Reliability of a measure of total lumbar spine range of motion in individuals with low back pain.

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October, 2012

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirement of the degree of M.Sc. in Rehabilitation Science

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Table of Abbreviations

LBP	**Low Back Pain**
ROM	**Range of Motion**
BS-11	**11-point box scale**
ODI	**Oswestry Disability Index**
ID	**Index of Dependability**
MDC	**Minimal Detectable Change**
G- Theory	**Generalizability Theory**
G- Study	**Generalizability Study**
D- Study	**Decision Study**
T12	**Twelfth Thoracic Vertebrae**
S1	**First Sacral Vertebrae**
SEM	**Standard Error of Measurement**
ANOVA	**Analysis of Variance**
ICC	**Intra Class Correlation Coefficient**
Mm	**Millimeter**
RDG	**Ronald Morris Disability Questionnaire**
HMD	**Head Mounted Display**
SD	**Standard Deviation**

3D	Three Dimensional
AP	Anterior-Posterior
ML	Medio-Lateral

Acknowledgements

This work could not be achieved without the assistance of many people. I would like to express my thankfulness to my supervisor Dr. Richard Preuss for his continuous support and guidance through all the period of my Master Program.

Through the years of this program, professor Preuss provided me with invaluable tools and skills to reach this level of knowledge and experience of research.

I want also to send all my appreciation and respect to my committee members Dr. Christian Larivière and Dr. Philippe Archambault for their priceless orientation and overtures. I would also like to thank Stella Nguekou- Damasfor and Dr. Richard Preuss for their help with the French translation of the thesis abstract, and Mohand Ouidir Ait El Menceur for his help with the programming for data analysis and visual feedback.

My genuine and faithful thanks to my parents for their unrivaled and endless love to reach this level of higher education. I am incapable to depict my gratitude to your support and cheer to pursue my education and dreams.

Contribution of Authors

The work contained within this thesis is presented in manuscript format and consists of one paper that will be submitted for publication in a peer reviewed journal. This paper will be co-authored with Dr. Preuss. In accordance with the guidelines of the Faculty of Graduate and Postdoctoral Studies at McGill University, I would like to declare the contribution of all co-authors. The idea for the project was conceived by Dr. Preuss. The experimental protocol was designed and piloted by myself and Dr. Preuss, with contributions from Drs. Christian Larivière and Philippe Archambault as members of my MSc thesis committee.

I was responsible for participant recruitment, data collection, data processing and statistical analyses. I was responsible for the preparation of the text and figures for the manuscript, receiving comments on drafts from both co-authors.

Abstract

Lumbar spine range of motion (ROM) is conventionally measured using multiple, individual anatomical plane movements. This is unwieldy for clinical research, because it relies on the assumption that a large proportion of subjects will present with the same impairment. The objective of this thesis work, therefore, was to assess the reliability of a novel measure of total lumbar spine ROM, to be used in future studies. We hypothesized that the reliability of this measure would be ≥0.9, so as to meet previously suggested criteria for monitoring individual patient progress.

Twenty subjects with chronic low back pain (LBP) were recruited for two testing sessions. At each session, subjects performed 3 series of 8 end-range, randomly ordered lumbar spine movements, at 45° intervals around the full circle, with the help of visual feedback. Lumbar spine motion was acquired using two, 6-degrees-of-freedom electromagnetic motion capture sensors placed on the skin over the spinous processes of the twelfth thoracic (T12) and first sacral (S1) vertebrae. The measure of interest was based on the relative position of T12 in the transverse plane of S1. Two curve fitting approaches - least-squares ellipse and cubic spline - were used to fit a shape to the 8 end-positions of movement in each series. The area of this shape was used to provide a measure of the total ROM, and the centre point to provide a measure of movement distribution and symmetry. Generalizability theory was used to assess the reliability of

the area of each shape, and of its centre point in the anterior-posterior and medio-lateral

axes of the transverse plane of S1.

The index of dependability for the total lumbar spine ROM (area) was excellent

(0.94 - 0.95), and moderate-to-excellent (0.59 – 0.91) for its distribution (centre points),

with slightly better values achieved with the spline-fitting approach. Analysis of

extrapolated data also indicated that similar values would be achieved using 3 repetitions

of the task in a single testing session.   These results support the use of this novel

measure of total lumbar spine ROM in future clinical studies.

Résumé

L'amplitude des mouvements de la colonne lombaire (ou ROM, pour range of motion en anglais) est traditionnellement mesurée à l'aide de multiples mouvements individuels exécutés sur les plans anatomiques. La technique utilisée pour obtenir cette mesure complique la recherche clinique, car elle repose sur l'hypothèse qu'une forte proportion de sujets présente la même déficience. L'objectif de cette thèse était donc d'évaluer la fiabilité d'une nouvelle mesure de mouvement global de la colonne lombaire, qui serait utilisée dans des études futures. Notre étude repose sur l'hypothèse que la fiabilité de cette mesure serait ≥ 0,9; de manière à répondre à des critères préalablement proposés pour suivre les progrès d'un patient unique.

Vingt sujets souffrant d'une lombalgie chronique (ou LBP, pour low back pain en anglais) ont été recrutés pour deux séances. À chaque séance, les sujets, aidés d'une rétroaction visuelle, ont effectué 3 séries de 8 mouvements de fin d'étendue de colonne lombaire, à 45 degrés d'intervalle autour d'un cercle complet, et ce, dans un ordre aléatoire. Les mouvements de la colonne lombaire ont été obtenus au moyen de deux capteurs électromagnétiques à 6 degrés de liberté, placés sur la peau au-dessus des apophyses épineuses de la douzième vertèbre thoracique (T12) et de la première vertèbre sacrée (S1). La mesure qui nous intéresse a été calculée d'après la position relative de T12 dans le plan transversal de S1. Deux méthodes d'ajustement de courbe ont été utilisées pour lier les 8 points de fin de mouvement dans chaque série : l'ellipse par les

moindres carrés et la fonction spline cubique. L'aire de la forme ainsi obtenue a servi à fournir une mesure de la ROM totale; et le point central, une mesure de la distribution et de la symétrie des mouvements. La théorie de la généralisabilité (en anglais Generalizability Theory) a été employée pour évaluer la fiabilité de l'aire de chaque forme et celle de son point central dans les axes antéro-postérieur et médio-latéral du plan transversal de S1.

L'indice de fiabilité était excellent (0,94 – 0,95) pour la ROM globale de la colonne lombaire (l'aire) et allait de modéré à excellent (0,59 à 0,91) pour la distribution des mouvements (points centraux), avec des valeurs légèrement plus élevées pour la méthode d'ajustement par spline. L'analyse des données extrapolées a également indiqué que des valeurs similaires seraient obtenues en utilisant 3 répétitions de la tâche dans une séance unique. Ces résultats appuient l'utilisation de cette nouvelle mesure de la ROM de la colonne lombaire dans de futures études cliniques.

Chapter 1 – Introduction

1.1 Background

Until the early 1990's, spinal range of motion (ROM) measurement was considered a basic part of physical examination of patients with low back pain (LBP)[1,2]. Historically, ROM measurements have aided clinicians in patient diagnosis and in monitoring their pathological status[3]. Furthermore, these measures have been used to guide the prescription of suitable intervention techniques. They have also been used to monitor the response of LBP patients to those interventions[4-9], including surgical procedures[10] and therapeutic exercises[4-8].

Despite these practices, current clinical practice guidelines no longer consider lumbar ROM measurement as one of the components of the physical examination[11]. The reason is that recent studies have failed to find any clear and consistent relationship between lumbar spine ROM and functional impairment in LBP subjects[12-14]. This finding has led to the suggestion that lumbar ROM should not be used as a functional measure of disability in LBP[12].

The validity of this suggestion is questionable for several reasons. First, these studies used various self-report questionnaires (e.g. Pain Disability Index, Oswestry Disability Questionnaire, and Roland-Morris Scale) to measure LBP-related disability. This measurement approach can be influenced by the psychological status of the

patient[15]. Specifically, these measures may be more greatly influenced by the emotional and cognitive functions of the patient than by his/her functional ability[16]. Therefore, they cannot be viewed as objective measures of impairment. The findings of Cox et al[17] suggest that there is a sparse correlation between physical impairment and self-assessment of pain and/or disability, an opinion that had been previously expressed by other researchers[18-20]. Instead, clinical evaluation of impairment may be better measured using functional measures in order to separate out any cognitive, behavioural or psychological factors[2].

Another problem in these studies is that the LBP population, when treated as a single group, is highly heterogenic[21]. This invalidates the idea that individuals with LBP should all share the same impairment in ROM. There does, however, appear to be some link between lumbar spine mobility and LBP for some patients. For example, both hypermobility and hypomobility, in the sagittal and frontal planes, have been reported as risk factors for LBP[22,23]. Measures of lumbar spine extension have also been used to reliably identify individuals with and without significant limitations due to LBP (Intratester ICC = 0.95; Intertester ICC = 0.94)[24]. Studies that have examined more homogenous subgroups of LBP patients have also found links to mobility. Hypomobility at one or more lumbar spine levels, for instance, is relevant in predicting which patients will benefit from spinal manipulation[6,25]. Hypermobility in lumbar flexion, on the other hand, may point towards lumbar spine instability as a cause of LBP[26]. These findings support the belief that the LBP population will have different kinds of impairments, some of which may be linked to specific changes in ROM and mobility.

In summary, there is a clear need for functional, objective measures to evaluate LBP-related disability and impairment. Lumbar spine ROM has been shown to be important in the presentation of many cases of LBP, so it is logical that ROM be evaluated in this regard. Because not all LBP patients will have the same specific limitations in their ROM, however, it may be more useful, in the initial evaluation, to use of a single measure that reflects the global mobility of the lumbar spine, in order to determine the importance of ROM on a case-by-case basis. The purpose of this study is to develop a measure of global lumbar spine ROM that produces reliable data in the evaluation of patients with LBP, and that has an acceptable minimal detectable change when used for repeated measurements over time (MDC).

1.2 Definition of ROM

Range of motion (ROM) has been defined as the arc of the movement that can occur at one or more joints[27]. This can occur in one of two general ways: actively, where a subject moves without any assistance or, passively, in which the movement occurs without any active role of the subject[28]. Active ROM is generally a better measure of patient function because it reflects the real functional capacity of the subject, without any assistance.

Quantifying ROM requires a measurement of the displacement that is achieved through the arc of movement of the involved joints. This displacement could be angular, measured in radians or degrees, or linear, measured in meters (or millimeters, centimeters, etc.). It can be argued that linear displacement, in most cases, is the more functional measure[29,30]. For example, picking up a pen from a table may require movement from multiple joints: trunk, shoulder, elbow, wrist, and fingers. However, the functional success is based on the final position of the hand, and not on the configuration of the joints used to achieve that position. Similarly, a functional measure of global lumbar spine ROM may be better reflected by the linear displacement of the cranial segment(s) relative to the caudal segment(s).

In chapter 2, we describe the initial development of a measure of active lumbar ROM based on the linear displacement of the twelfth thoracic vertebra (T12) relative to the position of the first sacral vertebra (S1), in the transverse plane of S1.

1.3 Measurement of Lumbar Spine ROM

Spinal ROM can be measured using various instruments and techniques. In this review, we broadly classify the instruments into two categories: high and low technology. Each one of these instruments, and the measurement techniques used with these instruments, has specific features and limitations[31,32]. The next sections provide an overview of low and high technology methods to assess lumbar ROM.

1.3.1   Low-Technology Instruments and Techniques

There are several approaches to measuring ROM described in the literature that involve either no measurement instrument, relying on visual observation, or simple, low technology instruments. The latter include tape measures, inclinometers, and goniometers. Some researchers consider low technology approaches to be preferable for clinicians, since they are generally simple to use, safe, and inexpensive[33]. These technologies, however, present several disadvantages.

The first approach to measuring lumbar spine ROM is visual estimation, in which no instrument is used. The typical technique for visual estimation of ROM is based on identifying specific landmarks, such as those that might be used for goniometry[31], and estimating the angle, in degrees, between the two landmarks. Theoretically, all

movements of the lumbar spine can be examined, but to our knowledge, no studies have been published that assess the reliability or validity of visual estimation of lumbar spine ROM. One report, though, places the inter-examiner reliability for visual estimates of cervical ROM between 0.42 (flexion and extension) and 0.82 (right rotation)[31]. Even for simpler joints like the knee, the reliability of visual estimation of ROM tends to be poor[34]. It is generally recommended, therefore, that physical therapists should not use visual estimation to assess ROM[35,36].

