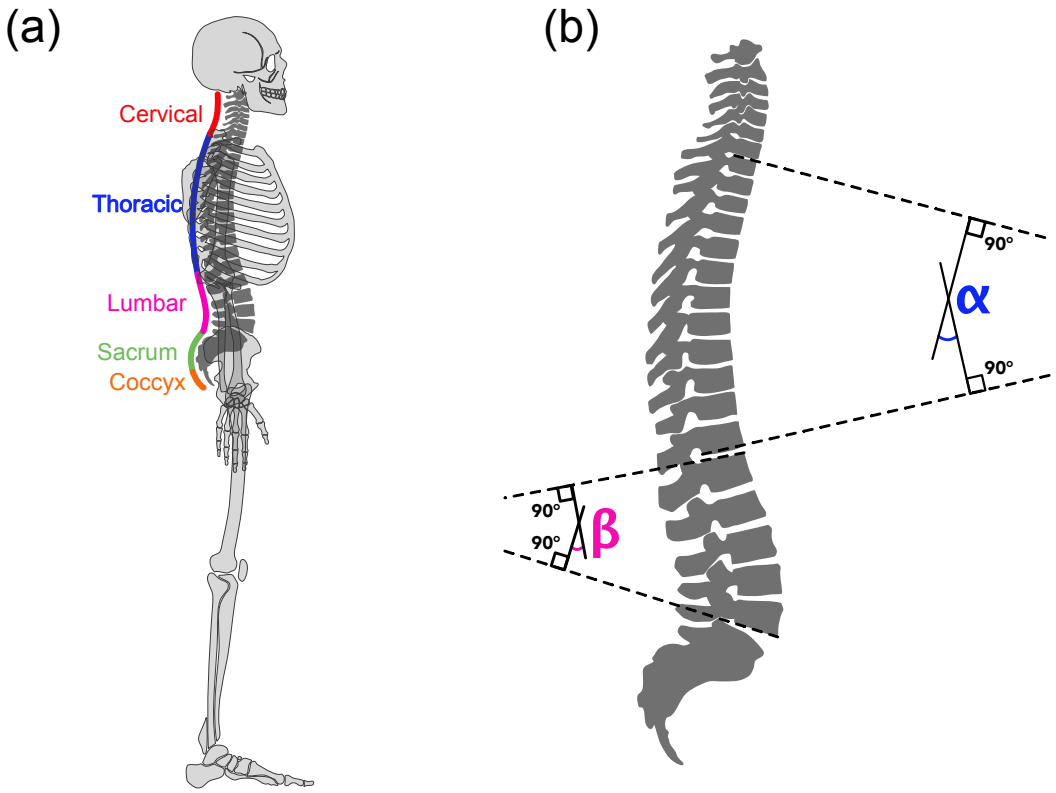


Figure 1.2: Sagittal view regions and measurement. (a) Spinal regions labelled in the sagittal plane. (b) A depiction of thoracic kyphosis and lumbar lordosis angle measurements denoted by α and β, respectively.

As the spine ages, natural changes within the elements change at varying degrees, such as facet joint arthritis, degenerative disc disease and back extensor muscle atrophy. These collective changes that gradually accumulate during the ageing process consequently result in altered in sagittal spine alignment. The changes manifest differently in different spinal regions. Just as the generally accepted normal throacic kyphosis angle ranges 20 degrees (a relatively large span), the average thoracic kyphosis angle also changes with age, creating a moving target to which we define normal[7,13]. The average thoracic kyphosis angle ranges from 20°-29° from childhood to the third decade[14], and from the onset of the 5th decade the angle begins to increase, in women a more rapid change than men is observed[15,16]. One study has shown

that the average thoracic kyphosis angle in older men after the 5th decade is 44° (± 13°) and the average in an equivalent group of women is 49° (± 16°), gradually increasing with each decade in both genders[16]. Furthermore, another study showed that by 55 to 60 years old the thoracic kyphosis angle in women averages 43° and from 76 to 80 years old the average angle is 52°[17]. While there is no absolute normal/abnormal threshold, the collective literature suggests that the average thoracic kyphosis angle gradually increases after the 4th and 5th decades. Age-related changes in the lumbar region do not follow the same pattern. The lumbar spine changes to compensate and maintain curvature equilibrium. One study of asymptomatic adults over 40 years old found that a loss of midlumbar spine lordosis was correlated with age[8] while another longitudinal study showed that the strongest influence on lumbar lordosis change over time in asymptomatic older people was the sacral inclination angle[18]. Figure 1.3 represents an interpretation of the data around the general pattern of asymptomatic thoracic and lumbar progression with age overlaid with a theoretical example of symptomatic disease progression of a thoracic vertebral fracture where the onset triggers direct changes in the thoracic region and compensatory changes in the lumbar region. The compensatory changes are described in more detail in the next section.

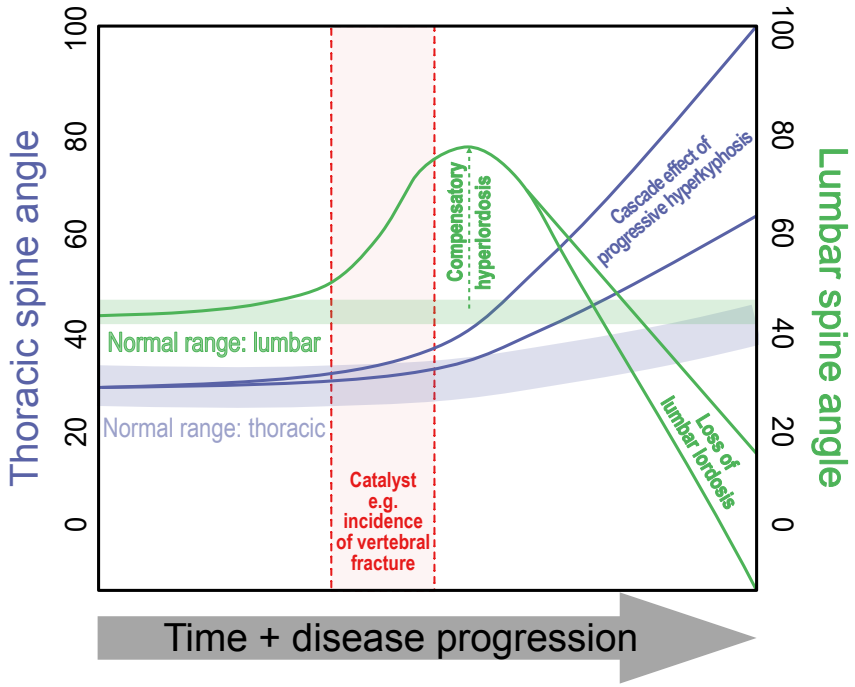


Figure 1.3: Thoracolumbar angle versus time. A graphical schematic of the natural ageing progression of sagittal spine and an example of a pathological progression represented by the darker green and purple lines set off by vertebral fracture in the thoracic spine.

1.2.3 "Abnormal" sagittal spine curvature

The recognition of abnormal alignment, particularly in the sagittal plane, is important due to its effects on several body systems, from the musculoskeletal system to the respiratory system. As mentioned previously, the spine protects the spinal cord and provides structural support for the organ systems located in the torso, therefore abnormal curvature can have a negative impact. While adult spinal deformity (ASD) is a general term for spinal deformity, is not interchangeable with abnormal sagittal spine curvature. ASD can include abnormal curvature or deformity solely in the sagittal plane, however it largely revolves around a primary scoliosis deformity. The Schwab classification and the Scoliosis Research Society classification are two common classification systems for ASD, and they address the sagittal plane as a secondary descriptor or modifier[19]. Unfortunately, no global classification system exists that addresses abnormal sagittal spine curvature as a primary condition, and this could be due to the multiple etiologies and mechanisms behind malalignment. Common aetiologies are degenerative, iatrogenic, congenital, post-traumatic or inflammatory conditions, such as scoliosis, osteoporosis, vertebral fracture, degenerative disc disease and Scheuermann's Disease, yet in most cases, the symptoms and consequences of malalignment can be more pertinent than the pathology behind it[15,20]. Among the multiple aetiologies, there are many contributors to abnormal spine curvature and malalignment; in addition to the bony structure of the vertebrae, curvature is influenced by the intervertebral discs, ligaments, and intrinsic spinal musculature[7,15]. In this respect, the aetiology of spinal malalignment is broad and multifaceted. While the structural vertebral changes are often associated with vertebral fractures, there is no direct correlation between the highest degrees of kyphosis and the presence of vertebral fractures[21]. Therefore while reference to aetiology of spinal deformity or malalignment can be important, the focus will equally be on the consequences of the resultant shape of the spine since presentations tend to follow similar patterns of compensation as the body strives for upright equilibrium.

The most common and most investigated presentation of sagittal spine malalignment is hyperkyphosis. Hyperkyphosis, defined as an exaggerated kyphosis curvature in the thoracic spine, is an abnormal presentation which can be a result of a degenerative or congenital spinal conditions and is also considered in itself a geriatric syndrome[7,15]. The prevalence of hyperkyphosis in older adults is estimated to be 20-40%, therefore many people are and will be affected[7]. Just as the 20°-40° range of 'normal' is wide, the average of kyphosis angle changes

with the natural course of ageing, thus further blurring the line between ‘normal’ and ‘abnormal’. As the ageing population has grown, so has the research around hyperkyphosis in the past several decades. While studies continue to expand knowledge in the field, it remains a relevant topic yet discrepancies and gaps in its understanding are still present. A primary example of the fluidity of the topic is the lack of a global definition for hyperkyphosis. While the threshold is often set at a Cobb angle over 40°, which is the 95th percentile of normal young adults[14], there have been different thresholds for hyperkyphosis established in research, from >40°, >45°, up to >50°[22]. These differing thresholds make it difficult to directly compare research studies.

Defining the lumbar region has similar challenges since a normal range in the lumbar spine is also difficult to clearly delineate. Higher lumbar angles are categorised as hyperlordosis and lower angles are hypolordosis, but again there is no defined threshold. Hyperlordosis is associated with specific local structural degeneration in conditions such as spondylolisthesis, but hyperlordotic curvature can also occur as a compensatory mechanism in response to changes in the thoracic or sacropelvic regions[8,23]. Hypolordosis is a more common with degenerative process in the lumbar spine, notably in degenerative disc disease[24,25]. Hypolordosis is also referred to as a ’loss of lumbar lordosis’ and when the degeneration of lumbar structures becomes more severe, it can completely reverse the natural lordotic curve into a kyphotic curve in advanced presentations[8,23,26]. These variable and interdependent thoracolumbar spinal changes lead to global sagittal spine alignment imbalances that are also associated with physiological and functional consequences.

Global sagittal imbalance is not synonymous with any of these thoracolumbar malalignments on their own but is a broadly detrimental resultant presentation. While neutral sagittal balance occurs when a vertical line (sagittal vertebral axis) from the C7 vertebral body passes within 2 cm of the superior endplate of the S1 vertebral body, positive imbalance is defined as the plumb line more than 2 cm anterior to this S1 landmark, as measured on a radiograph. Positive sagittal imbalance is an important consequence of sagittal deformity because of its negative impact on standing posture and energy expenditure[5]. When compensatory spinal alignment causes a positive sagittal imbalance, optimal alignment is compromised. This was conceptualised by Jean Dubousset as a “Cone of Economy” which explains the ergonomic standing posture and the limits of deviation from it in all directions (Figure 1.4)[1,5]. Deviating from optimal, yet still within the cone, increases muscular effort and energy expenditure; furthermore, deviation outside of the

cone results in a fall or need for external support[5]. Therefore, spinal malalignment in the sagittal plane results in a larger theoretical cone of balance requiring more strength and endurance in back extensors and general posterior chain musculature and consequential negative effects on aspects of physical mobility.

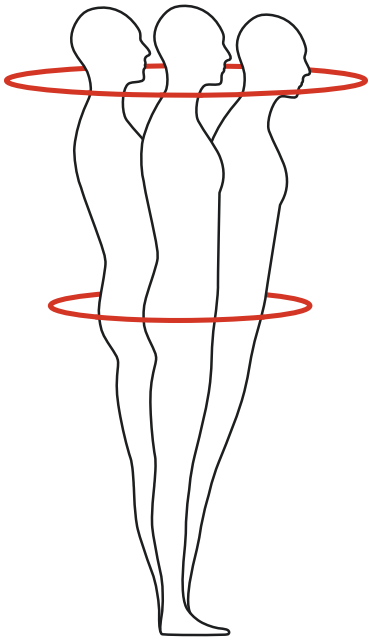


Figure 1.4: Cone of economy. Simplified depiction of the "Cone of Economy" for standing posture first described by Dubousset[1].

In order to explore the breadth of research that investigated the consequences of abnormal sagittal spinal curvature, a literature search was performed using PubMed, AMED and CINAHL databses. The searches included the combination of two main criteria categories: sagittal spine curvature (thoracic kyphosis or lumbar lordosis or hyperkyphosis) and function. Relevant studies of all methodological designs and populations were screened and identified to capture a broad view of sagittal spine curvature and its associated consequences. Reference lists from these studies were examined to identify other relevant publications. Selected studies were appraised and synthesised using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework to consider the risk of bias, inconsistency, indirectness, imprecision and publication bias of the evidence[27]; the findings are summarised in Table 1.1.

Since abnormal sagittal spine curvature leads to inefficiency and unoptimised posture, balance and physical function are often compromised. For example, in lab-based measurements of postural balance by a stabilometer, which is a tool that measures the change in centre of mass (CoM) on a controlled platform, poorer postural balance was correlated with lumbar

Table 1.1: Evidence table for consequences of sagittal spine curvature

Associated consequence	No. of participants (studies)	Summary of relationship	Effect size	Quality of evidence (GRADE framework)
Gait	308 (4)	Reduced lumbar lordosis associated with slower walking speed; increased kyphosis and flexed posture associated with poorer gait performance and more gait variability	Small to moderate	Low. Due to risk of bias (observational study design) and indirectness (differences in populations)
Balance	187 (2)	Reduced lumbar lordosis associated with poorer postural balance and single leg balance; hyperkyphosis associated with better tandem balance	Small to moderate	Low. Due to risk of bias (observational study design) and indirectness (differences in populations)
Physical function	5137 (3)	Increased hyperkyphosis associated with worse physical function	Moderate	Moderate. Due to risk of bias (observational study design); level increased due to magnitude of effect
ADLs	763 (2)	Increased kyphosis associated with ADL decline	Moderate	Moderate. Due to risk of bias (observational study design)
Back extensor musculature	1087 (1)	Increased kyphosis associated with lower back extensor muscle density	Moderate	Low. Due to risk of bias (observational study design) and indirectness (differences in populations)
Shoulder pain and function	2674 (9)	Increased kyphosis associated with shoulder pain and reduced function and with no pain or reduced function	Small	Low. Due to risk of bias (observational study design) and inconsistency of results
Respiratory function	230 (2)	Increased kyphosis associated with decreased lung function; association not observed in small sample of men	Small	Low. Due to risk of bias (observational study design) and inconsistency of results
Falls risk	5743 (7)	Reduced lumbar lordosis and increased kyphosis associated with increased falls risk; increased kyphosis also not associated with falls risk	Small to large	Low. Due to risk of bias (observational study design), indirectness (differences in populations) and inconsistency of results
Quality of life	144 (2)	Increased spinal inclination and kyphosis associated with decreased quality of life	Moderate	Low. Due to risk of bias (observational study design), indirectness (differences in populations)
Mortality	1963 (2)	Hyperkyphosis associated with increased mortality	Moderate	Low. Due to risk of bias (observational study design)

kyphosis and positive sagittal imbalance in a general elderly population and in older people with osteoporosis[28,29]. Aspects of dynamic balance have also been measured more functionally and have shown similar results. Sangtarash et al. measured thoracic kyphosis and tested 10 different gait tasks in osteoporotic women and found that increased thoracic kyphosis was correlated to lower gait performance[30]. De Groot et al. measured spatiotemporal gait characteristics in elderly people and found that those with flexed posture had more variable gait structure in both the medial-lateral and anterior-posterior direction, regardless of the presence of vertebral fracture[31]. Additionally, in a group of older men, lumbar lordosis angle was correlated with decreased standing static balance and gait performance, as measured by gait speed, timed up-and-go test, 10 m obstacle test and the six-minute walk test[32].

There are also studies with findings that describe consequences of sagittal curvature specifically in the lumbar region, but show thoracic kyphosis is not correlated with postural balance[29] and that elderly women with hyperkyphosis had better static balance and tandem gait than those with normal kyphosis[33]. Ishikawa et al. showed that lumbar kyphosis affected spinal inclination, which effectively created a positive sagittal imbalance thus bringing upright posture to the outer limits of the Cone of Economy; consequently, in an osteoporotic population that may also have weaker back extensor musculature, anterior-posterior postural balance is challenged specifically with lumbar kyphosis, not thoracic kyphosis[29]. In the study by Alin et al. they found an association between increased hyperkyphosis and better single leg balance and forward and backward tandem walking; the authors theorised that the people with hyperkyphosis may have stronger gluteal muscles to compensate for the increased thoracic kyphosis curvature thus better performance with balance tasks[33]. Additonally, in a large cohort (n=1100) of participants over 50 years old, walking speed, chair stand time and self-reported physical impairment did not associate with thoracic kyphosis[34].

Balance and gait deficits are important outcomes to measure as they are two of the strongest risk factors of falls, and falls are a serious and prevalent public health issue with heavy economic burden as a third of people aged 65 years and older suffer a fall each year, 10% resulting in serious injury or hospitalisation[35–38]. There have been studies that have looked both prospectively and retrospectively at the ability of spinal curvature angles to predict self-reported falls. While it has been shown that kyphosis predicted a higher incidence of falls in older adults[39,40], several studies have found that lumbar lordosis angle, not thoracic kyphosis, was a predictor of

falls both prospectively and retrospectively[41–43]. These mixed findings suggest there is a more complicated and nuanced relationship between sagittal spine curvature, balance and gait and, consequently, falls.

Sagittal spine curvature has consequences beyond functional mobility. Hyperkyphosis is associated with increased cervical and shoulder pain possibly influenced by mechanical overload, degenerative changes, and lifestyle factors[44]. Additionally, pulmonary decline was associated with increased thoracic kyphosis in older women as well as impaired respiratory function in women with osteoporosis and vertebral fracture[34,45]. On an activity and participation level, altered spinal alignment is associated with impaired activities of daily living (ADLs) such as reaching activities and performing heavy housework[46] and increased daily dependence[47]. In people with osteoporosis and vertebral fracture there was an association between increased positive sagittal alignment and decreased quality of life (QoL)[48], and a similar association in people with ASD, in particular those with positive sagittal alignment, having lower QoL scores[49]. In a study that compared disability in chronic diseases, sagittal malalignment had the greatest physical component decrease of health-related QoL with ageing compared to the normal ageing U.S. population, a magnitude similar to common chronic diseases such as diabetes, heart disease, rheumatoid arthritis[50].

1.2.4 Current methods of measurement

The consequences outlined indicate the importance to be able to recognise and measure altered sagittal spine curvature. It is essential to have an accurate and reliable method to measure sagittal spine curvature to differentiate normal versus abnormal, but more importantly to identify progressive change. While radiographic sagittal spine alignment metrics are crucial to take into account during corrective surgery[5], most people will suffer the adverse associated consequences before, or without, surgical consideration, therefore understanding and testing non-radiographic measurement tools is also critical.

Radiography – the gold standard

Currently the long-standing gold standard to measure the spine in the sagittal plane requires a lateral radiograph of the spine[11,51,52]. In 1948, an American orthopaedic surgeon, John R. Cobb, first described a method to measure the spinal deformity in the coronal plane from a

posterior-anterior view radiograph using an angle between vertebral orientations; this method became known as the Cobb angle[11]. Shortly after, the modified Cobb angle was created to describe the thoracic kyphosis angle in the sagittal plane[11]. The modified Cobb angle is the intersection of a vector that extends parallel from the superior endplate of T1 and a vector that extends parallel from the inferior endplate of T12, but commonly the superior endplate of T4 is used as it is more reliably unobstructed by the shoulder complex on the radiograph (Figure 1.5)[11].

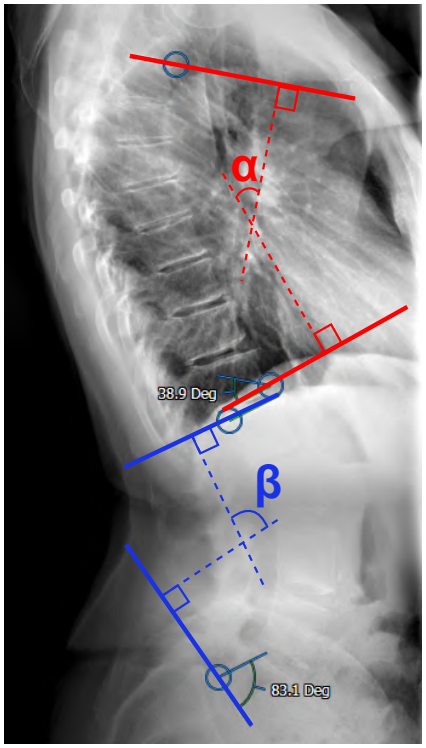


Figure 1.5: Cobb angle measurement method. The alpha angle measures the thoracic spine from T4 to T12, and the beta angle measures the lumbar spine from L1 to L5.

Using a modified Cobb method in the lumbar region, the angle is generated from the superior endplate of L1 and inferior endplate of L5 (Figure 1.5)[11,52]. In this thesis, as in current common practice, the Cobb angle will refer to the angle generated from any region using the Cobb method. While this method is the most widely used, other methods have since been developed, including the centroid method. The centroid method estimates the centre of the vertebral body by using the intersection of diagonals drawn from the four corners. An angle is then created from the intersection of lines connecting two adjacent vertebral centroids[52]. Despite the development of other techniques, the Cobb method is still the most widely accepted in measurement in all regions of the spine in both clinical and research settings[11,52,53]; however, it

has its disadvantages and limitations. The Cobb method measures the angle from two vertebral endplates which leaves it vulnerable to overestimating an angle if the vertebrae has a structural deformity, e.g. vertebral fracture[54]. Additionally, endplates can be difficult to identify accurately due to overlaying structures or radiography quality[11,51]. Any of these potential variants can lead to the creation of a vector which is not orthogonal to the true spinal curve[11,51]. Another disadvantage of radiographic measurements is the additional ionising radiation exposure, which can have detrimental effects with additive doses; this is one reason radiographs are requested less frequently and with caution[55]. In addition, radiographs are relatively expensive procedures and are not widely accessible in non-hospital settings. While radiographs have been accepted as the gold standard, these disadvantages are not new or recently identified, which is why numerous non-radiographic surface methods have been developed over the past four decades to avoid some of these obstacles.

Non-invasive methods of measurement

Non-invasive methods to measure sagittal spine curvature include any method that does not employ internal imaging, rather they measure the surface. The non-invasive category excludes radiographs as well as magnetic resonance imaging and most ultrasound methods. Barrett et al. published a systematic review of the reliability and validity of non-radiographic methods to measure the thoracic spine. Using the Risk of Bias in Systematic Reviews (ROBIS) tool[56], the systematic review was appraised and revealed an overall low risk of bias allowing for confidence in using the systematic review findings (see Appendix A1 for full appraisal). Barrett et al. identified 15 different methods, including: arcometer, flexicurve index, flexicurve angle, Debrunner's kyphometer, SpinalMouse, manual inclinometer, digital inclinometer, 3D ultrasound, rasterstereography, stereovideography, goniometer, electrogoniometer, spinal wheel, panograph, and photogrammetry[57]. From these 15 methods, the strongest evidence base for the reliability of measurement was the flexicurve index, Debrunner kyphometer and the SpinalMouse; the strongest evidence base for the validity of measurement was flexicurve index and arcometer. In a more recent review by Sedrez et al., psychometric properties of the thoracic spine as well as the lumbar spine were assessed[58]. Again employing the ROBIS tool, the systematic review was appraised and was found to have an overall low risk of bias (full appraisal in Appendix A2). All previously listed methods from Barrett et al. were included in the 2016 review, as well as

the lordosimeter and the optoelectronic system[58]. The flexicurve, arcometer and DeBrunner's kyphometer were identified to be tools with the strongest evidence of reliability and validity in the thoracic and lumbar spine[58].

In addition to using the findings from the two aforementioned systematic reviews, a literature search was conducted to identify all relevant studies of psychometric properties for non-invasive methods of sagittal spine measurement published after 2014. The databases MEDLINE, AMED, CINAHL, Web of Science and SportDiscus were searched to include the three following criteria categories: (1) spinal curvature (thoracic kyphosis or lumbar lordosis or spinal curvature or thoracic or kyphosis) and (2) psychometric properties (reliability or validity or sensitivity or responsiveness) and (3) tests (instrument or tool or test or measure or inclinometer or flexicurve or kyphometer or radiograph or Cobb). After screening and selecting relevant studies, those published before 2014 were compared to the results of the two systematic reviews to ensure there were no large gaps in their selected studies; the studies more recently published were appraised using the Clinical Appraisal Tool and the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) risk of bias tool[59]. The most notable difference between studies published after 2014 was the increase in the development and testing of more advanced technology-based tools such as depth cameras[60], motion analysis[61–64] and smartphone applications[65–67].

Of the tools with psychometric properties tested, they can generally be divided into two approaches based on how they obtain the curve: (1) measuring the top and the bottom of a region to infer the curve or (2) by creating the full representation of the curve. The former is exemplified by the inclinometer, goniometer, arcometer and the kyphometer, while the latter includes the flexicurve, SpinalMouse, panograph and surface topography methods. When trying to determine change of shape or curvature over time, the full spinal curvature may be more sensitive to change especially in terms of regional changes[57,68].

As previously mentioned, the systematic reviews identified the Debrunner kyphometer, SpinalMouse, arcometer, inclinometer, and flexicurve as the tools most supported by the research studies, but each has advantages and disadvantages to their use. The evidence behind these tools was evaluated based on the GRADE framework and is summarised in Table 1.2. While the DeBrunner kyphometer, an adapted protractor with two long arms, has moderate quality evidence for the high reliability (intrarater ICC = 0.92-0.98 and interrater ICC = 0.91-0.98)

and low quality evidence for the moderate to high validity (r = 0.62-0.76), the tool is only used to measure thoracic kyphosis, thus limiting it to the thoracic region[57]. The SpinalMouse, a computer-assisted device that is traced manually along the spine to produce digital curvature measurements, also has low quality evidence for its high reliability (intrarater ICC = 0.73-0.99 and interrater ICC = 0.67-0.99), yet shows low validity (r = 0.39-0.47) in the thoracic spine with low quality evidence, and low quality evidence for high reliability (intrarater ICC = 0.84-0.93, interrater ICC = 0.87-0.97, test-retest ICC = 0.88-0.99) and low to moderate criterion validity (ICC = -0.030-0.490) in the lumbar spine[57,58,69]. Unfortunately, the high cost of the SpinalMouse acts as a barrier to its wider accessibility. The arcometer, a ruler device with three perpendicular arms that line up along the spine, has low quality evidence for the high reliability (intrarater ICC = 0.99 and interrater ICC = 0.98-0.99) and high validity (r = 0.94-0.98) in the thoracic spine[57], and it has low quality evidence for poor to high reliability (intrarater ICC = 0.45-0.89, interrater ICC = 0.89-0.96, test-retest ICC = 0.43) and poor validity (r_s = 0.037-0.71) in the lumbar spine[58,70]. The arcometer has low prevalence within research trials and in the clinic therefore limiting its practical relevance. The digital inclinometer, a tool to measure angles with respect to a referenced zero, has moderate quality evidence showing high reliability (intrarater Cronbach's α = 0.83, ICC = 0.87-0.92) and moderate quality evidence for high validity (ICC = 0.86) but a significant difference between multiple raters in the thoracic spine; it has low quality evidence for high test-retest reliability (Cronbach's α= 0.87, ICC = 0.90) in the lumbar spine[57,58,66,71]. The digital inclinometer is a tool that benefits from ease of use and accessibility in the clinic. The flexicurve, a flexible ruler moulded along the spine, has moderate quality evidence for high interrater reliability (ICC = 0.94-0.96) and high intrarater reliability (ICC = 0.87-0.96), and low quality evidence for moderate validity (r = 0.686-0.756) in the thoracic spine[57,58]; it has moderate quality evidence for moderate to high reliability (intrarater ICC = 0.62-0.97, interrater ICC = 0.54-0.99, test-retest ICC = 0.80) and low quality evidence for moderate to high validity (ICC = 0.91 and r = 0.50-0.99) in the lumbar spine[58,72,73]. The flexicurve is widely used in research trials and clinically, and it is one of the most cost-effective tools for surface spinal measurement.

All of these surface measurement tools are challenged in their validity against the radiograph by the nature of error that stems from comparing skin surface measurement to structural vertebral alignment[74,75]. Skin surface measurements use the spinous processes as landmarks as opposed to the vertebral body orientation used as reference in the Cobb method; additionally

Table 1.2: Evidence table for non-invasive measurement tools

Non-invasive measurement tool	No. of participants (studies)	Summary of findings	Quality of evidence (GRADE framework)
Thoracic kyphosis			
Flexicurve	297 (5)	High interrater and intrarater reliability	Moderate. Due to imprecision and risk of bias
	267 (6)	Moderate to high criterion validity	Low. Due to imprecision and risk of bias
DeBrunner kyphometer	299 (4)	High interrater and intrarater	Moderate. Due to imprecision and risk of bias
	203 (2)	Moderate to high criterion validity	Low. Due to imprecision and risk of bias
SpinalMouse	238 (6)	High interrater and intrarater reliability	Low. Due to imprecision and risk of bias
	26 (1)	Moderate criterion validity	Low. Due to imprecision, risk of bias, and indirectness of evidence
Arcometer	175 (2)	High interrater and intrarater	Low. Due to imprecision, risk of bias and indirectness of evidence
	52 (1)	High criterion validity	Low. Due to imprecision, risk of bias and indirectness of evidence
Digital inclinometer	180 (4)	High interrater and intrarater reliability	Moderate. Due to imprecision and indirectness of evidence
	11 (1)	Higher criterion validity	Low. Due to imprecision, risk of bias and indirectness of evidence
Rasterstereography	441 (10)	High interrater and intrarater reliability	Moderate. Due to risk of bias
	511 (4)	Moderate to high criterion validity	Moderate. Due to risk of bias
Lumbar lordosis			
Flexicurve	167 (5)	Moderate to high interrater and intrarater rater reiliability	Moderate. Due to imprecision and risk of bias
	97 (3)	Moderate to high criterion validity	Low. Due to imprecision and risk of bias
SpinalMouse	238 (6)	High interrater and intrarrater reliability	Low. Due to imprecision, risk of bias, and indirectness of evidence
	26 (1)	Low to moderate criterion validity	Low. Due to imprecision and risk of bias
Arcometer	70 (2)	Low to high interrater and intrarater reliability	Low. Due to imprecision, risk of bias, inconsistency of results
	92 (2)	Low concurrent validity; high criterion validity	Low. Due to imprecision, risk of bias, inconsistency of results
Digital inclinometer	39 (2)	Moderate to high interrater and intrarater reliability	Low. Due to imprecision and risk of bias
Rasterstereography	505 (9)	High interrater and intrarater reliability	Moderate. Due to risk of bias
	414 (6)	Moderate to high criterion validity	Moderate. Due to risk of bias

the influence of body mass and adipose tissue can increase error in surface measurements[74,75]. This leads to generally higher reliability and reproducibility compared to the lower accuracy and agreement between methods when measured against gold standard radiograph, even in the highest quality methods. Therefore, new methods are often compared not only to radiographs but to well-tested surface measurement tools commonly used in clinical practice and research studies in order to measure concurrent validity.

After evaluating and considering the psychometric properties, along with the accessibility and practical utility of the tools, three methods were chosen to be described in further detail in the next sections. The flexicurve and inclinometer represent common clinical tools each using a different general approach to measuring curvature, and surface topography represents a category of measurement growing in use with technology advancements.

The flexicurve is commercially available and employed for multiple uses across domains from maths to architecture to construction. It was first described in the literature for use in spinal measurement in 1959[76] and research into the psychometric measurement properties increased in the 1980's[77,78]. Once the flexicurve is moulded to the spinal shape, it is traced onto graph paper and aspects of the tracing are manually measured. There are two main methods of calculation: an index or an angle. For the kyphosis index, the apex kyphosis height is divided by the length of the entire thoracic curve (h/L), and for the kyphosis angle the following equation is used: arc tan (h/L1) + arc tan (h/L2), where L1 and L2 are defined by the intersection of height along the length. The flexicurve is now a widely used clinical and research tool which has been shown to have high reliability and moderate to high validity in the thoracolumbar spine, but with conflicting levels of evidence[57,68]. The standard error of measurement (SEM) is 0.4-0.96 for kyphosis index and 1.39-1.80 for lordosis index[74,79]. Its biggest advantage is its low cost and simplicity which has led to its adoption in research and clinically, yet the manual calculation of this paper-based method does not allow for computerised analysis.

The digital inclinometer is composed of two linked inclinometers that digitally produce a relative angle. For sagittal spine measurement, one inclinometer is placed at the superior spinous process of interest and a second inclinometer is placed at the inferior spinous process of interest. Each inclinometer has two "feet" that create a base to measure from and the difference between the two angles is automatically calculated and is digitally displayed. From a limited body of mixed quality evidence, it has shown high reliability and moderate to high validity yet

within a smaller body of psychometric property research than the flexicurve[57,58]. The SEM, as measured by the intrarater reliability, is 3.8°[80]. A primary advantage of this tool is its portability and quick measurement, yet the nature of the indirect measure limits the ability to describe other characteristics of the curve.

Surface topography refers to the 3D topographical mapping of the surface of the back. It differs from the flexicurve and digital inclinometer as it is a computer-based method, but it aligns more closely with the flexicurve approach since it measures and records the actual curvature of the spine. This type of measurement has become increasingly more prevalent and widely researched with an expanding number of devices and tools used. An automated stereophotogrammeric technique called the ISIS (Integrated Shape Imaging System) scanner was a landmark development 1983 for 3D measurement of scoliosis curvature and other similar techniques such as the Moiré method and video rasterstereography were being explored at that time[81]. Since then, surface topography technology has been evolving rapidly, and like with technology in general, it has become more streamlined, less expensive and more capable. Rasterstereography using the DIERS formetric 4D system has specifically become more researched and has been shown to be a reliable and robust technology but still with a relatively stationary and costly set-up[82]. It has mixed quality evidence for high reliability (intrarater ICC = 0.92-0.96 and interrater ICC = 0.98) in the thoracic spine[57,73], and similarly mixed quality evidence for high reliability (intrarater ICC = 0.83-0.99, interrater ICC = 0.78-0.97) and moderate to high validity (r = 0.46-0.82) in the lumbar spine[58,83–85]. While the general concept of surface topography has remained the same, even in the past decade the methods and hardware/technology have advanced, making the hardware smaller and more portable and the software more accurate and intuitive. One example of technological innovation is use of the Microsoft Kinect hardware for surface measurement of the back. This thesis describes the protocol development and psychometric testing of the Kinect sensor, and a further focus on the history, evolution, and technical aspects of the Kinect sensor will be discussed in Chapter 3.

1.3 Motivations and justification of research

The motivation and direction of this research stemmed from clinical experience and previous research. In the collective measurement of hundreds of spinal shapes from participants in a

large trial that included people with osteoporotic vertebral fractures[86], the presentation and patterns of spinal curvature were more heterogeneous than expected. Thousands of sheets of graph paper with curved tracings of the participants' spines hinted at important differences beyond a singular angle calculated from them. This led to questions such as: 'Why are some spines so flat?', 'Why is the apex in the upper thoracic region or why in the thoracolumbar junction?' and 'Why do people with some of the most severe thoracic angles seem to walk better than people with lesser angles?' These questions led first to the literature, then ultimately to the development of a PhD research project to delve deeper into the gaps in the knowledge base revolving around spinal curvature in the sagittal plane.

Since abnormal sagittal spine curvature affects at least 20-40% of older adults and has been shown to predict mortality[87], it is an extremely important physical characteristic to describe and understand. Other impactful consequences, such as pain, decreased quality of life, impaired mobility and higher falls risk[7,39,40,88], are associated with abnormal sagittal spine curvature and further motivated the pursuit of a better understanding. Since the focus of sagittal spine curvature is typically on thoracic kyphosis, it was important to look beyond the thoracic spine. Moreover, without an established gold standard non-invasive surface measurement tool, there was a need to explore novel technologies for sagittal spine curvature measurement. Underlying the ambition to improve the measurement methods was the aim to explore the sagittal spine curvature relationship with aspects of physical function, and conflicting evidence in this realm[29,30,33,39,40,42] provided justification for this research into the interaction between these characteristics.

1.4 Aim and Objectives

The overarching aim of this thesis was to explore sagittal spine curvature by validating a new measurement tool, implementing it and relating spinal curvature to physical function. Specifically, the objectives were:

1. To analyse the extent of the relationship between thoracic kyphosis severity and physical function in an osteoporotic population with vertebral fractures.

2. To test the level of intrarater and interrater reliability and concurrent and criterion validity of the thoracolumbar spine measurement using a surface topography method.

3. To implement the surface topography method to measure thoracolumbar curvature in a population with symptomatic degenerative spinal conditions and to analyse the extent of the relationship between sagittal spine curvature with measures of physical function.

Chapter 2

Thoracic kyphosis and physical function secondary analysis

2.1 Summary of contents

This chapter contains a secondary, exploratory analysis from primary data collected as part of a large, multi-centre randomised controlled trial (RCT). In an effort to explore the specific relationship between thoracic kyphosis and physical function outcome measures both cross-sectionally and longitudinally, this data analysis describes how these measures relate and how kyphosis severity may affect physical function changes over time in an osteoporotic vertebral fracture (OVF) population.

