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Clinical Study

Reliability and measurement error of sagittal spinal motion parameters in 220 patients with chronic low back pain using a three-dimensional measurement device

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Abstract

BACKGROUND CONTEXT: A basic premise for any instrument measuring spinal motion is that reliable outcomes can be obtained on a relevant sample under standardized conditions.
PURPOSE: The purpose of this study was to assess the overall reliability and measurement error of regional spinal sagittal plane motion in patients with chronic low back pain (LBP), and then to evaluate the influence of body mass index, examiner, gender, stability of pain, and pain distribution on reliability and measurement error.
STUDY DESIGN/SETTING: This study comprises a test-retest design separated by 7 to 14 days.
PATIENT SAMPLE: The patient cohort consisted of 220 individuals with chronic LBP.
OUTCOME MEASURES: Kinematics of the lumbar spine were sampled during standardized spinal extension-flexion testing using a 6-*df* instrumented spatial linkage system.
METHODS: Test-retest reliability and measurement error were evaluated using interclass correlation coefficients ($ICC_{1,1}$) and Bland-Altman limits of agreement (LOAs).
RESULTS: The overall test-retest reliability ($ICC_{1,1}$) for various motion parameters ranged from 0.51 to 0.70, and relatively wide LOAs were observed for all parameters. Reliability measures in patient subgroups ($ICC_{1,1}$) ranged between 0.34 and 0.77. In general, greater ($ICC_{1,1}$) coefficients and smaller LOAs were found in subgroups with patients examined by the same examiner, patients with a stable pain level, patients with a body mass index less than below 30 kg/m^2, patients who were men, and patients in the Quebec Task Force classifications Group 1.
CONCLUSIONS: This study shows that sagittal plane kinematic data from patients with chronic LBP may be sufficiently reliable in measurements of groups of patients. However, because of the large LOAs, this test procedure appears unusable at the individual patient level. Furthermore, reliability and measurement error varies substantially among subgroups of patients.

Keywords: Low back pain; Spine; Measurement; Motion analysis; Biomechanics; Functional evaluation; Instrument; Device; Reproducibility; Reliability

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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Introduction

When a given human kinematic quantity is measured repeatedly in the same subject under standardized conditions, the outcomes typically vary among successive measurements. This may occur as a result of natural biological variation in the subject, variation in the measurement process, or both [1]. Quantification of this variation is crucial to enable clinicians to decide whether a clinically observed change represents a real change. One such measure of spine function is range of motion (ROM). Methods for measuring lumbar spine ROM include a number of technologies and methods such as inclinometers, the Schober test, measurement of fingertip-to-floor distance, and video analysis of markers placed on anatomic landmarks. Recently, devices applying computerized three-dimensional (3D) technology have been introduced. The main advantage of these 3D instruments is their ability to provide quantitative real-time assessment of 3D lumbar spinal kinematics that extends beyond the simple recording of ROM. Thus, real-time information about movement velocity, acceleration, and other potentially relevant parameters of the motion can be achieved, even during coupled or combined motion, without any known risk to the patient. Research indicates that 3D regional lumbar spinal motion instruments may be useful in quantifying lumbar spine kinematics and may be valuable in generating functional diagnoses in patients with back pain, and also appears to be useful for evaluating the effectiveness of given rehabilitation therapies and for prescribing specific rehabilitation programs [2].

A potential drawback when dealing with movable instruments to record spinal motion in humans is that substantial variation may originate from the measurement instrument itself as well as from the patient, the examiner, and the interface between the patient and the instrument [3,4]. Research has indicated that different measurement systems might yield noncomparable values for the same spinal movement because of differences in either the manner in which the device is attached to the subject or the accuracy with which the device records the movements in a given plane [5,6]. However when assessing longitudinal changes in an individual's pattern of mobility using a given instrument, such as when monitoring progress during rehabilitation, it becomes of primary importance to ensure the device itself yields precise measurements and that reliable outcomes can be obtained using the instrument.

Previous studies have described the intra- and interexaminer reliability and measurement error of lumbar motion recordings, but to our knowledge, sources leading to variation from distinct biological factors such as different diagnostic groups of patients with low back pain (LBP), the influence of body mass index (BMI), gender, and differences in pain level have not been addressed [7–16]. More knowledge is needed about how these factors affect the reliability and measurement error of spinal motion analysis in LBP, and hence potentially limit the clinical utility of such testing in various patient groups with LBP.

The overall aim of this study was to evaluate the reliability and measurement error of regional sagittal plane lumbar spinal motion assessed in a large cohort of patients with chronic LBP (N=220) using noninvasive 3D measurement technology and to quantify underlying sources leading to variation among repeated measurements. Specifically, we aimed (1) to evaluate the overall reliability and measurement error of regional spinal motion in the sagittal plane in 220 patients with chronic LBP measured at two test occasions separated by 7 to 14 days, and to evaluate the level of usability (individual, group, or none); and (2) to evaluate the influence of BMI (more or less than 30 kg/m^2), examiner (same or different examiner), gender (male or female), pain (stable or unstable pain level), and diagnostic group (LBP with or without radiation) on the reliability and measurement error of these measurements.

Material and methods

Study population

During a period of 3 years, 220 subjects were recruited for a randomized clinical trial at the Wolfe Harris Center for Clinical Studies at Northwestern Health Science University, Minneapolis, MN, USA [17]. Inclusion criteria were patient with LBP who were 18 to 65 years old; who had Quebec Task Force classifications 1, 2, 3, or 4 [18]; and who had a primary complaint of mechanical LBP of at least 6 weeks' duration with or without radiating pain to the lower extremity. Mechanical LBP was defined as pain that had no specific identifiable etiology but that could be reproduced by back movements or provocation tests. Exclusion criteria were previous lumbar spine fusion surgery, progressive neurologic deficits, aortic or peripheral vascular disease, pain scores of less than 3 points (on a 0–10-point scale), ongoing treatment for back pain by other healthcare providers, or participation in pending or current litigation. Participants were recruited through local newspaper advertisements, community posters, and postcard mailings, and an initial screening was conducted by telephone.

Test procedures

The test-retest design included two visits to the research clinic, separated by 7 to 14 days. The tests constituted part of the baseline examination before inclusion in the randomized clinical trial [17]. At the first visit, participants' anthropometric data (height, weight) were obtained and all subjects completed a self-administered questionnaire that elicited information on health history and demographics. Subsequently, chiropractic and medical clinicians reviewed the health history and performed a physical examination, including a complete neurologic examination, orthopedic tests, and manual static and motion palpation of the lumbar spine and