Assessment of ROM may also be done using a standard, flexible tape measure. Various techniques have been described for using this instrument, but generally involve measuring the change in linear distance between two landmarks following movement (e.g. Schober's method) or a functional displacement relative to a fixed reference point (e.g. fingertips to floor). Theoretically, any movement can be examined if the appropriate reference points can be chosen. In practice, however, measures of lumbar spine ROM have generally been limited to sagittal plane motions: flexion and extension. Two common approaches – Schober's method and fingertips to floor – are described in the following paragraphs.

For the Schober method, the measure is taken by first asking the subject to stand erect, with feet at approximately shoulder width. Two points are then identified and marked with a pen: the midpoint between the superior aspects of the iliac crests, and another point 10cm superior to this. The tester sits behind the subject and asks him/her to bend forward, keeping the knees fully extended throughout the entire motion. The distance between the two markings is taken in the erect and fully flexed positions, with

the difference representing the measure of interest. A similar approach may also be used

for lumbar spine extension[37-44]. Schober's method for lumbar extension has been

reported to differentiate reliably between subjects with and without significant limitations

due to LBP (Intratester ICC = 0.95; Intertester ICC = 0.94) [24]. These measures, however,

have a weak correlation with radiographic measurements[45], likely due to a combination

of inconsistent identification of landmarks and deformation of the skin during

movement[46]. From the standpoint of developing a single measure that reflects the global

mobility of the lumbar spine, this approach is not feasible as it is restricted to measures of

sagittal plane motion.

Another common form of tape measurement for lumbar spine ROM is the

fingertips-to-floor approach, where the subject is asked to stand on a platform and reach

down as far as possible with fully extended knees. The measure is taken between the

fingertips and the platform. If the fingertips pass beyond the platform, it will be reported

as a positive value; if not, it will be reported as a negative value. Kippers, Parker [47]

assessed the reliability and validity of this approach through measuring elbow, shoulder,

wrist, finger, and spine motions. The inter-tester reliability of the measures taken with

the tape was excellent (ICC= 0.97), but extremely poor for the measures of vertebral

flexion (ICC= 0.10). The authors, and others, concluded that this approach should be

primarily regarded as a measure of hamstring extensibility, and that it is not valid as a

measure of spinal ROM[44,46,47].

Goniometry has also been applied to the measurement of lumbar spine ROM.

The standard goniometer is composed of two arms joined at a common axis. It is used to

measure the angle, in degrees, between two defined anatomical landmarks. The lumbar

movements that are typically assessed using this instrument are in the sagittal and frontal

planes. For example, Fitzgerald[43] described goniometric measures of lumbar spine ROM

as follows. Side bending to the right or left is measured by positioning the subject

upright, with the axis at the level of the lumbosacral junction. The stationary arm is kept

perpendicular to the floor, and the movable arm is maintained in line with the C7 spinous

process. For extension, the subject is also in an upright position, but the tester sits facing

the subject's lateral side. The axis is placed at the most rostral part of the iliac crest, in

line with the midaxillary line, and the stationary arm is kept perpendicular to the floor.

The movable arm is positioned parallel to the midaxillary line and the subject has to

move into lumbar spine extension while maintaining the knees fully extended. This

approach described by Fitzgerald[43] produced data with high inter-observer reliability

coefficients for extension and left lateral bending (r=0.88, 0.91, respectively), with

slightly lower coefficients for right lateral bending (r=0.76). Despite these promising

results, other groups have suggested that it is not possible to assess compound and

complex motions with the traditional goniometer[48], which raises questions regarding

validity of such instrument. Thus, this instrument would not be useful for the

development of a global measure of lumbar spine mobility.

Finally, among the low-technology instruments, the inclinometer may be the tool

with the best face validity for measuring lumbar spine ROM, and it has been

recommended for the measurement of thoraco-lumbar ROM by the American Medical

Association[1]. Inclinometers come in many forms (e.g. mechanical vs. electrical; analog

vs. digital), but they all work on the principle of providing a reading for the angle of the instrument (typically in degrees) relative to the gravity vector. Lumbar ROM is best measured using a dual inclinometer approach[1]. For measures of lumbar spine flexion and extension, the subject begins in an upright position, on a flat surface. The tester then palpates T12 and S1 and places an inclinometer over each landmark. Before the movement begins, a reference measure is taken of this upright position (some models allow this reference position to be set to "zero", either with a moving dial or electronic calibration). The subject is then instructed to move slowly into flexion or extension until the maximum excursion is reached. A second reading for each inclinometer is recorded in this position, relative to the initial reference measure. The final ROM measure is the difference between the reading of the T12 and S1 inclinometers. The reliability of measures using the dual inclinometer technique has been tested in both healthy individuals and patients with LBP[40,44,49-57]. These studies have revealed variable and conflicting results for the reliability of LBP ROM in the sagittal plane, ranging from poor for extension (r = 0.15 to 0.42)[9,40,50,58] to high for flexion (r = 0.73 to 0.88)[9,40,50,59]. High correlations (0.73-0.98) have been found with measures taken from radiographic analysis[9,50], adding validity to this approach. A similar procedure may also be used to measure frontal plane movements in the lumbar spine[1,60], and an approach to assessing axial rotation in the lumbar spine has also been described[61]. The utility of these measures outside the sagittal plane has been questioned, however, due to issues related to reliability[60] and measurement error[61]. Based on this, the inclinometer may be the best choice of the low-technology instruments for measurement of sagittal plane lumbar spine

ROM, but it does not appear to have the versatility required to develop a global measure of lumbar spine mobility.

A recent review of the reproducibility of measures to assess lumbar spine function, including mobility, concluded that it is difficult to recommend any of the above measures as a reference for lumbar spine function[62]. Many of these tests produce measures of ROM in the sagittal plane that are reliable enough for group comparisons (reliability coefficient ≥ 0.7)[62], but contain enough measurement variability not to be practical for individual comparisons where much higher reliability coefficients (0.90-0.95) are required[63]. Briefly, lower reliability tests are unlikely to be useful for monitoring individual patients' progress because the standard error measurement (SEM [see section 1.4.1 Generalizability Theory]) is the basis for the calculation of the confidence interval. This, combined with the limited versatility of the instruments described above, indicates that low-technology instruments are not useful for the purpose of the current study.

1.3.2 High-Technology Instruments and Techniques

High-technology instruments may be preferable to the low-tech instruments described in the previous section as they provide higher accuracy and stability of measurement. Several high-technology instruments exist that can be used to measure lumbar spine ROM. These include radiographic analysis, camera-based systems, and electromagnetic tracking systems.

Techniques based on radiographic (or Roentgenographic) analysis are considered the "gold standard" for lumbar spine ROM measurement, as they allow for the measurement of actual vertebral positions, without errors resulting from the relative movement of the skin and soft-tissues[64]. These devices function in a manner similar to standard light photography but use a type of electromagnetic radiation (X-rays) that has a much lower frequency than visible light and can pass through the body.

In general, there are two different radiographic techniques that can be used for ROM analysis. The simplest is plain-film radiography, where an image is taken in a single plane and measures of relative position of the relevant bony landmarks are taken from this image. Two images are taken for each movement: one representing the upright position and the other representing the maximum excursion. For lumbar flexion, for example, two lines may be drawn parallel to the superior aspect of L1 and S1 on a lateral view, with another two intersecting lines drawn perpendicular to the first two. The

resultant angle of the intersection of the second set of lines is measured by a protractor[65].

The movements that can be assessed using this technique are in the sagittal (lateral

views) and frontal (anterior-posterior views) planes. For movements on the transverse

plane, and for more complex movements, a 3-dimensional analysis is required. These 3-

dimensional approaches require concurrent images of the spine from two or more

angles[66] and can be used to reconstruct 3-dimensional images of the vertebrae from

which position measurements can be taken. Despite its advantages, however,

radiographic imaging is expensive, takes a long time, and exposes subjects to what is

often an unnecessary dose of radiation[9,67]. Moreover, there is a limitation caused by the

size of the film or examination bed[68,69]. All of this makes this approach difficult to use in

daily clinical practice and impractical for the current project.

Camera-based systems are the most popular technology used in human motion

capture. The technique is referred to as photogrammetry, in which the position of an

object is determined in a three dimensional space on the basis of its observed location

within the 2 dimensional fields of a number of cameras[70,71]. The most common approach

is to track the position of body-mounted markers. A cluster of at least three markers is

needed to measure the position and orientation of each body segment in three

dimensions. Each of these marker clusters is assigned a Cartesian coordinate system. The

calculations of the angles between two clusters, or body segments, are based on

mathematical functions such as the Euler rotations. To represent lumbar spine motion,

for example, one marker cluster could be positioned relative to T12, with another

positioned relative to S1. Using this approach would enable the measurement of complex spine movements, as measures could be taken with 6 degrees of freedom.

Camera-based systems have been used to assess lumbar spine motion during walking[72] and complex functional movements[72,73]. They have not, however, been widely tested for reliability when assessing lumbar spine ROM, potentially due to their inherent drawbacks for measuring spine motion. The major source of measurement error with such systems is skin displacement, which may move the markers relative to the underlying anatomical landmarks, and affect the accuracy of the kinematic calculations[74]. This error is compounded by the need for multiple markers. Furthermore, when a cluster of markers covers only a small area, as when tracking spine motion, the errors due to skin motion will be amplified relative to the actual movement being recorded (poor signal-to-noise ratio), further affecting the accuracy of these calculations[73]. Marker occlusion is also a potential limitation with such systems, particularly during movements such as backward bending, where the camera's line of sight to the markers may be compromised. Because of these issues, and the availability of other technologies, camera-based systems are not the method of choice for studying lumbar ROM.

Electromagnetic motion-capturing devices are widely used as kinematic measurement tools[75], and have been used for the measurement of lumbar spine motion for over two decades[76]. The technology includes a transmitter, which emits a low frequency electromagnetic field in a determined space, and one or more body-mounted sensors that are placed within this field. The system software then determines the position and orientation of each sensor relative to the transmitter[77]. Electromagnetic

motion-tracking technology allows tracking with six degrees of freedom, which means

that both Cartesian coordinates and orientation can be measured for each sensor[77,78].

This technique permits quantitative assessment of linear position and angular orientation,

including the detection of coupled movements. One technique to assess lumbar spine

motion involves mounting sensors at the level of T12 and S1, and using matrix Euler

rotations to determine the relative position and orientation of the T12 sensor in the

coordinate system of the S1 sensor.   To assess ROM, a reference measurement is taken

at neutral position, and then the subject is instructed to perform the movements of

interest. Appropriate positioning of the sensors allows flexion and extension to be

represented as rotation around the X-axis, side bending around the Y-axis, and axial

rotation around the Z-axis[79]. As with the camera-based systems, measurement errors will

be present due to skin movements[80]. Electromagnetic tracking systems, nevertheless,

provide two major advantages over camera-based system. They do not suffer line-of-

sight limitation, allowing all spine movements to be easily acquired (sensors may even be

affixed under the patient's clothes). The sensors in modern systems are also very small,

with a single sensor able to provide position and orientation data in three dimensions,

thus reducing the errors that would accrue using clusters of skin-mounted markers.

Previous studies using electromagnetic tracking systems found ROM testing on the

lumbar spine for multiple spine motions to be highly reliable, often with reliability values

>0.9[79]. Based on these advantages, electromagnetic tracking may be considered the best

option to measure lumbar spine ROM.

For the current project, the measurement approach described in the previous paragraph was employed. Two sensors were mounted on the subject's skin over the spinous processes of T12 and S1. A rotation matrix for each sensor was then derived from the position and orientation data of the sensors in relation to the transmitter-embedded reference frame. The measure of interest was the position of T12 relative to S1 in the transverse plane of S1. This was determined by multiplying the 4x4 rotation-translation matrix for the T12 sensor by the inverse of the rotation-translation matrix for S1, using custom software written in Matlab.