2.2 Background and study aims

Osteoporosis is a common disease characterised by low bone mineral density and deterioration in bone structure, resulting in skeletal fragility and fractures. OVFs are estimated to affect at least 20% of older adults in the UK, with 0.6% to 1.1% of this population incurring a new vertebral fracture each year[89,90]. OVFs cause spinal deformity often resulting in height loss and hyperkyphosis, with each fracture increasing kyphosis by 3°-4° on average[91]. OVFs and hyperkyphosis both typically progress with age, and while they can progress in parallel and be overlapping in their presentation, they are not synonymous physiological phenomena[16]. Hyperkyphosis affects approximately 40% of older people, a third of which have at least one vertebral

fracture[7,87]. In older people, the presence of vertebral fracture independent of spinal curvature is associated with an increased risk of death, and hyperkyphosis independent of vertebral fracture is also associated with increased risk of death; thus older people with concurrent OVF and hyperkyphosis have the highest mortality[20]. Hyperkyphosis and OVFs also alter spinal biomechanics, and with each increase of 15° of kyphosis there is a 1.9 times increase in the risk of sustaining a subsequent vertebral fracture[17]. In addition to spinal deformity and height loss, the symptoms of OVF and hyperkyphosis include pain, limitations in physical function, reduced activities of daily living and social participation, lower self-image, fatigue and restrictive pulmonary function, all of which can negatively and persistently impact on quality of life (QoL)[6,45,46,48,49,91]. Increased kyphosis angles in people with and without osteoporosis have been associated with decreased gait stability and performance, as well as decreased postural and balance stability[30,92,93]. The literature is mixed on whether kyphotic posture or vertebral fracture are more strongly associated with balance deficits and falls risk, possibly due to the overlap in these phenomena[40,94,95].

In an attempt to better understand the relationship between thoracic kyphosis and physical function in people with OVF, data from secondary outcomes of the Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE) trial were used for exploratory analysis of 4-month and 12-month changes. The PROVE trial was a large RCT designed to test the clinical effectiveness of three different physiotherapy approaches[86]. While the main results of the PROVE trial found no statistically significant differences in main outcomes (back extensor endurance and QoL) between the three physiotherapy intervention approaches, thoracic kyphosis demonstrated a clinically important improvement in the exercise and manual therapy arms at 12 months[86] suggesting there may be important kyphosis changes and relationships to be explored.

The aims of this study were to (1) compare descriptive characteristics based on kyphosis severity, (2) examine the correlative relationship between kyphosis severity and physical function and (3) investigate whether kyphosis severity affected improvement in physical measures after physiotherapy intervention in people with OVF.

2.3 Methods

2.3.1 Design

This study was a secondary, exploratory analysis of data collected during the PROVE trial, a large, multicentre 3-arm RCT[86]. The PROVE trial recruited from 21 hospitals across England and randomised participants into one of three groups: exercise therapy, manual therapy, or a single session of physiotherapy education. The two active intervention groups, exercise and manual therapy, consisted of up to seven sessions of one-to-one outpatient physiotherapy plus a home exercise programme over a 12-week period. Clinical assessments were performed at baseline, 4 months and 12 months[96]. The trial design and main findings were registered (ISRCTN 49117867) and followed CONSORT guidelines. This post-hoc exploratory analysis was not included in the registered protocol; permission to conduct the secondary analysis was given by the Principal Investigator in adherence to the trial data protection agreement. The trial was granted ethical approval by the South Central - Portsmouth Bristol Research Ethics Committee (12/SC/0411) (Appendix B1).

2.3.2 Participants

Potential participants were recruited via osteoporosis clinic visits or by mail from electronic medical record screening. Men and women over the age of 18 were included if they: had a diagnosis of primary osteoporosis confirmed by a radiograph or by Dual X-Ray Absorptiometry (DEXA) scan in the lumbar region (<2.5 SD young adult mean); had at least one previous OVF; were postmenopausal, if they were female; were able to walk 10 metres independently (with or without an assistive device); and were able to understand and participate in a physiotherapy programme[96]. People were excluded if they had any condition that prevented them from participating in exercise or physiotherapy safely or a condition that would confound results, including: severe unstable cardiovascular or pulmonary disease, significant psychiatric or neurological conditions, bone loss secondary to metabolic diseases, a primary presentation of back pain with radiating lower limb symptoms, or if they had undergone vertebroplasty, facet joint injection or any physiotherapy treatment in the previous 12 weeks[96]. For this secondary analysis study, a participant's data were only included if they had completed their baseline thoracic kyphosis measurement.

2.3.3 Procedures

All participants were given ample time to read Participant Information Sheet (Appendix B2) and ask questions about the trial. Subsequently they provided informed consent (Appendix B3) for participation in the trial. The trial was conducted in accordance with the Declaration of Helsinki. A blinded physiotherapist assessor performed a standardised research assessment visit at baseline and participants were then randomised into a treatment group. A blinded physiotherapist assessor also performed the follow-up assessments at 4 and 12 months. During research visit information was extracted about participant characteristics including age, gender, height, body mass index (BMI), number of spinal fractures, back pain and self-reported physical function, and tests of physical outcome measures were also performed as described below.

2.3.4 Outcome measures

There were numerous outcomes captured during the research visits (the complete list is included in the case report form in Appendix B4), but the outcomes of interest for the secondary analysis are described below.

Thoracic kyphosis was measured with a flexicurve which was moulded along the spine from the spinous process of C7 to L1[68]. A trained physiotherapist palpated the surface anatomical landmarks and marked the spinous processes with a removable skin pencil. Once moulded, the flexicurve was removed and the curve traced onto 5mm graph paper. The mean of three measurement trials was used. The kyphosis index (KI) was calculated using the maximum perpendicular height (mm) and the length (mm) of the region: KI=(maximum height ÷ length of C7 to L1)× 100. The kyphosis index was then transformed to the equivalent of a thoracic kyphosis Cobb angle using the conversion equation[68]: thoracic kyphosis = (KI × 3.1461) + 5.1166.

Physical function measures included the Six-minute walk test (6MWT), the Functional Reach (FR) test, and the Short Performance Physical Battery (SPPB), all have established reliability and validity in older adults[68,97,98]. The 6MWT measures functional walking capacity which is important for community mobility[98]. The 6MWT has high reliability and is moderately valid in relation to physical performance and self-reported physical function in older adults[97]. In the test, participants walk at a self-selected speed between two cones covering as much distance as

possible in six minutes[98]. The FR test measures aspects of anterior-posterior postural balance and has been associated with recurrent falls[99,100]. In the FR test, participants held their arm at 90° shoulder flexion and reach forward as far as possible while keeping the arm horizontal with the ground and feet static. The SPPB is a group of three tests that measures multiple aspects of physical performance including lower extremity strength, static balance and gait speed[101]. The three tests that make up the battery are: the number of sit-to-stands performed in 30 seconds, balance in progressively advanced foot positions (feet side by side, semi-tandem, tandem), and gait speed over an eight-foot distance. The combined score of these three tests ranges from 0 (the lowest score) to 12 (the highest score)[102]. An in-depth description of standardised testing for each of these three outcome measure is described in the previously published PROVE trial protocol[96].

The pain domain from the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) questionnaire, a validated disease-specific QoL questionnaire for people with OVF, was used for back pain measurement; the pain score ranges from 0-100, with 100 being the most severe pain[103]. Back extensor endurance was measured using the Time Loaded Standing (TLS) test, a valid test in this population[104,105].

2.3.5 Statistical analysis

Since there is a loose spectrum of normal and abnormal thoracic kyphosis, with normal ranges that gradually increase with age, no absolute threshold of normal thoracic kyphosis exists in this population, thus the data were divided into four subgroups based on quartile ranges of thoracic kyphosis measured at baseline, in congruence with methods performed by other large cohorts of similar populations[106,107]. Standard descriptive statistics were used to summarise participant characteristics at baseline. Descriptive baseline demographics and characteristics were analysed based on the kyphosis severity quartiles using a one-way ANOVA for the continuous variables and chi-square tests for categorical variables; the Tukey test was used for post-hoc analyses. Pearson's correlations were run to explore the baseline relationship between kyphosis and 6MWT, FR and SPPB. Linear mixed models were utilised to examine the effect of time and kyphosis while accommodating for the missing data and unequal variances in the repeated measures of the dataset. Separate models were constructed for each of the four dependent variables (thoracic kyphosis, 6MWT, FR, SPPB). For each model, kyphosis severity quartiles

(Q1-Q4) and the repeated time point (baseline, 4-months and 12-months) served as main effects and the kyphosis severity x time point interaction was inputted. Repeated covariance type was unstructured or Toeplitz, depending on the -2 Log Likelihood (-2LL), Akaike Information Criterion (AIC) and Schwarz's Bayesian Criterion (BIC) values. The models were first run unadjusted, then adjusted for physiotherapy intervention group, gender, height, BMI, age, number of spinal fractures, back extensor endurance, and pain severity, and finally modified to represent the significant and most relevant covariates for each model. Pairwise comparisons were analysed using the Sidak test. In all statistical tests, a p value <0.05 was considered statistically significant. Estimated marginal means (EMM), which are the means that have been controlled for by the relevant covariates included in the model, were used to express changes in outcome measures. Cohen's d was used to express effect sizes (ES) of EMM differences. Analyses were performed using SPSS Statistics version 25.

2.4 Results

The study sample was comprised of 604 participants, 11 were excluded from the full trial dataset (n=615) due to missing baseline thoracic kyphosis measurements. All of the follow-up data from the included participants were used; incomplete follow-up datasets were analysed in the linear mixed models in order to accommodate for missing longitudinal data. In this study, 87% (n=525) were female, the mean (SD) age was 71.7 (8.8) years and the mean (SD) thoracic kyphosis angle 47.4° (17.3°). The population quartiles based on the thoracic kyphosis were divided as follows: the first quartile (Q1) spanning 8.7°-35.5° in the hypokyphosis to normal kyphosis range; the second quartile (Q2) spanning 35.6°-46.0° in the normal kyphosis range; the third quartile (Q3) spanning 46.1°-56.9° in the moderate hyperkyphosis range; and the fourth quartile (Q4) spanning 57.0°-119.8° in the severe hyperkyphosis range (Figure 2.1). Participant baseline characteristics compared by quartile showed the severely hyperkyphotic group was older, shorter, had more spinal fractures, lower back extensor endurance and more severe pain (Table 2.1). BMI (F(3,592)=0.309, p=0.819) and gender ($\chi^2(3) = 5.860$, p=0.119) showed no significant differences between kyphosis severity quartiles.

Table 2.1: PROVE descriptive characteristics by kyphosis severity quartiles

Baseline characteristics	Quartile (n)	Mean (95% CI)	F	p-value
Age (y)	Q1 (n=151)	70.40 (68.82, 71.99)		
	Q2 (n=151)	70.64 (69.27, 72.01)		
	Q3 (n=151)	70.98 (69.53, 72.43)		
	Q4 (n=151)	74.77 (73.49, 76.06)[a]		
	Total (n=604)	71.70 (70.98, 72.42)	8.156	<0.0005
Height (cm)	Q1 (n=151)	161.1 (159.8, 162.4)		
	Q2 (n=151)	159.8 (158.5, 161.1)		
	Q3 (n=146)	158.5(157.1, 159.9)[b]		
	Q4 (n=149)	154.7(153.4, 156.2)[c]		
	Total (n=597)	158.6 (157.9, 159.3)	16.292	<0.0005
BMI (kg/m^2)	Q1 (n=151)	25.2 (24.5, 25.9)		
	Q2 (n=151)	25.6 (24.9, 26.3)		
	Q3 (n=146)	25.6 (24.7, 26.5)		
	Q4 (n=148)	25.6 (25.0, 26.3)		
	Total (n=596)	25.5 (25.1, 25.9)	0.309	0.819
Spinal fractures (number)	Q1 (n=128)	2.03 (1.78, 2.29)[d]		
	Q2 (n=135)	2.67 (2.32, 3.01)		
	Q3 (n=139)	2.71 (2.37, 3.04)		
	Q4 (n=142)	2.81(2.48, 3.14)		
	Total (n=544)	2.56 (2.40, 2.73)	4.564	0.004
Back extensor endurance (s)	Q1 (n=146)	76.92(64.97, 88.88)[e]		
	Q2 (n=149)	53.61 (44.93, 62.29)		
	Q3 (n=149)	42.22 (34.11, 50.33)		
	Q4 (n=148)	28.3(23.57, 33.02)[f]		
	Total (n=592)	50.17 (45.61, 54.72)	21.55	<0.0005
Pain domain of Qualeffo-41 (0-100, 100 indicating the highest pain score)	Q1 (n=151)	48.09 (44.77, 51.41)		
	Q2 (n=149)	50.40 (46.81, 54.00)		
	Q3 (n=148)	55.40 (51.75, 59.04)[g]		
	Q4 (n=150)	57.13 (5.56, 60.69)[h]		
	Total (n=598)	52.74 (50.97, 54.52)	5.586	0.001

a: Q4 significantly older Q1 (p<.0005), Q2 (p<.0005), Q3 (p=.001)
b: Q3 significantly shorter than Q1 (p=.036)
c: Q4 significantly shorter than Q1 (p<.0005), Q2 (p<.0005), Q3 (p=.0001)
d: Q1 significantly fewer spinal fractures than Q2 (p=.034), Q3 (p=.002), Q4 (p=.004)
e: Q1 significantly higher TLS scores than Q2 (p=.001), Q2 (p<.0005), Q4 (p<.0005)
f: Q4 significantly lower TLS scores than Q2 (p<.0005)
g: Q3 significantly higher pain scores than Q1 (p=.021)
h: Q4 significantly higher pain scores than Q1 (p=.002), Q2 (p=.004)

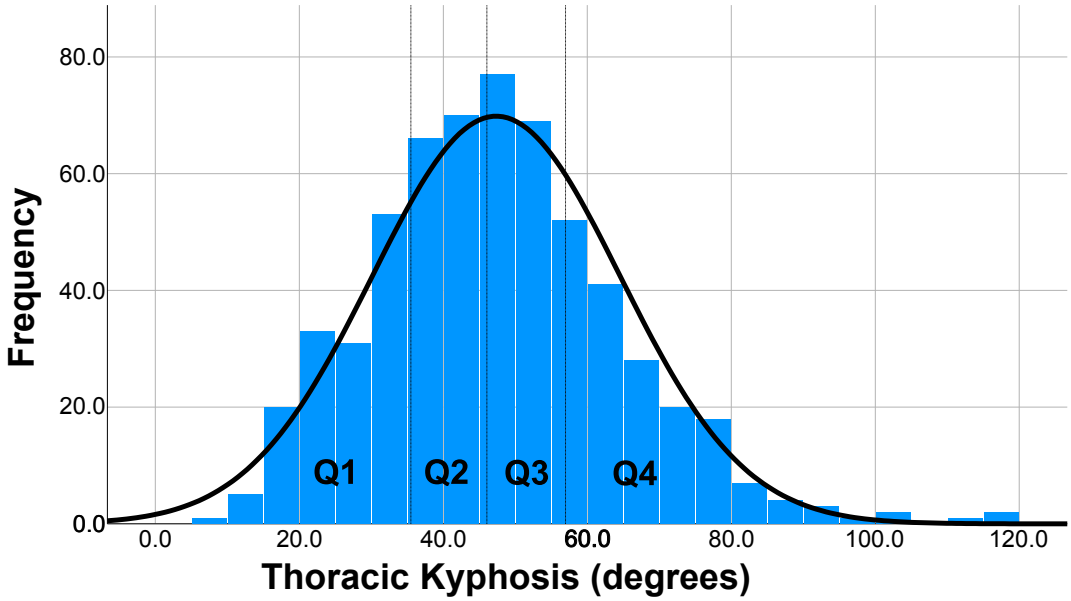


Figure 2.1: Kyphosis severity quartiles. Q1 = Normal/hypokyphosis group; Q2 = Normal kyphosis group; Q3 = Moderate hyperkyphosis; Q4 = Severe hyperkyphosis.

2.4.1 Thoracic kyphosis

The mixed model for thoracic kyphosis showed that both the main effects (kyphosis severity and time point) and their interaction were significant (Table 2.2). In the severely hyperkyphotic group (Q4), the kyphosis angle reduced by 5.7° (95%CI 3.5, 7.8, d=0.23) at 4 months and 8.0° (95%CI 5.4, 10.7, d=0.30) at 12 months from baseline. The moderately hyperkyphotic group (Q3) showed a similar pattern of significant reductions, but at a smaller scale: 2.4° (95%CI 0.3, 4.6, d=0.11) at 4 months and 3.0° (95%CI 0.4, 5.6, d=0.12) at 12 months. A significant kyphosis quartile severity main effect confirmed the wide distribution of kyphosis curvature profiles and appropriate differentiation between severity subgroups for the analysis. Figure 2.2 graphically shows the interaction between the time point and kyphosis severity quartiles with significant decreases in thoracic kyphosis at 4 months and 12 months for Q3 and Q4, when adjusting for age, height, back extensor endurance, and intervention group, yet there is no change at any time point in the normal groups (Q1, Q2).

Table 2.2: Effects from mixed models of outcome measures from PROVE

Outcomes	Effects	Model estimate (β)	SE	95% CI	p value
Thoracic kyphosis	Intercept	72.962	6.415	60.365, 85.559	0.000
(Adjusted mixed effects model: -2LL= 10761.087, AIC= 10805.087, BIC= 109.22.283; unstructured covariance structure)	Time				0.000
	Baseline	8.037	1.091	5.893, 10.181	0.000
	4 months	2.363	0.997	0.403, 4.323	0.018
	12 months	0	0	n/a	n/a
	Kyphosis severity quartiles				0.000
	Q1	-35.5	1.466	-38.381, -32.619	0.000
	Q2	-21.67	1.47	-24.559, -18.781	0.000
	Q3	-13.015	1.507	-15.976, -10.054	0.000
	Q4	0	0	n/a	n/a
	Time*Kyphosis severity				0.000
6MWT	Intercept	427.628	98.696	233.776, 621.481	0.000
(Adjusted mixed effects model: -2LL= 17661.754, AIC= 17709.754, BIC = 17837.239; unstructured covariance structure)	Time				0.049
	Baseline	1.12	9.096	-16.674, 19.067	0.895
	4 months	8.988	8.181	-7.071, 25.048	0.272
	12 months	0	0	n/a	n/a
	Kyphosis severity quartiles				0.004
	Q1	36.284	13.949	8.880, 63.687	0.010
	Q2	43.409	13.856	16.188, 70.630	0.002
	Q3	31.400	14.060	3.778, 59.023	0.026
	Q4	0	0	n/a	n/a
Functional reach	Intercept	-8.163	7.211	-22.326, 6.000	0.258
(Adjusted mixed effects model: -2LL= 9875.605, AIC= 9917.605, BIC= 10029.197; Toeplitz covariance structure)	Time				0.106
	Baseline	0.218	0.759	-1.271, 1.708	0.774
	4 months	0.868	0.708	-0.514, 2.267	0.221
	12 months	0	0	0	n/a
	Kyphosis severity quartiles				0.000
	Q1	3.354	0.957	1.476, 5.232	0.000
	Q2	2.17	0.958	0.291, 4.050	0.024
	Q3	0.563	0.976	-1.352, 2.478	0.564
	Q4	0	0	n/a	n/a
SPPB	Intercept	14.265	0.717	12.856, 15.673	0.000
(Adjusted mixed effects model: -2LL= 5801.361, AIC= 5839.361 BIC = 5940.299; Toeplitz covariance structure)	Time				0.000
	Baseline	-0.144	0.173	-0.485, 0.196	0.406
	4 months	0.355	0.167	0.026, 0.683	0.034
	12 months	0	0	n/a	n/a
	Kyphosis severity quartiles				0.011
	Q1	0.938	0.265	0.418, 1.457	0.000
	Q2	0.560	0.264	0.042, 1.078	0.034
	Q3	0.348	0.269	-0.180, 0.875	0.196
	Q4	0	0	n/a	n/a

2.4.2 Physical function outcomes

Six-minute walk test

The baseline measures of the 6MWT and thoracic kyphosis showed a weak correlation between higher thoracic kyphosis angles and shorter walking distances ($r = -0.238$, $p<0.0001$). The mixed model showed significant time point ($F(2,485.1)=3.042$, $p=0.049$) and kyphosis severity quartile ($F(3,539.3)=4.459$, $p=0.004$) main effects when adjusted for age, height, gender, back extensor endurance, pain and intervention group (Table 2.2). The estimated marginal mean (EMM) of the severe hyperkyphosis group (Q4) was lower than the normal kyphosis group (Q2) by 39.63 metres (95%CI 8.77, 70.49, $d=0.14$) $p=0.004$ (Figure 2.2). The significance of time point as a main effect suggests 12-month 6MWT scores were improved from baseline; pairwise comparisons revealed the moderately hyperkyphotic group showed an improvement of 25.16 metres (95%CI 3.50, 46.82, $d=0.001$) at 12 months compared to baseline. Although this quartile group was the only one to demonstrate a long term improvement, there was no significant interaction between time and kyphosis severity.

Functional reach test

The baseline measures of FR and thoracic kyphosis showed a weak negative correlation ($r = -0.304$, $p<0.0005$). In the mixed model adjusting for age, height, gender, back extensor endurance, pain and intervention group, time point was not a significant main effect ($F(2,750.2)=2.253$, $p=0.106$), but kyphosis severity quartile ($F(3,556.1)=6.685$, $p<0.0005$) was a significant main effect (Figure 2.2, Table 2.2). The adjusted mean FR score for Q4 was 22.0cm (95% CI 21.0, 23.0) and Q1 and Q2 showed higher EMMs by 3.0cm (95%CI 1.1, 4.9, $d=0.14$) and 2.3cm (95%CI 0.4, 4.1, $d=0.10$), respectively, compared to Q4.

Short Performance Physical Battery

The baseline measures of SPPB and thoracic kyphosis also showed a weak correlation ($r = -0.254$, $p<0.0001$) between worse kyphosis angles and poorer SPPB scores. The mixed model for the SPPB outcome showed significant main effects for kyphosis severity quartiles ($F(3,547.9)=3.75$, $p=0.011$) and time point ($F(2,718.4)=15.252$, $p<0.0005$) adjusting for age, back extensor endurance, pain and intervention group (Table 2.2). When SPPB scores were

compared based on kyphosis severity quartile, the severely hyperkyphotic performed worse and had an average score 0.72 points (95% CI 0.14, 1.3, d=0.15, p=0.007) lower than Q1 (Figure 7). SPPB EMMs improved from baseline to 4 months (0.42 (95%CI 0.24, 0.60, d=0.23, p<0.0005) and maintained improvement from baseline at 12 months (0.25 (95%CI 0.05, 0.45, d=0.12, p=0.010)), and pairwise comparisons indicated significant short-term improvements in Q2-Q4 specifically (Figure 2.2).

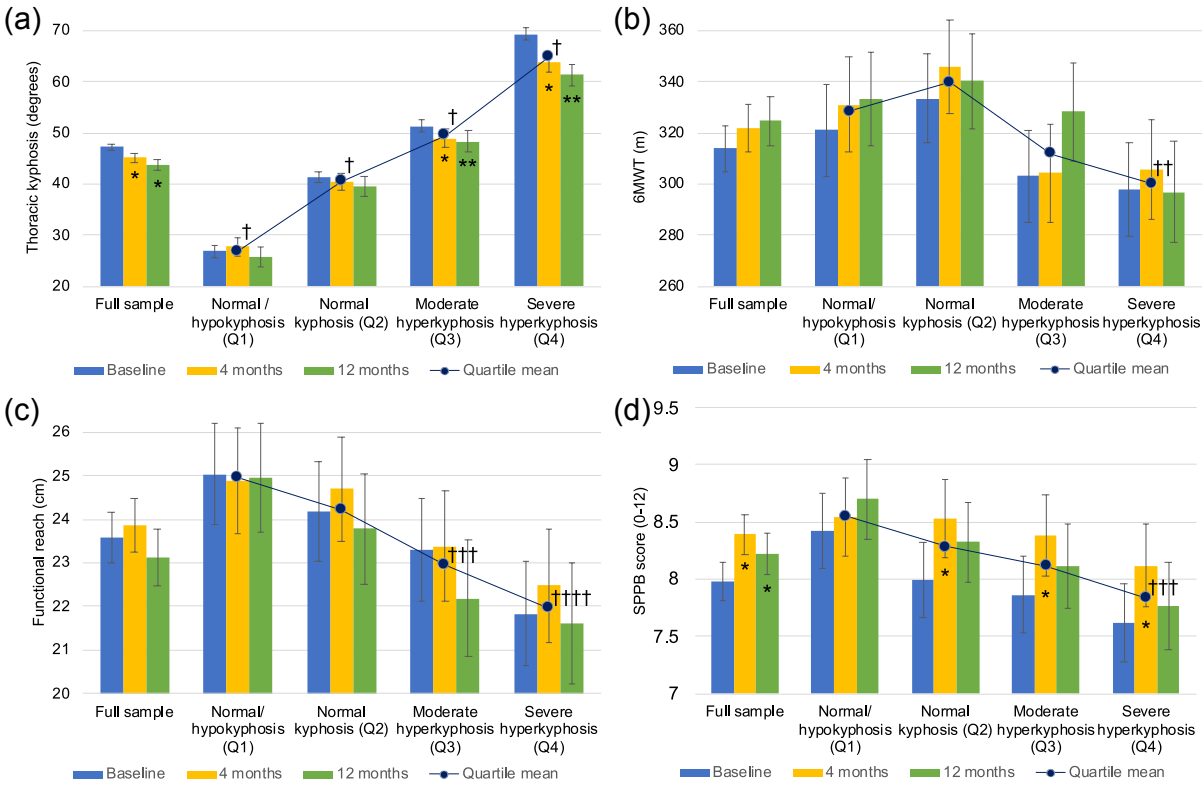


Figure 2.2: EMMs (95% CI) of outcome measures by kyphosis severity and time. a) Thoracic kyphosis mixed model shows significant differences between all severity quartile groups, significantly lowered kyphosis angle at 4 months and 12 months compared to baseline in Q3 and Q4; b) 6MWT mixed model shows significantly shorter distance completed in Q4 compared to Q2; c) FR mixed shows significantly lower distance reached in Q3 and Q4 groups compared to normal kyphosis; d) SPPB mixed model shows significantly lower scores in Q4 compared to the Q1, and overall significantly higher scores at 4 months and 12 months compared to baseline. * significantly different from baseline, ** significantly different from baseline and 4 months, † significantly different from all other quartiles, †† significantly different from Q2, ††† significantly different from Q1, †††† significantly different from Q1 and Q2

2.5 Discussion

The findings support previous studies in the literature, showing that increasing hyperkyphosis severity is positively correlated with increased age, number of spinal fractures, and pain, and

negatively correlated with increased back muscle endurance, walking capacity, balance and physical performance. Despite being older, having more OVFs, more pain and weaker back extensors, participants presenting with higher degrees of hyperkyphosis were responsive to all of the physiotherapy treatments administered within the PROVE trial, and importantly demonstrated significant, clinically-relevant improvement in thoracic curvature. While the main findings of the PROVE trial did not show statistically significant differences between the three physiotherapy approaches, this secondary analysis was designed to investigate longitudinal changes in physical measures based on thoracic kyphosis. Longitudinal findings from the model analysis in this study indicated that adjusted short-term improvements in the SPPB scores were maintained in the long term for all quartile groups, suggesting that this aspect of physical function has the potential to improve after a course of physiotherapy regardless of the severity of thoracic kyphosis curvature and even when significant factors such as age, back extensor endurance and pain were taken into account.

2.5.1 Thoracic kyphosis response to physiotherapy

The interaction between kyphosis severity quartile and time reveals that the participants responded differently according to the severity of their thoracic kyphosis curvature at the beginning of the trial. The results suggest that the mean thoracic kyphosis improvement in the full group at 4 and 12 months was driven by participants with moderate and severe hyperkyphosis. Subdividing the full sample into quartiles gave a detailed picture of the change in thoracic kyphosis; reflecting more clearly which participants improved their posture. These findings would not have been elucidated without quartile analysis because when the group is analysed as a whole, the mean change is smaller and not statistically significant[86]. The magnitude of kyphosis angle improvement in the most severely hyperkyphotic group is at a clinically important level. The large thoracic kyphosis improvement (8°) at 12 months in the severe hyperkyphosis quartile is similar to results from the Study of Hyperkyphosis, Exercise, and Function (SHEAF) Trial, an RCT which implemented an intensive 12-week targeted kyphosis-reduction exercises and postural training in participants with hyperkyphosis due to a number of different clinical conditions, reported a 6.9° improvement at 6 months in a hyperkyphotic population >75 years old[108]. Interestingly, our model found no significant effect from the type of physiotherapy treatment (manual therapy, exercise therapy or a single education session). The PROVE trial did not include a non-treatment

arm, but cohort research has shown that thoracic kyphosis increases over time in an ageing population and with vertebral fracture[109], therefore we attribute changes in thoracic kyphosis angle to be a response to a physiotherapy exposure. While there was a lack of significant change in Q1 and Q2, it did not indicate an insufficient intervention in these subgroups since they were not in an abnormal range of thoracic kyphosis and thus limited in their ability to change. The natural course of detrimental kyphosis progression in an older population has been established[91,109], thus staving off a yearly 1°-2° increase of kyphosis can be considered beneficial in itself. Left untreated kyphosis would be expected to progress, along with an accompanying deterioration in QoL and increased risk of mortality and complications such as falls and fractures[20,91,110]. Of further relevance in this population, an increase of 3°-4° of kyphosis is consistent with an incident vertebral fracture[109]. Kado et al. have also shown that in older women with vertebral fracture, the presence of hyperkyphosis increased the mortality risk by 1.58 per SD increase in kyphosis angle[20]. Hence, preventing deterioration can be considered beneficial. Therefore, both the reduction in thoracic kyphosis angle in hyperkyphotic subgroups as well as the stabilisation of thoracic kyphosis angle in normal kyphosis subgroups are both pertinent and important clinical findings.

2.5.2 Thoracic kyphosis and physical function

When examining the link between the severity of thoracic kyphosis and physical function over time, there remain many uncertainties in the relationship. In alignment with previous literature which has found an association between thoracic kyphosis and aspects of physical function[87,106,111], findings in this analysis support this correlation between an increasing degree of kyphosis and decreasing physical function measures. The dimensions of physical function explored in these analyses focus on 6MWT, FR and SPPB, which target distinct dimensions of physical function and demonstrate different relationships with thoracic kyphosis.

Six-minute walk test

The 6MWT was designed to measure functional exercise capacity and is validated in older, community dwelling adults[97]. Since the progression of thoracic kyphosis has been associated with poor pulmonary function, the six minute walk test has been applied in previous research trials as a measurement that could act as a proxy evaluation of aspects of aerobic capacity[108].

Our results suggest that there is a difference in functional walking capacity between those with severe hyperkyphosis and normal kyphosis. These findings are consistent with other studies that find an association between increased kyphosis and poorer functional gait performance and walking capacity[30,46]. It is not unexpected that we found only a weak correlation at baseline between 6MWT and thoracic kyphosis since there are many factors that influence the 6MWT, such as aerobic capacity, lower extremity muscle strength, balance, walking ability and pain, and thoracic kyphosis is only one contributing factor. However, cross-sectional analyses do not shed light on how kyphosis severity can affect change in walking or functional exercise capacity. The results from the 6MWT mixed model suggest that even when scores are adjusted for age, height, BMI, back extensor endurance and physiotherapy intervention, there remains a difference in functional exercise capacity between severe hyperkyphosis and normal kyphosis subgroups. Because functional capacity involves many systems and walking is dependent on numerous variables, this model adjusted for important factors, and yet there was still difference between functional capacity based on the severity of kyphosis. While there was a significant time effect, the pairwise comparisons revealed only a long-term improvement of 25 metres with a very small effect size in the moderate hyperkyphosis quartile; this improvement did not meet the MCID threshold of 50 metres in older adults[112]. In the previously mentioned SHEAF trial, the 6MWT scores remained statistically unchanged at 6 months both within each group and between intervention and control groups[108]. Similarly, in the PROVE trial no changes were seen in 6MWT following manual therapy intervention which included postural training; in contrast, significant short-term changes were seen in 6MWT following the multi-component exercise therapy intervention which included a graduated walking programme[86,108]. Interpreting these results together, it suggests that while kyphosis curvature is associated with walking capacity, changing curvature by itself does not have a strong influence on functional walking capacity as this involves the interaction of several physiological systems.

Functional reach

The FR test measures dynamic anterior-posterior postural balance as the ability to anticipate and react to changes as the body moves through space. Increased age impacts systems involved in postural control therefore it is an important metric to measure[113]. In addition to postural balance and strength, FR also requires sufficient joint range of motion and muscle

length[114]. Baseline correlation analysis shows a weak, negative correlation, and the FR EMMs between quartiles show significant differences between normal kyphosis and hyperkyphosis groups. Hirose et al. also found increased thoracic kyphosis correlated with decreased FR distance in a community-dwelling elderly population[115]. The severely hyperkyphotic group (Q4) EMM distance was 21.9 cm (95%CI 21.0, 23.0) compared to Q1 distance of 25.0 cm (95% CI 24.0, 25.9). Both distances are above the fall risk cut off for frail elderly adults (<18.5cm), but poorer FR results are linked to higher risk of functional decline[116,117]. However, kyphosis severity does not appear to affect change in FR after physiotherapy in the short- or long-term. One reason we may not see thoracic kyphosis curvature influencing change in FR could be due to the other contributing physiological factors, such as joint range of motion, postural muscle strength, balance, muscle length and reaching strategy, which might compensate for kyphosis curvature, thus this test alone cannot measure dynamic balance[118]. Therefore, while those with hyperkyphosis have lower FR scores, kyphosis severity in itself has not been shown to limit or significantly affect the change in FR scores after a physiotherapy intervention.

Short Performance Physical Battery

The SPPB is a cluster of tests designed to measure lower extremity physical performance by measuring aspects of static balance, functional lower extremity strength and gait speed. The SPPB brings together multiple components of physical performance, yet it does not test multidirectional or dynamic balance. The SPPB mixed model analysis suggested that kyphosis severity does relate to SPPB scores, with the most severely hyperkyphotic demonstrating lower physical performance. Eum et al. also examined the relationship between SPPB and kyphosis severity based on quintiles in community-dwelling older adults and found as kyphosis increased, physical performance deteriorated[119]. Compared to Eum et al., the kyphosis distribution of this population had a higher mean and was shifted towards more hyperkyphotic curvatures, yet the same inverse relationship between kyphosis severity and lower SPPB scores remained[119]. The adjusted mixed model incorporating time demonstrated a significant short-term improvement with a small effect size with improvement sustained at 12 months. This suggests that even when age, back extensor endurance, pain and physiotherapy intervention are taken into account, there are short- and long-term improvements among the whole group. When stratified by quartile, the improvements over time are apparent in all groups, showing that even hyperkyphotic groups

with moderate and severe curvatures had the capacity to improve their physical performance. The short-term EMM improvement of 0.42, while statistically significant, falls short of the MCID of 1.0 for community-dwelling older adults, however the mean baseline scores in this population are lower than the normative values in which the MCID was determined[112]. Balzini et al. did not show a difference in SPPB based on flexed posture, but did show that older women with severely flexed posture had a significantly slower gait velocity; this gait velocity was measured at a longer distance leading to a possible explanation that gait measured over only an eight-foot distance in the SPPB may not be a sensitive enough to influence change in the total score within the battery of tests[120]. While it is clinically interesting that hyperkyphotic groups exhibited improvement, this suggests that improvement is not influenced by kyphosis severity.

2.5.3 Clinical implications

Thoracic kyphosis angle improvement in participants with hyperkyphosis is not surprising considering they are a population that lie outside of normal range and have the most room for improvement, leaving normal kyphotic curvatures with a ceiling effect. This is clinically important in two respects: the magnitude of thoracic kyphosis improvement after physiotherapy is influenced by the patient's initial thoracic kyphosis severity, and patients with severe hyperkyphosis and OVFs do have the potential to respond to physiotherapy. This exploratory analysis has also shown that severely hyperkyphotic participants are generally older, have more vertebral fractures, less back extensor endurance, more restricted functional walking capacity, worse functional reach, poorer physical performance and more pain compared to those without hyperkyphosis, and has helped to shed more light on the relationship between aspects of physical function and hyperkyphosis severity in people with OVF. In the context of physical performance, as measured by a combination of gait speed, static balance and lower extremity leg strength, severe hyperkyphosis leads to lower scores, yet regardless of curvature severity there was improvement over time.

2.5.4 Limitations

As this was a secondary analysis of an RCT, the trial was not designed or powered for these specific statistical analyses of secondary outcome measures, as the PROVE trial used QUALEFFO-41 as the primary outcome to inform the power calculation. This dataset was analysed as a

longitudinal dataset and although the intervention group was not found to have a significant effect as a covariate, it was adjusted for in all mixed models. Additionally, due to the nature of a large, multicentre physiotherapy intervention RCT focused on an older clinical population, there was a relatively high percentage of missing data (21% kyphosis outcome data missing at 12 months). Because of the missing data and the large outcome data variation, linear mixed method analyses were employed to mitigate these in the dataset; however, the interpretation of results must bear in mind the associated limitations and assumptions. Another limitation was the non-invasive clinical tool used to capture thoracic kyphosis, the flexicurve. While it is a widely-used tool in research and in the clinical setting that avoids additional ionising radiation exposure, Spencer et al. have recently shown that the flexicurve is more inaccurate as the angle of thoracic kyphosis increases and progressively underestimates the thoracic kyphosis angle starting from 40°[121]. Because the thoracic kyphosis analyses are based predominantly around kyphosis quartiles, this could slightly alter the statistical threshold between moderate and severe, but the general trends of hyperkyphosis would likely remain as reported.

2.6 Conclusions

Hyperkyphosis presentation in people with OVF(s) is associated with greater pain, lower back extensor endurance and poorer walking capacity, balance and physical performance. Importantly, presenting with severe hyperkyphosis does not limit the ability to respond to a programme of physiotherapy. Both thoracic kyphosis curvature and physical performance improved in the short term for people with moderate and severe hyperkyphosis, and while physical performance improvements were maintained at 12 months, thoracic kyphosis continued to improve. These patterns were apparent in the models without adjusting for covariates and remained when adjusting for influential factors such as increased age, pain and poorer back extensor endurance.

