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**Article Title:** Reliability of a Measure of Total Lumbar Spine Range of Motion in Individuals with Low Back Pain

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

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Abstract

Measuring lumbar spine range of motion (ROM) using multiple movements is impractical for clinical research, because finding statistically significant effects requires a large proportion of subjects to 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.

Keywords: generalizability theory, spine kinematics, outcome measures
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, and a means of assessing low back pain-related impairment. Current clinical practice guidelines, however, no longer include ROM testing as a key aspect of spinal assessment. This is based largely on the absence of any clear, consistent relationship between ROM and functional impairment or disability in individuals with low back pain. Recent efforts to identify homogeneous subgroups of individuals with low back pain, however, have found lumbar hyper- and hypo-mobility, as well as lumbar flexion ROM, to be relevant factors in the sub-classification of patients with acute low back pain. Specifically, Flynn et al. identified lumbar hypomobility, with manual testing, as a factor predicting LBP relief with thrust manipulation. Hicks et al., on the other hand, found that hypermobility and increased lumbar flexion as a proportion of total forward bending were both associated with the success of stabilization exercises. Measures of lumbar spine ROM have also been identified as significant risk indicators of recurrent low back pain in adolescents. The lack of a clear relationship between low back pain and spine ROM, therefore, may be more a reflection of the heterogeneity of the physical impairments associated with low back pain 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. A clinical study using the six cardinal plane measures, however, would require a large number of subjects due to the number of statistical comparisons that would have to be 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 for clinical research in patients with low back pain. 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. We also expected the minimal detectable change for this measure to be small enough so as to be realistically achievable following a rehabilitation intervention program.

Methods

Subjects

Twenty subjects with sub-acute or chronic, non-specific low back pain (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 low back pain 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). 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 for visual feedback (e.g. infectious eye disease, discomfort wearing the head mounted display). Subjects were excluded if their pain intensity was below 2/10 on the 11-point box scale, or if their level of low back pain-related disability was less than 12% on the Oswestry Disability Index, 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 11-point box scale, or more than an 11% change in their Oswestry Disability Index score, between testing sessions.

All subjects included in the study had low back pain lasting for more than one month (subacute or chronic low back pain, as defined by Chou et al.), with a median duration of 54 months (range 2 – 360 months). At the start of the first session, the mean 11-point box scale score was 3.1 (SD 0.9), with a range from 2 to 6, and the mean Oswestry Disability Index score was 25.8% (SD 8.5%), with a range from 12% to 44%. At the start of the second session, the
mean 11-point box scale score was 2.8 (SD 1.0), with a range from 2 to 5, and the mean Oswestry Disability Index 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. 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).

**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 1A).

Lumbar spine motion was acquired in three dimensions using a TrakSTAR motion capture system (Ascension Technology Corporation, Milton, USA). Two sensors were affixed to the subjects’ skin over the spinous process of the first sacral vertebra and spinous process of the twelfth thoracic vertebra using custom made urethane clips and double-sided tape. The measure of interest was based on the position of the twelfth thoracic vertebra sensor relative to the first sacral vertebra, in the transverse plane of the first sacral vertebra. This relative position was determined by multiplying the 4 x 4 rotation-translation matrix for the twelfth thoracic vertebra by the inverse of the rotation-translation matrix for the first sacral vertebra.
Subjects performed three (3) trials of eight (8) maximal lumbar spine movements during each session, as illustrated in Figure 1B. The movement directions were in the sagittal and frontal planes, and at 45° diagonals between these planes. For each movement, the subject was asked to lean as far as possible in the prescribed direction. Video eyewear (Wrap TM 920 Vuzix Corporation, New York, USA) was used to provide visual feedback to the subjects of the position of the twelfth thoracic vertebra relative to the first sacral vertebra. 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 the first sacral vertebra. A circle was superimposed on the asterisk, showing the real-time position of the twelfth thoracic vertebra sensor in the transverse plane of the first sacral vertebra (Figure 1C). For each movement, the subjects were instructed to move the circle along the appropriate radius of the asterisk. For each trial, the 8 movements were performed in a random order. After each movement in the trial, the subjects were asked to verbally report their pain intensity. If an increase in pain intensity of more than 2 points from the baseline 11-point box scale 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 movement series, if desired.

Two curve-fitting approaches – ellipse and spline - were then used to fit a shape to the point of maximum relative excursion of the twelfth thoracic vertebra 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 et al.20 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 total available excursion of T12
in the transverse plane of the first sacral vertebra. The centre position of these shapes (along both the anterior-posterior and medio-lateral dimensions of the transverse plane of the first sacral vertebra) 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).

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.

**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 and medio-lateral 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 × 2 × 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. The variance estimates for each of these facets were then used to calculate the index of dependability and the standard error of measurement. The index of dependability 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).\textsuperscript{22, 23} The index of dependability is analogous to the intraclass correlation coefficient described by Shrout and Fleiss\textsuperscript{24}. Like the intraclass correlation coefficient, the index of dependability 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.\textsuperscript{25} The standard error of measurement is the square root of the absolute error variance.\textsuperscript{23}

The D-study makes use of the variance estimates from the G-study to estimate the index of dependability and standard error of measurement 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, index of dependability and standard error of measurement estimates were produced for all combinations of 1 to 3 sessions and 1 to 5 trials per session.