1.4 Reliability

Reliability is defined as "the degree to which test scores are free from errors of measurement"[81]. In other words, reliability represents the level of consistency that can be expected in a subject's scores when taken under specific conditions.

Classical theory assesses reliability on the basis of one condition or source of measurement error, known as a facet. It cannot provide a proportion of each measurement error relative to the total error, and cannot assess the effect of facets' interactions[82]. As such, classical test theory is constrained to describe multiple "types" of reliability. The most common of these are inter-rater, internal consistency, intra-rater, and test retest. Inter-rater reliability is described as the degree to which the ratings of different observers are proportional when expressed as deviations from their means[83]. Internal consistency represents the correlations among items in a measure[84]. Intra-rater reliability assesses the consistency between two or more quantitative measurements taken by the same observer[85]. Test-retest reliability assesses the consistency of rank-ordered scores at different points in time[83]. Classical test theory also has the further drawback that it can only account for changes in the relative ranking of the scores in the data set (relative variance) and not for changes in absolute scores (absolute variance)[82].

Generalizability theory, on the other hand, does not suffer from these limitations. It can be used to make either absolute or relative decisions and can assess for the effects

of all sources of measurement error in a data set, as well as the interaction effects between these facets[82,86,87]. (See generalizability theory section). Generalizability theory can be considered to fill the gap of undifferentiated measurement errors found in classical test theory[88].

1.4.1   Generalizability Theory

Analysis of data using generalizability theory is comprised of two parts: the generalizability study (G-study) and the decision study (D-study).

The first step in the G-study uses a repeated-measures analysis of variance (ANOVA). It estimates the variance in the subjects' scores attributable to each of the different sources of measurement error in the study (facets) that could lead to variations in the subjects' measures, as well as all interaction effects. Facets are the independent variables considered in the analysis of variance. For example, the facets for this study (see Chapter 2) are the different sessions and trials, with the subject scores representing the object of measurement (the dependent variable).

The variances attributable to the object of measurement, each facet, and all interactions effects are then used to calculate a G-coefficient. The relative G-coefficient only accounts for the variance attributed to the object of measurement and its interactions with the different facets in the study design[86]. As with classical test theory, it is used to make relative decisions (how well the outcomes maintain their rank order over different facets). More rigorous and conservative estimates of reliability are derived from the absolute G-coefficient, also known as the phi coefficient or the index of dependability (ID)[89]. This measure accounts for all sources of measurement error in the study design and expresses both the degree of consistency of individual differences among subjects and the rank ordering of measures. The ID is calculated by dividing the variance

attributed to the subjects by the sum of this variance and the absolute error variance. For the calculations in chapter 2, the following formula was used[90]:

$$ID = \frac{\sigma_S^2}{\sigma_S^2 + \sigma_{ABS}^2} \tag{1}$$

Where σ_s^2 is the error variance due to subjects, and σ_{ABS}^2 is the absolute measurement error variance. The latter, in turn, can be calculated as:

$$\sigma_{ABS}^2 = \frac{\sigma_d^2}{n_d} + \frac{\sigma_t^2}{n_t} + \frac{\sigma_{sd}^2}{n_d} + \frac{\sigma_{st}^2}{n_t} + \frac{\sigma_{dt}^2}{n_d n_t} + \frac{\sigma_{sdt}^2}{n_d n_t} \tag{2}$$

where σ_d^2 and σ_t^2 are, respectively, the variances attributed to the different days of testing and to the different trials, and σ_{sd}^2, σ_{st}^2, σ_{dt}^2 and σ_{sdt}^2 are the variances attributed to all levels of interaction between subjects (s), days (d), and trials (t), with n_d and n_t representing the number of days and trials.

Interpretation of the ID is analogous to the interpretation of the intraclass correlation coefficient (ICC) described by Shout and Fleiss[91]. Like the ICC, the ID ranges from $(0 - 1)$, with 0 representing no reliability and 1 representing perfect reliability (<0.4 poor, $0.4 - 0.75$ moderate, >0.75 excellent)[92].

If the results of the G-study indicate that the study data have adequate reliability, then the variance estimates are considered generalizable and can be used to build up the decision study (D-study). In the decision study, the user is able to assess the effects of manipulating the influence of one or more facets by changing the number of conditions for the different facets and recalculating the ID, SEM and MDC (see following section)[82,86,87]. In the current study, this procedure has been used to make a decision

about the minimum number of trials and/or sessions needed to reach the target reliability

value (see Chapter 2).

1.5 Minimal Detectable Change (MDC)

The square root of the absolute error variance is the standard error of measurement (SEM)[90] and is therefore inversely related to the ID.

$$SEM = \sqrt{\sigma_{ABS^2}} \qquad (3)$$

The SEM derived from the G-study and the D-study can be used to calculate the minimal detectable change (MDC) in the measure when averaged over the corresponding number of facets. This change is defined as the minimal amount of change that is not likely to be due to chance variation in measurement[93]. In other words, it represents how much change must occur in the measured values for that change to be considered statistically significant (i.e. a true change). Various different approaches have been used to calculate the MDC. For the current study, we used the following formula:

$$MDC = 1.96 * \sqrt{2} * SEM \qquad (4)$$

where the 1.96 derives from the 95% confidence interval, and $\sqrt{2}$ is included because two measurements (test and retest) are involved in measuring change[94].

1.6 Patient Population

Approximately 80% of the public will suffer from LBP during their adult life[95-98], making it one of the most common reasons for physiotherapy consultation. Evidence based management of LBP, however, is difficult, as approximately 90% of LBP cases have no clear, identifiable cause, and are therefore classified as non-specific[99]. On this basis, we have targeted this heterogeneous, non-specific LBP population for this work, with the purpose of developing a LBP related disability measure to aid in the identification of more homogeneous groups of patients, and to subsequently to assess the effectiveness of treatment interventions..

LBP may also be classified on the basis of symptom duration: acute (< one month), subacute (one month- three months), or chronic (> three months)[100]. The current study included individuals with chronic LBP, as this tends to reflect a substantial proportion of patients treated in physiotherapy. We do acknowledge, however, that the course of LBP is not easy to assess based solely on duration. For most individuals with LBP, pain intensity tends to diminish spontaneously, to some degree or another, during the acute phase. Approximately 62% of LBP sufferers, however, continue to experience pain for more than one year, either on a continuous or intermittent basis[101]. Two thirds of sufferers also report relapses of acute pain[101]. This suggests that the absence of pain may not reflect the absence of an underlying biomechanical problem. These epidemiological

data help to reinforce the need to develop better objective measures of impairment that are not clouded by the limitations inherent in self-report measures.

For the purposes of this study, subjects were considered to have LBP if their pain was located primarily between the buttock and ribs, and were considered subacute or chronic if the pain had lasted for more than 4 weeks[11]. The LBP was classified as non-specific based on the absence of self-reported signs, or prior diagnosis, of serious underlying condition (such as cancer, infection, or cauda equina syndrome), spinal stenosis or radiculopathy, or another specific spinal cause (such as vertebral compression fracture or ankylosing spondylitis)[11]. Previous radiological findings of degenerative changes in the lumbar spine did not exclude participation[11]. Our patient population was also limited to adults aged 18 to 49 years. The upper age limit was based on evidence that LBP in individuals 50 years of age and older is statistically more likely to be related to a serious pathology such as cancer (positive likelihood ratio 2.7) or spinal stenosis (positive likelihood ratio > 3.0)[102].

1.6.1   Clinical Outcome Measures

Two self-reported, clinical outcome measures were used in the current work as a means of ensuring that the participants' pain levels and associated disability reflected those of a clinical population (i.e. to establish a threshold level of LBP), as well as to monitor changes in pain between testing sessions. These measures were not, however, used to compare pain intensity or pain-related disability between participants, due to the limitations in self-report measures addressed above. Both measures have been validated and are available in French and English.

The first measure, the 11-point Box Scale (BS-11), also known as the numerical pain rating scale, is a self-report measure of pain intensity[103]. Individuals are asked to rate their pain from 0 to 10, where 0 represents no pain at all and 10 is the highest pain imaginable. This scale has been shown to correlate very strongly with other self-report measures of pain intensity, and is considered to be the easiest for subjects to use [103]. A score of 2/10 can be considered as a cut-off level for true pain, based on the minimal detectable change for this tool in patients with LBP[104]. The BS-11 completed by participants in the current study is included in Appendix 2.

Using this tool, prospective participants with a reported pain intensity of ≥2/10 on an BS-11[103], for both first and second sessions, were considered for inclusion in the current study (Chapter 2). Furthermore, in order to ensure that the clinical status for all

participants was stable enough for a reliability study, subjects were excluded if they reported more than a clinically-important 2-point change on the BS-11[104]. Testing was also paused during each session if the reported pain intensity changed by two points or more, in order to allow a return to the baseline level.

The second tool is the Oswestry disability index (ODI) which is a self-report measure of LBP-related disability[105]. The ODI is widely used, both clinically and in research, and has been translated into many different languages[106]. It is highly correlated with the other widely used, self-report measure of LBP-related disability – the Rolland Morris Disability Questionnaire (RDQ) – showing similar test–retest reliability, internal consistency, discriminating power, and ability to detect change over time[107]. We chose the ODI because of its ease of use (only 10 items), easy interpretability (scored as a percentage)[108], and availability of normative data[109]. The ODI completed by participants in the current study is included in Appendix 1.

Using this questionnaire, prospective participants who reported a score of ≥12% on the ODI were considered for inclusion in the study, as this score falls outside of the range reported by pain-free ("normal") individuals[110]. To ensure that the clinical status for all participants was stable for a reliability study, subjects were excluded if they reported more than a clinically-important 11% change in their ODI score[111], or if their score fell below 12%. .

1.6.2   Additional Exclusion Criteria

Subjects were excluded if they reported any of the following: known neurological or respiratory condition, because this might affect participation or performance; current pregnancy, because of the unknown effects of electromagnetic motion capture on this population and because this group of individuals may have specific causes of LBP related to hormonal changes (e.g. relaxin)[112]; any condition that would interfere with the use of an electromagnetic motion capture system (e.g. cardiac pacemaker, metal prosthetic); any condition that would prevent the use of the head mounted display (HMD) for visual feedback (see next section) such as infectious eye disease (e.g. conjunctivitis), discomfort wearing the HMD, or an inability to bring the visual display into the focus.

1.7 Visual Feedback

Based on the findings of a pilot study[113], we decided to provide visual feedback of lumbar spine position in order to help direct the subjects' movements. In this pilot study, 11 participants with a recent history of LBP were asked to perform the assessment protocol described in Chapter 2, without the aid of visual feedback for lumbar spine position. The results demonstrated only moderate reliability values for the measures of interest. Analysis of the movement patterns during testing showed that participants were often not moving in the prescribed directions, separated at 45° intervals. In some cases, there was an interval of less than 5° between two "different" movements (Figure 1).   On this basis it was hypothesized that more precise movements would likely improve the reliability of the measures. The proposed solution was to provide the participants with real-time feedback about the movements of their lumbar spine.

