

2013 Outstanding Paper Runner-up

## Reliability of computer-assisted lumbar intervertebral measurements using a novel vertebral motion analysis system

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### Abstract

**BACKGROUND CONTEXT:** Traditional methods for the evaluation of in vivo spine kinematics introduce significant measurement variability. Digital videofluoroscopic techniques coupled with computer-assisted measurements have been shown to reduce such error, as well as provide detailed information about spinal motion otherwise unobtainable by standard roentgenograms. Studies have evaluated the precision of computer-assisted fluoroscopic measurements; however, a formal clinical evaluation and comparison with manual methods is unavailable. Further, it is essential to establish reliability of novel measurements systems compared with standard techniques.

**PURPOSE:** To determine the repeatability and reproducibility of sagittal lumbar intervertebral measurements using a new system for the evaluation of lumbar spine motion.

**STUDY DESIGN:** Reliability evaluation of digitized manual versus computer-assisted measurements of the lumbar spine using motion sequences from a videofluoroscopic technique.

**PATIENT SAMPLE:** A total of 205 intervertebral levels from 61 patients were retrospectively evaluated in this study.

**OUTCOME MEASURES:** Coefficient of repeatability (CR), limits of agreement (LOA), intra-class correlation coefficient (ICC; type 3,1), and standard error of measurement.

**METHODS:** Intervertebral rotations and translations (IVR and IVT) were each measured twice by three physicians using the KineGraph vertebral motion analysis (VMA) system and twice by three different physicians using a digitized manual technique. Each observer evaluated all images independently. Intra- and interobserver statistics were compiled based on the methods of Bland-Altman (CR, LOA) and Shrout-Fleiss (ICC, standard error of measurement).

**RESULTS:** The VMA measurements demonstrated substantially more precision compared with the manual technique. Intraobserver measurements were the most reliable, with a CR of 1.53 (manual, 8.28) for IVR, and 2.20 (manual, 11.75) for IVT. The least reliable measurements were interobserver IVR and IVT, with a CR of 2.15 (manual, 9.88) and 3.90 (manual, 12.43), respectively. The ICCs and standard error results followed the same pattern.

**CONCLUSIONS:** The VMA system markedly reduced variability of lumbar intervertebral measurements compared with a digitized manual analysis. Further, computer-assisted fluoroscopic imaging techniques demonstrate precision within the range of computer-assisted X-ray analysis techniques. © 2014 Elsevier Inc. All rights reserved.

### Keywords:

Reliability; Lumbar; Computer assisted; Intervertebral measurement; Videofluoroscopy; Vertebral motion analysis

FDA device/drug status: Approved (KineGraph Vertebral Motion Analyzer).

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## Introduction

Imaging modalities such as standard roentgenograms (X-rays), computed tomography, and magnetic resonance imaging have become essential to the evaluation of bone and soft tissue in patients with spinal pathologies. These techniques capture valuable static images of the spine, yet lack the capability of providing detailed information about spinal motion. Dynamic end-range X-rays, the standard for assessing range of motion (ROM) and vertebral translation are typically evaluated by measuring intervertebral rotation and translation (IVR and IVT) through manual identification of vertebral margins using a ruler and protractor or digital techniques involving medical imaging software. However, the error associated with these methods is high and within the range of currently proposed motion guidelines [1–5].

Current thresholds for indication of successful fusion, motion preservation, and instability are not well defined. The US Food and Drug Administration defines successful fusion for Investigational Device Exemption trials as less than 5° IVR and less than 3 mm IVT in the sagittal plane, although others have reported upper IVR thresholds anywhere from 1° to 4° [6–8]. Successful motion preservation for total disc replacement has been reported as low as 2° to 3°, obviously well within the range of successful fusion guidelines [9,10]. Reimbursement guidelines for instability (InterQual, McKesson, San Francisco, CA, USA) suggest IVR greater than 22° and IVT greater than 3 mm as unstable, whereas the American Medical Association indicates bounds anywhere from 15° to 25° and 4.5 mm [11]. Lower thresholds of 10° IVR and 4 mm IVT are also commonly accepted to infer instability [12,13]. Given the wide range of proposed motion guidelines and arbitrary definitions for quantification of instability, a better understanding of spinal motion characteristics through standardized, accurate, and reliable functional analysis is clearly necessary.

Techniques utilizing landmark verification protocols, computerized image processing software, and automatic vertebral tracking algorithms have been evaluated that demonstrate more accurate and reliable intervertebral motion measurements in functional radiographic images [14–19]. These methods utilize either plane film radiographs or digitized videofluoroscopy (DVF) to capture images of the lumbar spine, the latter of which is capable of capturing spinal motion with less radiation exposure than that of traditional end range X-rays. Prior studies have evaluated accuracy and reliability of computer-assisted DVF measurements and have demonstrated errors comparable to those obtained from computer-assisted X-ray techniques. These studies have reported IVR accuracy and reliability errors in the range of 0.13° to 1.18° (standard deviation) [15–20].

To the authors' knowledge, only one study to date has formally evaluated and compared intra- and interobserver reliability of automated versus manual measurements. Pearson et al. [5] compared the Quantitative Motion Analysis system, today's clinical standard in dynamic plane film analysis,

with a digitized manual technique. The results support conclusions that computer-assisted processing methods significantly improve intervertebral motion measurements. However, no such evaluation is available for DVF techniques. Further, no automated system to date has been formally evaluated that attempts to control initial sources of variability in clinical radiographs by means of standardizing patient bending angles and image acquisition techniques. A system described by Breen et al. [21] used DVF with motorized recumbent patient bending platforms to demonstrate maximum errors (root mean square) of under 2°; however, a formal reliability analysis was not completed.

A new system for evaluation of spinal motion has recently been approved by the FDA for commercial use, utilizing upright and recumbent patient bending platforms with DVF and automated vertebral tracking algorithms (KineGraph Vertebral Motion Analysis [VMA], OrthoKinematics, Austin, TX, USA). This study assesses intra- and interobserver reliability of this system using a prospective analysis of retrospectively collected image data.

## Materials and methods

### Image acquisition

The VMA system utilized a combination of upright and recumbent controlled patient bending platforms, a standard 12-inch surgical C-Arm (OEC 9800 Series, General Electric, Fairfield, CT, USA), and an adjacent computer-mounted console equipped with data acquisition hardware (Accustream Express As205A, Foresight Imaging, Chelmsford, MA, USA) and proprietary control software. The independent bending platforms consisted of a radiolucent disc, which acted as the center of rotation, while adjustable components accommodated for varying physical patient characteristics and bolsters secured the pelvis to isolate trunk bending as the torso completed a predetermined total ROM of 70° at a rate of approximately 5° per second.

The upright motion platform guided active lumbar bending, under the weighted condition, while constricting flexion extension (FE) to the sagittal plane. The recumbent platform controlled passive lumbar bending, which minimized the gravitational and muscular forces that present during standing radiographs. Patient positioning on each platform can be visualized in Fig. 1. FE angles spanned a range of  $\pm 35^\circ$  for recumbent motion, and the ROM presets were adjusted to allow for 20° of extension and 50° flexion for upright motion. This compensated for the reduced capability of lumbar extension resulting from extended hips in an erect posture.

Upon initiation of the test movement, a fluoroscopic sequence of lumbar motion was captured at 8 pulses per second. Flexion and extension were captured as separate sequences, which began in a neutral position, progressed to the predefined maximum angle, and returned to neutral. The console PC grabbed real-time images from the C-Arm analog video output port, which were digitized at a depth of

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