The results of this analysis opened the door to more questions regarding sagittal spinal shape and curvature. While the findings revealed a clinically important message for patients with hyperkyphosis and OVF, the weak relationship between thoracic kyphosis and the physical function measures point to an interest in the role of the lumbar spine. While there was improvement in thoracic kyphosis in participants with a hyperkyphotic thoracic spine, both the change and involvement of the lumbar spine is unknown since it was not measured in this trial. Other studies

suggest that lumbar curvature may be more influential than thoracic curvature[29,32], therefore it appears to be an important region to measure and factor in to the relationship with physical function. Additionally, the drawbacks of the flexicurve for spinal measurement, especially in a hyperkyphotic population, indicated support for exploration of surface topography technology in order to more robustly describe and analyse the sagittal spine curvature, particularly looking into the full thoracolumbar region. The next chapter will introduce and describe the development a surface topography measurement method which was motivated by the findings from this exploratory analysis.

Chapter 3

The Microsoft Kinect sensor: background and method development

3.1 Summary of contents

This chapter introduces the Microsoft Kinect sensor technology, from its broad technical aspects and versatile use in many domains to its specific application for surface topography measurement of sagittal spine curvature. It describes the development and preliminary testing of the method protocol for sagittal spine measurement using the Kinect sensor.

3.2 Introduction of the Microsoft Kinect sensor

As previously described in Chapter 1, surface topography techniques measuring the contours of the back have been researched and have been evolving for the past four decades. The Microsoft Kinect is most commonly recognised as a gaming system; however, it is a cost-effective device commercially available for diverse uses outside of gaming. The first generation of the Kinect sensor was introduced in 2010 and because of its versatility and relatively low cost, it quickly gained popularity beyond its target audience. The Kinect sensor has since been used in research in variety of healthcare domains, some examples include: posture and movement assessment; disease screening; tailored games for use in rehabilitation intervention; 3D models to help with intervention planning and surgery; and assisting in medical imaging for oncological radiation treatment[122]. Few research studies have used this method to measure the sagittal alignment

of the spine, but the technology does have the potential to provide robust data to analyse the curvature of the spine.

3.2.1 Evolution of Kinect sensor technology

The first generation (V1) of the Microsoft Kinect works by projecting structured light and computing the distance and forming the object by triangulation[122,123]. Instead of the use of two cameras for traditional triangulation which had been the method previously used, the novelty of the Kinect sensor V1 was its use of one camera and one infrared (IR) emitter. The surface of the object is reconstructed based on the correlation between the undistorted projected beam and the distortion created by the object. In this method, however, extreme distortion could lead to errors and missing areas in the image reconstruction[122].

The second generation (V2) of the Microsoft Kinect was introduced in 2013 with new time-of-flight (ToF) technology. ToF is based on the time that the IR light emitted travels to an object and back to the sensor, therefore it is fundamentally different from the structured light technique from Kinect sensor V1. The Kinect sensor V2 has three components: infrared (IR) emitter, IR sensor and a colour camera. The IR emitter projects an IR light that will reflect off an object, then return to the IR sensor where the phase shift, or phase delay, is calculated and the distance can be determined[122,123]. This process occurs simultaneously in the whole projected area[122]. A three-dimensional (3D) image is reconstructed by cloud of 200,000+ pixels each with x, y, z coordinates that encode the distance to describe the surface of an object, and additionally the colour is detected for each point[122,123]. ToF is unique in that it can create a depth image which produces a direct 3D reconstruction without employing traditional computer-vision algorithms[123]. Because the capture rate is 30 frames per second, it can be employed in application for real time monitoring and movement capture[122]. The Kinect sensor V2 has been tested extensively to determine the accuracy and the sources of bias and error in the system. It contains a depth image (measured in pixels) of 512 x 424 with a field of view that is 60° in the vertical plane and 70° in the horizontal plane at a maximum range of 4.5 meters[2,122]. The device has good depth accuracy of <2mm between 0.5 metres and 2 metres distance from the sensor in both the horizontal and vertical planes as depicted in Figure 3.1[2]. The Kinect sensor V2 has two general sources of bias: systematic (directly related to the sensor) and non-systematic (related to the scene or environment content)[123]. Systematic bias includes: depth precision, which

is good in this second generation (<2mm); the potential of interference of the IR light from daylight; and the material or colour of the object in which sharp edges, semi-transparency and reflective surfaces is a common source of error[122,123]. Non-systematic bias includes one large source of error which is object motion blur; it can cause an overshoot or undershoot of phase shift calculation[123]. These sources of bias were taken into account during preliminary testing and protocol development when considering markers, environmental setting and participant instructions.

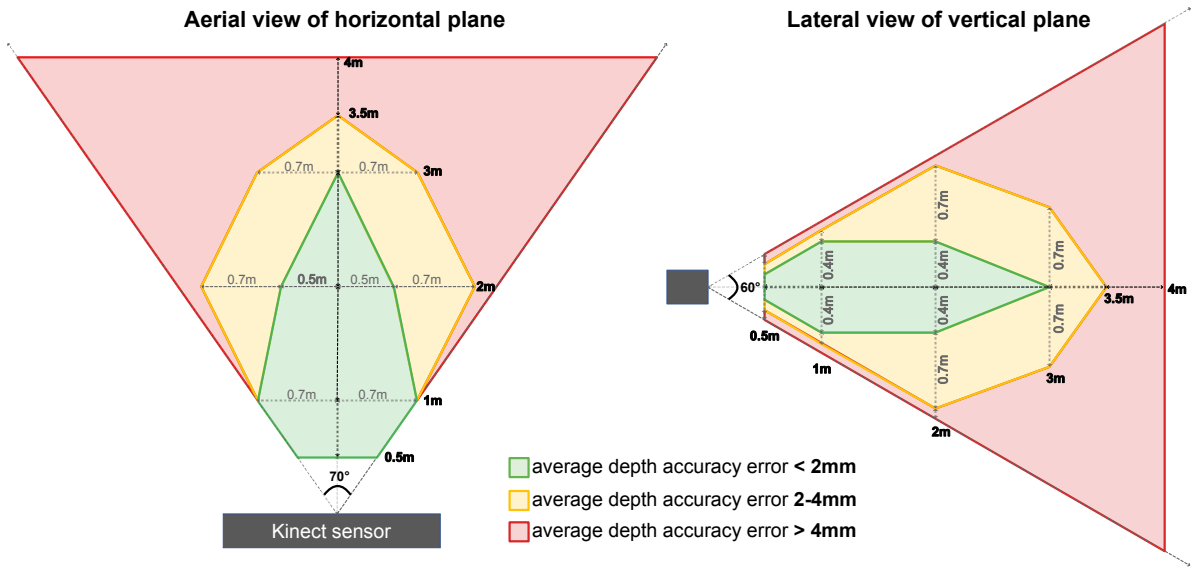


Figure 3.1: Kinect sensor V2 accuracy projection. This is a visualisation of the Kinect sensor V2 zones of accuracy adapted from Yang et al.[2]

3.2.2 Kinect sensor use in postural control and spinal measurement

Several studies have used the Kinect sensor V1 to assess posture and postural control[124,125]. Clark et al. determined the Kinect sensor V1 to have excellent concurrent validity in an assessment of kinematic strategies of postural control compared to 3D motion analysis in group of healthy individuals (n=20)[124]. A study by Diego-Mas et al. found an agreement between ergonomic postural assessment in the Kinect sensor V1 compared to human observers[126], and a more recent study by Castro et al. tested the use of the Kinect sensor V1 to measure posture in the frontal plane by shoulder height difference as a proxy measurement for scoliotic alignment[125]. Because of the relatively recent release of the Kinect sensor V2, the body of research is actively growing but there are few studies using the new ToF technology specifically in the field of posture and spinal alignment. The most relevant research, conducted by Quek et al., tested the reliability

Table 3.1: Evidence table for Kinect sensor spinal measurement properties

Kinect sensor spinal outcome	**No. of participants (studies)** ***Population***	**Study description**	**Summary of findings**	**Quality of evidence (GRADE framework)**
Thoracic kyphosis	33 (1) *Healthy volunteers*	Standing and sitting static sagittal spinal curvature (x3 measurements). Kinect intrarater reliability and concurrent validity assessed; flexicurve reference test.	Combined position reliability ICC (95%CI) = 0.81-0.98 (0.60-0.99); validity ICC (95%CI) = 0.76-0.82 (0.48-0.92).	Low. Due to risk of bias (small sample size) and indirectness of evidence (population not representative)
Postural balance (sagittal trunk movement)	20 (1) *Healthy volunteers*	3 repetitions of postural movements. Kinect inter-trial reliability and concurrent validity assessed; VICON camera system reference test.	Trunk anterior-posterior: reliability, ICC (95%CI) = 0.54 (0.15-0.79); validity, r = 0.99	Low. Due to risk of bias (small sample size), indirectness of evidence (population not representative) and imprecision (wide confidence intervals for estimate of reliability)

and concurrent validity of the Kinect sensor V2 for the measurement of thoracic kyphosis in a healthy population (n=33)[127]. Validity was measured against the flexicurve in both standing and sitting positions and showed good correlation (ICC = 0.76-0.82) and excellent intrarater reliability in standing (ICC = 0.96-0.98) which were coefficient values higher than the flexicurve[127]. These results demonstrated a good foundation for the use of the Kinect sensor V2 and pointed to further psychometric property testing in populations with more diverse spinal presentations.

Of these studies, only Quek et al. and Clark et al. used participants to test the reliability and validity of a spine-related measure against a reference test, indicating a small body of research around the psychometric properties of the Kinect sensor in this domain[124,127]. The findings and level of evidence from these two relevant Kinect sensor studies are summarised in Table 3.1. Overall, the current level of evidence and recommendation for use of this tool as an outcome measure at this point is *low* based on the GRADE framework.

3.2.3 Potential use in sagittal spine curvature

The Kinect sensor V2 has promising attributes yet sparse psychometric properties for sagittal spine measurement in participants with a wide range of age and spinal presentation. There are several potential benefits of developing a method to use the Kinect sensor V2 to measure sagittal spine curvature. First, it is a tool that is diverse in its use, as mentioned previously, and it has the potential as a 3D measure to be used in numerous spinal deformity conditions, including osteoporosis, scoliosis, kyphoscoliosis, degenerative disc disease and many other conditions. Second, there is a high ratio of the robustness of data that can be collected to its ease of use. Compared to the previously described non-invasive physical measurement tools, it can digitally store the data collected and more easily and quickly analyse it. Third, the Kinect sensor V2 captures the actual curvature of the spine rather than inferring the angle only from endpoints therefore hypothetically allowing more detectable change within different regions of the curve[57,68]. The following sections describe the methods and results of the studies designed to test the Kinect sensor V2's reliability, accuracy and utility.

3.3 Development of method protocol for the Kinect sensor

Surface topography measurement of the spine has been mainly driven by the need for an accurate and reliable method to measure change in people with adolescent idiopathic scoliosis (AIS) as the condition has traditionally required repeated radiographic imaging from adolescence into adulthood. Due to the surface cosmetic defects that transpire from the rotation of the spine, the frontal and transverse malalignment can be measured as a proxy by the consequential changes in the spine, rib cage and scapular surface. While the surface topography technology has specifically advanced to measure the full dorsal surface, sagittal alignment has also been a secondary measure captured and therefore not fully explored. Working from a software programme designed to measure AIS cosmetic defect of the back, explicit measurement of the sagittal plane curvature was developed and tested. From this point on, the focus of the thesis is on the Kinect sensor V2, therefore any mention of the 'Kinect sensor' will be exclusively referring to the second generation.

3.3.1 Kinect software programmes

The primary programme used to transform the image data was the Parser programme (Oxford Metrics plc/Staffordshire University Stanford Polygon PLY, version 2.6) which was developed by Dr Thomas L. Shannon and originally aimed to measure scoliotic spinal change by cosmetic defect proxy[128]. The Kinect Fusion Explorer software (Microsoft Corporation, Seattle, Washington, U.S.A) from Microsoft was used to initially capture the image. The images were then processed through MeshLab, an open source software system for 3D mesh visualisation[129], where the background environment as well as body parts other than the torso were removed. This narrowed 3D data cloud file could then be used in the Parser programme. Parser operated by creating a reference plane from a manually selected trifecta of points that included the spinous process of the 7th cervical vertebra (C7) and right and left posterior superior iliac crest (PSIS). From this reference plane, points captured along the midline of the spine could be extracted and converted into a comma delimited file. Additionally, the manually palpated spinous process of the 1st lumbar vertebrae (L1) was identified.

3.3.2 Preliminary testing

Testing prior to the first study was used to establish a feasible and practical protocol. Several volunteers were used in preliminary testing to develop a standardised script for describing the measurement and instructions for future participants. Since the aim was to obtain a static image capture, it was found that any significant movement resulted in a poor image capture and consequential non-systematic bias. From this initial testing, the slight lag time between reconstructing the live image and capturing the image was discovered. In order to more consistently help the participant stand relatively motionless for the required 1-2 seconds, it was found to be best to have them hold the standing position while counting aloud: “3-2-1.” It was also discovered that physically demonstrating the standing position with elbows bent and arms held out in front of them was more successful than a verbal description of the standing position.

In addition to improving instructions and the standardised operating procedure, testing was performed to estimate the practical bounds of the cone of accuracy described by Yang et al.[2] Figure 3.2 depicts the locations where the images were captured of a single subject (n=1), all within the ‘green zone’ of the cone of accuracy where the average depth accuracy

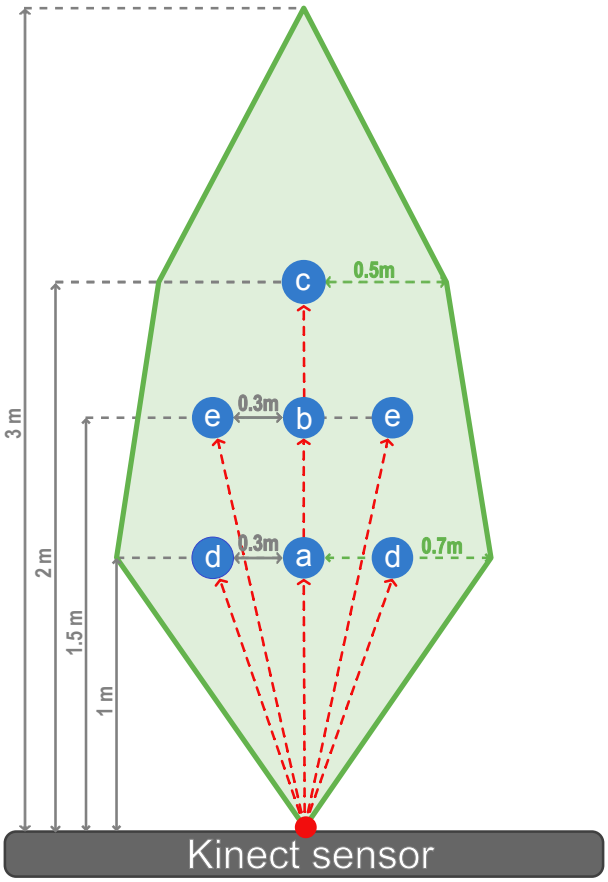


Figure 3.2: Aerial view of preliminary testing. The schematic shows 7 testing locations grouped into 5 categorical positions (a-e); the green area represents the highest depth accuracy zone of <2mm established by Yang et al.[2]

error was measured to be <2mm[2]. Two to four images were captured in each of the seven positions which were determined based on the distance (1 metre, 1.5 metres, 2 metres) and lateral location (centred, 0.3-metre right, 0.3-metre left) from the Kinect sensor. From these positions, five categories were formed: 1-metre, 1.5-metres, 2-metres, 1-metre off-centre and 1.5 metres off-centre. The mean values were compared using an ANOVA based on the collective three groups based on distance, and separately analysed using the five positional categories. The results showed significant mean differences for the kyphosis index (KI). Post hoc Tukey analysis ($p<0.005$) showed the centred KI values were significantly lower at 2-metres compared to 1-metre (-0.80, 95% CI -1.36, -0.24) and 1.5-metres (-0.86, 95%CI -1.43, -0.30) (Figure 3.3). Further analysis compared the means between the five positional categories to distil differences based on positioning off-centre. It showed that the KI values measured 1-metre off-centre were significantly lower than all other positions and 1.5-metre off-centre were significantly higher than 1-metre off-centre and 1.5 metre centred (Figure 3.3). These results suggest that there is

variability when the subject is not aligned in the centre and if further than 1.5 metres, therefore instructing a participant to stand at 1 metre directly in front of the Kinect sensor was the most accurate and practical location to standardise, especially considering space-limited clinical and research testing environments.

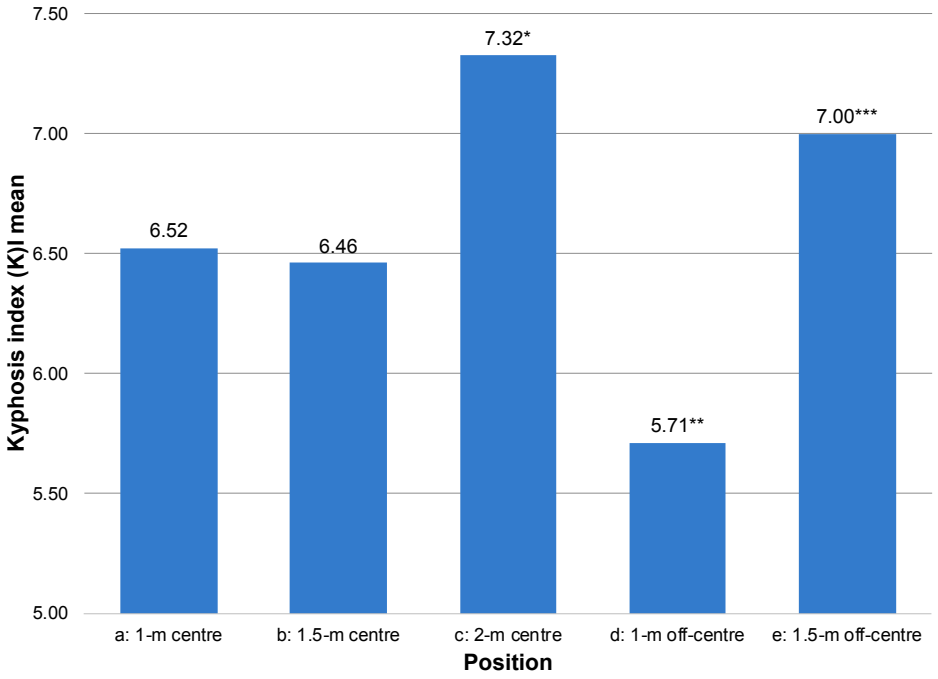


Figure 3.3: Comparing means of multiple positions. Post hoc analysis of the means of each position shows significant differences found at locations farther and off-center from Kinect sensor; *c higher than a, b, d; **d lower than a, b, c, e; ***e higher than b, d.

Overall, the preliminary testing showed that some variation in location was acceptable, for example capturing the image between 1m and 1.5m aligned in the centre; however, in order to standardise the protocol for assessor and participant benefit, a line on the ground one metre from the Kinect sensor proved to be easier for instruction. The line also allowed for the participant to more automatically align their dorsal surface relatively parallel to the sensor. Additionally, 1m was chosen over 1.5m due the practicality of compact testing space within a clinical setting.

3.3.3 Measurement protocol

After preliminary testing was complete, a measurement protocol was established as the following. An experienced musculoskeletal physiotherapist would palpate the spine and place adhesive markers to identify the specific anatomical landmarks: C7, L1, and right and left PSIS (Figure 3.4). The spinous process of C7 would be identified by palpating the prominent spinous process

in the cervicothoracic junction, confirmed by active cervical extension and flexion. The spinous process of L1 would be identified by its relationship to L4 which was identified by its location horizontal to the level of the iliac crests and two vertebrae superior to the sacral base; after confirmation of L4, the assessor would count the spinous processes up to L1. Bilateral PSIS locations would be identified by surface dimples at the level of S2. Participants would be instructed to stand facing away from the sensor with their heels on a line marked one metre from the sensor. The sensor would be mounted on a tripod and aligned parallel to the ground with the height adjusted to be level with the participants' mid-scapular region (Figure 3.5). Instructions would be given to look straight ahead and stand in 'best posture' with arm positioning forward with their shoulders and elbows at 90° in an effort to simulate the instructions given during a clinical lateral view spinal radiograph. Participants would stand in the instructed position for less than 3 seconds as the image was captured. They would then be instructed to relax their arms and move in between image captures before resuming the initial positioning.

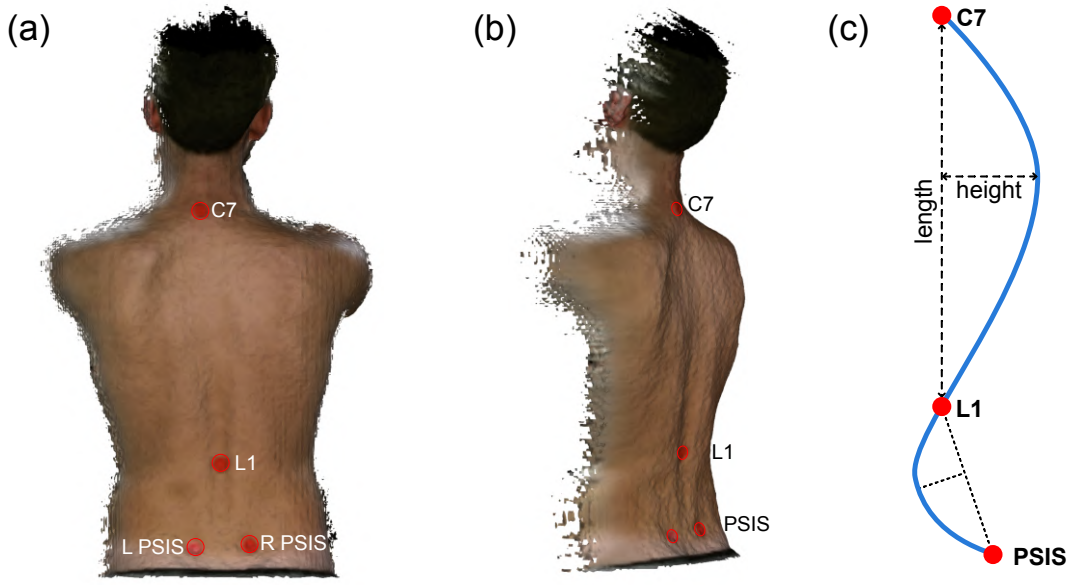


Figure 3.4: Anatomical landmarks and index schematic. (a) Reconstructed 3D image using MeshLab software from the posterior viewpoint of the Kinect sensor; (b) same image rotated to partially view the sagittal plane; (c) schematic in sagittal view of anatomical markers used to calculate kyphosis index and lordosis index.

On the side of image capture and data processing and analysis, the Kinect Fusion Explorer software would be used on a laptop computer which would be connected to the Kinect sensor. The depth threshold would be set at minimum 0.50m and maximum 2.0m. All images would be uploaded to MeshLab where extraneous pixels would be removed. The 3D reconstruction of the

dorsal surface would be processed through the bespoke software programme, Parser, requiring manual identification of the landmarks in order to then obtain coordinates along the surface spinal column. The raw data would be transformed into a fitted curve using a 6th order polynomial, subsequently the angle indexes and other sagittal curvature descriptors would be calculated in Microsoft Excel. Angle indexes would be determined by the length of the target spinal region and the maximum height which is an accepted method widely used with flexicurve measurement and validated against the Cobb angle[68], e.g. kyphosis index = (height ÷ (length from C7 to L1)) × 100; the same method is applied to the lumbar region with the length extending from L1 to bisection of right and left PSIS (Figure 3.4).

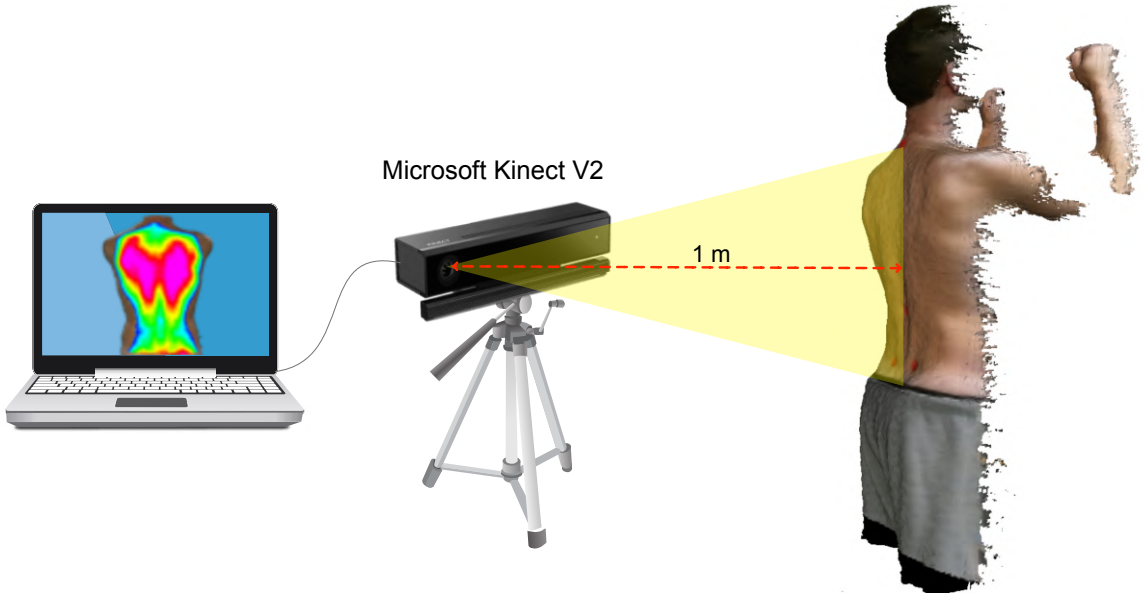


Figure 3.5: Kinect sensor set up. This schematic shows the experimental set up in which the Kinect sensor was mounted onto a tripod and connected to a laptop for image capture.

3.4 Conclusions

The Kinect sensor, specifically ToF, was developed and improved upon from previous iterations of surface topography technology. The development of the specific method protocol for the Kinect sensor to act as measurement tool for sagittal spine curvature was based on preceding literature and preliminary testing. The original algorithm dedicated to measure cosmetic surface defect in AIS was adapted in this research to identify and differentiate thoracic and lumbar regions and to calculate the angle indexes, equivalent to the well-tested method using a flexicurve ruler. The

next chapter describes the use of these procedures to test the reliability of the method.

Chapter 4

Reliability testing of the Kinect sensor

4.1 Summary of contents

This chapter includes the reliability findings from two studies. The first study was conducted to test the intrarater and interrater reliability of the method in adult volunteers, and the second study reports the test-retest reliability findings from a subgroup of the Walking and balance related to sagittal Spine Posture and Alignment (WiSPA) study. The former was published in the Journal of Back and Musculoskeletal Rehabilitation in 2020.

4.2 Measurement intrarater and interrater reliability

4.2.1 Background and study aims

In any performance measurement, it is crucial that psychometric properties are tested. As there was only one published research study testing the Kinect sensor for spinal kyphosis measurement[127], it was important to build upon this initial testing and test other aspects of reliability in the thoracolumbar spine. The primary aim of this study was to estimate the extent of the reliability and reproducibility of sagittal spine curvature measurement method using the Kinect sensor.

4.2.2 Methods

Design

This cross-sectional study included the measurement comparison of two assessors at one time point. It was evaluated according to the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) and on the COSMIN pathway for reliability[130]. The study was granted ethical approval by the Oxford Brookes University Faculty Research Ethics Committee (reference 1217-35) (see Appendix C1).

Participants

Potential participants were recruited by convenience sampling from the Oxford Brookes University community. Men and women over 18 years old were eligible to participate if they could stand independently and if they had no neurological disorders affecting their posture. There were no exclusion criteria based on the presence of abnormal spinal curvature or back pain.

Procedures

All participants were given ample time to read Participant Information Sheet (Appendix C2) and ask questions about the study. They provided informed consent (sample form in Appendix C3) and the study was conducted in accordance with the Declaration of Helsinki. During the research visit, two assessors completed Kinect sensor measurements, and measurement procedures followed the protocol described in the Chapter 3. The first assessor was an experienced musculoskeletal physiotherapist who palpated the participant's spine and placed adhesive markers at C7, L1 and rights and left PSIS. Both assessors gave standardised instructions for positioning as outlined in Chapter 3. Between each image capture, the participant was instructed to walk away then return to the same standing position and posture. The first assessor captured three images and was blinded to the results of each capture. On the same research visit, the second assessor, a non-clinician, captured three subsequent images using the same anatomical landmarks previously identified. The second assessor was blinded to previous assessor's results as well as their own.

Outcome measures

The Kinect sensor data were captured, transformed and analysed according to the procedures described in Chapter 3. The outcome measures were the angle indexes were calculated using the length of the target spinal region and the maximum height. In the thoracic region, kyphosis index = (height÷(length from C7 to L1))×100; in the lumbar region, the length extended from L1 to bisection of right and left PSIS.

Statistical analysis

A sample size calculation for the ICC with significance level at 0.05, power at 0.80, acceptable reliability at 0.75 and expected reliability at 0.90 required at least 19 participants[131].Descriptive statistics and reliability coefficients were calculated. Reliability was based on ICC with 95% confidence intervals; intrarater reliability was based on a single rater, absolute agreement, two-way mixed effects model (ICC 3,1), and interrater reliability was based on a single rater, consistency, two-way random-effects model (ICC 2,1)[132]. Levels of reliability used were: poor reliability <0.40, moderate reliability 0.40-0.75, good reliability 0.75-0.90, and excellent reliability >0.90[133]. Standard error of measurement (SEM) and minimal detectable difference (MDD) were determined by the equations: $SEM = SD \times \sqrt{1 - reliability^2}$ and $MDD = SEM \times 1.96 \times \sqrt{2}$. Comparison of multiple means were analysed using repeated measures ANOVA (p<0.05). Data was analysed using SPSS software version 24.

4.2.3 Results

Thirty-seven participants aged between 18 and 79 years old had a mean (SD) age of 51.7 (20.6) years old. The mean BMI (SD) was 24.9 (3.3) kg/m^2 and 57% were female. Descriptive statistics of kyphosis and lordosis indexes are reported in Tables 4.1 and 4.2. The kyphosis and lordosis indexes had very high intrarater and interrater ICC scores (0.960-0.973) (Tables 4.1-4.2).

The means of the six images captured were compared. There were no significant differences between the means in the lumbar region, F(3.91,133.01)=1.566, p=0.188; however there were significant differences between the means in the thoracic region, F(5,170)=5.317, p<0.001 (Table 4.1). To look at the differences in the thoracic spine as they related to age and the severity of kyphosis, means within these subgroups showed that in participants who were less than

Table 4.1: Descriptive statistics and reliability of the thoracic spine from the Reliability study

THORACIC REGION									
	Assessor 1			Assessor 2			Both assessor		
	Image 1	Image 2	Image 3	Image 4	Image 5	Image 6	1st images pooled	2nd images pooled	3rd images pooled
n	37	36	37	37	36	36	74	72	73
Mean	10.6	10.26ł	10.12	10.62	10.45	10.33	10.61ǂ	10.35	10.22
SD	3.19	3.09	3.19	3.1	3.18	3.23	3.17	3.16	3.24
Range	4.76-17.75	4.47-16.98	4.36-17.46	5.06-17.52	4.45-18.32	4.55-18.09	4.76-17.75	4.45-18.32	4.36-18.09
SEM	0.54	0.53	0.54	0.53	0.54	0.55	0.54	0.54	0.55
MDD	1.50	1.47	1.50	1.47	1.50	1.52	1.50	1.50	1.52
ICC coefficient (95% CI)	Intrarater 0.960 (0.926, 0.979)			Intrarater 0.975 (0.956, 0.987)			Inter-rater 0.971 (0.954, 0.984)		

ł significant difference from mean of Image 1 ($p=0.009$) and mean of Image 4 ($p=0.001$)
ǂ significant difference from 2nd pooled images ($p<0.001$) and 3rd pooled images ($p<0.001$)

Table 4.2: Descriptive statistics and reliability of the lumbar spine from the Reliability study

LUMBAR REGION									
	Assessor 1			Assessor 2			Both assessors		
	Image 1	Image 2	Image 3	Image 4	Image 5	Image 6	1st images pooled	2nd images pooled	3rd images pooled
n	37	36	37	37	36	36	74	72	73
Mean	9.74	9.55	9.51	9.29	9.37	9.51	9.52	9.46	9.51
SD	4.23	4.07	4.08	4.19	4.34	4.34	4.19	4.18	4.18
Range	1.77-21.68	1.74-20.47	0.95-19.59	1.90-20.85	1.43-21.22	0.93-19.34	1.77-21.68	1.43-21.22	0.93-19.59
SEM	0.72	0.69	0.69	0.71	0.74	0.74	0.71	0.71	0.71
MDD	2.00	1.91	1.91	1.97	2.05	2.05	1.97	1.97	1.97
ICC coefficient (95% CI)	Intrarater 0.973 (0.954, 0.985)			Intrarater 0.977 (0.960, 0.988)			Interrater 0.971 (0.954, 0.984)		

65 years old or who had normal kyphosis, image captures 1 and 4 were significantly higher than image capture 2 (Figure 4.1). In participants who were 65 years or older or who were hyperkyphotic, there were no significant differences between the means of each capture (4.1). The data were further reformatted to pool the first, second and third images from both assessors (Tables 4.14.2) in order to determine if posture changed based on the capture order in reference to the introduction of a new assessor. For pooled thoracic data, there was a significant effect between the means, $F(1.76,122.86)=11.257$, $p<0.001$; the mean of the first images pooled had a significantly larger kyphosis index ($p<0.001$) compared to the second images and third images (Table 4.1). For pooled lumbar data, there was no statistically significant differences, $F(2,140)=0.004$, $p=0.996$ (Table 4.2). The participant-facing time required for instruction and positioning was less than 30 seconds and actual image capture was three seconds. For each participant, the image capture and analysis all images were less than five minutes.

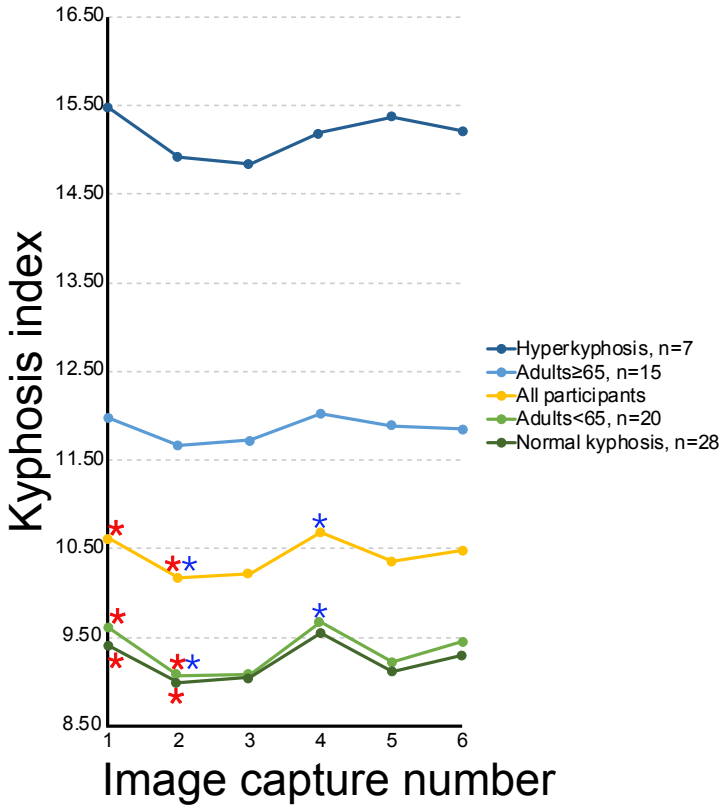


Figure 4.1: Subgroup repeated measures graph. After stratifying repeated measures by age and by the degree of thoracic kyphosis (hyperkyphosis 13.1), the hyperkyphotic group and older adults showed no significant within group differences. With statistical differences denoted by the asterisk signs of the same color for each line: adults <65 y.o. showed significant differences between captures 1 and 2 ($p=0.045$) and captures 2 and 4 ($p=0.007$); the normal kyphosis group showed difference between the 1st and 2nd captures ($p=0.003$).

4.2.4 Discussion

The ICC results show that the Kinect sensor has high intrarater and interrater reliability in the both thoracic and lumbar regions. It was a quick method to administer with the participant and it took less than five minutes to complete both image capture and analysis of both regions. The analysis took the bulk of the time as it was not a fully automated process, yet there is potential for it to become more automated. In any setting, this would be a quick, reliable, and inherently safe non-radiographic method to measure thoracic and lumbar curvature concurrently in order to use it as an outcome measure with a patient-friendly visual representation of the back.

Of the numerous non-radiographic methods developed to measure sagittal spine curvature, most have focused on measuring the thoracic region, some measure the lumbar region, and few measure both regions simultaneously. Commonly used non-invasive measurement methods of thoracic kyphosis in research trials, such as the flexicurve and DeBrunner kyphometer, have shown high intrarater and interrater reliability and moderate validity[57,68]. In the lumbar region, the flexicurve has been shown to have moderate to high reliability and moderate validity[55,77]. In one study that measured thoracic and lumbar regions concurrently with a flexicurve, the method involved taking a digital picture of the flexicurve against graph paper and manually plotting coordinates from the curve[55], which would be a time-consuming and tedious task. While modern non-radiographic methods have been developed, such as the SpinalMouse and rasterstereography, cost has been a barrier to the practical constraints of their use in a research or clinical setting[57].

While the use of the Kinect sensor to measure frontal and rotational curvature in AIS populations has been growing quickly, to date, only one other published study has used the second generation of the Kinect sensor to specifically measure sagittal spine curvature. In the study by Quek et al., the participant population had a mean (SD) age of 31 (11) years and standing kyphosis index mean (SD) of 9.78 (2.4)[127]. Our study found similar reliability values in a population that more closely represents the adult life span and also importantly included older adults with degenerative spinal changes. Study participants averaged 52 years old with a kyphosis index mean (SD) of 10.36 (3.2), indicating a larger range in spinal shape and a notably wider diversity in age. A fifth of the participants in our study surpassed the threshold for hyperkyphosis, which is a kyphosis index 13.19[119]. With this diverse sample we can expand the generalisability of our results since it is known that adults undergo a natural course of change in

sagittal spine curvature in the later decades of life with degenerative spinal diseases furthering the change, as hyperkyphosis is prevalent in 20-40% of older adults[15,17].