Figure 1: Pilot data for two different subjects with ellipse and spline- fitting shape
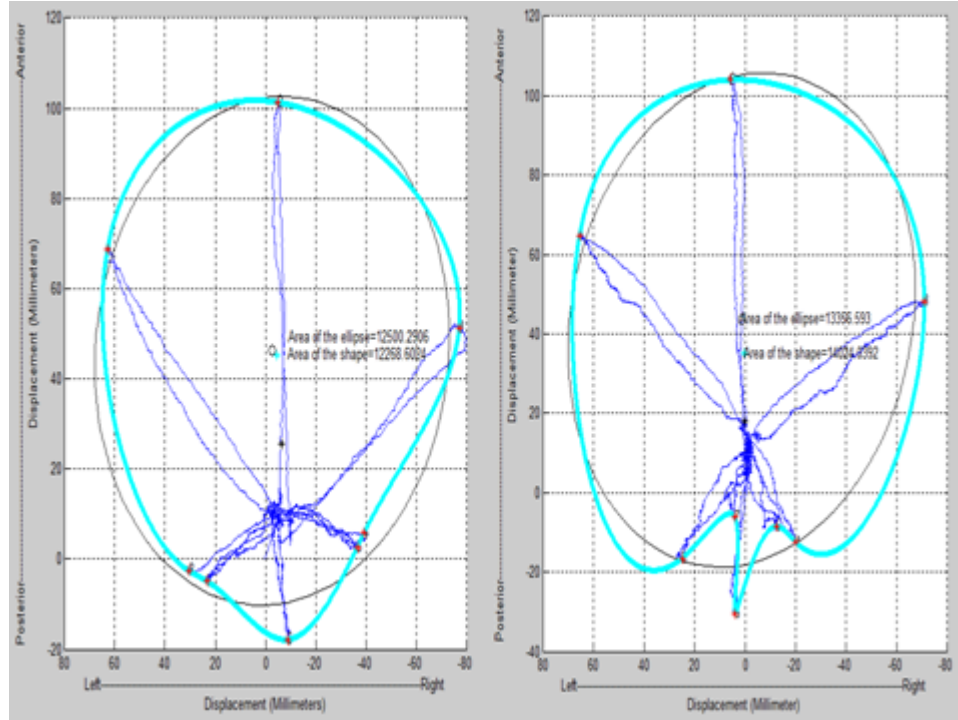
Visual feedback was provided using Wrap TM 920 Video Eyewear (Vuzix

Corporation, New York, USA) (Figure 2), held in place using a piece of black, elastic

fabric covering the area between nose and forehead. As detailed in Chapter 2, subjects

saw an asterisk shape representing the 8 directions of movement, separated at 45°

intervals, in the transverse plane of S1 (Figure 3). Rotation of the asterisk was tied to the

axial rotation of the pelvis, as represented by the S1 sensor (rotation of the asterisk to the

right indicated pelvic rotation to right in the global reference frame, and vice versa). A

red circle was superimposed on the asterisk shape, showing the live, real-time sensor

position of the T12 sensor in the transverse plane of S1. The centre of the asterisk

represented the upright sitting position.   During movement, subjects were instructed to

move the red circle along the spoke of the asterisk representing the desired movement

direction.

Figure 2: Head mounted display

Chapter 2- Manuscript

2.1 Reliability of a Measure of Total Lumbar Spine Range of Motion in Individuals with Low Back Pain.

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2.2 Abstract

Measuring lumbar spine range of motion (ROM) using multiple movements is impractical for clinical research, because it relies on the assumption that most subjects will present with the same impairment. The purpose of this study was to develop a single measure representing the total available lumbar ROM. Twenty participants with low back pain performed three series of eight lumbar spine movements, in each of two sessions.   For each series, an ellipse and a cubic spline were fit to the end-range positions, measured based on the position of the twelfth thoracic vertebra in the transverse plane of the sacrum. The area of each shape provides a measure of the total available ROM, while their centre reflects the movements' symmetry. Using Generalizability Theory, the index of dependability for the area and anterior-posterior centre position was found to be ≥ 0.90, but was slightly lower for the medio-lateral centre position. Slightly better values were achieved using the spline-fitting approach.   Further analysis also indicated that excellent reliability, and acceptable minimal detectable change values, would be achieved with a single testing session. These data indicate that the proposed measure provides a reliable and easily interpretable measure of total lumbar spine ROM. Specific recommendations are discussed.

2.3 Introduction

Until recently, measurement of lumbar spine range of motion (ROM) was considered a routine part of clinical examination for patients with low back pain (LBP), and a means of assessing LBP-related impairment.[1,2] Current clinical practice guidelines, however, no longer include ROM testing as a key aspect of spinal assessment.[11] This is based largely on the absence of any clear, consistent relationship between ROM and functional impairment or disability in individuals with LBP.[12-14] Recent efforts to identify homogeneous subgroups of individuals with LBP, however, have found lumbar hyper- and hypo-mobility, as well as lumbar flexion as a proportion of total forward bending, to be relevant factors in the sub-classification of patients with acute LBP.[6,25,26] Measures of lumbar spine ROM have also been identified as significant risk indicators of recurrent LBP in adolescents.[23] The lack of a clear relationship between LBP and spine ROM, therefore, may be more a reflection of the heterogeneity of the physical impairments associated with LBP than evidence of the irrelevance of spine ROM for physical function.

The heterogeneity of patients with LBP also complicates the design of clinical research into the association of ROM with LBP. Traditional cardinal plane measures of lumbar spine ROM have been shown to be highly reliable, with reliability coefficients (e.g. intra-class correlation coefficients) often > 0.9[54,65,79]. A clinical study using the six cardinal plane measures, however, would require a large number of subjects due to the number of statistical comparisons being run. Furthermore, as different patients are likely

to have different limitations for each measure, the number of patients with any given limitation may not be sufficient to identify a statistically significant association with that measure and less specific measures such as pain intensity or pain-related disability. This problem can be addressed through the use of a single measure that reflects the total available ROM of the lumbar spine. Such a measure would reveal global variance in ROM (e.g. hyper- or hypo-mobility), independent of the direction(s) or cardinal plane(s) in which ROM is altered. This would require fewer statistical comparisons, and would be more likely to capture a global association between ROM and other variables of interest. To be of use, however, such a measure would have to be reliable for patients with LBP. Furthermore, if such a measure were to be used as a tool to study the effects of clinical interventions, it would need to have a realistically achievable minimal detectable change (MDC).

The aim of the current study was to develop a quantitative, reliable and easily interpretable outcome measure, representing the total available lumbar spine ROM, to be used in patients with LBP. Based on previous studies examining the reliability of ROM measurement in the lumbar spine, we hypothesized that the reliability coefficient for this new measure would be $\geq$ 0.9, so as to meet previously suggested criteria for monitoring individual patient progress [114]. We also expected the MDC for this measure to be small enough so as to be realistically achievable following a rehabilitation intervention program.

2.4 Materials and Methods

2.4.1 Subjects

Twenty subjects with sub-acute or chronic, non-specific LBP (7 males, 13 females), with a mean age of 30.1 (SD 8.4) years, participated in the study. Subjects were recruited from the community in Montreal, and provided informed, written consent. Approval for the study was granted by the local research ethics board.

Subjects were considered to have non-specific LBP if their pain was located primarily between the gluteal folds and ribs, without prior diagnosis or self-reported signs of serious underlying pathology (such as cancer, infection, or cauda equina syndrome), spinal stenosis or radiculopathy, or other specific cause (such as vertebral compression fracture or ankylosing spondylitis).[11] Subjects were excluded if they self-reported any of the following: neurological or respiratory condition that might affect participation or performance; current pregnancy; any condition that would interfere with the use of an electromagnetic tracking system (e.g. cardiac pacemaker, metal prosthetic); any condition that would prevent the use of a head mounted display (HMD) for visual feedback (e.g. infectious eye disease, discomfort wearing the HMD). Subjects were excluded if their pain intensity was below 2/10 on the 11 -point box scale (BS- 11)[103], or if their level of LBP-related disability was less than 12% on the Oswestry Disability Index (ODI)[110], at the start of either testing session (see Data Acquisition). In order to

ensure that the clinical status of all subjects was stable enough for a reliability study, subjects were also excluded if they experienced more than a clinically-important 2-point change on the BS- 11[104], or more than an 11% change in their ODI score[111], between testing sessions.

All subjects included in the study had LBP lasting for more than one month (subacute or chronic LBP, as defined by[11], with a mean duration of 96.8 (SD 105.8) months. At the start of the first session, the mean BS- 11 score was 3.1 (SD 0.9), with a range from 2 to 6, and the mean ODI score was 25.8% (SD 8.5%), with a range from 12% to 44%. At the start of the second session, the mean BS- 11 score was 2.8 (SD 1.0), with a range from 2 to 5, and the mean ODI was 23.7% (SD 7.5%), with a range from 14% to 36%.

Sample size calculations for a target reliability coefficient of 0.9 (95% confidence interval: 0.7-1.0) indicated that at least 15 participants were required, based on 2 repetitions of the measurement protocol over 2 individual testing sessions.[115] As our analysis made use of the generalizability theory, we targeted a larger sample size of 20 participants, with the measurement protocol repeated 3 times during each of 2 sessions, in order to provide additional statistical power for the G-Study (see Statistical Analysis).

2.4.2 Data Acquisition

Data acquisition took place over two testing sessions, separated by at least 3 days, but by no more than one week. During each session, subjects were asked to wear loose fitting clothing, including pants or shorts with an elastic waist band, so as not to interfere with sensor placement. The subjects were then positioned in a semi-kneeling position, on a wooden kneeling chair, with a strap fastened securely across the thighs in order to limit movement of the lower limbs (Figure 3 A).

Lumbar spine motion was acquired in three dimensions (3D) using a TrakSTAR motion capture system (Ascension Technology Corporation, Milton, USA). The TrakSTAR is a direct-current, electromagnetic system based on induction-sensor technology. Two sensors were affixed to the subjects' skin over the spinous process of first sacral vertebra (S1) and spinous process of twelfth thoracic vertebra (T12) using custom made urethane clips and double sided tape.

Subjects performed a series of eight (8) maximal lumbar spine movements, to the end of range, at 45 o intervals about the full circle (Figure 3 B), constituting one trial of the movement task. For each trial, the 8 movements were performed in a random order, with 3 trials performed during each testing session. After each movement in the trial, the subjects were asked to verbally report their pain intensity during the movement. If an increase in pain intensity of more than 2 points from the baseline BS- 11 score was reported, testing was paused until pain intensity returned to within 1 point of baseline. Subjects were also permitted a 1 minute break between each trial, if desired.

The measure of interest was based on the position of the T12 sensor relative to S1, in the transverse plane of S1. This was determined by multiplying the 4 x 4 rotation-translation matrix for T12 by the inverse of the rotation-translation matrix for S1. Two curve-fitting approaches – ellipse and spline - were then used to fit a shape to the point of maximum relative excursion of T12 during each of the 8 individual movements in a trial. The ellipse-fitting approach used a direct, least square fit of an ellipse as described by Fitzgibbon and Fisher[116]. The spline-fitting approach used a piecewise polynomial form of the cubic spline interpolant. The area of the resulting shapes was used to provide a general measure of the total lumbar spine ROM. The centre position of these shapes (along both the anterior-posterior and medio-lateral dimensions of the transverse plane of S1) was used to provide a measure of the distribution (symmetry) of this available motion, relative to the upright sitting position of each subject. All of the above calculations were performed using custom software written in Matlab (The Mathworks, Natick, USA)

During the testing, video eyewear (Wrap TM 920 Vuzix Corporation, New York, USA) was used to provide visual feedback for the subjects of the position of T12 relative to S1. Subjects were presented with an asterisk shape representing the 8 directions of movement, with the centre of the asterisk representing the upright sitting position, and the plane of the asterisk representing the transverse plane of S1. A circle was superimposed on the asterisk, showing the real-time position of the T12 sensor in the transverse plane of the S1 (Figure 3 C). For each movement, the subjects were instructed to move the circle along the appropriate radius of the asterisk.

In order to minimize the effects of learning with this novel task, the subjects were asked to practice each of the 8 movements, through partial range of motion, prior to data acquisition. This was continued until the tester was satisfied that the subject was performing the movements correctly. No more than 4 practice repetitions were required by any subject.

