

# Robot for Ligament Tensioning and Assessment of Spinal Stability

Global Spine Journal  
2022, Vol. 12(2S) 535–585  
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DOI: 10.1177/21925682211059178  
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## Abstract

**Study Design:** An *in vitro* human cadaveric biomechanics study.

**Objective:** A proof-of-concept study to quantify whether or not differences in segmental mobility associated with spinal instability could be detected by a robotic distraction system.

**Methods:** Testing was performed in fresh human cadaveric tissue. A prototype Robotic Middle Column Distractor was attached unilaterally to the pedicles of L3-4. Distraction forces up to 150 N were applied first in the intact state, and following discectomy of L3-4. Motions were recorded by time-indexed visual and fluoroscopic images, and analyzed to measure actual motions achieved. Functions of the robot unit were monitored during the procedure and evaluated qualitatively.

**Results:** A difference of 2.5 mm in z-axis motion was detected at 150 N load between the intact and post-discectomy states. The robot coupled with the image analysis method was able to clearly detect the difference between the intact (“stable”) and post-discectomy (“unstable”) spine. Data analysis of fluoroscopic images taken during the procedure showed greater motion than perceived by the investigators from qualitative review of visual data. All monitored robot functions performed within design parameters without error.

**Conclusion:** The study demonstrates the feasibility and utility of utilizing an intraoperative robotic distractor to measure the amount of spinal mobility present at a level. This could lead to an important clinical tool for both diagnostic functions as well as operative assist functions.

## Keywords

biomechanical phenomena, proof-of-concept study, robotics, robotic surgical procedures, cadaver, feasibility studies

## Introduction

Segmental lumbar instability can be a significant cause of low back pain. The diagnosis of instability relies on interpreting flexion-extension radiographs<sup>1</sup> in combination with the clinical presentation of pain associated with prescribed movements. Its presence can be one factor among many in determining whether or not a spinal stabilization surgery, such as lumbar fusion, for example, is indicated.<sup>2</sup>

However, the definition of instability itself is nuanced and has been debated for decades. On the one hand, segmental instability relates to the radiographic movement of one vertebra relative to another, while clinical instability requires observable signs of the patient’s symptoms. There is not a single universally accepted operational definition of spinal

instability.<sup>3</sup> The de facto definition that has entered into use via payers’ policies and indications utilized for FDA-regulated Investigational Device Exemption Studies is a fixed amount of motion of one vertebra relative to another, as documented on radiographic studies.<sup>4</sup> Interestingly, the amount of motion specified in the FDA studies vs that written in to current

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insurance policies is not always the same.<sup>5</sup> The requirement for radiographic documentation is consistent, though.

Lumbar instability may be present and diagnosable pre-operatively. However, a spine that was radiographically stable pre-operatively may become unstable after a decompression procedure. Since the radiographic test for instability is performed pre-operatively, usually with flexion-extension radiographs, there is no similar quantitative way for the surgeon to assess and document that instability is now present, following the decompression.

Lacking a quantitative method, qualitative means are generally employed instead. For example, the manipulation of a spinal segment with a Kocher clamp (the “Kocher Test”) or a spinal spreader may be used to confirm instability more directly. However, the ability to quantitatively record, measure, and document such tests by the surgeon is limited, leaving the outcomes of the test to primarily be recorded qualitatively via dictation.

The lack of consistent qualitative studies is well-documented by Davis et al. Their investigation of an improved method via a computer-assisted vertebral motion analysis system shows the inconsistencies inherent in current techniques.<sup>6</sup>

Nunley<sup>7</sup> noted in a survey study that third-party payers were reducing or withholding payment based on inadequate and/or incomplete documentation associated with the diagnosis of spinal instability, resulting in significant lost revenues for the surgeon.

Additionally, the emergence and continued development of non-motion stabilization treatments, such as “flexible rods,” intraspinal spacers, and other posterior-stabilizing treatments creates an additional need. Properly indicating these treatments requires the need to stratify not just whether a spine is stable or unstable, but *the amount of segmental motion* (or lack thereof) which exists.