Understanding the difference between the means of repeated measurements led to a potentially important difference caused by degenerative spinal changes. The significant differences between means appeared to be driven by younger adults within normal spinal curvature ranges. This suggests that degenerative changes may decrease the variability in 'best posture' over a series of six image captures possibly due to reduction in spinal mobility, yet the small sample size of this study limits extrapolation of these particular findings. Additionally, analysing the difference between repeated measurements based on the order by pooling the data of the two assessors was important to help identify the best protocol for future use. The data in the thoracic and lumbar regions indicate only one significant mean difference, which was in the thoracic spine during the first image capture, suggesting that the second image capture may be more reliable to use. Since taking a second image only adds approximately 15 seconds to the overall testing time, the method would remain quick to execute with two image captures.

Since the first assessor palpated and identified the anatomical landmarks, these study results focus on the error of the sensor hardware, bespoke software, procedural instructions, the participants' interpretation of 'best posture' and innate postural variability. It is known that spinal landmark palpation is variable, even between experienced physiotherapists[134,135], therefore removing additional anatomical palpation and identification eliminated error stemming from two assessors' palpation skills. Innovative research has been conducted to develop automatic estimation of anatomical landmarks which could offer a good solution to error generated from palpation, however further validation for this system is still required[136].

While the sample size is adequate for ICC analysis of reliability for the full sample, it is not powered to measure differences in the subgroups based on age or the degree of curvature, which is a limitation to the generalisability of this part of the findings. With these limitations in mind, the results of this study lay the groundwork to test other aspects of Kinect sensor measurement reliability on the COSMIN pathway, such as test-retest reliability. Overall, these results suggest that using the Kinect sensor to simultaneously measure thoracic and lumbar curvature in the sagittal plane is reliable, relatively quick and reproducible.

4.3 Measurement test-retest reliability

4.3.1 Background and study aim

In order to have confidence in the change in an outcome measure, the test-retest reliability is an important psychometric property to test. The aim of this subgroup testing was to estimate the intrarater test-retest reliability in a clinical population.

4.3.2 Methods

Design

A small subgroup of participants from the cohort of the WiSPA study (described fully in Chapter 6) were measured by the same assessor at two time points with an interval of 3-14 days between them. This analysis was a secondary objective within the WiSPA study which was granted ethical approval by North West - Greater Manchester Central Research Ethics Committee (19/NW/0111).

Participants

Potential participants were recruited and enrolled into the WiSPA study as described in Chapter 6. For this subgroup, it was a convenience sample of participants who were practically able attend an additional research visit at the Nuffield Orthopaedic Centre before commencing their six sessions of group physiotherapy.

Procedures

A physiotherapist with musculoskeletal experience served as the assessor for both measurement time points.The time interval between the measurements was designed to be practical while still allowing for analysis of the test-retest reliability. In between these assessments, participants did not undergo any intervention aimed at changing spinal alignment or posture, and the time span between was a short enough that natural degenerative changes would not take place. The only deviation from the procedural methods described in Chapter 3 was that participants were instructed to stand looking forward and were given no postural cueing in an effort to capture

Table 4.3: Test-retest reliability results from WiSPA study cohort (n=9)

	ICC	Lower CI95%	Upper CI95%	p value
Thoracic kyphosis index				
Normal posture	0.859	0.496	0.966	0.001
Best posture	0.607	-0.040	0.896	0.031
Lumbar lordosis index				
Normal posture	0.883	0.567	0.972	<0.0005
Best posture	0.873	0.537	0.97	<0.0005
Kyphosis percentage				
Normal posture	0.905	0.637	0.978	<0.0005
Best posture	0.963	0.844	0.991	<0.0005

their normal posture. After two image captures, they were then instructed to stand in their 'best posture' for two additional image captures.

Outcome measures

The outcome measures tested were KI, LI and kyphosis percentage obtained by Kinect sensor images. Kyphosis percentage represents the percentage of the length of the curve that is kyphotic (see the Methods section of Chapter 5 for detailed description).

Statistical analysis

Two-way mixed, consistency, single measures ICC was used to determine reliability. Data was analysed using SPSS software version 25.

4.3.3 Results

There were nine participants included in this analysis. Test-retest reliability was high for thoracic kyphosis normal posture (ICC = 0.859), moderate for thoracic kyphosis best posture (ICC = 0.607), and high for lumbar lordosis normal and best posture (ICC = 0.833 and ICC = 0.873, respectively) (Table 4.3). Additionally, the kyphosis percentage showed very high reliability for both normal and best posture (ICC = 0.905 and ICC = 0.963, respectively).

4.3.4 Discussion

Although underpowered, the analysis of test-retest reliability was completed in a small but relevant cohort of people with spinal conditions. Since it was a convenience sample nested within a cohort study, there was no sample size calculation determined. The findings estimated all measures to be highly reliable in this small sample, with the exception of thoracic kyphosis best posture which showed moderate reliability. When examining the raw data, the lower reliability and wide confidence interval in thoracic kyphosis best posture was influenced by one participant with a substantial discrepancy between test-retest measurements. This could be related to back pain or muscular fatigue, but these characteristics were not taken into account and an adequate sample size would provide a more accurate picture of the ICCs. The results add to the profile of psychometric properties for the sagittal spine curvature measurement using the Kinect sensor, yet it is a research area which would benefit from a powered sample size for future testing.

4.4 Conclusions

Sagittal spine measurement using the Kinect sensor was successfully performed and aspects of the reliability and reproducibility were tested. The method was shown to have good test-retest reliability in a small clinical population and excellent intrarater and interrater reliability in a healthy population. The next chapter describes a study of the concurrent and criterion validity of this method in a clinical population.

Chapter 5

Validity testing of the Kinect sensor

5.1 Summary of contents

This chapter describes the **MAPS Study: Measuring Alignment and Posture in the Spine**, which tested the criterion and concurrent validity of the Kinect sensor compared to the gold standard of measurement and two commonly used clinical surface measurement tools in a clinical population.

5.2 Background and study aims

As described in Chapter 1, the gold standard for measuring sagittal spine curvature is the Cobb method from a lateral view spinal radiograph[11,52]. While it is a method that directly measures vertebral orientation and alignment, it has its drawbacks, including the operating and instrument costs, reliance on the morphology of two vertebral endplates versus the entire spinal shape, and importantly, the exposure to ionising radiation[11,51]. Due to the various obstacles that radiographs pose to convenient and regular measurement of the spine, there have been numerous non-radiographical, surface measurement tools developed and tested for both research and clinical use. While there are advantages specific to each tool, the shortcomings have left space for advanced technologies to step in to offer a more complete measurement tool in terms of accessibility, accuracy, robustness and versatility. Only two other studies[60,127] have specifically been designed to measure psychometric properties of the sagittal spine curvature and neither was in a clinical population. The primary aim of this study was to estimate the criterion validity of

thoracolumbar sagittal spine measurement by comparing the Kinect sensor to the radiograph. The secondary aims were to estimate the concurrent validity of the Kinect sensor compared to the flexicurve and digital inclinometer and to estimate the correlative relationships of exploratory curvature measures in a clinical population.

5.3 Methods

5.3.1 Design

This study was designed to assess criterion validity by retrospective analysis and to assess concurrent validity cross-sectionally. Criterion validity describes the extent to which a measure compares to the gold standard test, and concurrent validity describes the measure compared to another measure assessed at the same time. It was conducted and evaluated according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[137] and Critical Assessment Tool[59] guidelines on the COSMIN pathway for validity. The study was granted ethical approval by the South West - Central Bristol Research Ethics Committee (17/SW/0239) (see Appendix D1).

5.3.2 Participants

Potential participants were recruited via clinicians during clinic visits or by mail through electronic medical screening. The study had two parts, evaluating criterion and concurrent validity. Men and women over 18 years old were included in the concurrent validity study aspect if they were attending the specialist orthopaedic hospital for a spinal condition. If they had undergone a lateral radiograph of the full spine in the previous year, they were also involved in the criterion validity aspect of the study. Exclusion from participation included people who could not stand independently or had a diagnosed neurological condition affecting trunk control during standing; additionally, if a participant had a change in functional status or had undergone a medical procedure or treatment between the time of the radiograph and the research visit, they were excluded from the criterion validity analysis.

5.3.3 Procedures

All participants were given ample time to read Participant Information Sheet (Appendix D2) and ask questions about the study. Subsequently they provided informed consent (sample form in Appendix D3) for participation in the study. The study was conducted in accordance with the Declaration of Helsinki. During the research visit, a single assessor measured each participant using the three non-radiographical tools. The assessor, with more than 5 years of musculoskeletal physiotherapy experience, palpated the participants' spine as described in Chapter 3 and placed adhesive markers to identify C7, L1, and right and left PSIS. These marked landmarks were used for all clinical measurements. The order of measurement for the three tools was randomly selected at the time of participant registration. Demographic information including age, gender, height and weight was collected as well as back pain severity and medical history.

5.3.4 Outcome measures

Study outcome measures included thoracic and lumbar measurement using four tools: the Kinect sensor, radiograph (if applicable), flexicurve and digital inclinometer. Angles or angle indexes were measured by each tool and the thoracic/lumbar (T/L) ratio was calculated by: kyphosis angle or index ÷ lordosis angle or index. The full case report form is included in Appendix D4.

Kinect sensor

The procedures for the Kinect sensor were based on the protocol development from Chapter 3. Based on the previous reliability study findings which showed the variability of the first image captured, two images were captured and the second image was used for analysis. Participant positioning and instructions were conducted as described in Chapter 3. The assessor could see the image of the back momentarily but was blinded to the curvature measurements since the index was not calculated until after the research visit. Kinect data analyses were conducted using the software and methods previously described. Outcome measurements included KI, LI, T/L ratio and the additional analysis of *kyphosis percentage*. Kyphosis percentage is a characteristic of interest that emerged when examining numerous curvature images where the whole thoracolumbar curvature was kyphotic, but the corresponding kyphosis index did

not indicate an abnormal value. Therefore, this metric was potentially interesting in addition to the indexes and T/L ratio. To calculate the kyphosis percentage, kyphosis was established by a line from C7 to S2, the area above the line was considered kyphosis and the area after the intersection of the line and the curve was considered lordosis; kyphosis percentage was calculated by: $(\text{length of kyphosis region} \div \text{total length}) \times 100$ (Figure 5.1).

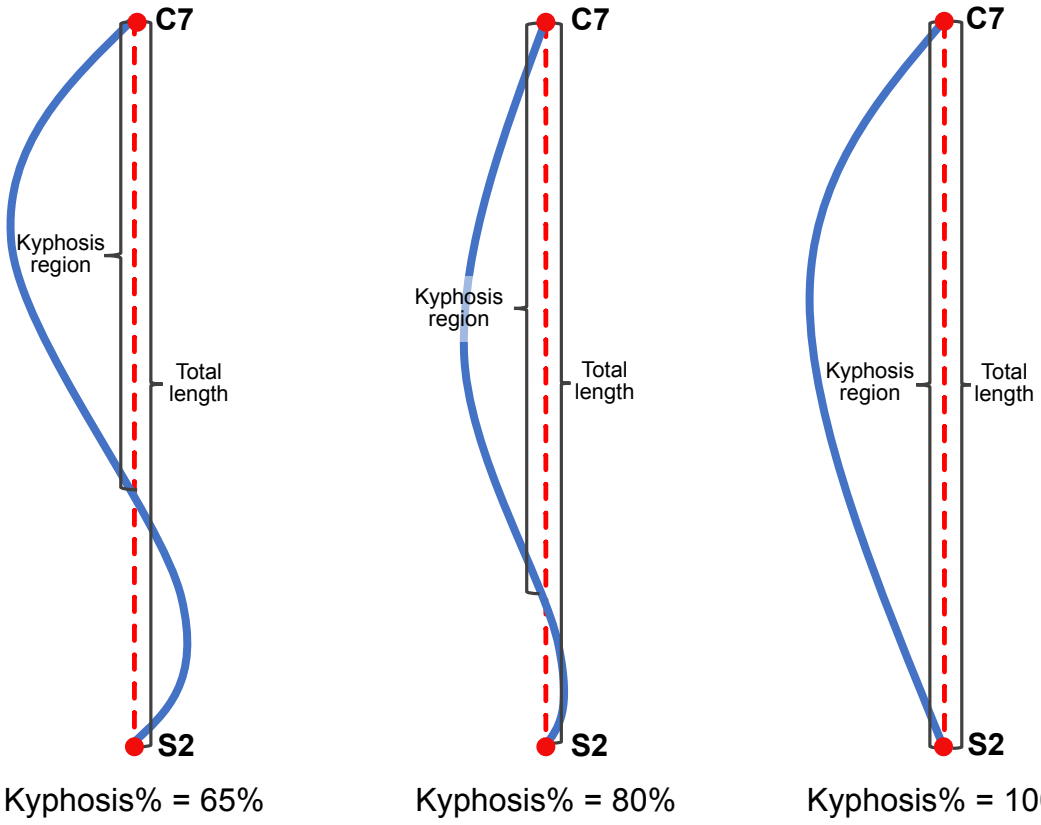


Figure 5.1: Example of kyphosis percentage curvatures. These are simplified schematics that illustrate kyphosis percentage from three theoretical curvature profiles.

Flexicurve and digital inclinometer

The assessor instructions for positioning during the flexicurve measurement were consistent with the previous instructions for the Kinect sensor. Using the marked anatomical landmarks previously described, the flexicurve was placed along the participant's spine from C7 to S2 and transferred to the graph paper with L1 marked on the tracing. From the traced spinal curve, the curvature length and height were manually measured, and KI and LI were obtained using the same equation from the Kinect procedures. For conversion to an angle from the KI, the following conversion from Greendale et al.[68] was used: $(3.1461 \times KI) + 5.1166$.

Using the standardised participant instructions, the assessor measured the thoracic angle with the dual digital inclinometer (The Saunders Group, Inc, Chaska, MN, U.S.A.) by placing one unit at C7 and the second unit at L1. The lumbar angle was measured by placing one unit at L1 and the second at the bisection of PSIS (based on the same anatomical markers as described). A digital angle was recorded for each region therefore the assessor could not be blinded.

Radiograph Cobb method

For participants with a standing lateral radiograph of the spine who met the study eligibility, the digital radiographic image was retrospectively assessed using the modified Cobb method. The thoracic kyphosis angle was digitally generated from the intersection of a line parallel to the superior vertebral endplate of T4 and inferior endplate of T12; T4 is used instead of T1 in kyphosis measurement due to the obstructed view of the upper thoracic vertebrae[52]. the lumbar lordosis angle was generated from the intersection of the superior endplate of L1 and inferior endplate of L5[11,52].

5.3.5 Statistical analysis

The sample size was calculated based on the following assumptions: (1) an effect size of r^2 = 0.57, obtained based on Greendale et al.[68] which tested the criterion validity of the flexicurve, and (2) a high correlation (ICC = 0.77) found between the Kinect sensor and flexicurve measureing standing kyphosis[127]; with these assumed values and an alpha error of 0.05 and power 0.80, a sample size of at least 26 participants was required. Descriptive statistics of the participants and curvature characteristics were analysed and described. Preliminary analyses tested each variable of interest for normality using the Shapiro-Wilk test, then visually examined the linear relationship between variables using a scatterplot matrix. Correlation analysis was based on Pearson's correlation coefficients for normal variables and Spearman's Rank-order correlation for non-parametric variables. Correlation coefficients were interpreted as very high (.90 to 1.00), high (.70 to .90), moderate (.50 to .70), low (.30 to .50), and negligible (.00 to .30)[138]. A simple linear regression analysis of the radiographic Cobb angle was used to create a conversion equation for the Kinect KI. Agreement between measurement values was assessed using Bland-Altman plots. Normality of differences for the plots was tested using the Shapiro-Wilk test. Statistical significance determined by $p<0.05$. Data was analysed using SPSS version 24

Table 5.1: Demographic and physical participant characteristics from the MAPS study

Full sample, n=38	
Age, y (mean ± SD (range))	58.7 ± 16.9 (22-82)
BMI, kg/m^2 (mean ± SD (range))	24.85 ± 4.22 (19.10-37.55)
Gender (female n (%))	29 (76%)
Pain (symptomatic n (%))	23 (60.5%)
Radiograph subgroup, n=29	
Age, y (mean ± SD (range))	56.9 ± 18.2 (22-82)
BMI, kg/m^2 (mean ± SD (range))	24.73 ± 4.34 (19.14-37.55)
Gender (female n (%))	23 (79%)
Pain (symptomatic n (%))	20 (70%)

software.

5.4 Results

Thirty-eight participants were recruited to the concurrent validity study and 29 of these participants had a recent radiograph eligible for primary outcome comparison and analysis for criterion validity. In the full sample, the mean (SD) age was 58.76 (16.91) years old and body mass index (BMI) was 24.85 (4.22); 76% were female and 61% reported back pain (Table 5.1).

Participants had a diverse range of primary spinal conditions including osteoporosis (n=4), ankylosing spondylitis (n=4), low back pain with and without radiating symptoms (n=8), vertebral fracture (n=2), mild to moderate scoliosis (n=17), and spinal stenosis (n=3). Descriptive measurements of the spinal curvature display an array of both thoracic and lumbar curves, spanning beyond normal ranges of thoracic kyphosis and lumbar lordosis (Table 5.2). The mean time span between the radiograph and the research visits was 49 days. There were no missing data.

5.4.1 Thoracic spine

The correlation coefficients indicated good concurrent validity within the thoracic spine between the Kinect sensor and flexicurve (r_s = 0.911, p <.0005) and the Kinect sensor and digital inclinometer (r = 0.817, p < .0005) (Table 5.3). In the analysis of criterion validity, the

Table 5.2: Descriptive thoracolumbar curvature characteristics from the Kinect sensor and radiographs (MAPS study)

	Mean (SD)	**Range**
Kinect sensor, full sample, n=38		
Kyphosis index	14.32 (5.69)	5.54-30.37
Lordosis index	8.57 (3.97)	1.26-16.05
T/L ratio	2.24 (1.97)	0.54-11.70
Kyphosis percentage	77.10% (14.74)	(48%-100%)
Kinect sensor, radiograph subgroup, n=29		
Kyphosis index	13.39 (4.53)	6.70-25.18
Lordosis index	8.62 (4.01)	1.26-16.05
T/L ratio	2.24 (2.18)	0.54-11.70
Kyphosis percentage	75.03% (13.78)	(49%-100%)
Radiograph, n=29		
Thoracic kyphosis angle (degrees)	43.83 (14.03)	19.4-88.3
Lumbar lordosis angle (degrees)	40.90 (16.51)	14.8-83.1
T/L ratio	1.25 (0.66)	0.47-3.38

Table 5.3: Correlation matrix for all measurement methods of the thoracic spine, lumbar spine and T/L ratio

		Radiograph (n=29)	**Flexicurve (n=38)**	**Digital inclinometer (n=38)**
Thoracic spine	Kinect sensor	0.696**	0.911**†	0.817**
	Digital inclinometer	0.672**	0.759**†	
	Flexicurve	0.542*†		
Lumbar spine	Kinect sensor	0.322	0.737**	0.739**
	Digital inclinometer	0.344	0.767**	
	Flexicurve	0.277		
T/L ratio	Kinect sensor	0.454*†	0.713**†	0.574**†
	Digital inclinometer	0.454*†	0.665**†	
	Flexicurve	0.249†		

**p<.05; **p<.001, † indicates Spearman's Rank-order correlation coefficient*

Kinect sensor also demonstrated good correlation in the thoracic spine when compared to the radiograph (r = 0.696, p<.0005) (Table 5.3). A linear regression analysis of thoracic angle using the Kinect kyphosis index (KI) values produces a conversion equation (r^2 = 0.484): Thoracic angle = (2.155 × Kinect KI) + 15.052.

Using this conversion equation, the agreement between Kinect sensor values and radiograph angles was examined using a Bland-Altman plot (Figure 5.2). On examination of the plot, there is a minimal positive bias towards the radiographic angle with one outlier beyond the lower limit of agreement, and the Shapiro-Wilk test indicated that the distribution of differences was normal (p = 0.447). The Bland-Altman plots displaying the agreement between the flexicurve and digital inclinometers both show two outliers beyond the limits of agreement. The agreement between the Kinect and flexicurve show more dispersion and less agreement as the index increases with three outliers.

5.4.2 Lumbar spine

Correlation analysis of the lumbar spine showed good concurrent validity between the Kinect sensor and the flexicurve and digital inclinometer, (r = 0.737, p<0.0005 and r = 0.739, p<0.0005, respectively). There was no correlation between the radiograph and Kinect sensor (r = 0.322,

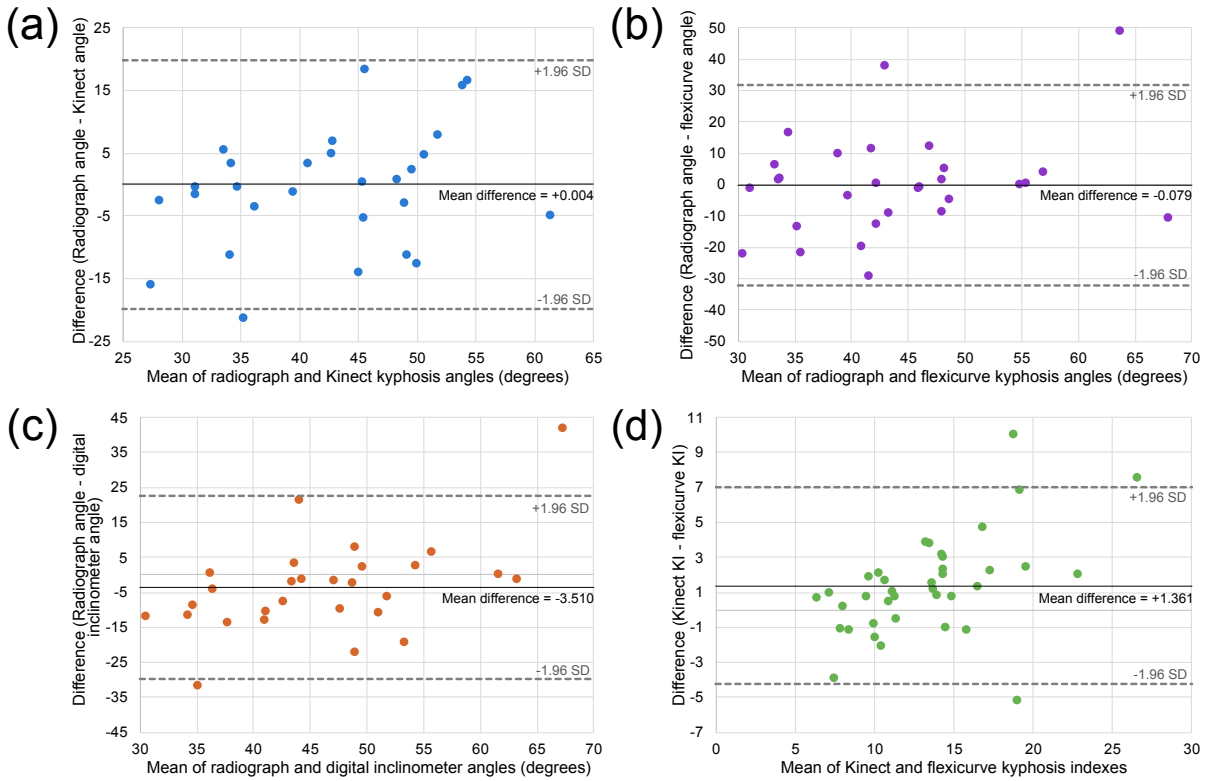


Figure 5.2: Bland-Altman plots for thoracic kyphosis. These plots display the thoracic kyphosis agreement between a) radiograph and Kinect sensor angles, b) radiograph and flexicurve angles, c) radiograph and digital inclinometer angles, and d) the Kinect sensor KI and flexicurve KI.

p=0.89) and similarly no significant correlation between the radiograph and the other measurement tools (Table 5.3). Since there was no detectable linear correlation between the Kinect LI and radiograph angle, a linear regression could not be used to convert the Kinect LI to an angle, thus agreement via a Bland-Altman plot could not be analysed.

5.4.3 Other sagittal spine curvature descriptors

Exploratory analysis of the T/L ratios and kyphosis percentage suggested correlative relationships with radiographic data. The correlation between T/L ratios showed significant positive correlations in all four measurement tools with the exception of the flexicurve to the radiograph. The Kinect sensor T/L ratio significantly correlated to the radiograph (r_s = 0.454, p=0.013), flexicurve (r_s = 0.713, p<0.0005) and digital inclinometer (r_s = 0.574, p<0.0005) (Table 5.3). Using a Bland-Altman plot to examine the agreement between the Kinect sensor and radiograph T/L ratios, two outliers occur beyond the lower limit of agreement (Figure 5.3).

The bias toward larger Kinect sensor T/L ratios appears as the mean increases. The two outliers affect the distribution of differences causing a violation of the test of normality. In addition

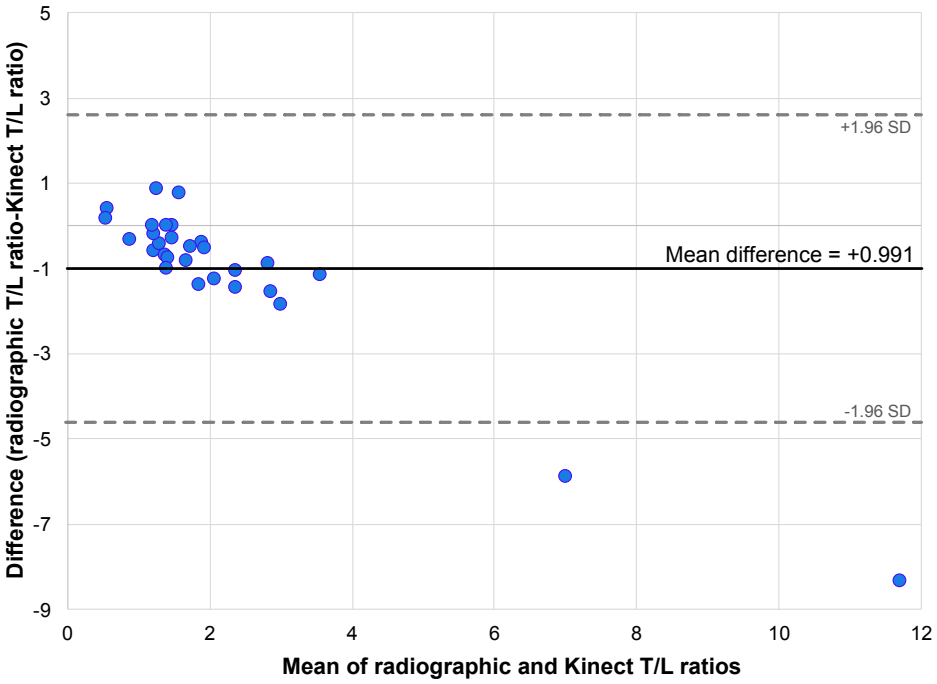


Figure 5.3: Bland-Altman plot for T/L ratio. This plot shows the agreement between the Kinect sensor and radiograph T/L ratios.

to the T/L ratios, the kyphosis percentage calculated from the Kinect sensor measurements showed a correlation with the radiographic lumbar angle (r = -0.408, p=0.028), radiographic T/L ratio (r_s = 0.592, p=0.001) and the Kinect sensor T/L ratio (r_s = 0.458, p=0.004).

5.5 Discussion

The Kinect sensor demonstrated concurrent validity with highly correlated measurements compared to the flexicurve and digital inclinometer in both the thoracic and lumbar regions of the spine. However, the criterion validity of the Kinect sensor, as measured by comparison with the gold standard Cobb angle of a lateral radiograph, was only established in the thoracic region. The T/L ratio measured by the Kinect sensor was highly correlated and in agreement with T/L ratio from the radiograph, and kyphosis percentage was correlated with the radiographic lumbar angle and T/L ratio.

5.5.1 Thoracic spine

The validity results in the thoracic spine demonstrate a consistently high correlation between all measurement tools. The Bland-Altman plots show agreement with the exception of a few

outliers. The consistency in which surface measurements correlate with the internal vertebral alignment is likely due to anatomical structure in the thoracic region of the spine. In the thoracic spine, the convex curvature naturally leads to less soft tissue covering the spinous processes, and therefore the surface curvature of this region is close in proximity to the underlying vertebrae in which a radiograph measures. Not only does the Kinect sensor correlate closely and agree with the radiograph, the flexicurve and the digital inclinometers also correlate to a similar extent. The flexicurve and the Kinect sensor have tighter correlations because they share a very similar method of curvature measurement and computation of an angle index. The digital inclinometer does not measure the curvature, but instead measures the surface angles at specific anatomical landmarks and does not allow for an actual visualisation of the curve as the Kinect sensor does. Since the flexicurve and digital inclinometer validity results from this study are comparable to previous studies[22,68,71], they serve as a direct reference for the performance of the Kinect sensor, which demonstrated higher correlation coefficients and better agreement with the gold standard in the thoracic region. When comparing the criterion validity of the Kinect sensor to other technologies, the Kinect sensor (r = 0.70) demonstrates a similar correlation to the radiograph as another surface topography method, rasterstereography (r = 0.75)[82]. These results suggest that the Kinect sensor performs similarly or better than other tools for thoracic kyphosis measurement. The strong correlative relationship between the Kinect sensor and flexicurve is comparable with the results from Quek et al. who found high correlation between these methods in a similar standing position (ICC = 0.77)[127].

5.5.2 Lumbar spine

Lumbar spine surface measurement has been less investigated in the validation of non-radiographic measurement tools. There are far fewer valid measurement tools and methods that examine the lumbar spine and they generally show poorer results than the thoracic region[58]. As the anatomical structure of the thoracic spine results in vertebral structures close to the surface, the concave curve of the lumbar spine leads to less exposure of spinous processes on the surface of the back as more soft tissue covers the area. The amount of soft tissue overlaying the bony structure is more variable in this region depending on the amount lordotic curvature and the amount of adipose tissue, possibly influenced by BMI. Additionally, the lumbar region spans over only five vertebrae, therefore the shorter spinal length can be more influenced by

error during surface measurement. These features of the anatomical structure make it difficult to directly compare a surface measurement to a radiograph and decreases accuracy; therefore, the method of comparing the lumbar region must be approached differently than the thoracic spine. These characteristics could be the reason the flexicurve and digital inclinometer correlation findings from this study (Table 5.3), as well as other validity studies, fail to show consistent correlative relationships with radiographic angles in the lumbar region[58]. However, one of the best performing tools, rastersterography, has demonstrated more promising results in a meta-analysis of seven studies that reported a strong correlation with the radiograph (r=0.71)[82]. Yet in the meta-analysis, the only study that did not investigate an AIS population measured a population with degenerative disc disease and the lumbar lordosis correlation with radiograph was weak[82,139], suggesting that certain homogenous populations, in particular AIS, may show better correlation with the radiograph. When the lumbar region has smaller lordosis angles or has a loss of lordosis, it influences the surface topography and begins to follow a closer pattern to the thoracic region. Loss of lordosis can be an acquired shape influenced by lumbar vertebrae or in response to regions above or below the lumbar region, and this change is associated with poorer functional outcomes[32,42], thus highlighting the importance of an accurate measurement tool.

Exploratory results of the T/L ratio and kyphosis percentage suggest a potential proxy measurement to detect a loss of lordosis. The Kinect sensor measurement of thoracic and lumbar regions concurrently has led to a more comprehensive view of spinal curvature as the relationship between the two regions is important to evaluate. When the T/L ratio is above 1, it suggests that the thoracic curvature is more dominant; a ratio below 1 suggests the lumbar curvature is more dominant. The amount of kyphosis in relation to the entire curve can shed light on the sagittal balance of the individual since as kyphosis close 100% does not describe the amount of curvature, but describes a lumbar region that is no longer naturally lordotic, which is required for a balance and equilibrium in an upright spine. The kyphosis percentage showed a significant moderate correlation with the radiograph lumbar angle, which was not detected between the Kinect LI and the radiograph lumbar angle. Additionally, the T/L ratio has been shown to have a correlative relationship with functional measures such as gait speed and balance[140]. While the Kinect lumbar measurement does not demonstrate direct validity against the gold standard, the Kinect T/L ratio, which was moderately correlated to the radiograph T/L

ratio, may provide value to measuring the Kinect LI in this context. These additional descriptors of the spine, notably the kyphosis percentage, may be helpful when looking at how the thoracic and lumbar regions affect or are affect by physical function.

5.5.3 Potential utility of the Kinect sensor

As the findings from this study show, the Kinect sensor allows for a quick, comprehensive capture of the thoracolumbar curvature which can be analysed to understand not only the thoracic spine angle, but the kyphosis percentage and the T/L ratio to better understand the full thoracolumbar sagittal curvature. The relationship between the two regions is important to evaluate. The additional descriptors of the spine, T/L ratio and kyphosis percentage, which are easily computed from the digital data produced by the Kinect sensor, may be helpful when looking at the relationship between the thoracolumbar spine and physical function, instead of relying on a single angle to approximate the spinal curvature. Lumbar lordosis, not thoracic kyphosis, has shown to significantly correlate with radiographic pelvic alignment parameters[4,141], an important aspect of sagittal spine curvature which is difficult to measure with surface measurement tools. Therefore, it is pertinent to include lumbar measurement when aiming to understand sagittal spine curvature instead of a sole focus on the thoracic region, especially in relation to physical function measures. An additional benefit of the Kinect sensor is its potential beyond the sagittal plane. Combining this comprehensive sagittal profile with its full capacity of the surface topography to measure the transverse and frontal planes could be a powerful clinical assessment tool. From the participant characteristics described this study, many had a diagnosed scoliosis and other degenerative spinal conditions often influence more than one anatomical plane. Since measurements the frontal and transverse planes in people with AIS have shown to be comparable with radiographic measures[128], it would be the natural next step to integrate all planes.

5.5.4 Limitations

The limitations in this study include the sample size, which was powered for validity analysis of the thoracic region, not powered for the lumbar region or the other curvature descriptors. While the clinical population had a variety of spinal curvature profiles, there were too few with severe hyperkyphosis to fully generalise into the hyperkyphotic population. In addition, the sample

may have been too heterogeneous to detect a correlation with the radiograph in the lumbar spine. From a methodological standpoint, the reference and index tests were not conducted concurrently for criterion validity due to practical and ethical considerations taken into account during the study design. The exclusion criteria aimed to mitigate spinal curvature changes during this gap since normal degenerative change is slow and short-term changes most likely to occur with a decline in physical status or as a result of a targeted intervention.

5.6 Conclusions

The findings from this study showed the Kinect sensor is a valid tool for thoracic spine measurement compared to the accepted gold standard radiograph. The Kinect sensor demonstrated concurrent validity in the thoracolumbar spine compared to the two commonly used clinical tools. Furthermore, the Kinect sensor demonstrates potential for a more robust and meaningful description of sagittal curvature in the thoracic and lumbar regions using the additional descriptors. Using this tested method and measurement tool, the final study described in Chapter 6 aimed to take into account the characteristics of sagittal spine curvature described in this chapter and relate them to aspects physical function, including gait, dynamic balance and self-reported outcomes of mobility and QoL.

Chapter 6

Clinical implementation of the Kinect sensor

6.1 Summary of contents

This chapter describes the **WiSPA Study: Walking and balance related to sagittal Spine Posture and Alignment**, which explores the relationship between physical function measures and sagittal spine curvature using the tested method for the Kinect sensor described in Chapters 3, 4 and 5.

6.2 Background and study aims

As introduced in Chapter 1, the relationship between sagittal spine curvature and physical function is tangled and unclear in many aspects. There is no clear consensus in the literature about the effect of thoracic kyphosis on balance and gait. While several studies have shown thoracic hyperkyphosis relating to poorer gait performance[30] and increased likelihood of future falls in both active older adults[39] and people with osteoporotic vertebral fractures[40], other studies have shown no significant association of postural balance and falls with thoracic kyphosis, yet found loss of lumbar lordosis and increased spinal inclination did associate[28,29,42,140]. Therefore, finding more clarity in the specifics of the relationship with dynamic balance is important to explore especially because of the serious implications for people, such as decreased QoL and increased risk of falls. Falls are of particular concern due to the prevalence in older adults and

the economic burden imposed from consequent hospitalisations and rehabilitation[36–38]. The fall statistics and altered gait performance are documented within the overall ageing population, but they are likely to be more concentrated in vulnerable populations, such as older adults with sagittal plane deformity or imbalance[31]. However, there remains conflicting evidence preventing clarity in this complex relationship.

The PROVE secondary analysis described in Chapter 2 attempted to shed light on the relationship between thoracic kyphosis and physical performance, functional reach and walking capacity in a population with OVF. The findings showed a weak correlation between thoracic kyphosis and these three aspects of physical function. Several other RCTs that have tested physiotherapy-related interventions and measured the effect on thoracic kyphosis, yet the focus has been solely on the thoracic region, not the lumbar region or other aspects of spinal curvature[108,142,143]. A focus on only the thoracic region of the spine can leave out pertinent information about how the sagittal spine curvature can influence physical function, as previous literature has highlighted[28,29,42,140]. Therefore, building on the PROVE exploratory analysis findings, the WiSPA Study was designed to look more closely into the relationship by expanding the sagittal spine curvature measurement to the thoracolumbar region with additional descriptors of the curvature and testing aspects of physical function that targeted dynamic balance, spatiotemporal gait analysis and self-reported outcome measures including health-related QoL, balance confidence and gait efficacy. Examining these aspects of the relationship longitudinally after physiotherapy exposure aimed to add to the understanding of how a specific physical profile of sagittal spine curvature associates or predicts physical function, falls risk and QoL.