Figure 3: Experiment position and direction of the movements
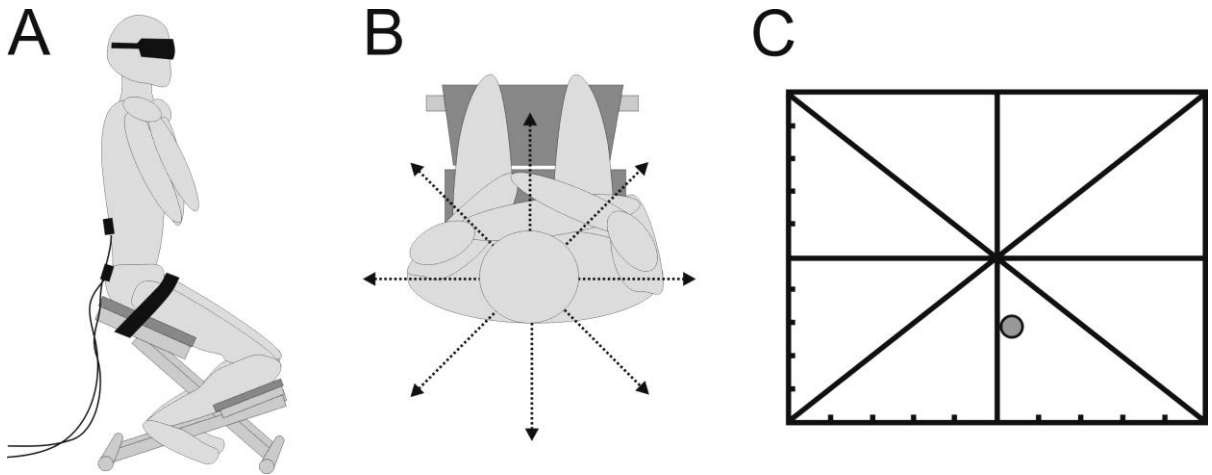
A. Experimental set-up for data acquisition. Subjects sat on a kneeling chair, with sensors affixed on the skin over T12 and S1, wearing video eyewear for visual feedback.
B. Eight (8) directions of movements (45° intervals) for each trail of the testing protocol.
C. Asterisk shape seen by the subjects, representing the 8 directions of movement in (B). The circle represents the real-time position of the T12 sensor in the transverse plane of the S1 sensor.

2.4.3   **Statistical Analysis**

Generalizability theory was used to assess the reliability of each of the measures described above: area of both the ellipse and spline shapes; centre position of both the ellipse and spline shapes along the anterior-posterior (AP) and medio-lateral (ML) axes. This approach consists of two steps: the generalizability study (G-study) and the decision study (D-study).

The G-study uses a repeated measures analysis of variance to estimate the variance in the subjects' scores that can be attributed to the different facets of the experimental design, using the experimentally acquired data. In the current study, these facets were the subjects, sessions, and trials ($20 \times 2 \times 3$), as well as the interactions between these variables. To simplify the interpretation of these results, proportions of the variances (relative to the total variance) attributable to each of these sources of variance were calculated, and any negative variance components obtained were set to zero.[117] The variance estimates for each of these facets were then used to calculate the index of dependability (ID) and the standard error of measurement (SEM). The ID was calculated by dividing the variance attributable to the subjects by the sum of this variance and the absolute error variance (sum of variance attributable to all other facets)[82,90]. The ID is analogous to the intraclass correlation coefficient (ICC) described by Shrout and Fleiss [91]. Like the ICC, the ID ranges from 0 to 1, and values < 0.4 are interpreted as poor, $0.4 -$ 0.75 as moderate, and > 0.75 as excellent reliability.[92] The standard error of measurement (SEM) is the square root of the absolute error variance.[90]

The D-study makes use of the variance estimates from the G-study to estimate the ID and SEM that would be achieved by changing one or more of the facets used to determine the absolute error variance; in this case the number of sessions and/or trials. This step allows the user to extrapolate the results beyond the experimental data. For the current study, ID and SEM estimates were produced for all combinations of 1 to 3 sessions and 1 to 5 trials per session.

Finally, the MDC was calculated using the SEM from the experimental data (G-study), and from each estimate of the SEM from the extrapolated data (D-study), using the following formula:

$$MDC = 1.96 * \sqrt{2} * SEM \qquad (4)$$

where the 1.96 derives from the 95% confidence interval, and $\sqrt{2}$ is included because two measurements (test and retest) are involved in measuring change.[94]

All statistical analyses were done in Matlab (The Mathworks, Natick, USA), and based on the approach described by Mushquash and O'Connor [82].

2.5 Results

Figure 4 illustrates an example of data from a single subject, for a single repetition of the 8 movement directions, including the shapes derived from the ellipse- and spline-fitting approaches.

Results for the G-study are presented in Table 1. The ID of the area for the ellipse- and spline-fitting approaches was 0.94 and 0.95 respectively. The ID of the centre position of these shapes was 0.90 and 0.91 respectively in the AP axis, and 0.65 and 0.59 for the ML axis.

The ID and MDC for each iteration of the D-study are illustrated in Figure 5. The number of trials had a greater impact on both the ID and MDC, for all variables, than the number of sessions. For the area of the ellipse and spline fits, the ID approached 0.9 with a single session and only two trials, with the addition of a third trial easily bringing this value above 0.9. For the centre points of both the ellipse and spline fits, the ID for the AP axis exceeded 0.9 with 5 trials in a single session. For the ML axis, however, the target ID of 0.9 was not achieved. The MDC for the centre point of the AP and ML axes, however, was less than 20 mm and 15 mm respectively with only 3 trials over a single session.

Figure 4: Data from a single subject, for one trial of the testing protocol.
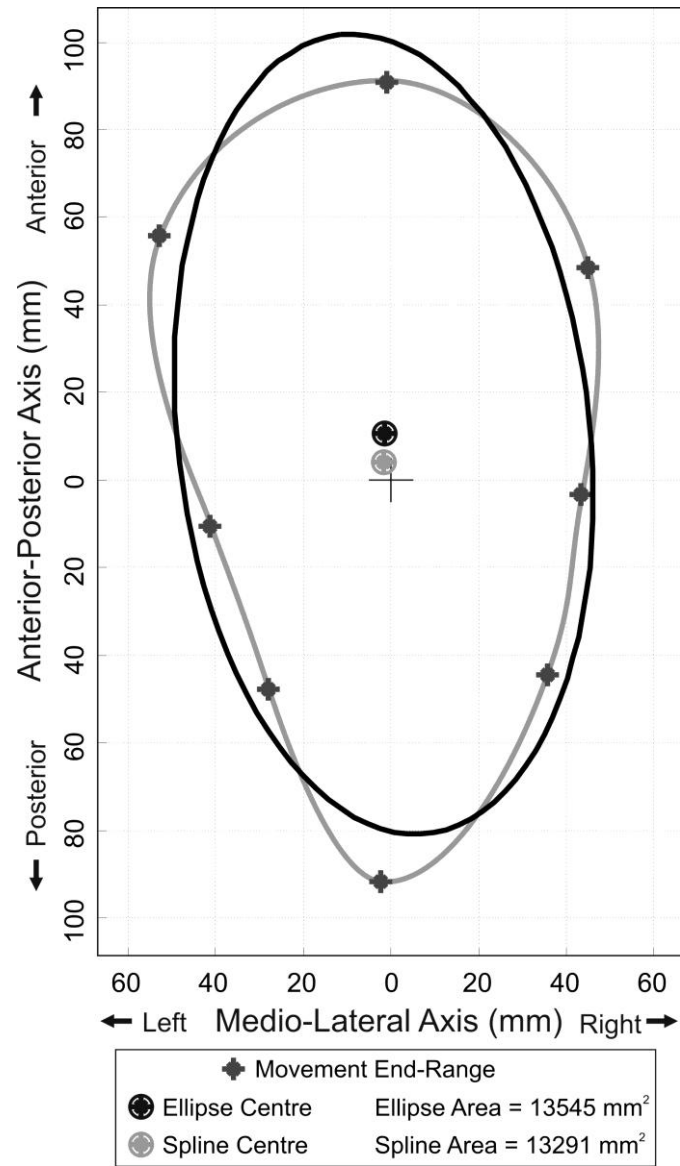
The 8 end-points of movement are illustrated, along with the findings from the ellipse- and spline-fitting approaches

Table 1: Results of the G-study

| | | Mean | SEM | MDC | ID | % Variance | | | | | | |
						S	Se	T	S*Se	S*T	Se*T	S*Se*T
Ellipse Area (mm²)		14725	1775	4921	0.94	80.4	0.0	0.7	0.0	11.0	1.3	6.5
Spline Area (mm²)		14210	1610	4462	0.95	82.1	0.0	0.8	0.0	7.5	1.7	7.8
Ellipse Centre (mm)	**AP**	30.4	5.8	16.0	0.90	66.5	0.0	0.2	0.0	10.1	3.6	19.6
	ML	-1.0	3.4	9.6	0.65	28.4	0.0	0.0	0.0	20.1	1.0	50.4
Spline Centre (mm)	**AP**	27.9	5.0	13.9	0.91	68.6	0.0	0.4	0.0	8.9	3.4	18.7
	ML	-0.9	3.4	9.4	0.59	24.3	0.0	0.6	0.0	26.2	0.0	48.9

SEM = Standard Error of Measurement; MDC = Minimal Detectable Change; ID = Index of Dependability; S = Subjects; Se = Sessions; T = Trials

Figure 5: Findings from the D-study
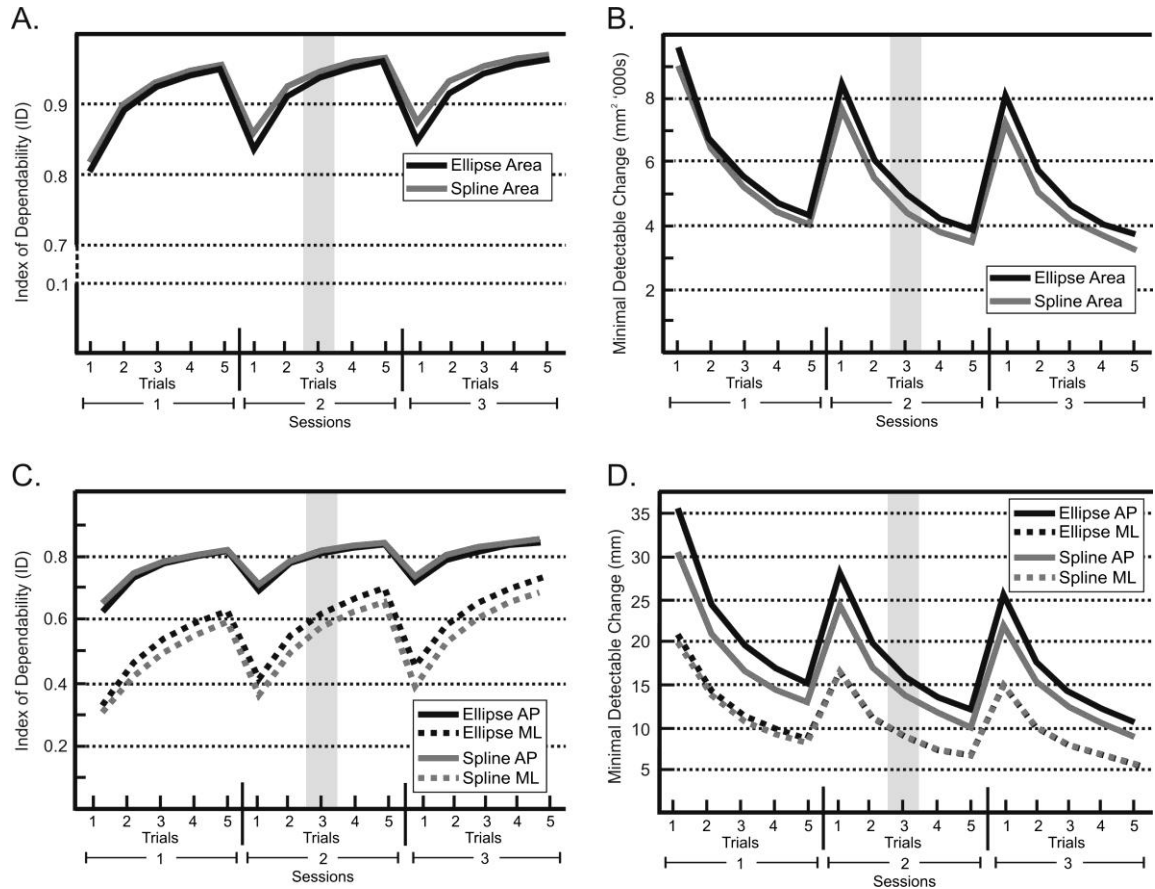
Gray rectangle represents findings from the G-study, for: A. Index of dependability for the area of the shapes fit by the ellipse- and spline-fitting approaches; B. Minimal detectable change for the area of the shapes; C. Index of dependability for the centre position of the shapes; D. Minimal detectable change for centre position of the shapes.