Finally, the correction of spinal deformities has focused on rotational and translational motions in 2 of the spine’s 3 planes of motion. We can think of the spine as being oriented relative to a cartesian coordinate system, where the *x*-axis is oriented in the medial-lateral direction, the *y*-axis in the anterior-posterior direction, and the *z*-axis along axis of the spine. Deformity correction techniques almost exclusively focus on translations along the *x* and *y* axes, and rotational motions, while failing to take into consideration the *z*-translation required for restoring the ligaments, particularly the posterior longitudinal ligament (PLL) to normal physiological tension. McAfee, et al have published a technique for more closely examining this “middle column” of the spine and calculating the appropriate final height of individual disc spaces.<sup>8</sup> However, the technique for precisely positioning the vertebrae for this *z*-axis restoration has not yet been defined.

In order to address these varied questions about spinal stability, qualitative documentation, ligamentous re-tensioning, and *z*-axis restoration, we have created a prototype surgical robot capable of measuring stability, making precise translational movements, and recording a data stream of its activity in

manner similar to the recorded data from anesthesia or EKG machines. This is the “orthopaedic data stream” (ODS).

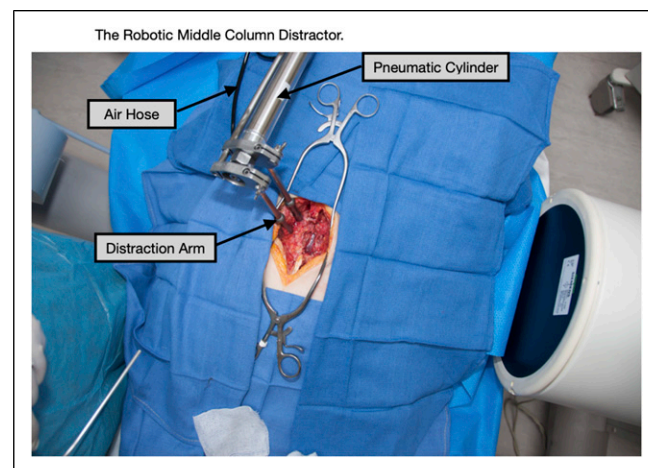
Presented here is a proof-of-concept study demonstrating the feasibility and utility of Robotic Middle Column Distraction for diagnosing the degree of spinal instability.

## Study Design

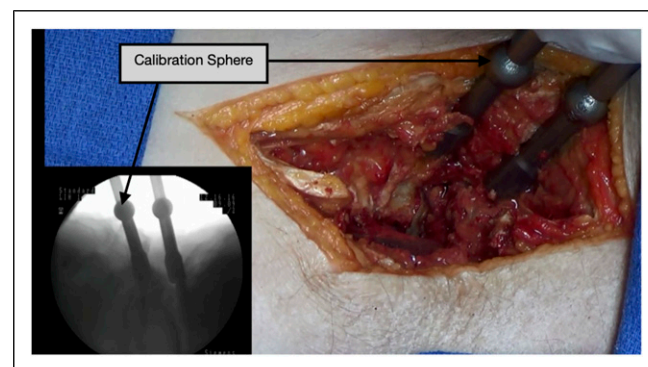
A prototype surgical robot, referred to as the Robotic Middle Column Distractor (RMCD) was previously designed and built. Its purpose is to apply controlled, physiologically appropriate force to the spine. See Figure 1.

The robot attaches to the spine via two threaded pins that are inserted into the pedicles. The pedicles were chosen as the attachment point in order to utilize an area with sound bony fixation, thereby minimizing artifacts from potentially loose fixation interfaces. At the top of the pedicle pin is a spherical ball that in turn seats into a spherical socket at the distal end of the robot’s distraction arms. The resulting ball-and-socket joint minimizes stresses on the bone arising from the distraction mechanism.