The original aims of this study were (1) to examine the feasibility using the Kinect sensor as an outcome measure tool in a clinical setting, (2) to measure the magnitude of sagittal spine curvature change after physiotherapy exposure and (3) to estimate the longitudinal relationship between sagittal spine curvature and physical function in people with degenerative spinal conditions. However, due to the unforeseen circumstance of the COVID-19 pandemic which disrupted the final six months of the study, the aims were modified post hoc in order to better interpret the data that were successfully collected. Since numerous follow-up physical assessments could not be conducted, the underpowered study remained viable to assess the feasibility of the Kinect sensor as an outcome measure, but other aims shifted to a more in-depth exploratory analysis of the potential relationships between sagittal spine curvature and physical

function.

Revised Study aims:

1. To examine the feasibility using the Kinect sensor as an outcome measure tool in a clinical setting.

2. To describe the sagittal spine curvature and clinical profile and compare descriptive profiles of osteoporosis and lumbar spinal stenosis clinical populations.

3. To estimate the extent of the association between sagittal spine curvature characteristics and physical and self-reported gait, balance and QoL outcome measures.

4. To compare the longitudinal change in self-reported QoL, balance confidence, and gait efficacy based on kyphosis severity.

6.3 Methods

6.3.1 Design

This was a longitudinal cohort study with outcome measures taken at three time points: baseline, post 6-week physiotherapy class and 6 months. The study was granted ethical approval by North West - Greater Manchester Central Research Ethics Committee (19/NW/0111) (see Appendix E1) and registered on the ClinicalTrials.gov database.

6.3.2 Participants

Potential participants were recruited via clinicians during physiotherapy visits in a specialist orthopaedic hospital. Men and women over 18 years old were included if they had a degenerative spinal condition and a referral to outpatient group physiotherapy; they were willing and able to give informed consent for participation; and if they were able to understand and participate safely in a physiotherapy measurement assessment. Exclusion criteria were the inability to stand independently or neurological conditions which altered motor function and/or postural control.

6.3.3 Procedures

All participants were given ample time to read Participant Information Sheet (Appendix E2) and ask questions about the study. Subsequently they provided informed consent (sample form in Appendix E3) for participation in the study. The study was conducted in accordance with the Declaration of Helsinki. Baseline measurement were collected before participants took part in a physiotherapist-led group class dedicated to one of two conditions: osteoporosis or lumbar spinal stenosis. Each class, with three to eight patients enrolled, involved both education and exercise components tailored to the spinal condition and level of the patients. The classes were held once per week for a total of six sessions. Participants were measured upon completion of the six group sessions and additionally 6 months after baseline.

6.3.4 Outcome measures

Physical and self-reported measures were collected at three time points, the physical outcomes included: spinal curvature, tragus-to-wall distance (TWD), timed loaded standing (TLS), four square step test (FSST), two-minute walk test (2MWT) and spatiotemporal gait analysis; and the self-reported outcome measures included: 36-item Short Form Health Survey (SF-36), Activities-specific Balance Confidence (ABC) Scale, Modified Gait Efficacy Scale (mGES), and pain visual analogue scale (VAS). The outcome measures are described below and the full case report form is included in Appendix E4.

Sagittal spine curvature was measured using the Kinect sensor conducted in accordance with the measurement protocol described in Chapter 3. Based on the findings from Chapter 5, the following relevant curvature outcomes were included: kyphosis index (KI), lordosis index (LI), Thoracic/Lumbar (T/L) ratio, and kyphosis percentage. For the KI and LI measures, a higher number indicated a larger spinal angle, for the T/L ratio, values over 1 indicated greater sagittal spine imbalance[144], and for kyphosis percentage, zero represented no kyphosis curvature and 100% represents full thoracolumbar kyphosis curvature.

Tragus-to-wall distance is a clinical measurement that estimates a person's global forward flexed posture; it has been shown to be reliable (ICC = 0.90-0.94) with moderate validity (r = 0.52)[145]. For the test, the participant stood with their heels against a wall and was prompted to stand up tall while looking straight ahead; from this position, the assessor ensured the

participant's head was in neutral and then used a tape measure to measure the horizontal distance from their tragus to the wall, with a shorter distance indicating less forward posture.

Time loaded standing is a clinical test that assesses back extensor muscle endurance; it has been shown to have moderate concurrent validity (r = 0.35-0.50) and high reliability (ICC = 0.81-0.89) in people with osteoporosis[104,105]. In this test, the participant held a set of 1.0-kg dumbbells in their hands and tried to maintain a position of 90° of shoulder flexion and extended elbows for as long as possible. The test could be stopped by the participant when fatigue or pain caused discomfort or when the assessor saw the test position could not be maintained. The time this position was held was recorded with a maximum test duration of 180 seconds.

The *Four Square Step Test* is a valid (r_s = 0.88) and reliable (ICC = 0.89-0.99) clinical measure of dynamic balance in older adults[146]. The participant was timed during multi-directional stepping into four different quadrants separated by canes. The participant was instructed to step forward over a cane, step to the right sideways over a cane, step backwards over a cane and step to the left sideways over a cane, then the sequence was immediately repeated in reverse and the time stopped. The participant started the task over if it was completed in the wrong sequence. The total time taken to complete this test was recorded, with a lower score indicating better balance performance.

The *Two-minute walk test* is a valid (r = 0.78-0.97) and reliable (ICC = 0.94-0.96) clinical test to measure walking capacity in older adults[147]. The participant walked 20-metre laps on a flat, unobstructed path for two minutes covering as much distance as possible; the distance completed during the two minutes was recorded. Participans walked with or without an assistive device according to their comfort and need.

Gait analysis was captured using an inertial measurement unit (IMU) (LPMS-B2, Life Performance Research, Japan) which sampled triaxial accelerometer and gyroscope data at a frequency of 100 Hz; it was placed on the participant's lower back at L4, which was considered their projected CoM[148]. The participant walked two lengths on an unobstructed 10-metre path at a self-selected pace and the IMU recorded spatiotemporal gait parameters[149]. The IMU data were analysed using a custom program written in LabVIEW2015 (National Instruments, Ireland) where vertical CoM excursion was obtained using IMU translatory acceleration in combination with quaternion rotation matrices and double integration[150]; spatiotemporal gait parameters were calculated using to Zijlstra's inverted pendulum model where step length was estimated

based upon vertical CoM excursion leg length[151]. The gait variables of interest in this ageing population[152] were: walking speed (m/s) (distance walked divided by time), stride length (m) (distance between two successive placements of the same foot), and cadence (steps/min) (number of steps taken per minute). Gait variability was derived by using the coefficient of variation (CoV) (ratio of SD over mean) of the stride length.

The *SF-36* is a widely used 36-item self-reported questionnaire that measures health-related quality of life. It contains 36 questions under eight domains. The total score is 0-100, with 100 being the highest quality of life; it can also be split into a Physical Component Score (PCS) and Mental Component Score (MCS), both converted to a similar 0-100 scale.

The *ABC Scale* is a 16-item self-reported questionnaire that measures a participant's falls-related self-efficacy. It is reliable and valid in an elderly population[153]. The scores range from 0-100%, with 100% representing the highest confidence in balance activities.

The *mGES* is a 10-item self-reported questionnaire that measures a participant's walking confidence in challenging everyday circumstances. It has shown excellent reliability, validity and consistency in the elderly population[154]. Scores range from 10-100 with 100 representing the most confidence in all of the tasks.

Pain VAS was used to measure self-reported pain intensity at rest and during movement on a scale from 0-10, 10 representing the worst pain possible.

6.3.5 Statistical analysis

Participant characteristics and baseline measures were analysed and described using standard descriptive statistics. The full sample was divided into two groups based on the primary underlying spinal condition and t-tests were used to compare the groups at baseline. Shapiro-Wilk tests of normality were run for each outcome of interest to determine the use of subsequent parametric or non-parametric tests. Associations between outcome measures were determined by Pearson's correlation or Spearman's Rank-order correlation. Correlation coefficients were interpreted as very strong (0.80 to 1.00), strong (0.60 to 0.79), moderate (0.40 to 0.59), weak (0.20 to 0.39), and negligible (0 to 0.19). Repeated measures ANOVA was used to investigate self-reported outcome measure changes over time. Separate analyses were conducted for the three dependent variables (SF-36, ABC scale and mGES) with a fixed variable of kyphosis severity (normal kyphosis and hyperkyphosis categorisation based on the threshold established

in Chapter 2). Age, TLS and sex were adjusted for in the analyses and irrelevant covariates removed. Pairwise comparisons were analysed using the Sidak test. Statistical significance determined by $p<0.05$. Data were processed and analysed using and SPSS version 25.0.

6.4 Results

Forty-one participants were recruited from established physiotherapy group classes over nine months. While the classes included six consecutive weekly sessions, they commenced every 7-10 weeks in order to practically ensure the class was fully enrolled with four to eight patients. The osteoporosis classes had fewer patients than originally projected by the lead physiotherapist due to a decreased number of appropriate patients referred to the department. Of the patients enrolled in the physiotherapy classes, all expressed interest in the study, but three patients did not participate because they were unable to attend a baseline assessment before their first class began. Three participants in the lumbar spinal stenosis classes dropped out of the class, and consequently the study, due to advanced symptoms. Twenty-nine full post-physiotherapy follow-up assessments were completed and an additional eight self-reported questionnaires were collected; the 12 missing follow-up assessments were attributed to study drop-out (n=3), illness or medical issues (n=5), and the COVID-related study pause (n=4). Thirteen full 6-month follow-up assessments were completed and an additional 22 self-reported questionnaires were collected; the 28 missing follow-up assessments were attributed to study drop-out (n=6) and COVID-related study pause or precautions (n=22) (Figure 6.1).

Of the 41 participants, 19 had a primary spinal condition of osteoporosis and 22 had a primary spinal condition lumbar spinal stenosis (Table 6.1). The mean (SD) age was 74.0 (7.4) years, BMI was 27.44 (5.30) kg/m^2, 27 participants were female, and 44% of participants reported one or more falls in the previous year. Five participants used assistive devices during community ambulation and during the physical assessments, including rollators (2 participants), two sticks (1 participant) and a single stick (2 participants). The two participants who used rollators did not perform the FSST.

Sagittal spinal curvature characteristics and all baseline outcome measures are described in Table 6.1 as well as the subgroups based on spinal condition to compare the baseline differences between them. There were no significant differences between age, BMI or previous falls in

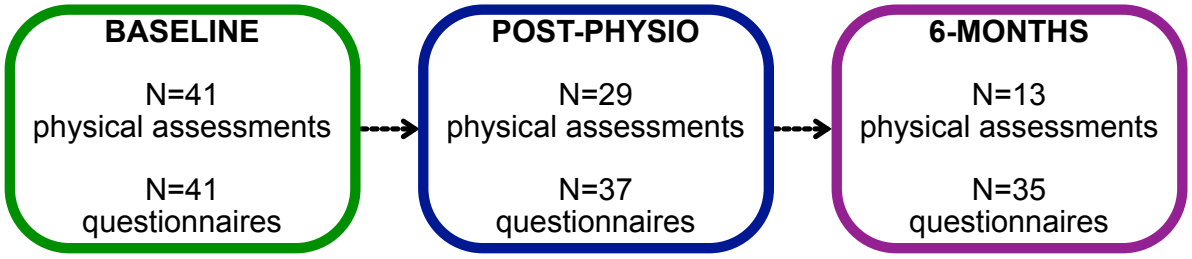


Figure 6.1: WiSPA study participant flow chart.

comparing both subgroups. The osteoporosis group did have significantly more females (84% compared to 50%) than the lumbar spinal stenosis group which is similar to the population-level prevalence of diagnosed osteoporosis between gender. The sagittal spine curvature descriptors showed no difference between LI, T/L ratio and kyphosis percentage, but the osteoporosis subgroup had significantly more severe thoracic kyphosis. The physical outcome measures showed differences in TWD and TLS, indicating that the osteoporosis subgroup had on average a more flexed standing posture and poorer back extensor endurance. Walking endurance, dynamic balance and all spatiotemporal gait parameters showed no difference between groups. All self-reported outcome measures of QoL, balance confidence, gait efficacy and pain showed no subgroup differences. The similarities enabled the spinal stenosis subgroup to act as a matched sample receiving group physiotherapy treatment. The marked difference in thoracic kyphosis indicates the importance of splitting the whole group and exploring the osteoporosis subgroup separately for potential curvature-physical function relationships.

Correlation tests between spinal curvature characteristics and physical function measures showed weak correlations as a whole group (Table 6.2). Analysis of the osteoporosis subgroup revealed several correlative relationships: LI had a significant moderate correlation with gait variability (r_s = 0.556, p = 0.02; R^2 = 0.309; b_1 = 0.017 (95% CI: 0.019, 0.195)). Additionally, there are several other moderate correlations which, although not significant, suggest an association that may emerge in an adequately powered sample. These correlations included KI with FSST (r_s = -0.416) and cadence (r_s = 0.436), LI with FSST (r_s = -0.424) and cadence (r_s = 0.419), and kyphosis percentage with mGES (r_s = -0.429).

Finally, repeated measures ANOVA analyses were conducted to measure longitudinal changes of balance confidence, gait efficacy and QoL based on baseline kyphosis severity and adjusted for age, sex and TLS. Sex was not a significant covariate and thus removed from

Table 6.1: Participant baseline measures for WiSPA study – full sample and subgroups with comparison

Baseline demographics & characteristics	**N**	**Full sample**	**OP**	**LSS**	**p value**
Age, y (mean (SD))	41	74.0 (7.4)	74.8 (9.1)	73.3 (5.6)	0.523
BMI, kg/m^2 (mean (SD))	41	27.77 (5.30)	26.68 (5.24)	28.71 (5.29)	0.224
Sex, n female (%)	41	27 (66%)	16 (84%)	11 (50%)	0.021
Falls in past year, n (%)	41	No falls = 23 (56%)	12 (63%)	11 (50%)	0.406
		1 fall = 15 (37%)	7 (37%)	8 (36%)	
		2+ falls = 3 (7%)	0 (0%)	1 (5%)	
Primary spinal condition, n (%)	41	OP = 19 (46%)			
		LSS = 22 (54%)			
Physical outcome measures	**N**	**Mean (SD)**	**OP**	**LSS**	**p value**
Sagittal spine curvature					
Kyphosis index	41	14.69 (6.50)	18.84 (6.96)	11.10 (3.15)	<0.0005
Lordosis index	41	8.98 (6.35)	10.71 (6.76)	7.49 (5.71)	0.107
T/L ratio	41	2.04 (1.48)	1.76 (1.46)	2.28 (1.49)	0.273
Kyphosis percentage	41	81% (13%)	84% (11%)	79% (15%)	0.211
TWD, cm	41	18.1 (4.4)	20.1 (3.0)	16.3 (4.6)	0.004
FSST, s	39	18.29 (9.22)	20.33 (10.64)	16.53 (7.64)	0.204
TLS, s	41	49.59 (51.51)	25.33 (29.52)	70.53 (57.58)	0.003
2MWT, m	41	95.96 (29.74)	92.74 (28.32)	98.74 (31.31)	0.526
Spatiotemporal gait parameters					
Walking speed, m/s	36	0.86 (0.22)	0.83 (0.22)	0.89 (0.22)	0.443
Cadence, steps/min	35	105.3 (13.6)	107.0 (14.9)	103.7 (12.4)	0.473
Stride length, m	35	1.24 (0.16)	1.23 (0.16)	1.25 (0.17)	0.706
CoV of stride length, m	35	3.31 (1.58)	3.06 (1.30)	3.53 (1.82)	0.388
Self-reported outcome measures					
SF-36 total score, 0-100	41	44.37 (12.46)	45.68 (10.18)	43.26 (14.28)	0.546
SF-36 PCS, 0-100	41	35.75 (13.48)	36.61 (13.45)	35.00 (13.77)	0.708
SF-36 MCS, 0-100	41	55.17 (19.62)	57.57 (17.05)	53.10 (21.78)	0.475
ABC Scale, 0-100%	41	59.48% (18.99%)	62.50 (17.21)	56.88 (20.43)	0.351
mGES, 10-100	41	65.71 (19.88)	69.79 (19.38)	63.18 (20.07)	0.226
Current pain level VAS, 0-10	41	4.3 (2.5)	3.8 (2.3)	4.8 (2.7)	0.210
Pain level VAS, 0-10	41	5.9 (2.1)	5.6 (1.9)	6.1 (2.3)	0.466

Table 6.2: Sagittal spine curvature and physical function correlations from the WiSPA study

		FSST	2MWT	Walking speed	CoV stride length	Stride Length	Cad-ence	SF-36	SF-36 PCS	SF-36 MCS	ABC	mGES
Full sample												
KI	r	-0.056	0.021	0.064	-0.074	0.027	0.168	-0.11	-0.035	-0.134	0.12	0.229
	n	39	41	36	35	35	36	41	41	41	41	41
LI	r	-0.18	0.012	0.032	0.161	-0.079	0.283	-0.166	-0.287	0.014	-0.078	-0.016
	n	39	41	36	35	35	36	41	41	41	41	41
T/L ratio	r	-0.002	0.106	0.089	-0.214	0.156	-0.068	0.13	0.281	-0.028	0.03	0.047
	n	39	41	36	35	35	36	41	41	41	41	41
Kyphosis %	r	0.156	-0.163	-0.202	-0.258	-0.094	-0.24	0.065	0.154	0.084	0.02	-0.067
	n	39	41	36	35	35	36	41	41	41	41	41
Osteo-porosis												
KI	r	**-0.416**	0.349	0.317	0.206	0.066	0.436	-0.002	0.053	-0.221	0.091	0.191
	n	18	19	18	17	17	17	19	19	19	19	19
LI	r	**-0.424**	0.136	0.300	**0.556***	0.064	0.419	-0.298	-0.397	0.014	0.082	-0.048
	n	18	19	18	17	17	17	19	19	19	19	19
T/L ratio	r	-0.051	0.175	-0.123	-0.358	0.029	0.086	0.126	0.384	-0.135	-0.082	-0.144
Kyphosis %	r	0 . 2 9	-0.286	-0.374	-0.296	-0.294	-0.380	0.078	0.148	-0.012	-0.3	-0.429
	n	18	19	18	17	17	17	19	19	19	19	19

the models. ABC scores were normally distributed as assessed by Shapiro-Wilk test (p>0.05) and the assumption of sphericity was not violated, as ($\chi^2(2)$ = 0.976, p=0.699). There was no significant interaction or main effect of time, but there was a significant between-subjects effect of kyphosis severity (F(1,30) = 10.562, p=0.003, partial η^2 = 0.260), with an ABC scale EMM of 56.03 (95%CI 49.64, 62.62) in normal kyphosis compared to 72.37 (95%CI 64.90, 79.85) in hyperkyphosis. Post hoc analysis with Sidak adjustment revealed a lower mean by 16.35 (95%CI 6.07, 26.62) was statistically significant (p=0.003). mGES scores were also normally distributed and with the assumption of sphericity ($\chi^2(2)$ = 0.937, p=0.390). Similar to the ABC scale, there was no significant interaction or main effect of time, but there was a significant between-subjects effect of kyphosis severity (F(1,30) = 11.19, p=0.002, partial η^2 = 0.272), with a mGES EMM of 61.20 (95%CI 54.39, 68.04) in normal kyphosis compared to 78.59 (95%CI 70.87, 86.32) in severe hyperkyphosis. EMMs over time Sidak adjustment revealed the lower score by 17.39 (95%CI 6.77, 28.01) was statistically significant (p=0.002). Figure 6.2 displays the main effects between kyphosis severity in ABC and mGES outcomes. Differing from the patterns of the ABC and mGES, SF-36 scores (normally distributed and sphericity assumed) showed no significant interaction or main effects of time or kyphosis severity.

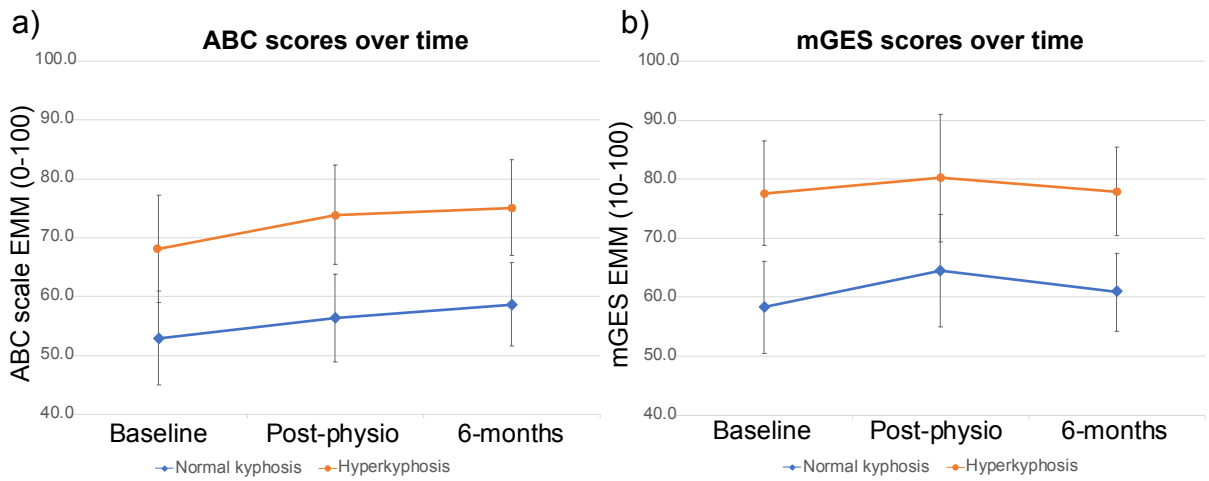


Figure 6.2: Longitudinal EMMs of ABC and mGES.Both outcome measures show a similar pattern of no change over time with a significant difference between normal kyphosis and hyperkyphosis scores with error bars representing 95%CI.

6.5 Discussion

The exploratory analysis of these study findings generally found good acceptance and performance of the Kinect sensor as a measurement tool, but weak or null relationships between sagittal spine curvature and physical function in the full sample of older adults with mixed degenerative spinal conditions. There was a high recruitment rate from patients enrolled in the classes. As a pragmatic study conducted in a clinical setting, both participants with osteoporosis and lumbar spinal stenosis as a primary condition were included. However, splitting the full sample and taking into account the differences between osteoporosis and lumbar spinal stenosis revealed patterns in the osteoporosis participants in particular.

6.5.1 Osteoporosis and lumbar spinal stenosis subgroup differences

The demographic comparisons at baseline showed age-matched populations between the two groups. At baseline they had a similar walking speed, QoL, ABC, mGES, and pain levels. The differences between groups were only in thoracic kyphosis, TLS and sex, as more females were represented in the osteoporosis subgroup. These differing characteristics were expected due known mechanisms of osteoporosis that can cause increased kyphosis which is associated with weaker back extensor musculature[155] and the higher incidence of the condition in females compared to males; thus TLS and sex could be considered for use as covariates where appropriate. Splitting the full sample was also important since the relationship between spinal curvature and physical function does not appear to occur independent of a symptomatic spinal condition. While previous studies have used non-specific older populations[34,108,119], symptomatic lumbar spinal stenosis and osteoporosis appear to confound the relationship between spinal curvature and physical function. While potential relationships can be established in the osteoporotic population, the same patterns are not apparent in lumbar spinal stenosis. This could be because the performance of physical function measures of interest is highly dependent on leg function and thus confounded by radiating lower limb symptoms caused by a stenotic spinal canal compressing the nerves. Therefore, it may not be possible to isolate a clear relationship between spinal curvature and physical function in an older population without analysing based on the presence or absence of certain symptomatic spinal conditions. The lack of associative relationships in the full sample could also be due to how these different spinal conditions progress and compensate

through the spine, pelvis and lower extremities[156–158]. In the osteoporotic population, it is more common for hyperkyphosis in the thoracic spine to lead initially to hyperlordosis in the lumbar spine to compensate. Once this compensation is no longer effective, the lumbar spine begins to flatten and the curvature transitions into full thoracolumbar kyphosis with resultant anterior sagittal imbalance[159]. The degenerative curvature changes and compensations in lumbar spinal stenosis progress in a different order. The thoracic spine remains relatively unchanged while flattening of the lumbar spine is the first sagittal spinal compensation that occurs in order to decrease the symptomatic effects of a narrowing lumbar spinal canal[160]. The flattening of the lumbar spine causes compensatory pelvic retroversion and can sometimes result in compensatory knee flexion and reduced thoracic kyphosis to maintain upright sagittal balance[74]. These examples demonstrate why the results from this study are weak when analysing both conditions together as well as why the literature around sagittal spinal curvature and physical function is at times contradictory.

6.5.2 Potential relationships in the osteoporosis subgroup

The associations in the full sample showed very weak correlations which could be hidden due the differences between the two spinal conditions as described above. However, analysis of the osteoporosis subgroup revealed several correlative relationships. Recognising the underpowered sample size in this subgroup (n=19), the relevance of the correlations was not based on the p-value but a threshold of 0.4 indicating moderate correlation. As the p-value is related to the sample size, it can be assumed that with a larger sample these correlations would emerge as statistically significant. The osteoporosis subgroup demonstrated potential associative relationships between aspects of sagittal spine curvature and dynamic balance, gait variability and cadence. Findings suggested moderate correlation of lumbar lordosis with gait variability and cadence. The positive correlations with gait variability and cadence meant that a higher degree of lumbar lordosis associates with higher cadence and gait variability; these compensatory curvature and gait characteristics have feasibly led to less than optimal walking efficiency in order to prevent a decline in walking speed[161]. De Groot et al. showed that in a group of older adults, without a specific diagnosed spinal condition, walking speed was no different between people with and without flexed posture, but gait variability, as measured by CoV of stride time, was higher in people with flexed posture[31]. This suggests that altered spinal curvature, not

specific to any spinal region, can lead to compensatory gait variation in order to maintain walking speed. While an increase in lordosis and increase in gait variability seems to contradict the negative impact of loss of lumbar lordosis, only a single participant in this subgroup had a loss of lumbar lordosis, therefore the sample had a narrow variability in lumbar curvature thus the correlation cannot extend into more advanced sagittal imbalances that include lumbar kyphosis. Thoracic kyphosis and lumbar lordosis were negatively correlated with FSST, meaning that higher degrees of curvature in both regions correlated with better FSST performance. While this seems counterintuitive that a higher degree of thoracic kyphosis would mean a better FSST score, it could be again attributed to the compensatory relationship between kyphosis and lordosis (r_s = 0.440, p=0.004). In these participants specifically, the more severely hyperkyphotic still exhibited lumbar lordosis compensation. Lastly, kyphosis percentage correlated negatively with mGES suggesting that when the thoracolumbar curvature becomes more predominantly kyphotic as a whole, gait efficacy scores are lower. Higher kyphosis percentage correlated with a slower walking speed (r = -0.374) which supports negative correlative relationship with self-reported gait efficacy. As kyphosis percentage is an exploratory curvature descriptor, it has not been specifically described in other studies, but generally supports the relationship of a kyphotic lumbar spine and poorer gait performance. Unfortunately, there is no clear and consistent picture of the associations from these analyses which is likely due to the small sample size and narrow variation in measurements such as lumbar lordosis. Without a larger variation and spectrum of spinal curvature profiles, correlations cannot emerge.

6.5.3 Kyphosis severity and self-reported outcomes

The repeated measure ANOVA was conducted to determine if there were differences in self-reported outcome measures over a 6-month period where a 6-week physiotherapy intervention was implemented. The findings suggest there is a difference between self-reported balance and gait scores based on thoracic kyphosis severity, yet this difference does not influence the change over time in a model adjusted for age and TLS. The balance confidence and gait efficacy between-group differences based on kyphosis severity were inverse to the expected results as participants with normal kyphosis had significantly lower scores on both scales than participants with hyperkyphosis. However, crosstabulation of kyphosis category versus spinal condition revealed heavily overlapped categories. This lopsided distribution therefore could

confound the results based on the symptomatic spinal condition where the most physically affected were participants who did not necessarily have severe hyperkyphosis, but instead have altered lumbopelvic alignment and lower extremity sensory and motor deficits. Pain and balance deficits have been shown to decrease self-reported walking capacity in the lumbar spinal stenosis population.

SF-36 analysis showed no differences over time or based on kyphosis severity. Since self-reported QoL is not easily or gradually changed over a 6-month period as seen in several large RCTs that tested a physiotherapy intervention on a similar population[86,162], significant changes in this population were not expected. Considering the circumstances in which half of these questionnaires were collected, there may have been some influence from COVID-19 which is discussed in the next section.

Overall, this analysis of self-reported measures did not show an effect over time and did not show that kyphosis severity affected the trajectory of change. While other dimensions of spinal curvature, especially related to the lumbar spine, appear to be important, thoracic kyphosis thresholds were used due to the establishment in the literature and in previous study findings in Chapter 2. The other spinal curvature measurements (LI, T/L ratio, kyphosis percentage) have little data or precedent to establish thresholds for comparison and the limited sample in this study did not allow for meaningful categorical curvature metrics to be established. Therefore, a larger study of spinal characteristics in the future could be better describe and analyse these surface measurements from the Kinect sensor.

6.5.4 Limitations

One of the most crucial limitations of the study was the poor follow-up rate of the cohort. A normal low attrition rate can be attributed to factors including the age and comorbidities of this population, but the timing of the study was the most influential. Unfortunately, the study which spanned over 18 months was interrupted by the COVID-19 global pandemic during month 12. The health crisis and impact on the NHS led to a several-month pause in research activities. Not only did this pause all non-COVID-related research activity, it paused standard care outpatient activity, including all physiotherapy classes, the exposure in the cohort. This directly prevented the post-physiotherapy physical assessments of four participants and impacted the 6-month follow-ups of 25 participants. Seven participants' 6-month follow-ups were due in the weeks

leading up to the first national lockdown and research pause causing some to decline their visit and others to fall within the official lockdown period. Ten participants could only be reached by post for a questionnaire follow-up as their 6-month follow-up occurred directly during the lockdown and research pause. The final eight 6-month follow-ups were due near the end of the lockdown; they were given the opportunity to have their physical assessment, with added precautions, once the study was given permission to resume follow-up assessments. Due to the uncertain circumstances, particularly in this population, only one participant accepted his final research assessment while the others were either still shielding or uncomfortable with the prospect of an in-person research assessment. In addition to the impact of the follow-ups, face-to-face outpatient physiotherapy was paused in the department and spinal group classes were cancelled with no imminent plans to resume, thus preventing any additional recruitment of participants. While questionnaire data were collected from participants during the lockdown, unprompted narrative feedback from participants via telephone and additional notes included with the questionnaires shed light on potentially biased QoL data. Many participants expressed increased difficulties socially, mentally and physically from the pandemic lockdown that they felt influenced the questionnaire answers, in particular the SF-36. While the questionnaire data were part of secondary outcomes, 6-month data may have to be interpreted in these circumstances in mind as almost half were collected during or just after the lockdown.

The original sample size target of 45 participants was based on a sample size calculation theoretically adequate to detect a relationship between thoracic kyphosis, walking and balance, with 80% power and 5% alpha error and an effect size of 0.2; it was also adequate to allow for 80% power and 5% alpha error in a two-tailed design to detect a difference in thoracic kyphosis beyond the minimal detectible change allowing for 20% loss to follow-up at 6 months. As discussed, this study did not meet the recruitment or follow-up targets, thus was not sufficiently powered. Based on the findings in this study, a future study of interest would be a similar repeated measures longitudinal cohort with a physiotherapy exposure divided instead by thresholds of kyphosis percentage with gait and dynamic balance outcomes in a population with a common spinal condition. A sample size for this hypothetical study if there were three comparison groups based on kyphosis percentage to detect a 0.2 effect size with 80% power and 5% alpha error would require 79 participants, assuming a 20% attrition rate.

6.5.5 Feasibility of outcomes

As a feasibility study conducted in a clinical setting, the outcome measures collected were well-accepted and practical to implement. Of particular interest, the Kinect sensor successfully collected all participant images and was relatively easy to use and set up in the confines of a curtained cubical. The thoracolumbar measures collected were also shown to be relevant. Instead of kyphosis only, lordosis and kyphosis percentage were independently related in some analyses, yet T/L ratio did not yield any results of interest in these findings. One outcome with more missing data than all of the others was the IMU gait analysis. The IMU had an error in five participants, therefore these spatiotemporal gait data were lost. In a more controlled research setting, these data would likely have been double checked and any lost data re-collected. However, in the clinical setting with several participants being tested at once with time and resource limitations, data were not double checked before participants finished the assessment. Although there were some missing data, the benefit of using the IMU was the capture of spatiotemporal gait parameters which are more sensitive measures compared to walking speed or walking capacity which can be collected with a stopwatch. Additionally, the IMU is a small, portable device which is more convenient and practical than multi-camera motion analysis or GaitRite methods. All other outcomes measures collected were widely used clinical measures and self-reported questionnaires with no administration or collection issues.

6.6 Conclusions

Overall, the Kinect sensor was a feasible tool to use for the capture of multiple sagittal curvature characteristics of the spine in people with degenerative spinal conditions. The findings suggest potential relationships between spinal curvature and aspects of walking and balance in people with osteoporosis. The findings also show the importance of the measuring and considering the lumbar region, and they highlight the impact of symptomatic spinal conditions which can confound potential relationships between spinal curvature and physical function. Limitations in sample size prevented generalisability of the results, but the study can provide the groundwork for further research into these relationships and the longitudinal predictive value of spinal curvature in specific clinical conditions measurable using the Kinect sensor.

Chapter 7

General discussion

7.1 Summary of contents

This final chapter discusses the main findings, the successes and challenges of the Kinect sensor, the future of its application, remaining gaps in the field and suggestions for future research.

7.2 Main findings

Measurement tools are a vehicle used to improve the understanding of how sagittal spine curvature evolves and changes, whether this is change caused by the natural ageing and degenerative processes or catalysed by a medical condition. However, the implications of an abnormal or unbalanced sagittal spine curvature are the underlying driver of this thesis. The original motivation of the PROVE exploratory analysis was to investigate how thoracic curvature presentation related to and possibly influenced physical function measures within the context of a large RCT of people with OVF. The findings from the exploratory analysis revealed a weak correlative relationship between thoracic kyphosis and walking capacity, functional reach and physical performance, and no predictive value of thoracic kyphosis severity on these physical function metrics after an exposure of physiotherapy. Combining the existing conflicting literature around sagittal spine curvature and physical function correlation with these results that showed a weak correlation when measuring the thoracic spine indicated that there was more to the landscape of the relationship than evidenced at the time. This led to a journey of

developing and validating a surface topography measurement method with an aim to expand the description of the sagittal spinal curvature by using the Kinect sensor to serve as an alternative to radiographs and other surface measurement tools. The method development and testing showed promising results with high intrarater and interrater reliability, good concurrent validity with two clinically-accepted surface measurement tools and aspects of criterion validity compared to the gold standard. Additionally, other measurement descriptors, T/L ratio and kyphosis percentage, demonstrated potential to serve as proxy measures for lumbar curvature or meaningful characteristic descriptors in themselves, both of which had never been described using the Kinect sensor or the flexicurve. This measurement method applied to the Kinect sensor together with the cluster of curvature descriptors were implemented directly in a cohort study designed to apply the findings from the three previous studies and further explore the relationship between sagittal spine curvature and physical function, specifically in people with degenerative spinal conditions. The Kinect sensor was successfully used as an outcome measurement tool, and while the findings indicated again only weak correlations, they did highlight the importance of the underlying condition as an influential factor and identified areas for more research.

7.3 The Kinect sensor

This thesis followed the path of a new measurement tool from identifying the need for a more robust, versatile measurement tool, to developing the method, to testing the reliability and validity, and finally to implementing it in a cohort study of a clinical population. While the results suggest it is a viable tool to measure sagittal spine curvature, there remain gaps in its psychometric property profile. While they could not be fully addressed in this body of research due simply to time and resource constraints, they are important areas to identify and test in the future.

7.3.1 Strengths and limitations of the Kinect sensor

The strengths and novelty of the Kinect sensor psychometric testing conducted include the contribution to the reliability, reproducibility, agreement and validity of this measurement method in relevant populations. While a similar method using the Kinect sensor had tested kyphosis in a young and healthy population[127], the studies in this thesis enrolled people with a wide range of spinal curvature presentations and with symptomatic spinal conditions and examined both

the thoracic and lumbar regions. Additionally, measurement and analysis included the lumbar region, which is often overlooked and overshadowed by the thoracic region, yet has been shown to be a critical aspect to measure. The T/L ratio and kyphosis percentage were determined using the depth data from the Kinect sensor and contributed to a more full description of sagittal spine curvature which expands upon a simplified spinal angle.

The limitations in the Kinect sensor testing revolve around sample size and generalisability. First, since there was more existing literature around thoracic kyphosis, the studies were statistically powered for thoracic spine measurement, not for the lumbar spine. Measurement in the lumbar region ended up having poorer accuracy than the thoracic region compared to the gold standard, which is reflected in other surface measurement tools as well[58]. Therefore, larger studies powered for the full thoracolumbar region would be beneficial for more insight into the validity of the lumbar region. Second, test-retest reliability was not adequately tested in this thesis. From the nine participants who were included, the analyses indicate potential moderate to high reliability for assessment between days. In order to help distinguish the source of error responsible for the gap in reliability between same-day and between-days intrarater reliability, testing on the same day would require the assessor to re-identify the anatomical landmarks, since in the intrarater reliability testing reported in this thesis, the same anatomical markers were used. Inevitable variation in posture, notably in the thoracic spine, and variation from landmark palpation are two areas that influence the reliability in this measurement method. However, these sources of error are not unique to the method established with the Kinect sensor since all methods involve unavoidable postural variation and most non-invasive methods involve surface palpation. Third, while no study excluded participants based on BMI, since there were relatively few participants with high BMI scores, there remains uncertainty about whether a threshold of BMI level would decrease accuracy of the method, particularly in the lumbar region. Testing this hypothesis would require a study that included more participants with higher BMI scores, and it would be of further interest to measure adipose tissue to distinguish the influence of fat deposit distribution compared to a general body mass score. Last, the generalisability and wider-scale use of the Kinect sensor as a spinal curvature measurement tool is a limitation. Because the Kinect sensor is a cost-effective hardware tool for the amount of power and technology it contains, its versatility stems from the programmability. Thus the software used in these studies was bespoke and designed for research only, therefore not easily replicated. Furthermore, as

technology evolves older versions gradually becomes irrelevant. For these reasons, the future use and generalisability of the Kinect sensor may not be directly viable, but the method remains relevant.