2.6 Discussion

The findings of this study clearly demonstrate excellent reliability for the proposed measure of total lumbar spine range of motion, using both the ellipse- and spline-fitting approaches. The level of reliability achieved for this measure, with only three trials in a single session, meets the level (≥ 0.90) suggested by the Scientific Advisory Committee of the Medical Outcomes Trust[118] for use in monitoring individual subject progress over time (i.e. for clinical use).

The measure of lumbar spine ROM presented in the current study is based on the excursion of the T12 vertebra relative to the sacrum, rather than on the orientation of one vertebral segment relative to another as is traditionally done. This approach, based on excursion, reflects many of the functional roles played by the spine, such as in reaching beyond arm's length. Furthermore, the orientation of the facet joints of the spine dictates that, for all but the simplest movements, the vertebrae will follow patterns of coupled rotations, which differ from subject to subject[119,120], rather than simple rotations in a Cartesian coordinate system. As such, it is more practical, and in many circumstances more easily interpretable, for a measure of total lumbar spine ROM to be based on relative vertebral excursion rather than the orientation of the vertebral segments needed to attain an end-range position.

Measurement of lumbar spine ROM based on excursion, rather than orientation, is not new. As with studies measuring lumbar spine ROM based on orientation[54,65,79],

studies measuring spine excursion[121,122] have reported excellent reliability, with ICC

values between 0.91 and 0.98 reported for individuals with LBP.[122] These studies have,

however, also followed the traditional approach of measuring individual motions in the

cardinal planes, and so do not address the issue that multiple measures poses for the

design of clinical research, as outlined in the introduction. The actual excursions

reported in these previous studies were also larger than those in the current study. This,

however, is likely explainable, in large part, by the different instrumentation used in

these studies.

In the current study, the proposed measure of total lumbar spine ROM – the total

area covered by the excursion of T12 in the transverse plane of S1 – showed excellent

reliability based on the experimental data (G-study - Table 1). This excellent reliability

was attributable to the combination of high inter-subject variability and low SEM

(absolute variance). Within that absolute variance, the effect of sessions and trials was

very small (> 1%), as was the interaction between subjects and sessions. The interaction

between subjects and trials, on the other hand, proved to be important, as was the 3 -way

interaction between facets (Table 1). The variance attributable to these facets explains

the results of the D-study, in which the effect of additional trials greatly outweighed the

effect of additional sessions for both the ID and MDC (Figure 5). As such, an ID of >

0.9 was reached with only 2 repetitions of the testing protocol, for a single session, using

the spline-fit approach, with this value far exceeding 0.9 for both fitting methods when a

third trial was added. MDC values, based on 3 trials, were ~ 35% of the overall mean for

the study participants. This is 2 - 3 times larger than the %MDC that would be achieved

using the mean and SEM values reported by[122] for individual cardinal plane excursions.

The measure proposed in the current study, however, is based on 8 separate movements. As such, this MDC appears to be quite reasonable in detecting a change in total lumbar spine ROM, relative to previously reported data.

For the symmetry of the total lumbar spine ROM, based on the centre point of the shapes fit using the ellipse and spline methods, the ID from the G-study was excellent for the AP axis (0.90 and 0.91 respectively), but much lower for the ML axis (0.65 and 0.59) (Table 1). The moderate ID found in the ML axis was largely explained by the low variance attributable to the subjects, which was smaller than the interaction of subjects, sessions, and trials (Table 1). This reflects the fact that most subjects in the current study were relatively symmetrical in their ML movements. Despite the moderate ID for the ML axis, the MDC for the centre point position was low for both axes (9.4 mm – 16.0 mm; Table 1), with very acceptable values achievable with only 3 repetitions of the testing protocol over a single session (> 20 mm for both axes; Figure 5).

Based on the findings above, a comparison between the two curve fitting methods used in this study suggests that the spline-fitting approach produces superior results to the ellipse-fitting approach in both the calculated ID and MDC, with the exception of ID in the ML axis (Table 1 and Figure 5). The MDC in the ML axis, however, is smaller with the spline-fitting approach than with the ellipse-fitting approach. As such, it appears that the spline-fit should be recommended over the ellipse-fit.

As with all studies, the current study has certain limitations. The study population was relatively young, with low levels of pain intensity and LBP-related disability that had been present for several years. As such the findings of the current study may not be generalizable to older individuals with LBP, or to individuals with

more acute or more intense and disabling LBP. The subjects in this study also presented a relatively symmetrical distribution of lumbar spine ROM in the ML axis, which contributed to the moderate ID for the centre position in this axis. The MDC for this measure, however, was quite small. Furthermore, global restrictions of lumbar ROM appear to be more common that asymmetrical restrictions.[123] As such, this factor is unlikely to affect the generalizability of these findings. The testing protocol used in the current study may have also been affected by factors such as variance in the placement of the sensors between sessions, or diurnal variation in spine height (which may or may not affect ROM). These factors are generally accounted for by the between session variance included in the statistical analysis (e.g. time of day for data acquisition was not standardized), and are unlikely to affect the interpretation of these findings.

In conclusion, the current study describes a simple and easily interpretable measure of total lumbar spine ROM that has excellent reliability and a reasonable MDC. The findings of the D-study further suggest that a favorable balance between reliability and efficiency is achieved with only three trials of the testing protocol in a single testing session.

2.7 Acknowledgements

Chapter 3- Summary and Conclusion

Measuring lumbar spine ROM was once considered to be one of the most important factors in determining the level of impairment of individuals with LBP. Recent research, however, has suggested that there is no clear link between lumbar ROM and LBP-related disability. As such, current clinical practise guidelines no longer considered ROM measurement as an essential component of an assessment of LBP.

The move away from assessing lumbar ROM is invalid for two principal reasons. First, the studies that failed to find a link between LBP-related disability and ROM based their measures of disability on self-reported questionnaires, which are highly influenced by the psychological status of the individual. A clinical assessment of impairment, on the other hand, should be based on objective measures of physical function. Second, the LBP population is highly heterogenic. As such, there is no reason to expect a clear, consistent association between lumbar ROM and LBP-related disability. This second point is supported by research aimed at developing more homogenous subgroups within the LBP population, and in which lumbar mobility has proven useful in guiding the sub-classification of these individuals.

The objective of the central study in this thesis was to develop an approach that would produce reliable, quantitative measures of global, lumbar spine ROM in individuals with LBP.

The approach described in Chapter 2 of this thesis was able to meet this objective. The approach itself is simple to perform, and provides an easily interpretable measure of total lumbar spine ROM that has excellent reliability and a reasonable MDC. Furthermore, this approach was able to produce highly reliable measurements with only three repetitions of the testing protocol in a single session.

The measure developed in this study can serve as a basis for further research into identifying more homogeneous subgroups within the LBP population, and to draw a clearer picture of the relationship between LBP and the functional mobility of the lumbar spine. This measure will also be valuable for the assessment of treatment outcomes, due to its ability to provide substantial information about the mobility of a complex biomechanical system with a single, easily interpretable value.

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Appendices

Appendix 1

<u>**Oswestry Disability Index**</u>

Section 1: Pain Intensity

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2: Personal Care

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally but it is very painful.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of self-care.
- ☐ I do not get dressed, wash with difficulty and stay in bed.

Section 3: Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4: Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me walking more than one mile.
- ☐ Pain prevents me walking more than a quarter of a mile.
- ☐ Pain prevents me walking more than 100 yards.
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5: Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than half an hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6: Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than half an hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7: Sleeping

- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain I have less than 6 hours sleep.
- ☐ Because of pain I have less than 4 hours sleep.
- ☐ Because of pain I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8: Sex Life (if applicable)

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9: Social Life

- □ My social life is normal and causes me no extra pain.
- □ My social life is normal but increases the degree of pain.
- □ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- □ Pain has restricted my social life and I do not go out as often.
- □ Pain has restricted social life to my home.
- □ I have no social life because of pain.

Section 10: Traveling

- □ I can travel anywhere without pain.
- □ I can travel anywhere but it gives extra pain.
- □ Pain is bad but I manage journeys over two hours.
- □ Pain restricts me to journeys of less than one hour.
- □ Pain restricts me to short necessary journeys under 30 minutes.
- □ Pain prevents me from travelling except to receive treatment.

Questionnaire d'incapacité d'Oswestry

Section 1 : Intensité de la douleur

☐ En ce moment, je ne ressens aucune douleur.
☐ En ce moment, j'ai des douleurs très légères.
☐ En ce moment, j'ai des douleurs modérées.
☐ En ce moment, j'ai des douleurs assez intenses.
☐ En ce moment, j'ai des douleurs très intenses.
☐ En ce moment, les douleurs sont les pires que l'on puisse imaginer.

Section 2 : Soins personnels (se laver, s'habiller, etc.)

☐ Je peux effectuer normalement mes soins personnels sans douleurs supplémentaires.
☐ Je peux effectuer normalement mes soins personnels, mais c'est très douloureux.
☐ Je dois effectuer mes soins personnels avec précaution et lenteur, et je ressens des douleurs.
☐ J'ai besoin d'aide pour les soins personnels, mais j'arrive encore à effectuer la plus grande partie de ceux-ci seul(e).
☐ J'ai besoin d'aide tous les jours pour la plupart de mes soins personnels.
☐ Je ne peux plus m'habiller, je me lave avec difficulté et je reste au lit.

Section 3 : Soulever des charges

☐ Je peux soulever des charges lourdes sans augmentation des douleurs.
☐ Je peux soulever des charges lourdes, mais cela occasionne une augmentation des douleurs.
☐ Les douleurs m'empêchent de soulever de lourdes charges depuis le sol, mais cela reste possible si elles sont sur un endroit approprié. (par ex : sur une table)
☐ Les douleurs m'empêchent de soulever des charges lourdes, mais je peux en soulever de légères à modérées si elles sont sur un endroit approprié.
☐ Je ne peux soulever que de très légères charges.
☐ Je ne peux rien soulever, ni porter du tout.

Section 4 : Marche

□ Les douleurs ne m'empêchent pas de marcher, quelle que soit la distance.
□ Les douleurs m'empêchent de marcher au-delà d'un km.
□ Les douleurs m'empêchent de marcher au-delà de 250 m.
□ Les douleurs m'empêchent de marcher au-delà de 100 m.
□ Je ne peux marcher qu'avec une canne ou des béquilles.
□ Je reste au lit la plupart du temps et dois me traîner jusqu'aux toilettes.

Section 5 : Position assise

□ Je peux rester assis(e) aussi longtemps que je le désire sur n'importe quel siège.
□ Je peux rester assis(e) aussi longtemps que je le désire sur mon siège favori.
□ Les douleurs m'empêchent de rester assis(e) plus d'une heure.
□ Les douleurs m'empêchent de rester assis(e) plus d'une demi-heure.
□ Les douleurs m'empêchent de rester assis(e) plus de dix minutes.
□ Les douleurs m'empêchent toute position assise.

Section 6 : Position debout

□ Je peux rester debout aussi longtemps que je le désire sans douleur supplémentaire.
□ Je peux rester debout aussi longtemps que je le désire, mais cela occasionne des douleurs supplémentaires.
□ Les douleurs m'empêchent de rester debout plus d'une heure.
□ Les douleurs m'empêchent de rester debout plus d'une demi-heure.
□ Les douleurs m'empêchent de rester debout plus de dix minutes.
□ Les douleurs m'empêchent de me tenir debout.

Section 7 : Sommeil

□ Mon sommeil n'est jamais perturbé par les douleurs.
□ Mon sommeil est parfois perturbé par les douleurs.
□ À cause des douleurs, je dors moins de six heures.
□ À cause des douleurs, je dors moins de quatre heures.
□ À cause des douleurs, je dors moins de deux heures.
□ Les douleurs m'empêchent totalement de dormir.

Section 8 : Vie sexuelle (si présente)

☐ Ma vie sexuelle est normale et n'occasionne pas de douleurs supplémentaires.
☐ Ma vie sexuelle est normale, mais occasionne parfois quelques douleurs supplémentaires.
☐ Ma vie sexuelle est presque normale, mais très douloureuse.
☐ Ma vie sexuelle est fortement réduite à cause des douleurs.
☐ Ma vie sexuelle est presque inexistante à cause des douleurs.
☐ Les douleurs m'empêchent toute vie sexuelle.