Distraction is achieved via a pneumatic cylinder that drives the distraction arms. The pneumatic cylinder is supplied with



**Figure 1.** The robotic middle column distractor.



**Figure 2.** Picture-in-picture sequenced imaging. Calibration spheres are used to determine the magnification of the fluoroscopy image.

controlled pressurized air. In the clinical setting, the operating room air supply would be used. For the purposes of this study, since the laboratory was not equipped with operating room air, a standard construction air compressor purchased at a local builders' supply store was utilized. The distraction arms are made with two integral spheres toward their distal tips, but located far enough away so as to avoid interfering with the surgical approach. See [Figure 2](#).

The control unit for the robot is situated outside the sterile field, and consists of a small custom-built electronic controller that features a motherboard containing a programmable logic component (PLC) and a digital pressure regulating valve capable of passing through from 0 to 100 pounds per square inch (PSI) of air pressure, though pressures much lower than the maximal are utilized during the regular operation of the RMCD. The valve is controlled by the PLC, and the PLC in turn is controlled by the surgeon. The range of distraction forces applied were from 0 to 150 N. The 150 N peak was utilized by (Kanayama) in a study examining spinal loading with a distractor instrumented with strain gauges<sup>8</sup> and is well below the range of failure loads of 264–384 N for the posterior longitudinal ligament (PLL) in isolation published by White and Panjabi.<sup>9</sup>

The surgeon's controls consist of a touchless gesture sensor, capable of sensing 6 different types of hand motions made over it: left-to-right, right-to-left, up-to-down, down-to-up, nearer-to-further, and further-to-nearer. The touchless sensor allows a surgeon to operate the device without having to contact any controls; an advantage for managing the sterile field.

For the experimental protocol, custom pins were placed in the pedicles of a sawbones model and in the cadaveric tissue. The RMCD was attached, and forces ranging from 0 to 150 N were applied stepwise by one of the investigators swiping his hand over the gesture sensor. Concurrently, a fluoroscopy unit recorded lateral views while a high-definition digital camera was utilized to simultaneously record visual information.

The images and videos were indexed against the amount of force applied. The actual resulting displacements were measured separately based on interpretation of the fluoroscopy images. Force vs displacement for each experimental setup was plotted.

The experiment was run once on a sawbones model for a test of the equipment and to familiarize the investigators with the controls, and then was run once in a cadaveric model utilizing a midline posterior approach. The cadaveric test was run first on the intact spine, then a disectomy was performed, including partial unilateral resection of the facet joint on the side of the approach.

The RMCD was connected to a standard laptop computer by USB cable to monitor the data stream output during the procedure. The data stream consisted of the sequence of commands given to the robot, indexed for the time elapsed since the unit was powered on.

## Objective

The current investigation was a proof-of-concept study primarily seeking to determine if applying a range of physiologically appropriate forces could be used to diagnose the degree of spinal stability present. The actual measurement being made was displacement relative to a known applied force. Since the magnitude of the force is physiological, the magnitude of displacements should be in a range similar to that observed on pre-operative radiographic studies. A secondary objective was to qualitatively evaluate the utility and usability of the RMCD.

At what point a particular spinal level is sufficiently hypermobile—or perhaps more accurately—abnormally mobile—to warrant a spinal stabilization procedure has been debated for decades. The concept and definition of “instability” has not reached consensus in the literature, despite the term having been introduced as early as 1962 by Harmon. There have been definitions based on clinical observations, radiological observations, and biomechanics studies.<sup>10</sup>

Intraoperative diagnosis of the hyper-mobility of a spinal level has been limited largely to manual manipulation of the level by the surgeon utilizing either a lamina spreader or by attaching a Kocher clamp to the spinous process. While this type of test is useful to the surgeon for confirming his or her own decision-making process, the qualitative and subjective nature inherent in it creates challenges for communicating and documenting that decision to interested third-parties (such as the patient's insurer). An additional objective of the current study is to determine if qualitative observations correlate to useful quantitative data obtainable by applying a standardized, physiologically appropriate force to the spine.