7.3.2 The future of the Kinect sensor

One advantage that the Kinect sensor has over physical measurement tools, such as the flexicurve, inclinometers, arcometers, etc., is the potential for markerless measurement using artificial intelligence (AI). Markerless measurement would decrease the measurement time and decrease variability of palpation, one of the current limitations. Additionally, it would be a COVID-friendly approach to spinal measurement allowing for less contact and increased physical distancing. This markerless AI programming has started to develop for the Kinect sensor, yet it requires a very large number of images to train the algorithms. The markerless development has become increasingly used to estimate joint centres in musculoskeletal models to measure movement[163,164] as well as in AIS populations to measure cosmetic asymmetries to equate to scoliotic curves[165]. The Kinect sensor advancements in scoliosis measurement have been leading the way because of the pressing need to develop accurate alternatives to decrease ionising radiation exposure from repeated radiographs; therefore it is feasible that a markerless system could be designed for sagittal spine measurement. Since sagittal plane measurement is more closely related to coronal plane measurement compared to markerless musculoskeletal models, markerless algorithms developed for AIS could be modified or built upon, similar to the Parser software in this thesis. The Kinect sensor also has the capacity to combine spinal curvature measurement and gait which, in the WiSPA Study, gait was measured solely using IMUs to gather spatiotemporal data. With additional software programming, the Kinect sensor also has the ability measure also measure functional movement and gait kinematics which could be paired with spatiotemporal information obtained by IMUs[166].

As the Kinect sensor is also touted for its advanced portable technology compared to its predecessors, it cannot be ignored or discounted that technology will and has already advanced past it. The Kinect sensor V2 was released in 2013 and in the time that has passed since the research in this thesis commenced, Microsoft has released an updated version targeted specifically at research utility. The Azure Kinect is a non-gaming version released in 2019. It was designed to utilise Microsoft's AI cloud platform, but the underlying technology did not

change as it did between the first and second generations of the Kinect sensor. This new unit is more compact and employs ToF which remains the state-of-the-art for 3D image capture. The Azure was only recently released, but there is already research being performed for scoliosis screening[167].

The value of the research conducted in this thesis can be utilised in the future by translating the tested methods of ToF technology to the Azure and other devices and expanding upon it by capitalising on the benefits of AI. The hardware is becoming smaller, more portable, and more user-friendly, as exemplified by the Azure and other smart devices. All of these assets contribute to furthering the actual use of this method of spinal measurement in research, clinical and home settings. Integration into the clinic and home would be a natural next step for this technology. Home use in particular would be a very impactful step as demonstrated by the sudden recent need for telehealth and telerehabilitation. In its current form, the Kinect sensor would not be a viable option for widespread use, however if the software and methods advance with the smaller, more powerful and more accessible hardware, it has enormous potential to be widely used benefiting patients with spinal conditions as well as a potential tool in screening, diagnostic or preventative health.

7.4 Sagittal spine curvature and physical function

While the future of the technology within the Kinect sensor is promising, its practical application in this body of research has served its purpose to explore sagittal spine curvature in order to relate it to physical function. In a strength of this thesis, the final study built upon outcome measures of the PROVE Trial by implementing the Kinect sensor and testing dynamic balance and spatiotemporal gait characteristics. Although the data from the WiSPA study was severely lacking due to the obvious sample size limitation, the findings suggested that there is a stronger spinal curvature relationship with gait and dynamic balance metrics in people with osteoporosis and no apparent relationship in people with lumbar spinal stenosis. The correlation of higher kyphosis and lordosis indexes with better FSST scores identified in the osteoporosis group is aligned with Alin et al. who tested an osteoporotic population with an older mean age[33] but not Sangtaresh et al. who tested a younger osteoporosis population[30]. The study highlighted the importance of a more homogenous research population or the comparison of specific

symptomatic populations due to many confounding factors that stem from the underlying spinal condition, specifically lumbar spinal stenosis where lower extremity symptoms may overshadow any impact from sagittal spine curvature. The WiSPA study results together with the current research continue to indicate that there cannot be a blanket relationship between sagittal curvature and physical function applied to older adults without consideration of factors such as age and spinal condition.

Additionally, it cannot be ignored that there could be added value with a more comprehensive examination of sagittal alignment that includes cervical alignment, sagittal vertebral axis, sacropelvic alignment, and even knee flexion, to shed more light on functional implications. However, in this kinetically linked chain of regional interdependence, the thoracolumbar region is located in the middle of the chain where the thoracic and cervical regions influence each other and the lumbar and sacropelvic regions influence each other[6,141]. Therefore, the thoracolumbar curvature may be the most crucial and informative area to measure if a full comprehensive sagittal profile cannot be measured. From an image capture using the Kinect sensor, multiple curvature metrics within the thoracolumbar spine can be calculated, and the WiSPA findings show that each metric is uniquely correlated to multiple physical function measures, suggesting the potential breadth of this single depth image.

7.4.1 Recommendations for clinical practice

Findings from the PROVE exploratory analysis and the cohort study have highlighted several points related to the relationship between spinal curvature and walking and physical performance. The PROVE analysis revealed that people with the most severe thoracic hyperkyphosis curvature have the potential to improve from physiotherapy by improving their kyphosis angle and improving their physical performance. Therefore, clinicians should not discount the improvement potential in patients with severe hyperkyphosis. The use of the Kinect sensor in this population with severe hyperkyphosis and OVF could additionally identify important changes in the lumbar spine and highlight the balance or imbalance between the thoracic and lumbar regions. The cohort study findings showed there may be more of a correlative relationship between spinal curvature and gait in people with osteoporosis compared to people with a primary diagnosis on lumbar spinal stenosis, suggesting that a clinical focus on thoracolumbar curvature may be more important in people with osteoporosis, but not necessarily in those with lumbar spinal stenosis.

7.5 Overall strengths and limitations

The strengths of this thesis lie in the original research that encompasses both measurement properties and implementation. Not only were measurement properties of the Kinect sensor tested in a clinical population for the first time, the method was also used as an outcome measure in itself and analysed with other important functional outcomes in pepole with symptomatic spinal conditions. The whole body of the research uniquely bridges the gap between technical aspects of a new technology with clinical application. Additionally, the findings from the final study have laid a foundation for futher research to explore the relationships found between sagittal spine curvature and dynamic balance and gait, specfically as they relate to different spinal conditions.

Along with these strengths, there were several limitations in this research. In particular, the sample sizes were not powered to give sufficient confidence in all of the findings from the studies conducted. The final cohort study suffered from substantial loss to follow up making analysis of change difficult to ascertain. On the measurement property side, the lack of adequate test-retest reliability testing ultimately limits the ability to determine meaningful and real change in spinal curvature, which is one of the most important goals of a non-invasive spinal measurement tool. In addition to the sample sizes, the sample populations posed a limitation to the interpretation and wider generalisation of the findings. In the reliability study, the sample of healthy adult volunteers provided less variable patterns of sagittal spine curvature compared to the clinical populations tested in the validity and cohort studies. The clinical populations tested had patterns of curvature, in both the sagittal and frontal planes, outside of normal ranges making the results more meaningful yet at the same time compromising accuracy and confidence in the findings for the sample size tested. These limitations are areas to consider in future research study designs.

7.6 Suggestions for future research

Areas for future research revolve around the many of the limitations previously discussed. Comprehensive testing of the psychometric properties of the Kinect sensor method would be beneficial in order to have a more complete understanding of the reliability and validity and limitations in different contexts. Additionally, similar testing of the method could be expanded to other devices that use ToF technology in order to stay up with the advancement and make use even more portable and accessible devices for clinicians and individuals at home. Further

prospective research into the impact of spinal curvature profiles on specific walking and balance impairments with consideration of spinal condition would be important to fill in remaining gaps in research. A larger and longer (>12 months) longitudinal study collecting similar curvature and physical function outcome measures could enable a clearer picture of where participants are on the compensatory spectrum of the sagittal spine curvature changes and this may allow for a more accurate prediction of physical function. Because spinal curvature changes are relatively slow, a time period of at least 12 months would be more appropriate to yield results. This could ultimately provide the clinician data to better inform interventions.

7.7 Conclusions

This thesis describes the development and testing of a surface topography method for analysis of sagittal spine curvature, which has potential for expanded utility with advancing iterations of the ToF technology. From a clinical aspect, this body of research has added to the complicated landscape encompassing spinal curvature and physical function. Specifically, the findings from the cohort study are foundational for further research into the relationship between sagittal spine curvature and physical function based on characteristics of the underlying symptomatic spinal conditions. Overall, the research as a whole has linked new technology with clinical measurement and has laid the groundwork for future research in this area.

Bibliography

1. Dubousset, J. *Three-dimensional analysis of the scoliotic deformity* (Raven Press Ltd., New York, 1994).

2. Yang, L., Zhang, L., Dong, H., Alelaiwi, A. & Saddik, A. E. Evaluating and improving the depth accuracy of Kinect for Windows v2. *IEEE Sensors Journal* **15**, 4275–4285 (2015).

3. Cramer, G. D. General Charcteristics of the Spine. In Cramer, G. D. & Darby, S. A. (eds.) *Clinical Anatomy of the Spine, Spinal Cord, and ANS*, chap. 2, 15–64 (Mosby, 2014), 3rd edn.

4. Sebaaly, A., Grobost, P., Mallam, L. & Roussouly, P. Description of the sagittal alignment of the degenerative human spine. *European Spine Journal* (2017).

5. Schwab, F., Patel, A., Ungar, B., Farcy, J.-p. & Lafage, V. Adult Spinal Deformity âĂŤ Postoperative Standing Imbalance Assessing Alignment and Planning Corrective Surgery. *Spine* **35**, 2224–2231 (2010).

6. Roussouly, P. & Nnadi, C. Sagittal plane deformity: An overview of interpretation and management. *European Spine Journal* **19**, 1824–1836 (2010).

7. Kado, D. M., Prenovost, K. & Crandall, C. Narrative Review : Hyperkyphosis in Older Persons. *Annals of Internal Medicine* 330–338 (2007).

8. Gelb, D. E., Lenke, L. G., Bridwell, K. H., Blanke, K. & McEnery, K. W. An Analysis of Sagittal Spinal Alignment in 100 Asymptomatic Middle and Older Aged Volunteers (1995).

9. Vialle, R. *et al.* Radiographic Analysis of the Sagittal Alignment and Balance of the Spine in Asymptomatic Subjects. *JBJS* **87** (2005).

10. Porto, A. B. & Okazaki, V. H. A. Procedures of assessment on the quantification of thoracic kyphosis and lumbar lordosis by radiography and photogrammetry: A literature review. *Journal of Bodywork Movement Therapies* (2016).

11. Vrtovec, T., Pernuš, F. & Likar, B. A review of methods for quantitative evaluation of spinal curvature. *European Spine Journal* **18**, 593–607 (2009).

12. Zhu, Y., An, Z., Zhang, Y., Wei, H. & Dong, L. Predictive formula of cervical lordosis in asymptomatic young population. *Journal of Orthopaedic Surgery and Research* **15**, 2 (2020).

13. Roghani, T. *et al.* The Reliability of Standing Sagittal Measurements of Spinal Curvature and Range of Motion in Older Women With and Without Hyperkyphosis Using a Skin-Surface Device. *Journal of Manipulative and Physiological Therapeutics* **40**, 685–691 (2017).

14. Fon, G., Pitt, M. & Thies Jr, A. C. Thoracic Kyphosis: Range in Normal Subjects. *AJR Am J Roentgenol* **134**, 979–983 (1980).

15. Katzman, W. B., Wanek, L., Shepherd, J. A. & Sellmeyer, D. E. Age-Related Hyperkyphosis: Its Causes, Consequences, and Management. *Journal of Orthopaedic Sports Physical Therapy* **40**, 352–360 (2010).

16. Schneider, D. L., Mühlen, D. V., Barrett-Connor, E. & Sartoris, D. J. Kyphosis does not equal vertebral fractures : the Rancho Bernardo study. *The Journal of Rheumatology* **31**, 747–752 (2004).

17. Ensrud, K. E., Black, D. M., Harris, F., Ettinger, B. & Cummings, S. R. Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group. *Journal of the American Geriatrics Society* **45**, 682–7 (1997).

18. Kobayashi, T., Atsuta, Y., Matsuno, T. & Takeda, N. A Longitudinal Study of Congruent Sagittal Spinal Alignment in an Adult Cohort. *Spine* **29**, 671–676 (2004).

19. Dagdia, L., Kokabu, T. & Ito, M. Classification of adult spinal deformity: Review of current concepts and future directions. *Spine Surgery and Related Research* **3**, 17–26 (2019).

20. Kado, D. M., Lui, L.-y., Ensrud, K. E., Fink, H. A. & Karlamangla, A. S. Hyperkyphosis Predicts Mortality Independent of Vertebral. *Annals of Internal Medicine* 681–688 (2009).

21. Ailon, T., Shaffrey, C. I., Lenke, L. G., Harrop, J. S. & Smith, J. S. Progressive spinal kyphosis in the aging population. *Neurosurgery* **77**, S164–S172 (2015).

22. Teixeira, F. a. & Carvalho, G. a. Reliability and Validity of Thoracic Kyphosis Measurements Using the Flexicurve Method. *Rev. Bras. Fisioter* **11**, 173–177 (2007).

23. Jackson, R. & McManus, A. Radiographic analysis of sagittal plane alignment and balance in standing volunteers and patients with low back pain matched for age, sex, and size: A prospective controlled clinical study. *Spine (Phila Pa 1976)* **19**, 1611–1618 (1994).

24. Jackson, R. P., Phipps, T., Hales, C. & Surber, J. Pelvic lordosis and alignment in spondylolisthesis. *Spine* **28**, 151–160 (2003).

25. Barrey, C., Roussouly, P., Perrin, G. & Le Huec, J. C. Sagittal balance disorders in severe degenerative spine. Can we identify the compensatory mechanisms? *European Spine Journal* **20**, 1–8 (2011).

26. Hammerberg, E. M. & Wood, K. B. Sagittal profile of the elderly. *Journal of Spinal Disorders and Techniques* **16**, 44–50 (2003).

27. Atkins, D. *et al.* Grading quality of evidence and strength of recommendations. The GRADE Working Group. *British Medical Journal (Clinical Research Ed.)* **328**, 328(7454):1490. (2004).

28. Kasukawa, Y. *et al.* Relationships between falls, spinal curvature, spinal mobility and back extensor strength in elderly people. *Journal of Bone and Mineral Metabolism* **28**, 82–87 (2010).

29. Ishikawa, Y., Miyakoshi, N., Kasukawa, Y., Hongo, M. & Shimada, Y. Spinal curvature and postural balance in patients with osteoporosis. *Osteoporosis International* **20**, 2049–2053 (2009).

30. Sangtarash, F., Manshadi, F. D. & Sadeghi, A. The relationship of thoracic kyphosis to gait performance and quality of life in women with osteoporosis. *Osteoporosis International* **26**, 2203–2208 (2015).

31. De Groot, M. H. *et al.* A flexed posture in elderly patients is associated with impairments in postural control during walking. *Gait and Posture* **39**, 767–772 (2014).

32. Miyazaki, J. *et al.* Lumbar lordosis angle (LLA) and leg strength predict walking ability in elderly males. *Archives of Gerontology and Geriatrics* (2013).

33. Alin, K. K., Grahn Kronhed, A.-C. & Salminen, H. The association between spinal curvature and balance in elderly women at high risk of osteoporotic fractures in primary health care. *European Journal of Physiotherapy* **9169**, 1–7 (2016).

34. Lorbergs, A. L. *et al.* Severity of kyphosis and decline in lung function: The framingham study. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences* **72**, 689–694 (2017).

35. Ambrose, A. F., Paul, G. & Hausdorff, J. M. Risk factors for falls among older adults: A review of the literature. *Maturitas 75* 51–61 (2013).

36. Deandrea, S. *et al.* Risk factors for falls in community-dwelling older people: A systematic review and meta-analysis. *Epidemiology* **21**, 658–668 (2010).

37. Tinetti, M. E. Preventing Falls in Elderly Persons. *New England Journal of Medicine* **348**, 42–49 (2003).

38. Davis, J. C. *et al.* International comparison of cost of falls in older adults living in the community: A systematic review. *Osteoporosis International* **21**, 1295–1306 (2010).

39. McDaniels-Davidson, C. *et al.* Kyphosis and incident falls among community-dwelling older adults. *Osteoporosis International* **29**, 163–169 (2018).

40. Van Der Jagt-Willems, H. C., De Groot, M. H., Van Campen, J. P., Lamoth, C. J. & Lems, W. F. Associations between vertebral fractures, increased thoracic kyphosis, a flexed posture and falls in older adults: A prospective cohort study. *BMC Geriatrics* **15**, 1–6 (2015).

41. Ishikawa, Y. *et al.* Relationships among spinal mobility and sagittal alignment of spine and lower extremity to quality of life and risk of falls. *Gait and Posture* **53**, 98–103 (2017).

42. Ishikawa, Y., Miyakoshi, N., Kasukawa, Y., Hongo, M. & Shimada, Y. Spinal sagittal contour affecting falls: Cut-off value of the lumbar spine for falls. *Gait and Posture* **38**, 260–263 (2013).

43. Kim, J. *et al.* The association between whole body sagittal balance and risk of falls among elderly patients seeking treatment for back pain. *Bone and Joint Research* **6**, 337–344 (2017).

44. Barrett, E., O'Keeffe, M., O'Sullivan, K., Lewis, J. & McCreesh, K. Is thoracic spine posture associated with shoulder pain, range of motion and function? A systematic review. *Manual Therapy* **26**, 38–46 (2016).

45. Lombardi, I., Oliveira, L. M., Mayer, A. F., Jardim, J. R. & Natour, J. Evaluation of pulmonary function and quality of life in women with osteoporosis. *Osteoporosis International* **16**, 1247–1253 (2005).

46. Ryan, S. D. & Fried, L. P. The impact of kyphosis on daily functioning. *Journal of the American Geriatrics Society* **45**, 1479–1486 (1997).

47. Sugai, K., Michikawa, T., Takebayashi, T. & Nishiwaki, Y. Association between muscle strength, mobility, and the progression of hyperkyphosis in the elderly: the Kurabuchi Cohort Study. *Journals of Gerontology, series A* (2019).

48. Hu, Z. *et al.* Global sagittal alignment in elderly patients with osteoporosis and its relationship with severity of vertebral fracture and quality of life. *Archives of Osteoporosis* **13** (2018).

49. Pellisé, F. *et al.* Impact on health related quality of life of adult spinal deformity (ASD) compared with other chronic conditions. *European Spine Journal* **24**, 3–11 (2014).

50. Bess, S. *et al.* The health impact of symptomatic adult spinal deformity: Comparison of deformity types to United States population norms and chronic diseases. *Spine* **41**, 224–233 (2016).

51. Briggs, A. M. *et al.* Radiographic measures of thoracic kyphosis in osteoporosis: Cobb and vertebral centroid angles. *Skeletal Radiology* **36**, 761–767 (2007).

52. Harrison, D. E., Cailliet, R., Harrison, D. D., Janik, T. J. & Holland, B. Reliability of centroid, Cobb, and Harrison posterior tangent methods: which to choose for analysis of thoracic kyphosis. *Spine* **26**, 227–234 (2001).

53. Polly, D. W. *et al.* Measurement of lumbar lordosis. Evaluation of intraobserver, interobserver, and technique variability. *Spine (Phila Pa 1976)* **21**, 1530–1536 (1996).

54. Goh, S., Price, R. I., Leedman, P. J. & Singer, K. P. The relative influence of vertebral body and intervertebral disc shape on thoracic kyphosis. *Clinical Biomechanics* **14**, 439–448 (1999).

55. de Oliveira, T. S. *et al.* Validity and Reproducibility of the Measurements Obtained Using the Flexicurve Instrument to Evaluate the Angles of Thoracic and Lumbar Curvatures of the Spine in the Sagittal Plane. *Rehabilitation Research and Practice* **2012**, 1–9 (2012).

56. Whiting, P. *et al.* ROBIS: A new tool to assess risk of bias in systematic reviews was developed. *Journal of Clinical Epidemiology* **69**, 225–234 (2016).

57. Barrett, E., McCreesh, K. & Lewis, J. Reliability and validity of non-radiographic methods of thoracic kyphosis measurement: A systematic review (2014).

58. Sedrez, J. A., Candotti, C. T., Fxxurlanetto, T. S. & Loss, F. Non-invasive postural assessment of the spine in the sagittal plane : a systematic review. *Motricidade* **12**, 140–154 (2016).

59. Brink, Y. & Louw, Q. A. Clinical instruments: Reliability and validity critical appraisal. *Journal of Evaluation in Clinical Practice* **18**, 1126–1132 (2012).

60. Hannink, E., Shannon, T., Barker, K. L. & Dawes, H. The reliability and reproducibility of sagittal spinal curvature measurement using the Microsoft Kinect V2. *Journal of back and musculoskeletal rehabilitation* **33**, 295–301 (2020).

61. Mousavi, S. J., Tromp, R., Swann, M. C., White, A. P. & Anderson, D. E. Between-session reliability of opto-electronic motion capture in measuring sagittal posture and 3-D ranges of motion of the thoracolumbar spine. *Journal of Biomechanics* **79**, 248–252 (2018).

62. Muyor, J. M., Arrabal-Campos, F. M., Martínez-Aparicio, C., Sánchez-Crespo, A. & Villa-Pérez, M. Test-retest reliability and validity of a motion capture (MOCAP) system for measuring thoracic and lumbar spinal curvatures and sacral inclination in the sagittal plane. *Journal of Back and Musculoskeletal Rehabilitation* **30**, 1319–1325 (2017).

63. Takács, M., Orlovits, Z., Jáger, B. & Kiss, R. M. Comparison of spinal curvature parameters as determined by the ZEBRIS spine examination method and the Cobb method in children with scoliosis. *PLoS ONE* **13**, 1–19 (2018).

64. Jáger, B. *et al.* Validation of a generally applicable method for the characterization of scoliotic deformities and sagittal spinal curvatures. *Periodica Polytechnica Civil Engineering* **62**, 1021–1029 (2018).

65. Salamh, P. A. & Kolber, M. The reliability, minimal detectable change and concurrent validity of a gravity-based bubble inclinometer and iphone application for measuring standing lumbar lordosis. *Physiotherapy Theory and Practice* **30**, 62–67 (2014).

66. Waś, J., Sitarski, D., Ewertowska, P., Bloda, J. & Czaprowski, D. Using smartphones in the evaluation of spinal curvatures in a sagittal plane. *Postepy Rehabilitacji* **30**, 29–38 (2016).

67. Koumantakis, G. A. *et al.* Reliability and Validity Measurement of Sagittal Lumbosacral Quiet Standing Posture with a Smartphone Application in a Mixed Population of 183 College Students and Personnel. *Advances in Orthopedics* 1–9 (2016).

68. Greendale, G. A., Nili, N. S., Huang, M. H., Seeger, L. & Karlamangla, A. S. The reliability and validity of three non-radiological measures of thoracic kyphosis and their relations to the standing radiological Cobb angle. In *Osteoporosis International*, vol. 22, 1897–1905 (2011).

69. Ripani, M. *et al.* Spinal curvature : comparison of frontal measurements with the Spinal Mouse and radiographic assessment. *Sports Medicine* **48**, 488–94 (2008).

70. Sedrez, J. A. *et al.* Can the adapted arcometer be used to assess the vertebral column in children? *Brazilian Journal of Physical Therapy* **18**, 538–543 (2014).

71. Sangtarash, F. Validity and Reliability of Dual Digital Inclinometer in Measuring Thoracic Kyphosis in Women over 45 Years. *Journal of Spine* **03** (2013).

72. Seidi, F., Minoonejad, H. & Youdas, J. W. Using a spine stabilizer instrument to control postural sway in standing lumbar curvature measurements by flexible curve. *Journal of Back and Musculoskeletal Rehabilitation* **28**, 311–316 (2015).

73. Sedrez, J. A. *et al.* Validação de um sistema de topografia para avaliação da coluna vertebral no plano sagital de crianças em diferentes perfis nutricionais. *Fisioterapia e Pesquisa* **23**, 163–171 (2016).

74. Barrett, E., Mccreesh, K. & Lewis, J. Intrarater and Interrater Reliability of the Flexicurve Index, Flexicurve Angle, and Manual Inclinometer for the Measurement of Thoracic Kyphosis. *Rehabilitation Research and Practice* **475870** (2013).

75. Mannion, A. F., Knecht, K., Balaban, G., Dvorak, J. & Grob, D. A new skin-surface device for measuring the curvature and global and segmental ranges of motion of the spine: reliability of measurements and comparison with data reviewed from the literature. *European Spine Journal* **13**, 122–136 (2004).

76. Troup, J. D., Hood, C. A. & Chapman, A. E. Measurements of the sagittal mobility of the lumbar spine and hips. *Rheumatology* **9**, 308–321 (1968).

77. Hart, D. L. & Rose, S. J. Reliability of a noninvasive method for measuring the lumbar curve*. *The Journal of orthopaedic and sports physical therapy* **8**, 180–4 (1986).

78. Bryan, J. M., Mosner, E., Shippee, R. & Stull, M. A. Investigation of the flexible ruler as a noninvasive measure of lumbar lordosis in black and white adult female sample populations. *J Orthop Sports Phys Ther* **11**, 3–7 (1989).

79. Macintyre, N. J., Bennett, L., Bonnyman, A. M. & Stratford, P. W. Optimizing reliability of digital inclinometer and flexicurve ruler measures of spine curvatures in postmenopausal women with osteoporosis of the spine: an illustration of the use of generalizability theory. *ISRN rheumatology* **2011**, 571698 (2011).

80. Czaprowski, D., Pawłowska, P., Gebicka, A., Sitarski, D. & Kotwicki, T. Powtarzalność, zgodność i rzetelność pomiaru krzywizn przednio-tylnych kreogonekgosłupa z wykorzystaniem inklinometru cyfrowego saundersa. *Ortopedia Traumatologia Rehabilitacja* **14**, 145–153 (2012).

81. Turner-Smith, A. R., Harris, J. D., Houghton, G. R. & Jefferson, R. J. A method for analysis of back shape in scoliosis. *Journal of Biomechanics* **21**, 497–509 (1988).

82. Krott, N. L., Wild, M. & Betsch, M. Meta-analysis of the validity and reliability of rasterstereographic measurements of spinal posture. *European Spine Journal* (2020).

83. Tabard-Fougere, A. *et al.* Validity and Reliability of Spine Rasterstereography in Patients With Adolescent Idiopathic Scoliosis. *Spine* **42**, 98–105 (2017).

84. Schroeder, J., Reer, R. & Braumann, K. M. Video raster stereography back shape reconstruction: a reliability study for sagittal, frontal, and transversal plane parameters. *European Spine Journal* **24**, 262–269 (2015).

85. Bassani, T., Stucovitz, E., Galbusera, F. & Brayda-Bruno, M. Is rasterstereography a valid noninvasive method for the screening of juvenile and adolescent idiopathic scoliosis? *European Spine Journal* **28**, 526–535 (2019).

86. Barker, K. L. *et al.* Physiotherapy rehabilitation for osteoporotic vertebral fracture: a randomised controlled trial and economic evaluation (PROVE trial). *Osteoporosis International* 277–289 (2019).

87. Kado, D. M., Huang, M.-H., Barrett-Connor, E. & Greendale, G. A. Hyperkyphotic Posture and Poor Physical Functional Ability in Older Community-Dwelling Men and Women: The Rancho Bernardo Study. *J Gerontol A Biol Sci Med Sci* **60**, 633–637 (2005).

88. Miyakoshi, N. *et al.* Comparison of spinal alignment, muscular strength, and quality of life between women with postmenopausal osteoporosis and healthy volunteers. *Osteoporosis International* **28**, 3153–3160 (2017).

89. European Prospective Osteoporosis Study (EPOS) Group *et al.* Incidence of Vertebral Fracture in Europe: Results From the European Prospective Osteoporosis Study (EPOS). *Journal of Bone and Mineral Research* **17**, 716–724 (2002).

90. O'Neill, T. W. *et al.* The prevalence of vertebral deformity in european men and women: The European vertebral osteoporosis study. *Journal of Bone and Mineral Research* **11**, 1010–1018 (1996).

91. Katzman, W. B., Huang, M.-H. M.-H., Lane, N. E., Ensrud, K. E. & Kado, D. M. Kyphosis and decline in Physical Function Over 15 Years in Older Comunity-Dwelling Women: The Study of Osteoportic Fractures. *Journal of Gerontology* **68** (2013).

92. Lynn, S. G., Sinaki, M. & Westerlind, K. C. Balance Characteristics of Persons With Osteoporosis. *Archives of Physical Medicine and Rehabilitation* **78**, 273–277 (1997).

93. Regolin, F. & Carvalho, G. A. Relationship between thoracic kyphosis, bone mineral density, and postural control in elderly women. *Revista Brasileira de Fisioterapia* **14**, 464–469 (2010).

94. Greig, A. M., Bennell, K. L., Briggs, A. M., Wark, J. D. & Hodges, P. W. Balance impairment is related to vertebral fracture rather than thoracic kyphosis in individuals with osteoporosis. *Osteoporosis International* **18**, 543–551 (2007).

95. Ziebart, C. *et al.* Are osteoporotic vertebral fractures or forward head posture associated with performance-based measures of balance and mobility? *Archives of Osteoporosis* **14**, 67 (2019).

96. Barker, K. L. *et al.* Physiotherapy rehabilitation for osteoporotic vertebral fracture (prove): Study protocol for an adaptive design randomised controlled trial. *Trials* **26**, S121 (2015).

97. Harada, N. D., Chiu, V. & Stewart, A. L. Mobility-related function in older adults: Assessment with a 6-minute walk test. *Archives of Physical Medicine and Rehabilitation* **80**, 837–841 (1999).

98. Steffen, T. M., Hacker, T. A. & Mollinger, L. Berg Balance Scale , Timed Up Go **82**, 128 –137 (2002).

99. Weiner, D. K., Duncan, P. W., Chandler, J. & Studenski, S. A. Functional Reach: A Marker of Physical Frailty. *Journal of the American Geriatrics Society* **40**, 203–207 (1992).

100. Duncan, P. W., Studenski, S., Chandler, J. & Prescott, B. Functional reach: Predictive validity in a sample of elderly male veterans. *Journals of Gerontology* **47**, 93–98 (1992).

101. Pavasini, R. *et al.* Short Physical Performance Battery and all-cause mortality: Systematic review and meta-analysis. *BMC Medicine* **14**, 215 (2016).

102. Guralnik, J. M. *et al.* A short physical performance battery assessing lower extremity function: Association with self-reported disability and prediction of mortality and nursing home admission. *Journals of Gerontology* **49** (1994).

103. Lips, P. *et al.* Quality of life in patients with vertebral fractures: Validation of the quality of life questionnaire of the European Foundation for Osteoporosis (QUALEFFO). *Osteoporosis International* **10**, 150–160 (1999).

104. Newman, M., Newman, R., Hughes, T., Vadher, K. & Barker, K. L. Is the timed loaded standing test a valid measure of back muscle endurance in people with vertebral osteoporosis? *Osteoporosis International* **29**, 893–905 (2018).

105. Shipp, K. *et al.* Timed Loaded Standing: A Measure of Combined Trunk and Arm Endurance Suitable for People with Vertebral Osteoporosis. *Osteoporosis International* **11**, 914–922 (2000).

106. Katzman, W. B., Vittinghoff, E. & Kado, D. M. Age-related hyperkyphosis, independent of spinal osteoporosis, is associated with impaired mobility in older community-dwelling women. *Osteoporosis International* **22**, 85–90 (2011).

107. Kado, D. M. *et al.* Hyperkyphosis, kyphosis progression, and risk of non-spine fractures in older community dwelling women: The Study of Osteoporotic Fractures (SOF). *Journal of Bone and Mineral Research* (2014).

108. Katzman, W. B. *et al.* Sex differences in response to targeted kyphosis specific exercise and posture training in community-dwelling older adults: a randomized controlled trial. *BMC musculoskeletal disorders* **18**, 509 (2017).

109. Kado, D. M. *et al.* Factors Associated With Kyphosis Progression in Older Women: 15 years experience in the Study of Osteoporotic Fractures. *J Bone Miner Res* **28**, 179–187 (2013).

110. Kado, D. M., Huang, M. H., Karlamangla, A. S., Barrett-Connor, E. & Greendale, G. A. Hyperkyphotic posture predicts mortality in older community-dwelling men and women: A prospective study. *Journal of the American Geriatrics Society* **52**, 1662–1667 (2004).

111. Katzman, W. B. *et al.* Physical function in older men with hyperkyphosis. *The journals of gerontology. Series A, Biological sciences and medical sciences* **70**, 635–40 (2015).

112. Perera, S., Mody, S. H., Woodman, R. C. & Studenski, S. A. Meaningful change and responsiveness in common physical performance measures in older adults. *Journal of the American Geriatrics Society* **54**, 743–749 (2006).

113. Hageman, P. A., Leibowitz, J. M. & Blanke, D. Age and gender effects on postural control measures. *Archives of Physical Medicine and Rehabilitation* **76**, 961–965 (1995).

114. Chow, S. B. & Moffat, M. Relationship of thoracic kyphosis to functional reach and lower-extremity joint range of motion and muscle length in women with osteoporosis or osteopenia: A pilot study. *Topics in Geriatric Rehabilitation* **20**, 297–306 (2004).

115. Hirose, D., Ishida, K., Nagano, Y., Takahashi, T. & Yamamoto, H. Posture of the trunk in the sagittal plane is associated with gait in community-dwelling elderly population. *Clinical Biomechanics* **19**, 57–63 (2004).

116. Thomas, J. I. & Lane, J. V. A pilot study to explore the predictive validity of 4 measures of falls risk in frail elderly patients. *Archives of Physical Medicine and Rehabilitation* **86**, 1636–1640 (2005).

117. Idland, G., Rydwik, E., Småstuen, M. C. & Bergland, A. Predictors of mobility in community-dwelling women aged 85 and older. *Disability and Rehabilitation* **35**, 881–887 (2013).

118. Wernick-Robinson, M., Krebs, D. E. & Giorgetti, M. M. Functional reach: Does it really measure dynamic balance? *Archives of Physical Medicine and Rehabilitation* **80**, 262–269 (1999).

119. Eum R, L. S. Is kyphosis related to mobility, balance, and disability? *American journal of physical medicine rehabilitation / Association of Academic Physiatrists* **92**, 980–9 (2013).

120. Balzini, L. *et al.* Clinical characteristics of flexed posture in elderly women. *Journal of the American Geriatrics Society* (2003).

121. Spencer, L., Fary, R., Mckenna, L., Ho, R. & Briffa, K. Thoracic kyphosis assessment in postmenopausal women: an examination of the Flexicurve method in comparison to radiological methods. *Osteoporosis International* **30** (2019).

122. Pohlmann, S., Harkness, E., Taylor, C. & Astley, S. Evaluation of Kinect 3D Sensor for Healthcare Imaging. *J. Med. Biol. Eng.* **36**, 857–870 (2016).

123. Hansard, M., Lee, S., Choi, O. & Horaud, R. *Time of Flight Cameras: Principles, Methods, and Applications*, vol. 95 (Springer, 2012).

124. Clark, R. A. *et al.* Validity of the Microsoft Kinect for assessment of postural control. *Gait Posture* **36**, 372–377 (2012).

125. Castro, A. P. G. *et al.* Evaluation of spinal posture using Microsoft Kinect TM : A preliminary case-study with 98 volunteers. *Porto Biomedical Journal* **2**, 18–22 (2017).

126. Diego-Mas, J. A. & Alcaide-Marzal, J. Using Kinect sensor in observational methods for assessing postures at work. *Applied Ergonomics* **45**, 976–985 (2014).

127. Quek, J., Brauer, S. G., Treleaven, J. & Clark, R. A. The concurrent validity and intrarater reliability of the Microsoft Kinect to measure thoracic kyphosis. *International Journal of Rehabilitation Research* **40**, 279–284 (2017).

128. Shannon, T., Chockalingam, N. & Jevtić, N. The Radiological and Clinical Assessment of a Cohort of AIS Patient. *The Spine Journal* **17**, S329 (2017).

129. Cignoni, P. *et al.* MeshLab: an Open-Source Mesh Processing Tool. *Sixth Eurographics Italian Chapter Conference* 129–136 (2008).

130. Kottner, J., Audig, L., Brorson, S., Donner, A. & Gajewski, B. J. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed **64**, 96–106 (2011).

131. Walter, S. D., Eliasziw, M. & Donner, A. SAMPLE SIZE AND OPTIMAL DESIGNS FOR RELIABILITY STUDIES **17**, 101–110 (1998).

132. Rankin, G. & Stokes, M. Reliability of assessment tools in rehabiliation: an illustration of appropriate statistical analyses. *Clinical Rehabilitation* **12**, 187–199 (1998).

133. Fleiss, J. L. *The Design and Analysis of Clinical Experiments* (John Wiley Sons, Inc., Hoboken, NJ, USA, 1986).

134. Harlick, J. C., Milosavljevic, S. & Milburn, P. D. Palpation identification of spinous processes in the lumbar spine. *Manual Therapy* **12**, 56–62 (2007).

135. McKenzie, A. M. & Taylor, N. F. Can physiotherapists locate lumbar spinal levels by palpation? *Physiotherapy* **83**, 235–239 (1997).

136. Bonnet, V. *et al.* Automatic estimate of back anatomical landmarks and 3D spine curve from a Kinect sensor. *Proceedings of the IEEE RAS and EMBS International Conference on Biomedical Robotics and Biomechatronics* **2016-July**, 924–929 (2016).

137. von Elm, E. *et al.* Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) in the International Journal of Medical Students. *BMJ* **335**, 806–808 (2007).