Section 9 : Vie sociale

☐ Ma vie sociale est normale et n'occasionne pas de douleurs supplémentaires.
☐ Ma vie sociale est normale, mais elle augmente l'intensité des douleurs.
☐ Les douleurs n'ont pas de répercussion significative sur ma vie sociale, excepté une limitation lors de mes activités physiques. (par ex : le sport, etc.)
☐ Les douleurs limitent ma vie sociale et je ne sors plus aussi souvent.
☐ Les douleurs limitent ma vie sociale à mon foyer.
☐ Je n'ai pas de vie sociale à cause des douleurs.

Section 10 : Voyage

☐ Je peux voyager partout sans douleur.
☐ Je peux voyager partout, mais cela occasionne une augmentation des douleurs.
☐ Les douleurs sont bien présentes, mais je peux effectuer un trajet de plus de deux heures.
☐ Les douleurs m'empêchent tout trajet de plus d'une heure.
☐ Les douleurs ne me permettent que de courts trajets nécessaires de moins de 30 minutes.
☐ Les douleurs m'empêchent tout trajet, sauf pour recevoir un traitement.

ODI Scoring:

- Items in each section are worth 0 to 5 points (first item = 0; last item = 5)
- Add up the points for each section (out of 50) and take a percentage (i.e. double the score)
  - E.G. an ODI of 16 = 32% disability:

Interpretation

- 0% to 20% (minimal disability)
  - Patients can cope with most activities of daily living. No treatment may be indicated except for suggestions on lifting, posture, physical fitness and diet. Patients with sedentary occupations (ex. secretaries) may experience more problems than others.
- 21%-40% (moderate disability)
  - Patients may experience more pain and problems with sitting, lifting and standing. Travel and social life are more difficult. Patients may be off work. Personal care, sleeping and sexual activity may not be grossly affected. Conservative treatment may be sufficient.
- 41%-60% (severe disability)
  - Pain is a primary problem for these patients, but they may also be experiencing significant problems in travel, personal care, social life, sexual activity and sleep. A detailed evaluation is appropriate.
- 61%-80% (crippled)
  - Back pain has an impact on all aspects of daily living and work. Active treatment is required.
- 81%-100%
  - These patients may be bed bound or exaggerating their symptoms. Careful evaluation is recommended.

References:

1. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine. 2000 Dec 15;25(24):3115-24.
2. Fairbank JC, Pynsent PB, The Oswestry Disability Index. Spine 2000; 25(22):2940-2952
3. Fairbank JCT, Couper J, Davies JB. The Oswestry low Back Pain Questionnaire. Physiotherapy 1980; 66: 271-273.
4. Vogler D, Paillex R, Norberg M, de Goumoëns P, Cabri J. Cross-cultural validation of the Oswestry disability index in French. Ann Readapt Med Phys 2008; 51: 379-385.

Appendix 2

The 11-Point Box Scale (BS-11)

Instructions:

If a zero (0) means "no pain", and a ten (10) means "pain as bad as it could be", on this scale of 0 to 10, what is your level of pain?

Put an "X" through that number.

0   1   2   3   4   5   6   7   8   9   10

L'échelle à 11-Pointes (BS-11)

Instructions:

Si un zéro (0) signifie «aucune douleur», et un dix (10) signifie «la pire douleur que cela pourrait être", sur cette échelle de 0 à 10, quel est votre niveau de douleur actuel?

Mettez un «X» sur ce nombre.

    0   1   2   3   4   5   6   7   8   9   10

Appendix 3

Consent Form (English version)

<u>INFORMATION AND CONSENT FORM</u>

UN CRITÈRE D'ÉVALUATION POUR DÉTERMINER LE CHANGEMENT
MINIMAL QUI PEUT ÊTRE MESURER DANS LE MOUVEMENT LOMBAIRE.

RESPONSABLE DU PROJET

Richard Preuss, pht, PhD
  Professeur adjoint   Chercheur régulier
  École de physiothérapie et   Centre de réadaptation
d'ergothérapie   Constance-Lethbridge
  Université McGill   Site du CRIR

SITE DE L'ÉTUDE

Centre de réadaptation Constance-Lethbridge
  Site du CRIR
  7005, Boul. de Maisonneuve Ouest
  Montréal, Québec, H4B 1T3

Tél. :   514-487-1891 poste 350 (R. Preuss)
Téléc. : 514-487-4079

Courriel : richard.preuss@mcgill.ca

You are invited to participate in a research study to test the properties of a new measure to assess movement in the lower back. This research project is being conducted by the above investigators, and will take place over two (2) testing sessions, each separated by at least three days and by no more than one week, at the Research Centre of the Constance Lethbridge Rehabilitation Centre, located at 7005 de Maisonneuve Boulevard West, Montréal, Québec. We greatly appreciate your interest in our work.

Before agreeing to participate in this project, please take the time to read and carefully consider the following information. This consent form explains the aim of this study, the procedures, advantages, risks and inconvenience, as well as the persons to contact for additional information, if necessary.

This consent form may contain words that you do not understand. We invite you to ask the researchers, and the other members of the staff assigned to the research project, any questions that you deem useful, and to ask them to explain any word or information that is not clear to you.

PURPOSE OF THE STUDY

The objective of this study is to develop a new, more easily interpretable measure to represent the total amount of movement available in the low back. By testing this measure on two different days, we will also determine how much normal variability exists in this movement, so that we can use this measure in future studies to assess the effect of an intervention or treatment.

NATURE OF YOUR PARTICIPATION:

After you have provided consent, your participation will involve:

First Session:

1. Answering some questions about your medical history in order to ensure that you meet the inclusion criteria for this study.
2. Preparing for data acquisition with the following procedures:
    a.   You will first be asked to lie on your stomach on a treatment table. Two flexible urethane clips will then be affixed to you lower back using double sided tape intended for use on skin.
    b.   You will then be asked to sit in a kneeling chair. Two motion capture sensors will be attached to the clips, and you will be asked to put on video eyewear that will provide you with visual feedback from the sensors on your back. The eyewear will be held in place using a piece of black, elastic fabric.

c. You will then receive instructions from the investigator about the movements to be performed for the testing, and you will be asked to practice these movements until you are comfortable with the visual feedback provided by the eyewear.

d. For the testing, you will be asked to perform a series of movements of the low back, in eight (8) directions, to your end of range of motion. These will be performed in a random order, and will be repeated 3 times. A 1 minute break between each series can be taken, if desired.

The first session, including preparation time, will take approximately 2 hours. Rest periods will be scheduled into the collection, but can be added at any point as necessary.

Second Session:

For the second session, only task 3 above will be repeated. This is being done in order to assess how repeatable the performance of the task is between days, and allow us to establish the expected margin of error when this task is used during a treatment program. In the interval between the test days, we will ask that you not participate in any activities that may affect your performance on this test. This session will be separated by at least three days and by no more than one week.

The second session, including preparation time, should take between 1 and 1½ hours. As in the first session, rest periods will be scheduled into the collection, but can be added at any point as necessary.

RISKS AND DISCOMFORTS

Because of the nature of the trunk movements, there exists some possibility of muscle or joint injury, or muscle fatigue. An investigator or an assistant will stand next to you during the data collection to provide added security. There also exists some possibility of skin redness as a result of the double sided tape used to attach the clips.

If an injury is incurred during the course of the study, the investigators will provide appropriate first aid, and will advise you about future care and management of the injury. We anticipate the potential risk of injury during these tasks to be minimal.

ANTICIPATED BENEFITS

There are no personal benefits to be derived from participating in this study. We anticipate, however, that the information obtained from your participation will be beneficial in the development of more effective treatment approaches for low back pain.

COMPENSATORY INDEMNITY

Participants in this study will receive a compensatory indemnity of $10 per hour for the time spent at the Research Centre.

RESPONSIBILITY CLAUSE

By accepting to participate in this study, you are not renouncing any of your rights, nor are you liberating the study investigators, or the institutions involved, of their legal and professional responsibilities.

CONFIDENTIALITY

Any personal data collected over the course of this study will be coded to ensure confidentiality. For quality control of the research project, your research records may be consulted by a person authorized by the Research Ethics Board (REB) of the CRIR institutions or the MSSS, which adhere to a policy of strict confidentiality. These data will be kept in a secure and locked location at the Constance Lethbridge Rehabilitation Centre, by the study investigators, for a period of 5 years following the completion of the study. Only the members of the research team and of the research ethics board will have access. You will not be identifiable in any publication of these data.

WITHDRAWAL FROM THE STUDY

Your participation in this study is completely voluntary. You are free to withdraw from the study AT ANY TIME without prejudice or penalty. If you chose to withdraw from the study, all data related to your participation will be destroyed, if you so desire.

INQUIRIES CONCERNING THIS STUDY

This research project has been reviewed and approved by the *Comité d'éthique de la recherche des établissements du CRIR*. If you have any questions about your rights and recourse or your participation in this research study, you can contact Me Anik Nolet, Research Ethics Co-ordinator for the CRIR'S Institutions at (514) 527-4527 extension 2649 or by e-mail anolet.crir@ssss.gouv.qc.ca If you require further information concerning the study (experimental procedures or other details), please do not hesitate to contact any of the study investigators at the numbers or addresses listed at the beginning of this document.

A copy of this form will be given to at the start of your participation in the study.

INFORMED CONSENT

I declare that I have read and understand the project, its nature and the extent of my participation, as well as the risks I am undertaking as explained in the present form. I have had the opportunity to ask any questions regarding the different aspects of this study and to receive satisfying answers.

I, the undersigned, voluntarily accept to participate in this study. I may withdraw at any time without prejudice of any kind. I certify that I have been given the necessary time to make my decision and I know that a copy of this form will be added to my file.

A signed copy of this information and consent form must be remitted to me.

SIGNATURES

Study Participant   Signature

_____   _____

Location _____   Date: ____ / ____ / ____

                                              (d)   (m)   (y)

I, the undersigned, _____, declare that I have

(a) explained the content of this form to the study participant;
(b) answered all questions regarding the current study, in a satisfactory manner;
(c) explained to the participant that they are free to withdraw from the study at any time without prejudice or penalty, and with complete confidentiality;
(d) given the study participant a signed, dated copy of this form.

_____

Signature of the principal investigator

or his representative

Location _____   Date: ____ / ____ / ____

                                        (d)   (m)   (y)

Consent Form (French version)

UN CRITÈRE D'ÉVALUATION POUR DÉTERMINER LE CHANGEMENT
MINIMAL QUI PEUT ÊTRE MESURER DANS LE MOUVEMENT LOMBAIRE.

RESPONSABLE DU PROJET
Richard Preuss, pht, PhD

    Professeur adjoint   Chercheur régulier
    École de physiothérapie et   Centre de réadaptation
d'ergothérapie   Constance-Lethbridge
    Université McGill   Site du CRIR

SITE DE L'ÉTUDE
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    7005, Boul. de Maisonneuve Ouest
    Montréal, Québec, H4B 1T3

Tél. :   514-487-1891 poste 350 (R. Preuss)
Téléc. : 514-487-4079

Courriel : richard.preuss@mcgill.ca

Vous êtes invités à participer à un projet de recherche portant sur la mesure du mouvement lombaire. Ce projet, mené par le chercheur mentionné ci-dessus, sera réalisé pendant trois sessions, espacées par au moins un jour mais pas plus d'une semaine, au Centre de recherche du Centre de réadaptation Constance-Lethbridge, situé au 7005 boul. de Maisonneuve Ouest, Montréal, Québec. Nous apprécions grandement votre intérêt.

Avant d'accepter de participer à ce projet de recherche, veuillez prendre le temps de comprendre et de considérer attentivement les renseignements qui suivent. Ce formulaire de consentement vous explique le but de cette étude, les procédures, les avantages, les risques et inconvénients, de même que les personnes avec qui communiquer au besoin.

Le présent formulaire de consentement peut contenir des mots que vous ne comprenez pas. Nous vous invitons à poser toutes les questions que vous jugerez utiles au chercheur et aux autres membres du personnel affecté au projet de recherche et à leur demander de vous expliquer tout mot ou renseignement qui n'est pas clair.

BUT DE L'ÉTUDE

Le but de cette étude est de développer une seule mesure qui représente le mouvement totale lombaire. En évaluant cette mesure sur trois jours différents, nous allons également déterminer la variabilité normale qui existe dans cette mesure, afin que nous puissions l'utiliser dans de futures études pour évaluer l'effet d'une intervention ou d'un traitement.