Finally, a method for measuring the length of the PLL at a degenerative level has been previously published.<sup>11</sup> If this measurement is known, it allows pre-operative planning to calculate the exact height of the disc space when the level is fused. An indirect way—and the only reasonable tool available to the surgeon today—of creating this final height is by judging the height of the intervertebral cage that is to be inserted. A more direct, and more accurate method, would be by determining known, definable points (such as the distance between distraction arms of the RMCD) at the start of and the end of the distraction movement. The difference between the 2 is the exact height that has been restored. Coupling this with the provision that only physiologically appropriate force is utilized to position the vertebrae, provides an operative method for sequentially decompressing and releasing the spinal anatomy until the exact height restoration has been achieved. Having achieved the correct Z-axis relationship of the vertebrae, the disc space can now be measured accurately for the correct cage size to maintain this space. Whether a static or expanding cage, or a piece of bone graft, is utilized is not important. The change in technique should result in more accurate positioning when compared to using the cage height as an indirect indicator of vertebral positioning.



## Methods

An initial test of the RMCD was conducted on a lumbar sawbones model to familiarize the investigators with the controls, aid in visualizing the types of movements to be expected, and to check the operating parameters of the robot.

Two different conditions were tested. (1) intact cadaveric spine, and (2) after performing a simulated discectomy including partial resection of the facet joint on one side for access to the intervertebral disc. For the cadaveric model, a midline approach was used to access the spine.

First the threaded pins were inserted into one pedicle of each vertebra L3 and L4 on the right side of the spine. Following pin placement, the RMCD was attached to the spherical heads of the pins. The relationship between specific air pressures input into the pneumatic cylinder and linear forces produced at the tips of the distraction arms of the RMCD had been previously characterized and validated by mechanical testing. Forces of 20, 35, 85, 110, 133, and 150 N were applied stepwise by one of the investigators swiping his hand over the gesture sensor. Input air pressures to achieve these loads were supplied by the RMCD's bedside control unit. Concurrently, a fluoroscopy unit recorded lateral views while a high-definition digital camera was utilized to simultaneously record visual information. The fluoroscopy and digital video units were connected by a RS232 cable in order to allow them to be activated at the same time, so that the resulting videos were time-indexed to each other.

For the sawbones model, the sequence was run just once. Its purpose was only for visualization, demonstration, familiarizing the investigators with the controls and process, and for providing simple-to-analyze video and fluoroscopy images for the subsequent data analysis technique.

The cadaveric model consisted of two conditions. First, in the "intact" condition, where only the approach to the spine had been made, and the threaded pins inserted into the pedicles. This served to provide a baseline stiffness measurement of an intact spine. After recording the intact condition data, one of the investigators—an experienced, fellowship-trained spine surgeon—performed a discectomy procedure. The approach to the disc was right-sided unilateral, and a portion of the facet joint on the side of the approach was resected to provide access to the intervertebral disc. Following the discectomy, the same stepwise forces were applied and recorded in the same manner.

After the experiments were complete, the digital video and fluoroscopy images were combined into a picture-in-picture format. The magnification of the images was calculated by measuring the diameter of the calibration spheres of the RMCD and comparing it to the known physical diameter of 15.0 mm. The use of the spherical geometry corrects for out-of-plane effects for the magnification.

A still image was frozen after each stepwise force application, and the distance between the centers of the tips of the RMCD arms was measured digitally with video measurement

software (Aequo) and adjusted for magnification as noted above.

The force vs displacement curves were plotted for the intact and post-discectomy conditions. In order to account for removing the laxity inherent in this sort of mechanical testing setup, the zero displacement point utilized in the calculations was a low, 35 N, force application, rather than the zero force application condition. This is referred to as "pre-tensioning" and is a common procedure in mechanical testing.

Prior to removal, the surgeon manually palpated the threaded pins to evaluate their stability in the pedicles following the distraction procedures.

The ODS was monitored visually on the laptop throughout the procedure for consistency of commands given vs reported at the time that the commands were given.