138. Hinkle, D. E., Wiersma, W. & Jurs, S. G. *Applied Statistics for the Behavioral Sciences* (2003).

139. Wanke-Jellinek, L. *et al.* Is there any use? Validity of 4D rasterstereography compared to EOS 3D X-ray imaging in patients with degenerative disk disease. *European Spine Journal* **28**, 2162–2168 (2019).

140. Imagama, S. *et al.* Influence of spinal sagittal alignment, body balance, muscle strength, and physical ability on falling of middle-aged and elderly males. *European Spine Journal* **22**, 1346–1353 (2013).

141. Le Huec, J. C., Thompson, W., Mohsinaly, Y., Barrey, C. & Faundez, A. Sagittal balance of the spine. *European Spine Journal* (2019).

142. Watson, S. L. *et al.* High-intensity exercise did not cause vertebral fractures and improves thoracic kyphosis in postmenopausal women with low to very low bone mass: the LIFTMOR trial. *Osteoporosis International* 1–8 (2019).

143. Greendale, G. A., Huang, M.-H., Karlamangla, A. S., Seeger, L. & Crawford, S. Yoga decreases kyphosis in senior women and men with adult onset hyperkyphosis: results of a randomized controlled trial. *Journal of American Geriatric Society* **57**, 1569–1579 (2009).

144. Kim, D. H., Choi, D. H., Park, J. H., Lee, J. H. & Choi, Y. S. What is the effect of spino-pelvic sagittal parameters and back muscles on osteoporotic vertebral fracture? *Asian Spine Journal* **9**, 162–169 (2015).

145. Viitanen, J. V., Heikkilä, S., Kokko, M. L. & Kautiainen, H. Clinical assessment of spinal mobility measurements in ankylosing spondylitis: A compact set for follow-up and trials? *Clinical Rheumatology* **19**, 131–137 (2000).

146. Dite, W. & Temple, V. A. A clinical test of stepping and change of direction to identify multiple falling older adults. *Archives of Physical Medicine and Rehabilitation* **83**, 1566–1571 (2002).

147. Connelly, D. M., Thomas, B. K., Cliffe, S. J., Perry, W. M. & Smith, R. E. Clinical utility of the 2-minute walk test for older adults living in long-term care. *Physiotherapy Canada* **61**, 78–87 (2009).

148. Auvinet, B. *et al.* Reference data for normal subjects obtained with an accelerometric device. *Gait and Posture* **16**, 124–134 (2002).

149. Esser, P., Dawes, H., Collett, J., Feltham, M. G. & Howells, K. Assessment of spatio-temporal gait parameters using inertial measurement units in neurological populations. *Gait and Posture* **34**, 558–560 (2011).

150. Esser, P., Dawes, H., Collett, J. & Howells, K. IMU: Inertial sensing of vertical CoM movement. *Journal of Biomechanics* **42**, 1578–1581 (2009).

151. Esser, P., Dawes, H., Collett, J. & Howells, K. Insights into gait disorders: Walking variability using phase plot analysis, Parkinson's disease. *Gait and Posture* **38**, 648–652 (2013).

152. Pirker, W. & Katzenschlager, R. Gait disorders in adults and the elderly: AÂăclinical guide. *Wiener Klinische Wochenschrift* **129**, 81–95 (2017).

153. Huang, T. T. & Wang, W. S. Comparison of three established measures of fear of falling in community-dwelling older adults: Psychometric testing. *International Journal of Nursing Studies* **46**, 1313–1319 (2009).

154. Newell, A. M., VanSwearingen, J. M., Hile, E. & Brach, J. S. The modified Gait Efficacy Scale: establishing the psychometric properties in older adults. *Physical therapy* **92**, 318–28 (2012).

155. Lorbergs, A. L. *et al.* A longitudinal study of trunk muscle properties and severity of thoracic kyphosis in women and men: The Framingham study. *Journals of Gerontology - Series A Biological Sciences and Medical Sciences* **74**, 420–427 (2019).

156. Barrey, C., Roussouly, P., Le Huec, J. C., D'Acunzi, G. & Perrin, G. Compensatory mechanisms contributing to keep the sagittal balance of the spine. *European Spine Journal* **22**, 834–841 (2013).

157. Lamartina, C. & Berjano, P. Classification of sagittal imbalance based on spinal alignment and compensatory mechanisms. *European Spine Journal* **23**, 1177–1189 (2014).

158. Lee, J. S., Lee, H. S., Shin, J. K., Goh, T. S. & Son, S. M. Prediction of sagittal balance in patients with osteoporosis using spinopelvic parameters. *European Spine Journal* **22**, 1053–1058 (2013).

159. Takeda, N. *et al.* Changes in the sagittal spinal alignment of the elderly without vertebral fractures: A minimum 10-year longitudinal study. *Journal of Orthopaedic Science* (2009).

160. Farrokhi, M. R., Haghnegahdar, A., Rezaee, H. & Sharifi Rad, M. R. Spinal sagittal balance and spinopelvic parameters in patients with degenerative lumbar spinal stenosis; a comparative study. *Clinical Neurology and Neurosurgery* **151**, 136–141 (2016).

161. Jerome, G. J. *et al.* Gait Characteristics Associated with Walking Speed Decline in Older Adults: Results from the Baltimore Longitudinal Study of Aging. *Archives of Gerontology and Geriatrics* **60**, 239–243 (2015).

162. Stanghelle, B. *et al.* Effects of a resistance and balance exercise programme on physical fitness, health-related quality of life and fear of falling in older women with osteoporosis and vertebral fracture: a randomized controlled trial. *Osteoporosis International* **31**, 1069–1078 (2020).

163. Xu, X. & McGorry, R. W. The validity of the first and second generation Microsoft Kinect for identifying joint center locations during static postures. *Applied Ergonomics* **49**, 47–54 (2015).

164. Asadi, F. & Arjmand, N. Marker-less versus marker-based driven musculoskeletal models of the spine during static load-handling activities. *Journal of Biomechanics* **112**, 110043 (2020).

165. Ghaneei, M., Ekyalimpa, R., Westover, L., Parent, E. C. & Adeeb, S. Customized k-nearest neighbourhood analysis in the management of adolescent idiopathic scoliosis using 3D markerless asymmetry analysis. *Computer Methods in Biomechanics and Biomedical Engineering* **22**, 696–705 (2019).

166. Saravanan, P., Yao, J. & Menold, J. Portable Gait Analysis System with an Integration of Kinect sensor and Inertial Measurement Units. *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care* **9**, 73–78 (2020).

167. Dimitrijević, D., Todorović, V., Nedić, N., Zečević, I. & Nedevschi, S. Toolbox for Azure Kinect COTS Device to be Used in Automatic Screening of Idiopathic Scoliosis. *Trends and Innovations in Information Systems and Technologies. WorldCIST 2020: Advances in Intelligent Systems and Computing* **1160** (2020).

Appendices

Appendix A

ROBIS appraisals

A.1 Barrett et al. appraisal

Barrett et al. 2014

ROBIS: Tool to assess risk of bias in systematic reviews

Phase 1: Assessing relevance (Optional)

ROBIS is designed to assess the risk of bias in reviews with questions relating to interventions, aetiology, diagnosis and prognosis. State your overview/guideline question (target question) and the question being addressed in the review being assessed:

Intervention reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Intervention(s):		
Comparator(s):		
Outcome(s):		

For aetiology reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Exposure(s) and comparator(s):		
Outcome(s):		

For DTA reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients):	Any healthy or patient group	same
Index test(s):	Any non-invasive method	same
Reference standard:	Radiography or established non-invasive method for validity; n/a for reliability testing	same
Target condition:	n/a as a review of reliability and validity	n/a

For prognostic reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients:		
Outcome to be predicted:		
Intended use of model:		
Intended moment in time:		

Does the question addressed by the review match the target question?	(YES)/NO/UNCLEAR

Phase 2: Identifying concerns with the review process

DOMAIN 1: STUDY ELIGIBILITY CRITERIA

Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified:

1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	Y/PY/PN/N/NI
1.2 Were the eligibility criteria appropriate for the review question?	Y/PY/PN/N/NI
1.3 Were eligibility criteria unambiguous?	Y/PY/PN/N/NI
1.4 Were any restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?	Y/PY/PN/N/NI
1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	Y/PY/PN/N/NI
Concerns regarding specification of study eligibility criteria	LOW/HIGH/UNCLEAR

Rationale for concern: While there was no explicit publication of objectiives/criteria, the stated eligibility criteria were clear and appropriate.

DOMAIN 2: IDENTIFICATION AND SELECTION OF STUDIES

Describe methods of study identification and selection (e.g. number of reviewers involved):

2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?	Y/PY/PN/N/NI
2.2 Were methods additional to database searching used to identify relevant reports?	Y/PY/PN/N/NI
2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	Y/PY/PN/N/NI
2.4 Were restrictions based on date, publication format, or language appropriate?	Y/PY/PN/N/NI
2.5 Were efforts made to minimise error in selection of studies?	Y/PY/PN/N/NI
Concerns regarding methods used to identify and/or select studies	LOW/HIGH/UNCLEAR

Rationale for concern: Methods were sound for the objective of this review

DOMAIN 3: DATA COLLECTION AND STUDY APPRAISAL

Describe methods of data collection, what data were extracted from studies or collected through other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias:

3.1 Were efforts made to minimise error in data collection?	Y/PY/PN/N/NI
3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	Y/PY/PN/N/NI
3.3 Were all relevant study results collected for use in the synthesis?	Y/PY/PN/N/NI
3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	Y/PY/PN/N/NI
3.5 Were efforts made to minimise error in risk of bias assessment?	Y/PY/PN/N/NI
Concerns regarding methods used to collect data and appraise studies	LOW/HIGH/UNCLEAR

Rationale for concern: While data collection was not duplicated and study characteristics were limited, the efforts to assess quality/ROB were appropriate.

DOMAIN 4: SYNTHESIS AND FINDINGS	
Describe synthesis methods:	
4.1 Did the synthesis include all studies that it should?	(Y)/PY/PN/N/NI
4.2 Were all pre-defined analyses reported or departures explained?	Y/PY/PN/N/(NI)
4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	(Y)/PY/PN/N/NI
4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	(Y)/PY/PN/N/NI
4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	Y/PY/PN/N/(NI)
4.6 Were biases in primary studies minimal or addressed in the synthesis?	(Y)/PY/PN/N/NI
Concerns regarding the synthesis and findings	(LOW)/HIGH/UNCLEAR
Rationale for concern: Synthesis was limited, but appropriate, due to the nature of the studies and outcomes.	

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

Phase 3: Judging risk of bias

Summarize the concerns identified during the Phase 2 assessment:

Domain	Concern	Rationale for concern
1. Concerns regarding specification of study eligibility criteria	Low	While there was no explicit publication of objectives/criteria, the stated eligibility criteria were clear and appropriate.
2. Concerns regarding methods used to identify and/or select studies	Low	Methods were sound for the objective of this review
3. Concerns regarding methods used to collect data and appraise studies	High	While data collection was not duplicated and study characteristics were limited, the efforts to assess quality/ROB were appropriate.
4. Concerns regarding the synthesis and findings	Low	Synthesis was limited, but appropriate, due to the nature of the studies and outcomes.

RISK OF BIAS IN THE REVIEW	
Describe whether conclusions were supported by the evidence:	
A. Did the interpretation of findings address all of the concerns identified in Domains 1 to 4?	(Y)/PY/PN/N/NI
B. Was the relevance of identified studies to the review's research question appropriately considered?	(Y)/PY/PN/N/NI
C. Did the reviewers avoid emphasizing results on the basis of their statistical significance?	(Y)/PY/PN/N/NI
Risk of bias in the review	RISK (LOW)/HIGH/UNCLEAR
Rationale for risk: Stated conclusions were qualified by the limitations of the studies and the review.	

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

A.2 Sedrez et al. appraisal

Sedrez et al. 2016

ROBIS: Tool to assess risk of bias in systematic reviews

Phase 1: Assessing relevance (Optional)

ROBIS is designed to assess the risk of bias in reviews with questions relating to interventions, aetiology, diagnosis and prognosis. State your overview/guideline question (target question) and the question being addressed in the review being assessed:

Intervention reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Intervention(s):		
Comparator(s):		
Outcome(s):		

For aetiology reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients/Population(s):		
Exposure(s) and comparator(s):		
Outcome(s):		

For DTA reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients):	Any healthy or patient group	same
Index test(s):	Any non-invasive method	same
Reference standard:	Radiography or established non-invasive method for validity; n/a for reliability testing	same
Target condition:	n/a as a review of reliability and validity	n/a

For prognostic reviews:

Category	Target question (e.g. overview or guideline)	Review being assessed
Patients:		
Outcome to be predicted:		
Intended use of model:		
Intended moment in time:		

Does the question addressed by the review match the target question?	YES/NO/UNCLEAR

Phase 2: Identifying concerns with the review process

DOMAIN 1: STUDY ELIGIBILITY CRITERIA

Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified:

1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	Y/PY/PN/N/(NI)
1.2 Were the eligibility criteria appropriate for the review question?	(Y)/PY/PN/N/NI
1.3 Were eligibility criteria unambiguous?	(Y)/PY/PN/N/NI
1.4 Were any restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?	(Y)/PY/PN/N/NI
1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	Y/(PY)/PN/N/NI
Concerns regarding specification of study eligibility criteria	(LOW)/HIGH/UNCLEAR

Rationale for concern: Although predefined objectives/criteria is unknown, the eligibility used was clear. Only minor concern is the inclusion of English language only.

DOMAIN 2: IDENTIFICATION AND SELECTION OF STUDIES

Describe methods of study identification and selection (e.g. number of reviewers involved):

2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?	(Y)/PY/PN/N/NI
2.2 Were methods additional to database searching used to identify relevant reports?	(Y)/PY/PN/N/NI
2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	(Y)/PY/PN/N/NI
2.4 Were restrictions based on date, publication format, or language appropriate?	(Y)/PY/PN/N/NI
2.5 Were efforts made to minimise error in selection of studies?	(Y)/PY/PN/N/NI
Concerns regarding methods used to identify and/or select studies	(LOW)/HIGH/UNCLEAR

Rationale for concern: No methodological concerns for ID and selection.

DOMAIN 3: DATA COLLECTION AND STUDY APPRAISAL

Describe methods of data collection, what data were extracted from studies or collected through other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias:

3.1 Were efforts made to minimise error in data collection?	(Y)/PY/PN/N/NI
3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	(Y)/PY/PN/N/NI
3.3 Were all relevant study results collected for use in the synthesis?	(Y)/PY/PN/N/NI
3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria?	Y/PY/(PN)/N/NI
3.5 Were efforts made to minimise error in risk of bias assessment?	(Y)/PY/PN/N/NI
Concerns regarding methods used to collect data and appraise studies	LOW/(HIGH)/UNCLEAR

Rationale for concern: Appropriate methods for data collection. The appraisal tool was not specifically designed for reliability studies, only validity.

DOMAIN 4: SYNTHESIS AND FINDINGS	
Describe synthesis methods:	
4.1 Did the synthesis include all studies that it should?	Y/PY/PN/N/NI
4.2 Were all pre-defined analyses reported or departures explained?	Y/PY/PN/N/NI
4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	Y/PY/PN/N/NI
4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis?	Y/PY/PN/N/NI
4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses?	Y/PY/PN/N/NI
4.6 Were biases in primary studies minimal or addressed in the synthesis?	Y/PY/PN/N/NI
Concerns regarding the synthesis and findings	LOW/HIGH/UNCLEAR
Rationale for concern: Limited but appropriate synthesis for the type of studies included.	

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

Phase 3: Judging risk of bias

Summarize the concerns identified during the Phase 2 assessment:

Domain	Concern	Rationale for concern
1. Concerns regarding specification of study eligibility criteria	Low	Although predefined objectives/criteria is unknown, the eligibility used was clear. Only minor concern is the inclusion of English language only.
2. Concerns regarding methods used to identify and/or select studies	Low	No methodological concerns for ID and selection.
3. Concerns regarding methods used to collect data and appraise studies	High	Appropriate methods for data collection. The appraisal tool was not specifically designed for reliability studies, only validity.
4. Concerns regarding the synthesis and findings	Low	Limited but appropriate synthesis for the type of studies included.

RISK OF BIAS IN THE REVIEW	
Describe whether conclusions were supported by the evidence:	
A. Did the interpretation of findings address all of the concerns identified in Domains 1 to 4?	Y/PY/PN/N/NI
B. Was the relevance of identified studies to the review's research question appropriately considered?	Y/PY/PN/N/NI
C. Did the reviewers avoid emphasizing results on the basis of their statistical significance?	Y/PY/PN/N/NI
Risk of bias in the review	RISK: LOW/HIGH/UNCLEAR
Rationale for risk: Based on limitations, the overall risk was low for the stated purpose of the review.	

Y=YES, PY=PROBABLY YES, PN=PROBABLY NO, N=NO, NI=NO INFORMATION

Appendix B

PROVE Trial secondary analysis

B.1 PROVE ethics approval letter

NRES Committee South Central - Portsmouth
Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1334
Facsimile: 0117 342 0445

08 August 2012

Dr Karen Barker
Clinical Director, Orthopaedics
Oxford University NHS Hospitals Trust
Nuffield Orthopaedic Centre
Windmill Road
Oxford
OX3 7HE

Dear Dr Barker

Study title:	**Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)**
REC reference:	**12/SC/0411**
IRAS project number:	**1078633**

Thank you for your letter of 02 August 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- The Sub-Committee agreed that in the situation where the research team may decide to halt an arm of the study there needs to be a simple explanation as to what will happen to the affected participants. Therefore on the PIS, in the section: 'Will anything change during the study?', please add the following wording: "We will be monitoring the participants carefully during the course of this study, and 10 months into the study if it is shown that one of the treatment arms is considerably less effective than the others we will stop recruiting any further participants into this treatment arm. Any existing participants will continue in this treatment arm until their participation finishes."

- On page 2, paragraph 5 of the sheet, please substitute 'their' for 'your'.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		27 June 2012
GP/Consultant Information Sheets	1	01 June 2012
Investigator CV		02 July 2012
Other: Letter of invitation - Main Study	1	01 June 2012
Other: Initial Approach Letter - Main Study	1	01 June 2012

Other: Reply Slip - Main Study	1	01 June 2012
Other: Letter of invitation - Qualitative Study	1	01 June 2012
Other: Reply Slip - Qualitative Study	1	01 June 2012
Other: Letter to non-respondents - Qualitative Study	1	01 June 2012
Other: Letter to non-respondents	3	02 August 2012
Other: Diary 1		
Other: Diary 2		
Participant Consent Form: Main Study	1	01 June 2012
Participant Consent Form: Qualitative Study	1	01 June 2012
Participant Information Sheet: Qualitative Study	1	01 June 2012
Participant Information Sheet: Main Study	3	02 August 2012
Protocol	2	01 May 2012
Questionnaire: Qualeffo		
REC application	3.4	27 June 2012
Response to Request for Further Information		02 August 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/SC/0411	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mrs Jayne Tyler
Vice-Chair

Email: scsha.sehrec@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Ms Heather House, Oxford University Hospitals NHS Trust*

NRES Committee South Central - Portsmouth

Attendance at Sub-Committee of the REC held in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr. Mark Cassidy	Lecturer in Radiography	Yes	
Mrs Jayne Tyler	Senior Fire Control Operator	Yes	Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Ruth Avery	REC Coordinator

B.2 PROVE Patient Information Sheet

Prove
Physiotherapy Rehabilitation of Osteoporotic Vertebral Fracture

UNIVERSITY OF OXFORD

Participant Information Sheet

Physiotherapy Research Unit
Nuffield Orthopaedic Centre
Oxford, OX3 7HE

Email:prove@ndorms.ox.ac.uk

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)

What is the purpose of the study?

This is a study about how best way to treat patients with osteoporosis. The PROVE team have been funded to investigate different types of physiotherapy treatments comparing exercise, 'hands on' manual therapy and advice to find out which type of physiotherapy is the most beneficial to offer people with osteoporosis who have a vertebral fracture.

Why have I been asked to participate?

You have been invited to take part in this study because you have osteoporosis.

Do I have to take part in the study?

It is up to you whether or not to take part. If you decide not to take part then your future medical care will not be affected in any way. You are also free to ask the researchers any questions you may have at any time during the study. If you decide to take part you would be given this information sheet to keep and be asked to sign a consent form.

Who can take part in the study?

Men and women with one or more vertebral fractures and osteoporosis can take part in the study if they:

- Have had their diagnosis of osteoporosis confirmed by an X-ray or bone (DEXA) scan
- May have had a vertebral fracture and/or back pain associated with osteoporosis lasting for more than 24 hours in the last 12 months
- Can walk at least 10 metres (with or without a walking aid)
- Have not had physical therapy (physiotherapy, osteopathy, chiropractic treatment) for back pain in the previous 12 weeks

What will happen if I take part in this study?

You will be asked to go to your local clinic and take part in a physiotherapy assessment. The physiotherapist will ask some questions about your osteoporosis and back pain and you would be asked to fill in questionnaires about how osteoporosis affects your daily life, about falls and activity levels. We would look at the curves of your spine, back strength, balance, walking, getting up from a chair and standing posture. This should all take about an hour.

When it is not known which treatment is best, the treatments need to be compared to each other. When participants join the study they will be allocated to one of three treatments and the allocation will be decided entirely by chance. A computer programme is used to ensure this.

The three treatments are:

- Best current practice. An advice session lasting up to one and a half hours with a physiotherapist who will provide advice about osteoporosis and discuss lifestyle choices and living with osteoporosis.

- Manual therapy. This includes gentle (pain free) “hands on” treatments, tape being used to help people maintain a better posture and a home stretching

programme. Up to 7 individual sessions with a physiotherapist will be offered over a twelve week period.

- Exercise. This includes balance, strengthening and stretches exercises. Up to 7 individual sessions with a physiotherapist will be offered over a twelve week period.

To be able to compare the three treatments we need to repeat the questionnaires and assessments after you have received their treatment. We will ask you to come back to clinic at approximately 16 weeks after you have joined the study, and again at one year. Also, we will ask you to complete the questionnaires again at 6 and 9 months and post them back to us (in a prepaid postage envelope).

Will I have to do anything at home as part of the study?

Depending on the group you are allocated you will be asked to carry out a home exercise program and fill in patient diaries to log the exercise program as well as fill in a calendar provided to you to log any falls and medical attention needed through the duration of your participation in the study.

Expenses and payments

Travel expenses (public transport, car mileage, car parking) will be reimbursed when coming to clinic for a research assessment.

What are the benefits of taking part in the study?

We do not expect any particular benefits from taking part. The information we get from this study will help us to treat future patients with vertebral fractures due to osteoporosis.

Is there any risk of taking part in this study?

There are no “new” treatments included in this study. The treatments are those already used with patients with osteoporosis.

What happens when the study ends?

We will inform your hospital /GP of the treatment that you have received and they will continue to treat your osteoporosis if / as appropriate.

What if I have any concerns?

If you have a concern or problem about any aspect of the study please speak to any one of the researchers who will do their best to answer your questions. Their contact details at the Physiotherapy Research Unit are at the top of this patient information sheet. You pay also contact the hospital's Patient Advice and Liaison Service (PALS) 01865 738126 or email PALSNOC@ouh.nhs.uk.

What if there is a problem?

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London, policy numbered :WD1200463). NHS indemnity operates in respect of the clinical treatment which is provided.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Karen Barker at 01865 737424 or at prove@ndorms.ox.ac.uk you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email ctrg@admin.ox.ac.uk

Will my taking part in this study be kept confidential?

All information that is collected about you for the study will be kept strictly confidential. We will ask you for your permission to look at your medical notes (so that we can check details such as bone scan findings). Information will be held in a secure place and questionnaire and assessment information sent from your local clinical site to the trial team will have your name and address removed first

All information will be securely stored for five years after the study has ended and then be destroyed.

Responsible members of the University of Oxford or the NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations.

What if new relevant information becomes available?

If new relevant information about physiotherapy treatments for vertebral fracture becomes available then your physiotherapist clinician or a member of the study team will tell you about it and discuss with you whether you want to continue in the study. If the study team believed it would be in your best interest for a person to withdraw from the study they would also discuss this with you. Your hospital/GP would be informed. If you decided to continue with receiving a study treatment you would be asked to sign an updated consent form.

What would happen if I don't want to continue with the study?

You can withdraw from the study at any point. You would be asked which type of withdrawal you would prefer – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study this will not affect your future NHS care in any way.

Would anyone else know if I was taking part?

We would ask for your permission to write to your GP to tell them you are taking part in this study.

What happens to the results of the study?

The results will be used to write a report and health journal articles so that health care professionals can use the results to help other patients in the future. In any report or publication we will not use your name or give any information that could identify you. We will send out a summary of the results to people who take part in the study when the study is complete.

Who is organizing and funding the research?

The main person responsible for the research is Dr Karen Barker from the Nuffield Orthopaedic Centre in Oxford. It is sponsored by the University of Oxford and is

being paid for by the National Institute of Health Research's Health Technology Assessment Programme who identified this as an important research question.

Who has reviewed this study?

The study was reviewed by independent experts when the study was being considered for funding. All research in the NHS is also looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NRES Committee South Central - Portsmouth REC Number 12/SC/0411.

Who do I contact for further information?

If you would like any further details about this study or would like to ask us any questions then please do not hesitate to contact us. You may speak to the local PROVE team. For further information you can contact the Varsha Gandhi the study co-ordinator at prove@ndorms.ox.ac.uk or on 01865 223489, email Varsha.Gandhi@ouh.nhs.uk or Tamsin Hughes on 01865 737424, email Tamsin.Hughes@ouh.nhs.uk

What do I do now?

If you would like to take part in this study then please fill in the reply consent slip and post it to us in the pre-paid envelope provided. If you have received this invitation in the post and we do not hear from you we will send you one further invitation.

Thank you for taking the time to read this Patient Information Sheet.

B.3 PROVE Informed Consent Form

Prove
Physiotherapy Rehabilitation of Osteoporotic Vertebral Fracture

UNIVERSITY OF OXFORD

Participant Consent Form – Main Trial
Lead Principal Investigator: Dr Karen Barker

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)

Please initial in box

I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
I consent for the PROVE team and the study physiotherapist to look at my medical records where these are relevant to osteoporosis and vertebral fracture	☐
I understand that relevant sections of the data collected during the study may be looked at by individuals involved in the study, or from authorized individuals from the University of Oxford and the NHS Trust where it is relevant to my taking part in this research. I permit these individuals access to my records.	☐
I consent to the research team holding the contact details I have previously sent them so that they can contact me for follow up information or if they need to check the information I have given them. I understand these details will be held securely and destroyed after a letter telling me the results of the study has been sent to me.	☐
I agree to my GP being informed of my participant in the study	☐
I am aware that the results of the study may be presented in research reports, scientificconferences and/or journals. However, the information I provide for the study will remain confidential.	☐
I am aware that depending on the group allocation I will be requested to fill in patient exercise diaries and calenders throughout the duration of my participation in the trial.	☐
I am aware that I will be contacted to give follow up information for this study; I will be sent postal questions (6, 9 months) invited to attend for study follow up (approximately at 4 and 12 months), complete monthly diaries (for 12 months) and telephoned at least twice. I am also aware that I may be invited to consider taking part in an interview study and give permission to be contacted for for this purpose.	☐
I agree to take part in the above study	☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

B.4 PROVE Case Report Form

Prove
Physiotherapy Rehabilitation of Osteoporotic Vertebral Fracture

CASE REPORT FORM

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture Study - PROVe study

Study Reference numbers
Ethics Ref: 12/SC/0411
Project ID: 1078633
Study Sponsor – University of Oxford

STUDY SITE: **Nuffield Orthopaedic Centre**

PRINCIPAL INVESTIGATOR: **Karen Barker**

PARTICIPANT INITIALS: | | | |

STUDY NUMBER: | | | |

I am confident that the information supplied in this case record form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.

Investigator's Signature: .....

Date of signature: | | | | | | | | | |
d d m m m y y y y

Please check only one box

☐ Baseline assessment ☐ 16 week assessment ☐ 12 month assessment

Participant Initials: ☐☐☐ Study Number: ☐☐☐

INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place.

Has the person freely given written informed consent? Yes ☐ No ☐

Date consent form signed: __ __ / __ __ / __ __ __ __

Original consent in study master file, copy given to participant Yes ☐ No ☐

Assessment

Date: __ __/__ __ __/__ __ __ __ Assessor Name_____

A. Demographic and Background Information

Date of Birth: __ __/__ __ __/__ __ __ __ Gender: Male ☐ Female ☐

Dominant hand: Right ☐ Left ☐ Both ☐

Height -☐☐☐ (cms) Weight - ☐☐☐ (kgs)

B. Relevant medical history:

Diagnosis of primary osteoporosis: Yes ☐ No ☐

Time since diagnosis MMM/YYYY - __ __/__ __ __/__ __ __ __

Radiology (from medical notes - Check spinal fractures: note date, location and number of spinal fractures)

Did you have a DEXA scan? ☐ Yes ☐ No

Most recent DEXA scan date - MMM/YYYY - __ __/__ __ __/__ __ __ __

Participant Initials: ☐☐☐ Study Number: ☐☐☐

Results - DEXA T-score lumbar spine ☐.☐

Fracture Sites (Check box(es)) – ☐ Lower lumbar (L3, L4, L5) ☐ Mid-Lumbar (L1, L2),

☐ Lower Thoracic (T6 -T12) ☐ Upper Thoracic (T1-T5)

Number of total spinal fractures - ☐☐

Number of previous non-spinal fractures in **past year** - ☐☐

Fracture Location			Fracture Date (DD/MMM/YYYY)
Shoulder	Right ☐	Left ☐	
Elbow	Right ☐	Left ☐	
Wrist	Right ☐	Left ☐	
Hip	Right ☐	Left ☐	
Knee	Right ☐	Left ☐	
Ankle	Right ☐	Left ☐	
Others	☐	☐	

Other previous fractures

Fracture Location			Fracture Date (DD/MMM/YYYY)
Shoulder	Right ☐	Left ☐	
Elbow	Right ☐	Left ☐	
Wrist	Right ☐	Left ☐	
Hip	Right ☐	Left ☐	
Knee	Right ☐	Left ☐	
Ankle	Right ☐	Left ☐	
Others	☐	☐	

Current mobility: (Circle only one from each relevant level of function)

Walking distance	Stairs	Aid Use
Unlimited	Normal (reciprocal)	None
500m-1km	One step at a time	Stick outdoors
100-500m	Down with rail	Stick always
<100m	Up & down with rail	2 sticks
Housebound	Unable down	2 Crutches
Unable	Unable	Walking frame wheeled walker

Falls history in past year

Number of falls - ☐☐

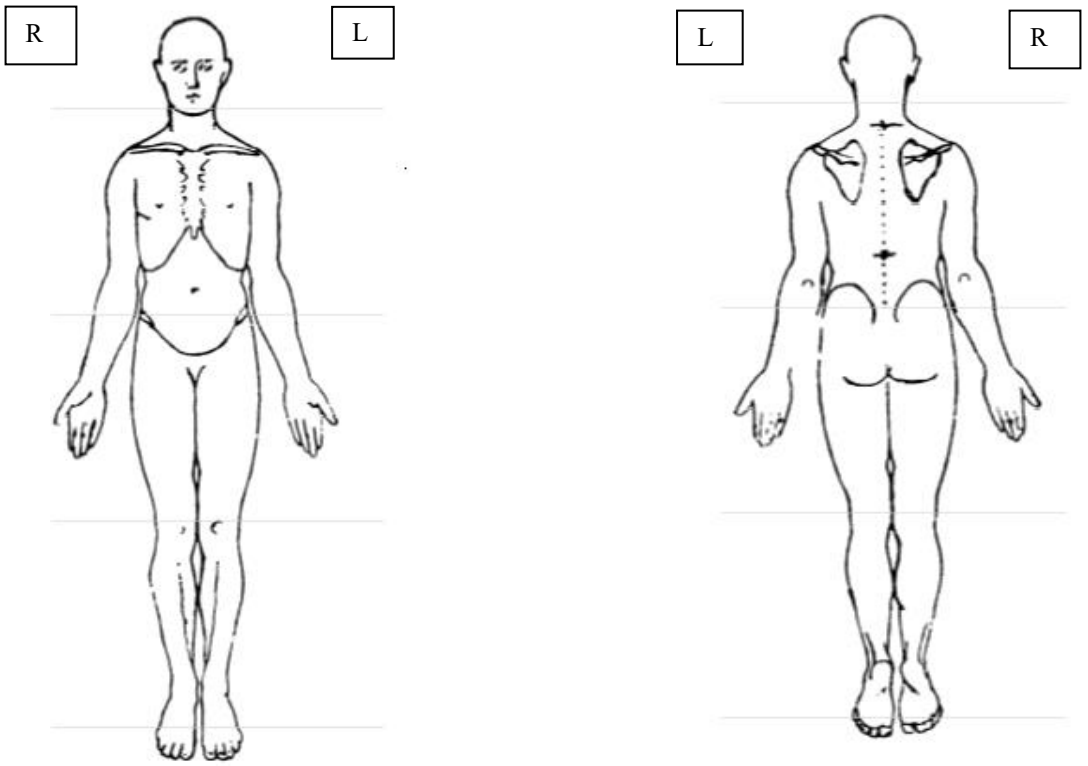
Falls History in General

☐ Frequent (≥ once a week) ☐ occasionally (≤ once a month) ☐ rarely (≤ once a year)

Participant Initials: ☐☐☐ Study Number: ☐☐☐

BODY CHART – past **two weeks**

Researcher please check the box(es) at the bottom of the chart to show any areas where the participant has experienced pain in the past **two weeks**. P = //////



Have you experienced any back pain in the last two weeks? (Please tick)

Yes ☐ No ☐

Pain Site ☐ Lower lumbar (L3, L4, L5), ☐ Mid-Lumbar (L1, L2), ☐ Lower Thoracic (T6 -T12) ☐ Upper Thoracic (T1-T5)

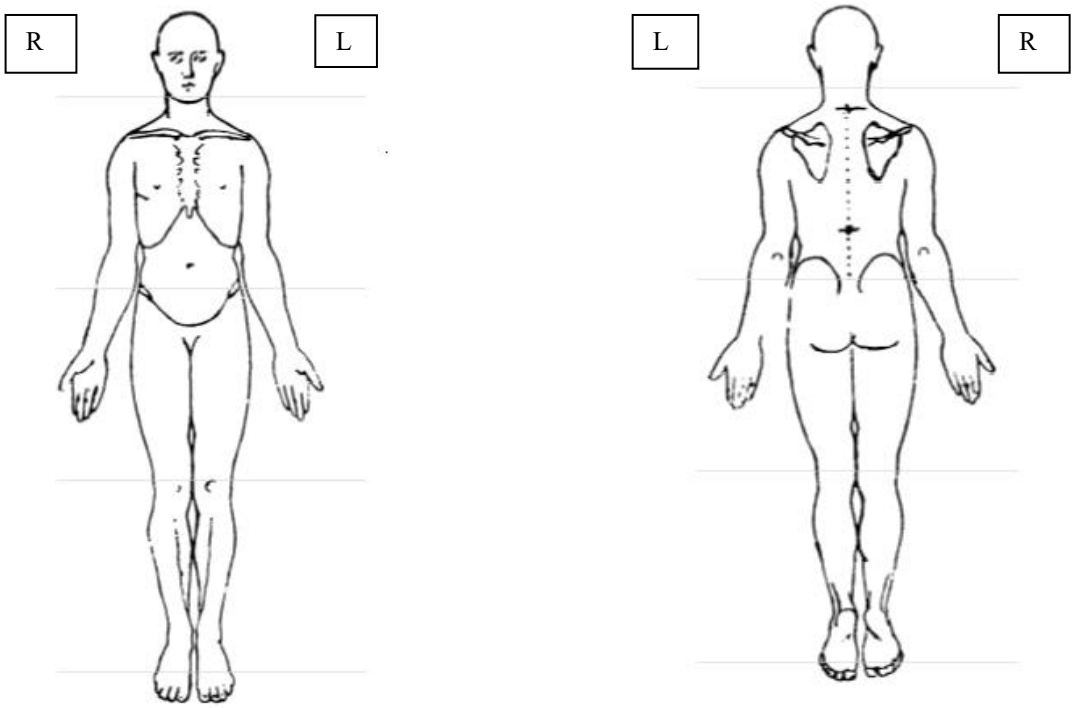
Mark on the scale below the severity of any back pain in the last two weeks.

0	1	2	3	4	5	6	7	8	9	10
No pain										Worst pain Imaginable

Participant Initials: | | | | Study Number: | | | |

BODY CHART – Today

Researcher please check the box(es) at the bottom of the chart to show any areas where the participant has experienced pain today. P = //////



Do you have any back pain today? (Please tick)

Yes ☐ No ☐

Pain Site ☐ Lower lumbar (L3, L4, L5), ☐ Mid-Lumbar (L1, L2), ☐ Lower Thoracic (T6 -T12) ☐ Upper Thoracic (T1-T5)

Mark on the scale below the severity of any back pain is today.