POUR PARTICIPER À CETTE ÉTUDE VOUS DEVEZ :

Session initiale :

1. Donner votre consentement avant le début de la session.
2. Répondre à certaines questions portant sur vos antécédents médicaux. Ceci permettra à l'équipe de recherche de s'assurer que vous rencontrez les critères d'inclusion de l'étude.
3. Préparation en vue de l'acquisition de données avec les procédures suivantes :

    a. Vous coucher sur le ventre sur une table de traitement. Deux clips uréthane souples seront alors apposés à votre région lombaire avec un adhésif pour la peau. Ces clips seront utilisés pour installer les capteurs (voir le point (c), ci-dessous).

    b. Effectuer un bref échauffement, composé de 4 "étirements de chat" - fléchir et étendre le dos à quatre pattes - à la fin de chaque mouvement, pendant environ 15 secondes.

  c. Vous tenir debout dans une position confortable, avec vos pieds sur la largeur des épaules. La position de vos pieds sera marquée sur le sol et deux capteurs seront attachés aux clips sur votre dos.

  d. Effectuer une série de mouvements maximaux du tronc, dans huit (8) directions. Ceux-ci seront effectués dans un ordre aléatoire et seront répétés 3 fois. Une pause d'une minute entre chaque série sera permise.

Sessions ultérieures:

Pour la deuxième et la troisième session, seulement la tâche 3 ci-dessus sera répétée. Cette tâche sera répétée pour nous aider à déterminer l'exactitude à laquelle notre mesure peut être répétée d'un jour à l'autre. Ceci nous aidera à déterminer le changement minimum qui peut être attribué à un programme de réadaptation et non seulement à une variation normale individuelle. Pendant l'intervalle entre les jours des sessions, on vous demande de ne pas participer aux activités qui pourront affecter votre performance sur la tâche ci-dessus. Les sessions seront espacées d'au moins un jour mais pas plus d'une semaine.

Note : La session initiale, incluant le temps de préparation, durera approximativement 2 heures. Durant l'acquisition des données, des pauses fréquentes seront prévues et des pauses additionnelles peuvent être ajoutées à n'importe quel moment au besoin. La deuxième session durera 1 heure ou 1 heure et demie.

RISQUES ET INCONVÉNIENTS POUVANT DÉCOULER DE VOTRE PARTICIPATION
Etant donnée la nature des mouvements du tronc, il existe une possibilité très faible de blessure musculaire ou articulaire, ou de fatigue musculaire. Pour cette raison, un des responsables du projet ou un assistant restera près de vous pendant toute la durée des tests. Il est également possible que la peau rougisse aux endroits où les clips sont placés, du fait de l'utilisation d'un adhésif.
Si une blessure nait au cours de l'étude, les soins appropriés seront fournis par le responsable du projet et vous serrez conseillés sur la gestion de la blessure. Nous évaluons le risque de blessure lors du déroulement de ce projet comme étant faible.

AVANTAGES POUVANT DÉCOULER DE VOTRE PARTICIPATION
Vous ne retirerez aucun avantage personnel en participant à cette étude. Toutefois, l'équipe de recherche s'attend à ce que les informations obtenues lors de cette étude puissent contribuer au développement de nouvelles thérapies pour les maux de dos.

INDEMNITÉ COMPENSATOIRE

Une indemnité compensatoire de 10 $ de l'heure sera offerte aux participants pour le temps passé au Centre de recherche.

CLAUSE DE RESPONSABILITÉ

En acceptant de participer à cette étude, vous ne renoncez à aucun de vos droits ni ne libérez les chercheurs ou les institutions impliquées de leurs obligations légales et professionnelles.

CONFIDENTIALITÉ

Tous les renseignements personnels recueillis à votre sujet au cours de l'étude seront codifiés afin d'assurer leur confidentialité. Seuls les membres de l'équipe de recherche y auront accès. Cependant, à des fins de contrôle du projet de recherche, votre dossier de recherche pourrait être consulté par une personne mandatée par le Comité d'éthique de la recherche (CÉR) des établissements du CRIR, qui adhère à une politique de stricte confidentialité. Ces données seront conservées sous clé au (lieu) par le responsable de l'étude pour une période de 5 ans suivant la fin du projet, après quoi elles seront détruites. En cas de présentation de résultats de cette recherche ou de publication, rien ne pourra permettre de vous identifier.

RETRAIT DE VOTRE PARTICIPATION

Votre participation au projet de recherche décrit ci-dessus est tout à fait libre et volontaire. Il est entendu que vous pourrez, à tout moment, mettre un terme à votre participation.

DEMANDE DE RENSEIGNEMENTS SUR CE PROJET DE RECHERCHE

Ce projet de recherche a été évalué et approuvé par la *Comité d'éthique de la recherche des établissements du CRIR*. Si vous avez des questions sur vos droits et recours ou sur votre participation à ce projet de recherche, vous pouvez communiquer avec Me Anik Nolet, coordonnatrice à l'éthique de la recherche des établissements du CRIR, au (514) 527-4527 poste 2649 ou par courriel à l'adresse suivante : anolet.crir@ssss.gouv.qc.ca. Si vous désirez obtenir de plus amples renseignements concernant le projet lui-même (procédures expérimentales ou autres détails), n'hésitez surtout pas à communiquer avec le responsable du projet au numéro de téléphone ou à l'adresse courriel indiqués au début de ce document.

Une copie de ce formulaire de consentement vous sera remise au début de votre participation.

CONSENTEMENT

Je déclare avoir lu et compris le présent projet, la nature et l'ampleur de ma participation, ainsi que les risques auxquels je m'expose tels que présentés dans le présent formulaire. J'ai eu l'opportunité de poser toutes les questions concernant les différents aspects de l'étude et de recevoir des réponses à ma satisfaction.

Je, soussigné(e), accepte volontairement de participer à cette étude. Je comprends que je peux me retirer en tout temps sans préjudice d'aucune sorte. Je certifie qu'on m'a laissé le temps voulu pour prendre ma décision et je sais qu'une copie de ce formulaire sera déposée dans mon dossier médical.

Une copie signée de ce formulaire d'information et de consentement doit m'être remise.

SIGNATURES

Nom du sujet   Signature

_____   _____

Fait à _____,   le _____, 20_____.

ENGAGEMENT DU CHERCHEUR

Je, soussigné (e), _____, certifie

    a) avoir expliqué au signataire les termes du présent formulaire;

    b) avoir répondu aux questions qu'il/elle m'a posées à cet égard;

    c) lui avoir clairement indiqué qu'il/elle reste, à tout moment, libre de mettre un terme à sa participation au projet de recherche décrit ci-dessus; et

    d) que je lui remettrai une copie signée et datée du présent formulaire.

_____

Signature du responsable du projet

ou de son représentant

Fait à _____, le _____ 20__.

Certificat d'éthique

Par la présente, le comité d'éthique de la recherche des établissements du CRIR (CÉR) atteste qu'il a évalué, lors de sa réunion du 17 janvier 2012, le projet de recherche CRIR-661-1111 intitulé :

« Reliability of an Outcome Measure to Assess the Total Lumbar Spine Range of Motion ».

Présenté par :   Fadi Al Zoubi, MSc
                    Richard Preuss, Ph.D.

Le présent projet répond aux exigences éthiques de notre CÉR. Le Comité autorise donc sa mise en œuvre sur la foi des documents suivants :

➢ Lettre d'introduction datée du 17 novembre 2011 ;
➢ Formulaire A daté du 16 novembre 2011 ;
➢ Formulaire d'évaluation du Centre de réadaptation Constance-Lethbridge, daté du 6 décembre 2011, mentionnant que le projet est acceptable sur le plan de la convenance institutionnelle ;
➢ Protocole de recherche (version du 13 février 2012) ;
➢ Formulaire d'information et de consentement (versions anglaise et française du 13 février 2012) ;
➢ Affiche de recrutement (version anglaise et française du 13 février 2012) ;
➢ Questionnaire d'incapacité d'Oswestry (versions anglaise et française) ;
➢ Questionnaire « The Start Back Screening Tool » (versions anglaise et française) ;
➢ Questionnaire « The 11-Point Box Scale (BS-11) » (versions anglaise et française).

Ce projet se déroulera dans le site du CRIR suivant : **Centre de réadaptation Constance Lethbridge**

Ce certificat est valable pour un an. En acceptant le présent certificat d'éthique, le chercheur s'engage à :

1.   Informer, dès que possible, le CÉR de tout changement qui pourrait être apporté à la présente recherche ou aux documents qui en découlent (Formulaire M) ;
2.   Notifier, dès que possible, le CÉR de tout incident ou accident lié à la procédure du projet ;
3.   Notifier, dès que possible, le CÉR de tout nouveau renseignement susceptible d'affecter l'intégrité ou l'éthicité du projet de recherche, ou encore, d'influer sur la décision d'un sujet de recherche quant à sa participation au projet ;
4.   Notifier, dès que possible, le CÉR de toute suspension ou annulation d'autorisation relative au projet qu'aura formulée un organisme de subvention ou de réglementation ;

5. Notifier, dès que possible, le CÉR de tout problème constaté par un tiers au cours d'une activité de surveillance ou de vérification, interne ou externe, qui est susceptible de remettre en question l'intégrité ou l'éthicité du projet ainsi que la décision du CÉR ;

6. Notifier, dès que possible, le CÉR de l'interruption prématurée, temporaire ou définitive du projet. Cette modification doit être accompagnée d'un rapport faisant état des motifs à la base de cette interruption et des répercussions sur celles-ci sur les sujets de recherche ;

7. Fournir annuellement au CÉR un rapport d'étape l'informant de l'avancement des travaux de recherche (formulaire R) ;

8. Demander le renouvellement annuel de son certificat d'éthique ;

9. Tenir et conserver, selon la procédure prévue dans la *Politique portant sur la conservation d'une liste des sujets de recherche*, incluse dans le cadre réglementaire des établissements du CRIR, une liste des personnes qui ont accepté de prendre part à la présente étude ;

10. Envoyer au CÉR une copie de son rapport de fin de projet / publication ;

11. En vertu de l'article 19.2 de la *Loi sur les services de santé et les services sociaux*, obtenir l'autorisation du Directeur des services professionnels de l'établissement sollicité avant d'aller consulter les dossiers des usagers de cet établissement, le cas échéant.

Me Michel T. Giroux
Président du CÉR

Date d'émission
13 février 2012

Composition du comité d'éthique de la recherche des établissements du CRIR

Mme Isabelle Bilodeau / Mme Saïda El Haïli (membre substitut)	Une personne possédant une vaste connaissance du domaine psychosocial en réadaptation
Dr Céline Lamarre / Mme Imen Khelia (membre substitut)	Une personne possédant une vaste connaissance du domaine biomédical en réadaptation
Mme Kathoune Témisjian / M. Stéphane McDuff (membre substitut)	Clinicien détenant une vaste connaissance des déficits sensoriel visuels ou auditifs
Mme Mariama Touré / à déterminer (membre substitut)	Clinicienne détenant une vaste connaissance des déficits moteurs ou neurologiques
M. Yannick Farmer / Mme Delphine Roigt (membre substitut)	Une personne spécialisée en éthique
Me Michel T. Giroux / Me Nathalie Lecoq (membre substitut)	Une personne spécialisée en droit
Mme Monique Provost / Mme Marie-Claude Lavigne (membre substitut)	Une personne non affiliée à l'établissement et provenant de la clientèle des personnes adultes et aptes
Mme Diane Gaumond / Mme Nadine Landry (membre substitut)	Une personne non affiliée à l'établissement et provenant de la clientèle des personnes mineures ou inaptes
M. Michel Sinotte / Mme Elizabeth Markakis (membre substitut)	Une personne siégeant à titre de représentante du public
Mme Suzette McMaster Clément	Une personne siégeant à titre de représentante du public
Mme Frédérique Courtois	Représentante de l'Université du Québec à Montréal
M. Cyril Duclos	Représentant de l'Université de Montréal
Mme Jadranka Spahija	Représentante de l'Université McGill
Me Anik Nolet	Secrétaire du CÉR et membre non-votant