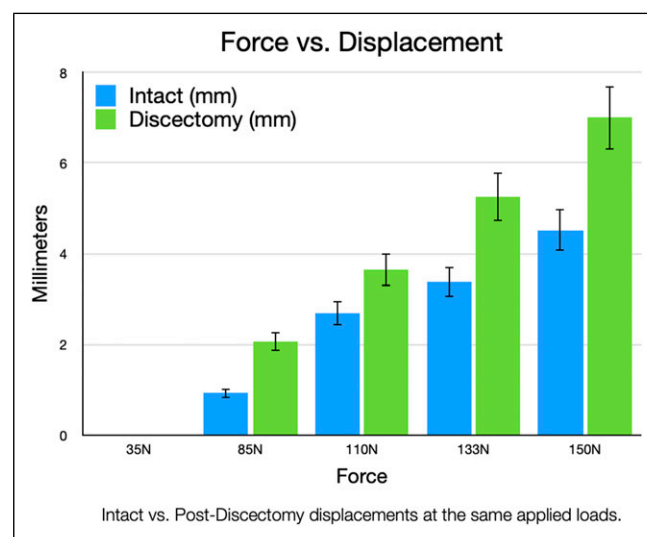


Figure 3. Z-axis displacement vs distraction force applied.

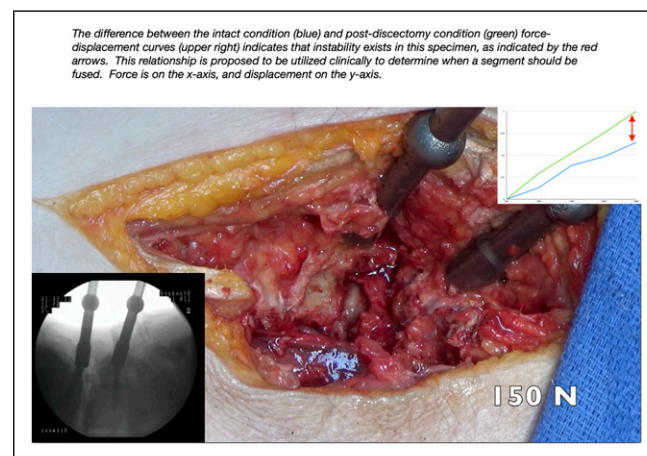


Figure 4. Force-displacement curve for diagnosing stability.

## Results

Visual examination of the video recordings showed an apparently expected result. The intact condition was barely seen to move visually, even at 150 N of applied force, while following discectomy, the motion of the spine appeared obvious. This was the qualitative result.

Analyzing the fluoroscopy data (see [Figure 3](#) and [Figure 4](#)) shows that the actual quantitative data demonstrated more motion than the investigators had perceived. The intact condition showed 4.5 mm of *z*-axis displacement at 150 N, which is a greater amount than had been estimated. Following discectomy, the *z*-axis displacement was 7.0 mm.

The controls functioned without any flaws throughout the procedure. Each gesture made was received and recorded by the RMCD unit. However, there was a slight lag time inherent in the control circuit—less than 1 s—but it was sufficient to cause an occasional hesitation by the investigators to proceed to the next step in order to obtain confirmation that the command had indeed been executed.

The data stream was monitored throughout the procedure, and showed no gaps, errors, or duplicative data. This demonstrated that the ODS could conceivably be output and recorded in the patient record in a time-indexed fashion from a spinal procedure.

Both qualitative visual and quantitative fluoroscopic evaluations of the spine's movement under load confirmed the ability to differentiate between a "normal" intact spine and an "abnormal" de-stabilized spine. Interestingly, however, the motion observed on the intact spine at 150 N of force exceeds the threshold (of 3 or 4 mm, depending on the source) amount of motion for "instability."

## Conclusion

Fundamentally, the proof-of-concept test was a success. The RMCD was able to provide physiological force to the spine in a simulated operative setting in a safe and reproducible manner. The force applied and manner of its application resulted in the ability to distinguish between a stable and an intentionally de-stabilized spine.