Finally, the minimal detectable change was calculated using the standard error of measurement from the experimental data (G-study), and from each estimate of the standard error of measurement from the extrapolated data (D-study), using the following formula:

\[ \text{MDC} = 1.96 \cdot \sqrt{2} \cdot \text{SEM} \]  \hspace{1cm} (1)

where MDC is the minimal detectable change, SEM is the standard error of measurement, 1.96 derives from the 95\% confidence interval, and \( \sqrt{2} \) is included because two measurements (test and retest) are involved in measuring change\textsuperscript{26}.

All statistical analyses were done in Matlab (The Mathworks, Natick, USA), and based on the approach described by Mushquash and O'Connor\textsuperscript{22}. 
Results

The findings of the G-study indicated that the index of dependability for the primary measure of global lumbar spine ROM – the area of excursion of the twelfth thoracic vertebra in the transverse plane of the first sacral vertebra – was excellent, with values of 0.94 and 0.95 for the ellipse- and spline-fitting approaches respectively (Table 1). The index of dependability for the centre position of this area, for the ellipse- and spline-fitting approaches respectively, was 0.90 and 0.91 in the anterior-posterior axis, and 0.65 and 0.59 for the medio-lateral axis (Table 1). Figure 2 illustrates an example these measures for a single subject, for a single repetition of the 8 movement directions.

The findings of the D-study indicated that the index of dependability for the area of lumbar excursion approached 0.9 with only two trials in a single testing session, for both curve-fitting approaches (Figure 3). The addition of a third trial easily brought this value above 0.9. For the centre points of both the ellipse and spline fits, the index of dependability for the anterior-posterior axis exceeded 0.9 with five trials in a single session (Figure 3). For the medio-lateral axis, however, the target index of dependability of 0.9 was not achieved. The values for the index of dependability, for each iteration of the D-study, are illustrated in Figure 3.

The findings of the G-study also indicated that the minimal detectable change in the area of excursion of the lumbar spine would be 4921 mm² for the ellipse-fitting approach, and 4462 mm² for the spline-fitting approach (Table 1). These values represent approximately 35% of the mean excursion. The D-study indicated that similar values were achievable using a single testing session (Figure 3). The D-study also indicated that, using three trials over a single session, the minimal detectable change in the position of the centre point position would be less
that 20mm in the anterior-posterior axis, and less than 15mm in the medio-lateral axis. The minimal detectable change values, for each iteration of the D-study, are illustrated in Figure 3.

**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 for use in monitoring individual subject progress over time.

The measure of lumbar spine ROM presented in the current study is based on the excursion of the twelfth thoracic 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, 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, studies measuring spine excursion have reported excellent reliability, with intraclass correlation coefficient values between 0.91 and 0.98 reported for individuals with low back pain. 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 the twelfth thoracic vertebra in the transverse plane of the first sacral vertebra – 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 standard error of measurement (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 effect (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 index of dependability and minimal detectable change (Figure 3). As such, an index of dependability of > 0.9 was reached with only 2 repetitions of the testing protocol, for a single session, using the spline-fit approach. This value far exceeded 0.9 for both fitting methods when a third trial was added. Minimal detectable change values, based on 3 trials, were ~ 35% of the overall mean for the study participants. This is 2 - 3 times larger than the percent minimal detectable change that would be achieved using the mean and standard error of measurement values reported by for individual cardinal plane excursions. The measure proposed in the current study, however, is based on 8 separate movements. As such, this minimal detectable change 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 index of dependability from the G-study was excellent for the anterior-posterior axis (0.90 and 0.91 respectively), but much lower for the medio-lateral axis (0.65 and 0.59) (Table 1). The moderate index of dependability found in the medio-lateral 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 medio-lateral movements. Despite the moderate index of dependability for the medio-lateral axis, the minimal detectable change 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 3).

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 index of dependability and minimal detectable change, with the exception of index of dependability in the medio-lateral axis (Table 1 and Figure 3). The minimal detectable change in the medio-lateral 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 low back pain-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 low back pain, or to individuals with more acute or more intense and disabling low back pain. It is also uncertain whether individuals with acute low back
pain would tolerate the testing procedure used in the current study, or whether a measure of lumbar spine ROM would be useful during the acute phase of low back pain. The subjects in this study also presented a relatively symmetrical distribution of lumbar spine ROM in the medio-lateral axis, which contributed to the moderate index of dependability for the centre position in this axis. The minimal detectable change for this measure, however, was quite small. Furthermore, global restrictions of lumbar ROM appear to be more common than asymmetrical restrictions. As such, this factor is unlikely to affect the generalizability of these findings. It remains to be determined, however, whether the minimal detectable change values for the measures in the current study are realistically achievable with focused treatment. 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. Finally, the validity of the current measure remains to be determined, as soft-tissue artifact prevents direct measurement of spine motion using skin-mounted sensors. As three-dimensional radiographic technologies become more accessible, and flexible enough to assess complex spine motions, comparison with such a gold-standard would be warranted.

In conclusion, the current study describes a simple and easily interpretable measure of total lumbar spine ROM that has excellent reliability and a reasonable minimal detectable change. 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.
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References


Figure 1 - A. Experimental set-up for data acquisition. Subjects sat on a kneeling chair, with sensors affixed on the skin over the twelfth thoracic vertebra and the first sacral vertebra, 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 twelfth thoracic vertebra sensor in the transverse plane of the first sacral vertebra sensor.
Figure 2 - 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.
Figure 3 - 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.
Table 1 Results of the G-study

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