0	1	2	3	4	5	6	7	8	9	10

No pain — Worst pain imaginable

C. Outcome Measures

1. Functional Reach Test

	Trial 1	Trial 2
Distance (cms)	☐☐.☐	☐☐.☐

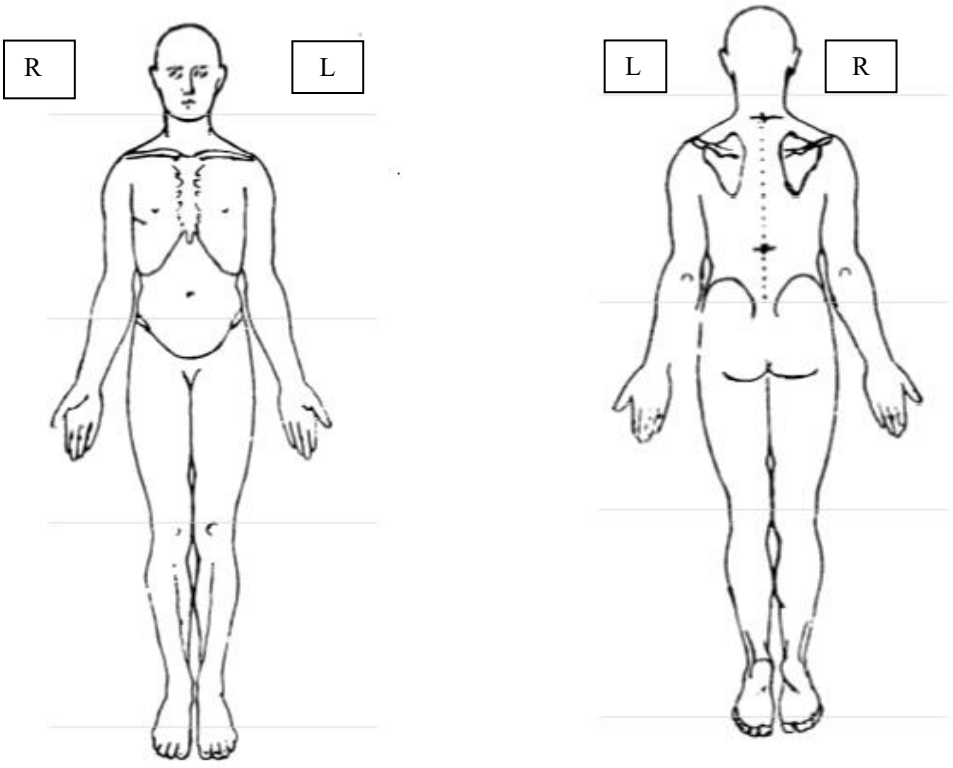
2. Timed Loaded Standing

Weight used (kg): ☐☐ Total time (seconds): ☐☐☐

Stopped by: participant ☐ physiotherapist ☐

Reason for stopping: pain ☐ fatigue ☐

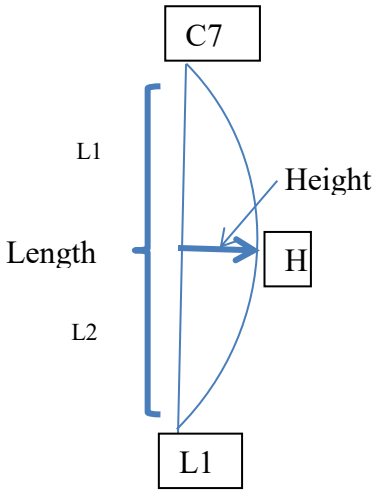
Location of any pain or fatigue on body diagram: Pain = ///// Fatigue = +



Pain Site ☐ Lower lumbar (L3, L4, L5), ☐ Mid-Lumbar (L1, L2), ☐ Lower Thoracic (T6 -T12) ☐ Upper Thoracic (T1-T5)

3. Flexicurve (mm) - use the graph paper to obtain readings

	Total Curve Length (C7 – L1)	**Curve Height (H)** (Perpendicular line from apex to base)	**Curve length 1 (L1)** (C7 to where height intersects base)	**Curve length (L2)** (L1 to where height intersects base)
1st				
2nd				
3rd				



4. Short Physical Performance Battery

Lower Limb Strength Repeated chair stands with arms folded. Stop at 5 stands or after 1 minute	**Number of stands completed: 1 2 3 4 5 (Circle)** **Time:** ☐☐ **sec (if 5 stands completed)**		
Balance Testing. Please circle level achieved. Must achieve level 2 (hold 10sec) to advance from a) to b) to c). 2. Held for 10 sec 1.Held for <10 sec; number of seconds held 0. Not attempted	**a) Side-by-side**	**b) Semi-tandem**	**c) Tandem**
	2 1 – state time ☐☐ sec 0	2 1 – state time ☐☐ sec 0	2 1 – state time ☐☐ sec 0

Gait Testing 2.44 metres	**Walk 1.** **Time:** ☐☐ **sec**	**Walk 2** **Time:** ☐☐ **sec**

5. Six minute walk test

Distance completed	☐☐ m ☐☐ cm	
Track Length		
Number of stops or rests (if any)		
Duration of stop		
Self-report rating of exertion CR10-RPE scale (0-10)	**Before 6 minute walk**	**After 6 minute walk**
	Breathing ☐	☐
	Legs ☐	☐

Checklist (check appropriate box)

Comorbidity questionnaire (General Health Questions)	☐ completed	☐ incomplete
PASE Questionnaire	☐ completed	☐ incomplete
Qualeffo 41	☐ completed	☐ incomplete
ED-5DL	☐ completed	☐ incomplete
Participant health diary	☐ given	☐ collected
Falls Calendar	☐ given	☐ collected

Assessor signature: _____

Assessor printed name: _____

Date: __ __/__ __ __/__ __ __ __

Adverse Events:

Has the patient experienced any Adverse Events since signing the Informed Consent?

Yes ☐ No ☐

If an adverse event has occurred please use DATIX (incident reporting system) to log and describe event and note below

Adverse Event 1	Details
Date of event: __ __ / __ __ / __ __ __ __	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes ☐ No ☐	Severity 1 = Mild 2= Moderate 3 = Severe
Action Taken	
Outcome 1= Resolved 2 = Recovered with sequelae 3= Continuing	
Withdrawn from study due to SAE? 1= No 2= Yes, happy for existing data to be used 3= Yes, data destroyed	

Adverse Event 2	Details
Date of event: __ __ / __ __ / __ __ __ __	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes ☐ No ☐	Severity 1 = Mild 2= Moderate 3 = Severe
Action Taken	
Outcome 1= Resolved 2 = Recovered with sequelae 3= Continuing	
Withdrawn from study due to SAE? 1= No 2= Yes, happy for existing data to be used 3= Yes, data destroyed	

Add more pages if there are more than 2 adverse events.

OFF STUDY FORM

Date Off Study: __ __ / __ __ / __ __ __ __
(DD/MM/YYYY)

Date Of Last Assessment: __ __ / __ __ / __ __ __ __
(DD/MM/YYYY)

Reason Off Study (Please mark only the primary reason. **Reasons other than Completed Study require explanation next to the response**)

- ☐ AE/SAE **(complete AE CRF & SAE form, if applicable)** _____
- ☐ Lost to follow-up _____
- ☐ Non-compliant participant _____
- ☐ Medical contraindication _____
- ☐ Withdraw consent _____
- ☐ Death **(complete SAE form)** _____
- ☐ Other _____

Appendix C

Reliability study

C.1 Oxford Brookes University ethics approval letter

Oxford Brookes University

Faculty of Health and Life Sciences

Decision on application for ethics approval

The Departmental Research Ethics Officer (DREO) has considered the application for ethics approval for the following project:

Project Title: Spinal curvature and physical activity

DREC Reference: 1217_35

Name of Applicant/s: Ian Parker, Erin Hannink
Name of Supervisor/s: Patrick Esser
Please tick one box

1. The Departmental Research Ethics Officer / Faculty Research Ethics Committee gives ethical approval for the research project. ☑

   Please note that the research protocol as laid down in the application and hereby approved must not be changed without the approval of the DREO / FREC

2. The Departmental Research Ethics Officer / Faculty Research Ethics Committee gives ethical approval for the research project, subject to the following:: ☐

3. The Departmental Research Officer / Faculty Research Ethics Committee cannot give ethical approval for the research project. The reasons for this and the action required are as follows: ☐

Signed: … ……
Approval Date: …05/01/2018……..…

Designation: Departmental Research Ethics Officer

(Signed on behalf of the Faculty Research Ethics Committee)

Date when application reviewed (*office use only*):……11/12/2017……

C.2 Reliability study Patient Information Sheet

Primary Investigator:
Dr Patrick Esser
Colonnade Building
Gipsy Lane
Faculty of Health & Life Sciences, Oxford Brookes University
OX3 0BP

Participant Information Sheet

Study title: **Spinal Curvature and Physical Activity**

You are being invited to take part in a research study about spinal curvature and physical activity. Before you decide whether or not you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?
The purpose of this study is to test how reliably we can measure the curvature of the back and to relate it to physical activity levels. The study will be a one-off visit which will take approximately 20 minutes. We will use the Microsoft Kinect camera sensor to take picture of your back with will create a 3D digital image. The research visit will require you to have multiple images taken of your posture. Additionally, you will be asked to provide some general information about yourself and complete a questionnaire about your physical activity.

Why have I been invited to participate?
We are inviting individuals to participate who are 18 years or older. We aim to include 30 people total in our study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you are student at Oxford Brookes University, choosing to either take part or not take part in the study will have no impact on your marks, assessments or future studies. Additionally, if you are a colleague, choosing to take part or not take part in the study will not affect your work relationship.

What will happen to me if I take part?
If you agree to take part in this study it will require approximately 20-30 minutes of your time. During the research visit, you will be asked to expose your back and you will be given a gown to wear for modesty. We will place temporary markers at 4 different places on your back. You will be asked to stand in front of the camera sensor for an instant image to be captured. You will also be asked to fill out a questionnaire with general questions about you and your physical activity level. This study does not require any exertion more than daily activities therefore we expect it to be very low risk.

What are the possible benefits of taking part?
There will be no direct benefits from participation in this study. However, you will be helping to contribute to a better understanding of back posture and physical activity levels.

Will what I say in this study be kept confidential?
Research data from this study will be kept securely at all times on encrypted devices. Data generated by the study will be retained in accordance with the University's policy on Academic Integrity. The data generated in the course of the research will be kept securely in paper or electronic form for a period of ten years after the completion of a research project.

What should I do if I want to take part?
If you would like to participate in this study, please contact Ms Erin Hannink (erin.hannink-2017@brookes.ac.uk) or Mr Ian Parker (15047171@brookes.ac.uk).

What will happen to the results of the research study?
The results of this study will be used in a BSc independent research module and as part of a PhD dissertation. For a copy of the published research, you may email Ms Erin Hannink (erin.hannink-2017@brookes.ac.uk).

Who is organising and funding the research?
This research is being conducted by students at Oxford Brookes University within the Department of Sport, Health Sciences and Social Work.

Who has reviewed the study?
This research has been approved by the University Research Ethics Committee, Oxford Brookes University.

Contact for Further Information
If you would like to contact for further information, please contact Ms Erin Hannink (erin.hannink-2017@brookes.ac.uk) or Mr Ian Parker (15047171@brookes.ac.uk). Should you have any concerns about the way in which the study has been conducted, please contact the Chair of the University Research Ethics Committee (ethics@brookes.ac.uk).

Thank you for taking time to read the information sheet.

C.3 Reliability study Informed Consent Form

OXFORD BROOKES UNIVERSITY

CONSENT FORM

The relationship between physical activity levels and spinal curvature in the sagittal plane

Dr Patrick Esser
Colonnade Building
Gipsy Lane
Faculty of Health and Life Sciences, Oxford Brookes University
OX3 0BP

		Please initial box
1.	I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.	☐
3.	I agree to take part in the above study.	☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Appendix D

MAPS study

D.1 MAPS ethics approval letter

South West - Central Bristol Research Ethics Committee
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol BS1 2NT
Email: nrescommittee.southwest-bristol@nhs.net

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

13 October 2017

Ms Erin Hannink
Research Physiotherapist
University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
Nuffield Orthopaedic Centre
Windmill Road
Oxford
OX3 7HE

Dear Ms Hannink

Study title:	**MAPS: Measuring Alignment and Posture in the Spine**
REC reference:	**17/SW/0239**
IRAS project ID:	**230019**

The Proportionate Review Sub-committee of the South West - Central Bristol Research Ethics Committee reviewed the above application on 16 October 2017.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Additional Condition:

- Parking costs should be covered as well as travel expenses for additional visits.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant. There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an

amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory. If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_02102017]		02 October 2017
Letter from sponsor [MAPS Sponsor Letter]		28 September 2017
Letters of invitation to participant [MAPS Participant Invitation Letter]	1.0	27 September 2017
Other [MAPS Case Report Form]	1.0	27 September 2017
Other [MAPS Eligibility Form]	1.0	27 September 2017
Other [MAPS Reply Slip]	1.0	27 September 2017
Participant consent form [MAPS Informed Consent Form]	1.0	27 September 2017
Participant information sheet (PIS) [MAPS Participant Information Sheet]	1.0	27 September 2017
Research protocol or project proposal [MAPS Protocol]	1.0	27 September 2017
Summary CV for Chief Investigator (CI) [Hannink CV]	1.0	01 September 2017
Summary CV for student [Hannink CV]	1.0	01 September 2017
Summary CV for supervisor (student research) [Delextrat CV]	1.0	19 June 2017
Summary CV for supervisor (student research) [Barker CV]	1.0	08 September 2017
Summary CV for supervisor (student research) [Dawes CV]	1.0	08 September 2017

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research

Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

17/SW/0239	**Please quote this number on all correspondence**

Yours sincerely

pp Jbaum

Dr Julie Woodley
Chair

Email: nrescommittee.southwest-bristol@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: Ms Heather House, Oxford University Hospitals NHS Foundation Trust

South West - Central Bristol Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 16 October 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Yes	
Dr Adrian Kendrick	Consultant Clinical Scientist	Yes	
Dr Julie Woodley	Senior Lecturer/ Chair of Faculty Ethics Committee	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lidia Gonzalez	REC Assistant

D.2 MAPS Patient Information Sheet

Physiotherapy Research Unit
Chief Investigator: Ms Erin Hannink
01865 737526 | erin.hannink@ouh.nhs.uk

Participant Information Sheet

MAPS Study

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study if you wish. This Participant Information Sheet tells you the purpose of the study, what will happen to you if you take part and provides information about conduct of the study. Please do ask if anything is unclear.

What is the purpose of the study?

This is a study that intends to measure the accuracy and repeatability of a low cost, quick measure of the spine. It compares different measurements to try to understand more about the 3D postural topography method, which is a special camera sensor that creates an instant digital 3D map of the back. We aim to see whether this 3D postural topography method is a useful, reliable measure of the spine.

Why have I been asked to participate?

You have been invited to take part in this study because you have had or will have an appointment at the Nuffield Orthopaedic Centre (NOC) involving a spinal condition.

Do I have to take part in the study?

It is up to you whether or not you take part. If you decide not to take part then your future medical care will not be affected in any way. You are also free to ask the researchers any questions you may have at any time during the study. If you decide

to take part you would be given this information sheet to keep and be asked to sign a consent form. The study team will be looking for 60-80 people to take part.

Who can take part in the study?

Men and women aged 18 or above can take part in the study if they:

- have had an x-ray of the spine or have spinal condition that affects the curvature
- are able to understand and participate safely in a physiotherapy assessment
- are able to stand independently
- do not have a neurological condition which alters motor function and postural control

What will happen if I take part in this study?

If you tell us you are interested a research physiotherapist will call you on the telephone and discuss the study or we will discuss the study with you while you're at the NOC for your appointment. You may also contact the research team directly at 01865 737526 with any questions. With your permission, the research team will access your NHS medical record to check that it is appropriate and safe for you to take part in the study and check that you meet the eligibility criteria. If you agree, a study visit will be arranged at your convenience. At the study visit, the study will be explained and if you are happy to proceed, you will be asked to sign a consent form to confirm that you would like to take part.

At the study visit we will ask a small number of questions about you and your general health and mobility. We will then ask you to participate in three measurements of your back. These are:

1. **3D postural topography** – A camera sensor will take an image of your back that creates an instant digital 3D map of your back.
2. **Flexicurve** – A flexible ruler will be gently moulded to your spine and then traced onto graph paper.

3. **Digital Inclinometers** – An inclinometer is a compass-like device that measures angles. Two inclinometers will be placed at different places of the spine.

You will be required to expose your back for measurements to be taken, however we will provide you with a hospital gown to wear for comfort and modesty if you wish. In between each measurement test you will be given a rest. We expect the study visit to take no longer than 50 minutes in total. The research team will reimburse your parking costs as well as travel expenses if you are making an additional visit to the hospital. The research team will also require access to your relevant medical records and if you have had an x-ray of the spine, they will use it to measure the angle of your spine. If your x-ray is used, all your personal information will be removed from the copies of the x-ray image and they will be stored securely.

What would happen if I don't want to continue with the study?

You can withdraw from the study at any point, please let the investigator know. If you choose to leave we will discuss with you how any data collected is managed – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study this will not affect your future NHS care in any way.

Is there any risk of taking part in this study?

All the assessments chosen have been used safely in the past. There are no known particular side effects of the assessments and an experienced physiotherapist will be with you throughout to monitor how you are doing and check you are safe. We don't expect these measures to cause you pain, but you may experience some mild discomfort whilst areas of the spine are being palpated to be marked.

Are there any possible benefits of taking part in this study?

For individual participants there will be no immediate benefit; however, the potential for benefit arises from improving measurement techniques for future patients.

What if I have any concerns?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Erin Hannink on 01865 737526 or email erin.hannink@ouh.nhs.uk. Alternatively you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office, email: ctrg@admin.ox.ac.uk.

You may also contact the hospital's Patient Advice and Liaison Service (PALS). The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact the PALS advisor at the Nuffield Orthopaedic Centre on 01865 221473 or email the PALS website at http://www.ouh.nhs.uk/patient-guide/pals.aspx.

Will my taking part in the study be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for one year after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting erin.hannink@ouh.nhs.uk.

The NHS hospital site will collect information from you and your medical records for this research study in accordance with out instructions. The NHS hospital will keep your name, NHS number and contact details confidential and will not pass this information to University of Oxford. The NHS hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the University of Oxford and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The University of Oxford will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. NHS will keep identifiable information about you from this study for one year after the study has finished.

All information which is collected about you during the research will be kept strictly confidential and securely stored. After the study we will securely store your personal identifying information, such as your name and address, longer than one year only if you have explicitly given permission on the Informed Consent Form to be contacted for future research, or have requested a copy of the study findings. Your anonymised research data will also be stored securely and separately from your personal data. These study files and data described above will be stored for five years following the conclusion of the study. Any information that leaves the NHS hospital site will be anonymous and all personal identifying details removed so you cannot be recognised. For any images that we use in any research publications or public presentations, the image will not be identifiable in any way. Each participant will be identified by a unique study number therefore all data, images, and copies of the x-ray will not be linked to the participant's name. The information collected may be used in an anonymous form to support other research in the future; however, it will not be possible to be identified by it.

What happens to the results of the study?

The results will be used to help the study team understand the methods we use to measure the spine. We plan to submit the research findings for publication in a

rehabilitation journal; however, all images and data used will be anonymised therefore you will not be identified in any report.

Participants will be asked if they wish to receive a copy of the study findings and this will be posted to those who indicate on the consent form that they do wish to receive them.

Who has reviewed and approved this study?

The study was reviewed by independent experts when the study was being considered. All research that takes place in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC), which is there to protect your safety, rights, wellbeing and dignity. The study has been reviewed by the South West-Central Bristol REC and has been given its approval.

Who is sponsoring and funding the research?

The study is being sponsored by the University of Oxford with funding support for the investigator, Erin Hannink, provided from the University of Oxford and Oxford University Hospitals NHS Foundation Trust.

Who do I contact for further information?

If you would like any further details about this study or would like to ask us any questions then please get in contact with Erin Hannink (telephone: 01865 737526, email erin.hannink@ouh.nhs.uk). Erin is a student studying for a PhD at Oxford Brookes University and will be using data collected from this study as part of her qualification.

What do I do now?

If you would like to take part in the study you may contact the investigator directly, or return the reply slip enclosed and a member of the team will contact you. If we do not hear from you, we may approach you on the day of your **clinic** appointment to check if you are interested in taking part. If you do not wish to take part, we will not contact you about the study again, and your decision will have no impact on the care you receive at the hospital.

Participation in future research

If you decide to take part in this study, you will be given the opportunity to indicate if you would like to be contacted to take part in future research studies. If you are interested in doing so your personal details would be kept and stored securely within the Physiotherapy Research Unit. Before accessing your medical records in relation to future studies, REC approval will be sought. Any future contact with you would be by letter in the first instance.

Thank you for taking the time to read this Patient Information Sheet and considering participation in this study.

D.3 MAPS Informed Consent Form

Physiotherapy Research Unit
Chief Investigator: Ms Erin Hannink
Tel: 01865 747526
Email: erin.hannink@ouh.nhs.uk

Participant study number:

CONSENT FORM

MAPS: Measuring Alignment and Posture of the Spine

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated **17 October 2017 (version 2.0)** for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I understand that if I have had a recent x-ray, it will be accessed and copied / stored securely to take measurements from it.	

5. I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it.		
6. I agree to take part in this study.		
Additional:		
7. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No
8. I would like to receive a copy of the study results, and understand that my contact details will be stored at the research site to enable this.	Yes	No

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

D.4 MAPS Case Report Form

CASE REPORT FORM

MAPS Study

Study Reference numbers
Ethics Ref no: 17/SW/0239
IRAS Project Ref no: 230019
Study Sponsor: University of Oxford

STUDY SITE:
Nuffield Orthopaedic Centre,
Oxford University Hospitals NHS Foundation Trust

PRINCIPAL INVESTIGATOR:
Erin Hannink

PARTICIPANT STUDY NUMBER:

I am confident that the information supplied in this case report form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.

Investigator's signature: _____

Date of signature:

d	d	m	m	m	y	y	y	y

Eligibility Criteria

1. Has the person met all inclusion criteria? YES ☐ NO ☐

**If any inclusion criteria are ticked 'no', the person is not eligible for the study.*

2. Do any of the exclusion criteria apply? YES ☐ NO ☐

**If any exclusion criteria are ticked 'yes', the person is not eligible for the study.*

INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place.

Has the person freely given written informed consent?

YES ☐ NO ☐

Date consent form signed: __ __ / __ __ / __ __ __ __

Original consent in site file, copy given to participant and scanned copy into NHS medical record?

YES ☐ NO ☐

Participant Study Number: **MAPS** - ☐☐☐

ASSESMENT

DATE: _____ ASSSESSOR:_____

A. Demographic and Background Information

Age (circle range): 18-29 30-39 40-49 50-59 60-69 70-79 80-89 90+

Gender: Male ☐ Female ☐

B. Relevant Medical History

1. Musculoskeletal/relevant medical conditions:

Condition	Date of onset

2. Do you have current back or neck pain? Yes ☐ No ☐

If yes, location: _____

VAS Pain rating

1	2	3	4	5	6	7	8	9	10

C. Outcome Measures

1. Postural topography

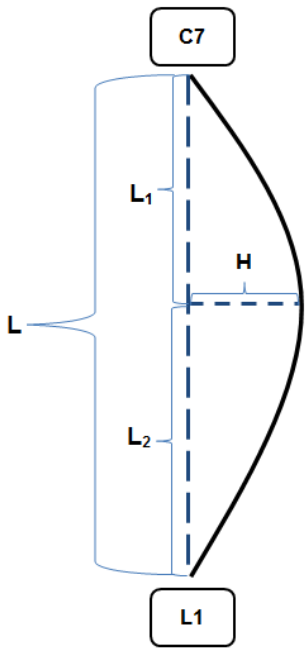
Were 2 images captured successfully? Yes ☐ No ☐

If not, why? _____

	Forward head posture (deg)	Kyphosis angle (deg)	Lumbar lordosis angle (deg)	C7 plumb line (mm)
Trial 1				
Trial 2				

2. Flexicurve (mm) – use graph paper to obtain readings

	Total curve length (L) [distance between C7 and L1)	**Curve Height (H)** [perpendicular line from apex to base]	**Curve length 1 (L_1)** [C7 to where height intersects base]	**Curve length (L_2)** [L1 to where height intersects base]
Trial 1				
Trial 2				



3. Inclinometers

	Trial 1	Trial 2
Thoracic angle (degrees) [C7-L1]		
Lumbar angle (degrees) [L1-S1]		

4. Retrospective standing lateral radiograph of the spine

Data collected from previous standard of care x-ray imaging:

Forward head posture (deg)	**Kyphosis Cobb angle** (deg)	**Lumbar spine Cobb** angle (deg)	**C7 plumb line** (mm)

Checklist

- Consent gained ☐
- Case report form completed ☐
- X-ray retrospectively assessed ☐
- Postural topography data saved and analysed ☐
- Flexicurve – graphs measured ☐

Assessor signature _____

Assessor printed name _____

Date _____

Appendix E

WiSPA study

E.1 WiSPA ethics approval letter

North West - Greater Manchester Central Research Ethics Committee
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8019

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

04 March 2019

Ms Erin Hannink
Physiotherapy Research Unit NOC
Windmill Road
Headington
OX3 7HE

Dear Ms Hannink

Study title:	**WiSPA: Walking and balance related to sagittal Spinal Posture and Alignment**
REC reference:	**19/NW/0111**
Protocol number:	**000000**
IRAS project ID:	**257830**

The Proportionate Review Sub-committee of the North West - Greater Manchester Central Research Ethics Committee reviewed the above application on 18 February 2019.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Extract of the meeting minutes

Other general comments

The Committee noted that this was a well-planned and well established study. They had no ethical issues with the study.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [OU Insurance]		24 January 2019
IRAS Application Form [IRAS_Form_28012019]		28 January 2019
IRAS Checklist XML [Checklist_04022019]		04 February 2019
Letter from sponsor [WiSPA Sponsorship letter]		24 January 2019
Letters of invitation to participant [WiSPA PIL]	1.0	24 January 2019
Other [WiSPA Reply Slip]	1.0	24 January 2019
Participant consent form [WiSPA ICF]	1.0	24 January 2019
Participant information sheet (PIS) [WiSPA PIS]	1.0	24 January 2019
Research protocol or project proposal [WiSPA protocol]	1.0	24 January 2019
Summary CV for Chief Investigator (CI) [CI CV Hannink]		09 January 2019
Summary CV for student [CV Hannink]		09 January 2019
Summary CV for supervisor (student research) [CV Barker]		22 January 2019
Summary CV for supervisor (student research) [CV Delextrat]		22 January 2019
Summary CV for supervisor (student research) [CV Dawes]		20 January 2019
Validated questionnaire [VAS questionnaire]		
Validated questionnaire [ABC questionnaire]		
Validated questionnaire [mGES questionnaire]		
Validated questionnaire [SF36 questionnaire]		

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

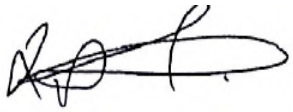
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

19/NW/0111	**Please quote this number on all correspondence**

Yours sincerely



PP: Dr George Gkimpas
Chair

Email: nrescommittee.northwest-gmcentral@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" [SL-AR2]

Copy to:

N/A N/A OUHFT R&D Department, Oxford University Hospitals NHS Foundation Trust

North West - Greater Manchester Central Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 18 February 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr J Addison	Retired Librarian	Yes	Vice Chair
Dr George Gkimpas	Clinical Fellow	Yes	Chair
Mrs D Hamburger	Retired Social Worker	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Katherine Ashley	REC Manager
Ms Zainab Tauqeer	REC Assistant

E.2 WiSPA Patient Information Sheet

Physiotherapy Research Unit
Nuffield Orthopaedic Centre
Windmill Road
Headington, OX3 7HE

Chief Investigator: Ms Erin Hannink
Tel: 01865 737526
Email: erin.hannink@ndorms.ox.ac.uk

PARTICIPANT INFORMATION SHEET

WiSPA: Walking and balance related to sagittal Spinal Posture and Alignment

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study if you wish. This Participant Information Sheet tells you the purpose of the study, what will happen to you if you take part, and provides information about conduct of the study. Please do ask if anything is unclear.

What is the purpose of the study?

This is a study intended to look at the relationship between your spinal alignment and aspects of your walking and balance. We will measure the alignment of your spine along with other physical measures, such as walking, balance and back strength, to see how they change after you have physiotherapy for your spinal condition. We will also ask you to answer questions about your walking and balance ability, your pain levels and your general health to help understand how it relates to your spinal alignment.

Why have I been invited?

You have been invited to take part in this study because you have been referred to physiotherapy for a spinal condition. We plan to include 45 participants who, like you, will have physiotherapy at the Nuffield Orthopaedic Centre (NOC).

What should I consider?

You may not participate in this study if you are unable to stand independently or if you have a neurological condition which alters your movement or posture. If you are already involved in other research studies, you may still be able to participate if the studies do not conflict. This can be discussed with the investigator before you enroll in the study.

Do I have to take part?

No, it is up to you whether or not you take part. If you decide not to take part, your current and future medical care will not be affected in any way.

What will happen to me if I decide to take part?

If you decide to take part, we will discuss the study again with you, answer any questions you might have and you would be asked to sign a consent form. With your consent we may access your medical records, but only when relevant to the study. You are also free to ask the researchers any questions you may have at any time during the study.

There will be four study visits:

Study visit 1 (75-90 minutes) will take place before you begin your physiotherapy class sessions at the NOC and it will be arranged separately from your clinical visits. At the beginning the investigator will collect some basic information about you (age and gender), relevant medical history, falls history, history of back pain and height and weight. The study visit will be similar to a physiotherapy assessment, it will include physical tests to measure your spinal alignment, walking, balance, and back muscle strength. They will include:

- Spinal alignment. The Microsoft Kinect Sensor V2 will be used for three-dimensional surface topography measurement of your back. The Kinect sensor, similar to a camera, will be mounted to a tripod and you will stand with you exposed back to the sensor for the image to be captured.

- Tragus-to-wall distance. In this test, you will stand with their heels against a wall and try to stand up as tall as possible while looking straight ahead. From this position, the investigator will use a tape measure to measure the horizontal distance from your ear/tragus to the wall.

- 2-minute Walk Test. You will walk 20-meter laps for two minutes. The distance walked during the two minutes will be recorded. Additionally, an inertial measurement unit (IMU) will be placed with double-sided adhesive to your back and you will walk part of the distance on a pressure-sensor mat to record your walking pattern. The IMU is very lightweight and you will not feel any difference when walking.

• Four Square Step Test. In this balance test, you are timed while stepping into four different squares which are separated by canes. The total time it takes to complete this test will be recorded.

• Timed Loaded Standing. In this test to measure shoulder and back muscle strength, you will be timed as you hold a set of 0.5-kg or 1.0-kg dumbbells in your hands with your arms straight out in front of you until it becomes too tiring.

In addition to the physical tests, you will fill out four questionnaires that ask about walking, balance, pain levels and general health.

Study visit 2 (10-20 minutes) will take place during one of your physiotherapy sessions but will only include the measure of your spinal alignment.

Study visit 3 (45-60 minutes) will take place on your final physiotherapy session. It will include the same physical tests and questionnaires as Study visit 1.

Study visit 4 (45-60 minutes) will take place 6 months after Study visit 1. We'll contact you by phone when it's time to return for this study visit. In this visit, we'll measure you again with the same physical tests and questionnaires as Study visit 1.

The study visits will take place at the NOC. The first and fourth visits will be arranged separately from your clinical visits while the second and third study visits can be arranged during your normal physiotherapy sessions at the NOC. During the study visits, you'll be required to expose your back for the spinal measurements to be taken, however we will provide you with a hospital gown to wear for comfort and modesty. For the balance and walking tests, you'll need to wear shoes you'd be comfortable walking in. In between each test or measurement, you'll be given a rest if you need it

Are there any possible disadvantages or risks from taking part?

All the tests and measures chosen have been used safely in the past. There are no known particular side effects of the assessments and an experienced clinician will be with you throughout to monitor how you are doing and check you are safe. We don't expect these measures to cause you pain, but you may experience some mild discomfort whilst areas of the spine are being palpated, and you may become tired after the physical tests, but it will be no more effort than a normal physiotherapy assessment. You will need to commit to extra time beyond your normal physiotherapy sessions, and you will also be required to make two additional visits to the NOC.

What are the possible benefits of taking part?

For individual participants there will be no immediate benefit; however, the potential for benefit comes from improving our understanding about spinal conditions for future patients.

Will I be reimbursed for taking part?

The research team will reimburse your travel expenses as well as parking costs for any additional visits to the hospital outside of your normal care.

Will my taking part in the study be kept confidential?

Yes. Information that is collected about you will be kept confidential. All of your data, including the measurements and questionnaires we collect, relevant medical information and the images of your back, will be identified by a specific participant study number only and you will not be identifiable from this. The images of your back will show only a narrow part of the centre of your back and any identifying tattoos or birthmarks will be permanently removed from the image so that it will not be possible to identify a person from the images. Any electronic data will be stored on University of Oxford password protected computer. Any study documents and data, such as the signed consent form, will be stored in a lockable secure room in the Physiotherapy Research Unit at the Nuffield Orthopaedic Centre. Only members of the WiSPA study research team will have access to the data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 1 year after the study has finished. We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study. If you agree to your details being held to be contacted regarding future research, we will then retain a copy of your consent form until such time as your details are removed from our database. We will keep the consent form and your details separate.

Oxford University Hospitals NHS Foundation Trust will use your name, NHS number, home address and contact details to contact you about the research study and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They will keep identifiable information about you from this study for 1 year after the study has finished.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/. You can find out more about how we use your information by contacting erin.hannink@ndorms.ox.ac.uk.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point, please let the investigator know. If you choose to leave we will discuss with you how any data collected is managed – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study your future NHS care will not be affected in any way.

What will happen to the results of this study?

The results will be used to help the study team understand the spinal curvature and alignment. We plan to submit the research findings for publication in a rehabilitation journal and present the findings at rehabilitation-related conferences. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. All images and data used will be anonymised therefore you will not be identified in any report. If you would like to receive the study results, you can contact the chief investigator, Ms Erin Hannink (tel: 01865 737526, email: erin.hannink@ndorms.ox.ac.uk).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Ms Erin Hannink (tel: 01865 737526, email: erin.hannink@ndorms.ox.ac.uk) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 738126 or PALS@ouh.nhs.uk.

Who is organising and funding the study?

The study is being sponsored by the University of Oxford with funding support for the investigator, Erin Hannink, provided from the University of Oxford Nuffield Department of Orthopaedic, Rheumatology and Musculoskeletal Sciences and Oxford University Hospitals NHS Foundation Trust PhD Studentship.

Who has reviewed the study?

The study was reviewed by independent experts when the study was being considered. All research that takes place in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC), which is there to protect your safety, rights, wellbeing and dignity. The study has been reviewed by the _____ REC and has been given its approval.

Participation in future research:

If you decide to take part in this study, you will be given the opportunity to indicate if you would like to be contacted to take part in future research studies. If you are interested in doing so your personal details would be kept separately from this study and stored securely on a password protected computer and database within the Physiotherapy Research Unit at the Nuffield Orthopaedic Centre. You will not be obliged to take part in any future research and you can be removed from this register at any time.

Further information and contact details:

Please contact Ms Erin Hannink by telephone (01865 737526) or e-mail: erin.hannink@ndorms.ox.ac.uk.

Thank you for taking the time to read this information.

E.3 WiSPA Informed Consent Form

Physiotherapy Research Unit
Chief Investigator: Ms Erin Hannink
Tel: 01865 747526 | Email: erin.hannink@ouh.nhs.uk

Study Code: | | — *Site ID Code:* | | — *Participant identification number:* | | | | |

CONSENT FORM

WiSPA: Walking and balance related to sagittal Spinal Posture and Alignment

Name of Researcher:

	If you agree, please initial box	
1. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.		
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.		
4. I understand that the images taken of my back will be analysed, but all images will be de-identified and it will not be possible to identify me from the images.		
5. I agree to take part in this study.		
Additional:		
6. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	Yes	No

Name of Participant	*Date*	*Signature*
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).

E.4 WiSPA Case Report Form

WiSPA **Baseline Form** Study code: **Wi -** Participant Study Number: ☐☐☐ Initials: ☐☐☐

CASE REPORT FORM: **WiSPA Study**

STUDY REFERENCES:

Ethics Ref no: 19/NW/0111
IRAS Project Ref no: 257830
Study Sponsor: University of Oxford

PRINCIPAL INVESTIGATOR: Erin Hannink

INFORMED CONSENT

Has the person freely given written informed consent? ☐Yes ☐No

Date consent form signed: __ __ / __ __ / __ __ __ __

Original consent in site file, copy given to participant and scanned copy in NHS medical record?

☐Yes ☐No

ASSESMENT

A. Demographic and Background Information

Age:	**Sex**:	**Height**:	**Weight**:	**Leg Length:**
__ __	☐ Male ☐ Female	__ __ __ cm	__ __ __ kg	__ __ __cm

B. Relevant Medical History & Pain

1. Musculoskeletal/relevant medical conditions:

Condition	Date of onset

2. Do you have current back or neck pain? ☐Yes ☐No If yes, location: _____

3. Falls history: Have you fallen in the past year? ☐Yes ☐No If yes, number of falls: ☐☐

C. Outcome Measures

Tragus-to-wall distance (TWD) *Measure the horizontal distance from the wall to the tragus (external opening of the ear) while patient stands in upright posture against the wall.*	☐☐.☐ **cm**
Four square step test (FSST) *After one practice attempt, time the patient as they correctly complete the full sequence without touching the sticks. Give the patient one additional attempt if they do not correctly complete the first time.*	☐☐.☐ **sec**
Timed loaded standing (TLS) *Time the patient as they hold up 0.5 kg or 1.0 kg weight in each hand with elbows extended and shoulders at 90^{O} flexion. Stop the test if starting position is not held or time exceeds 3 minutes.*	☐☐☐.☐ **sec**
Circle set of weights used: 0.5 kg's or 1.0 kg's	
2-minute walk test (2MWT) *Designate a 10-metre distance for patient to walk; record the distance completed after 2 minutes of walking.*	☐☐☐.☐ **m**
Gait analysis with IMU *Place sensor 1 at L4. Place sensor 2 at C7. Record gait during two 10-metre walks at a self-selected pace.*	Data successfully captured? ☐ Yes ☐ No
Postural topography image with Kinect sensor *Place markers at C7, L1 and B PSIS. Capture 2 images in 'normal' standing posture and 2 images in 'best posture.'*	Data successfully captured? ☐ Yes ☐ No
Test-retest to be completed on 2nd visit.	Data successfully captured? ☐ Yes ☐ No Date:

D. Checklist (please tick)

☐ Consent gained

☐ Case report form completed

☐ Questionnaires completed

- ☐ SF-36
- ☐ ABC Scale
- ☐ mGES
- ☐ Pain VAS

_____	_____	__ __ / __ __ __ / __ __ __ __
Assessor name	Assessor signature	Date

I am confident that the information supplied in this case report form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.

Principal Investigator's signature: _____

Date of signature:

d	d	m	m	m	y	y	y	y