The data stream shows promise as an inobtrusive way to capture objective time-indexed information about the amount of force applied to the spine. RMCD could easily be fitted with a cellular card in order to output data to an online database from anywhere the unit may be located.

The change in *z*-axis height could be reproducibly measured by a very simple technique. This demonstrates that a surgeon who has calculated a target *z*-axis restoration pre-operatively could utilize the RMCD to very accurately reach that target value intra-operatively. This methodology could supplant utilizing intradiscal spacers and "feeling" the ligament tension as a means for sizing interbody fusion cages.

Additionally, there was a clearly demonstrated difference in the shape of the force-displacement curves between the intact

and post-discectomy conditions (see [Figure 4](#)). This indicates that the technique is sufficiently sensitive to detecting the difference between a stable spine (which may not require fusion) and an unstable spine (which would require fusion), and then subsequently documenting and communicating that difference in a quantitative manner for medical record-keeping.

## Discussion

The prototype RMCD and pilot study were clearly a success. As in any product development endeavor, improvements are learned along the way as the project moves toward completion.

The current version of the robot utilized a simple pressure cylinder to apply a distraction force along the *z*-axis of the spine. While this method is acceptable, and sufficient for the diagnostic function of the device, it could be refined somewhat. Not shown in this study is a variation on the force application allowing the RMCD to apply force in the anterior-posterior direction, thereby manipulating spondylolisthesis or retrolisthesis in a controlled, safe, and reproducible manner.

To reach a pre-planned *z*-axis height restoration the current system requires a simple adjustment of the pressure (e.g., the force applied) to create the amount of distraction necessary. While this method works, it requires multiple fluoroscopy images to get right. A more efficient method, and one requiring fewer fluoroscopy images would be to replace the piston with an air stepper motor. This would allow the RMCD to control both force and *z*-axis displacement. It would also allow compressive force application, not only distraction.

Such a feature could become very useful in deformity correction, where perhaps several RMCD units can work in concert to carefully and precisely position the spine prior to rod contouring and placement. Additionally, having control of both force and displacement in a closed-loop feedback system would provide an additional level of safety whereby motions could be automatically stopped if the relationships between input force and resulting motion fall outside of expected physiological parameters. The rate of force application and allowed rate of motion would also be controlled at a rate slow enough—and even in stepwise movements—that the surgeon can intervene in case of unexpected conditions.

The image analysis method utilized in this study was fine for a laboratory setting. To utilize the method in a real operating room, the method should be automated by computer software that is capable of recognizing the landmarks on the RMCD unit. This should be fairly simple image analysis and edge-detection code. There is no need to automate finding bony landmarks or patient anatomy on the radiographs, since well-defined manufactured components with spherical landmarks are employed.

Important to note is that the RMCD is a very small, simple device. The electronic components are contained in a housing approximately the size of a laptop computer, and are placed on a stand near the operating table. It is not necessary to sterilize the electronics. The component utilized in the surgery is made completely of re-sterilizable materials, such as stainless steel,

silicone rubber, and polyacetal. A pair of disposable sterile-packed air hoses are the only non-reusable component in the system.

Having the ability to apply precise, controlled, repeatable forces to the spine opens the door to a wide variety of new applications. Performing a simple diagnostic test to verify the segmental stability of a level—at the time of surgery, rather than on pre-operative radiographic studies—that is the exact same test run with the same parameters and data capture regardless of which surgeon is performing it is a big step toward being able to standardize what are now qualitative, subjective tests. Additionally, having an intraoperative robotic distractor to assist with vertebral positioning provides new opportunities for improving techniques such as deformity correction.

Robotic vertebral positioning could increase a surgeon's efficiency. The RMCD could hold the distraction of the disc space exactly at the desired z-axis position. This would reduce the amount of a surgeon's attention that is required to be spent on adjusting manual distractors. It could also act as a "third hand" and perform minor functions such as slightly over-distracting the disc space (automatically keeping within physiological limits of force and motion) during cage insertion, and then compressing the level once the maneuver is completed.

Similarly, the additional assist could be of great utility in correcting spondylolisthesis *via* the y-axis RMCD function, while leaving both of the surgeon's hands free to perform other tasks during the correction. Unlike a human assistant, the robot will not tire and will provide the same consistent, constant force throughout the procedure. Alternately, it may turn out to be beneficial to provide cyclical periods of force vs relaxation during a procedure.

Such precise positioning, employing a combination of pre-operative z-height planning of the disc space and intra-operative ligamentous tension information will allow a new level of precision in sizing cages relative to the disc space being operated on. This will, in turn, reduce the stresses present between the endplates and the cages, and should theoretically help to reduce the incidence of subsidence.

Having an orthopedic data stream could be of great utility; it would allow the surgeon to document quantitatively what forces he or she applied to the spine, and what the intraoperative relative positions of the manipulated vertebrae were. Such a data stream could be seamlessly linked into and stored with other electronic patient records, and even with insurer's various reimbursement criteria. Integrating this data stream with other electronics records in such a way could be a useful tool for reducing paperwork and increasing documentation accuracy.

One surprising finding from this study was the mismatch between observer-perceived motion and actual measured motion. Observed motion is the basis of the qualitative intraoperative assessments of stability such as the so-called "Kocher Test," wherein a vertebra is manipulated via a Kocher clamp and the surgeon evaluates whether or not the level is stable. Performing stability testing via a precise, repeatable, robotic tool will increase the accuracy of such

testing, and allow for the determination of reference ranges for vertebral stability in the operative setting.

We believe this study represents an important step forward, and more study and development of this concept is warranted.

## Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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## References

1. Alqarni A, Schneiders AG, Hendrick PA. Clinical tests to diagnose lumbar segmental instability: a systematic review. *J Orthop Sports Phys Ther.* 2011;41:130-140.
2. Biely S, Smith SS, Silfies SP. Clinical instability of the lumbar spine: diagnosis and intervention. *Orthopaedic Practice.* 2006; 18:3-6.
3. Pope M, Panjabi M. Biomechanical definitions of spinal instability. *Spine.* 1985;10(3):255-256.
4. Sasso R, Kitchel SH, Dawson EG. A prospective, randomized controlled clinical trial of anterior lumbar interbody fusion using a titanium cylindrical threaded fusion device. *Spine.* 2004;29: 113-122.
5. Aetna, I. Spinal surgery: Laminectomy and fusion, 2004. [www.aetna.com/cpb/medical/data/700\\_799/0743.html](http://www.aetna.com/cpb/medical/data/700_799/0743.html).
6. Davis R, Lee DC, Wade C, Cheng B. Measurement performance of a computer assisted vertebral motion analysis system. *Internet J Spine Surg.* 2015;9:36.
7. Nunley, P. *Spine Surgeons' Perceptions of the Incidence and Impact of Third Party Payers' Delay or Denial of Coverage in the Pre-Authorization of Surgical Procedures and Subsequent Payments.* New York, NY: ISASS; 2016.
8. Kanayama M, Hashimoto T, Shigenobu K, Oha F, Ishida T, Yamane S. Intraoperative biomechanical assessment of lumbar spinal instability: Validation of radiographic parameters indicating anterior column support in lumbar spine fusion. *Spine.* 2003;28:2268-2272.
9. White A, Panjabi M. *Clinical Biomechanics of the Spine.* 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 1990:22.
10. Mulholland RC. The myth of lumbar instability: the importance of abnormal loading as a cause of low back pain. *Eur Spine J.* 2008;17:619-625.
11. McAfee P, Eiserman L, Cunningham BW, Mullinix KA, Brooks DM. Middle column gap balancing to predict optimal anterior structural support and spinal height in spinal reconstructive surgery. *Spine.* 2017;42:S19-S20.