

KineGraph VMA™

Vertebral Motion Analyzer

The spine in motion



PROOF

An innovative new spine motion analysis technology...

The KineGraph VMA™ is a new functional diagnostic test for the spine that provides the first clear view of spine motion available clinically.

Key benefits:

- Fast, painless, and less radiation¹³ than current standard of care (end-range x-rays)
- Reliable measurement and true functional test—a major upgrade to end-range x-rays
- Delivers valuable new diagnostic capabilities
- Provides new insights for implant device design
- Offers promise to improve spine diagnostics and clinical outcomes

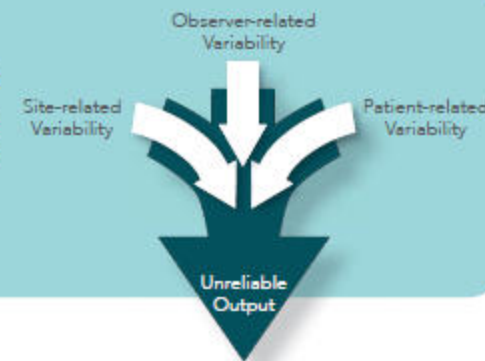
...replacing the 60-year-old standard of care

"Using [end-range x-rays] as a basis for diagnosing instability can lead to serious errors in classification." - W. Shaffer, MD (1990)¹

Replaces the 60-year-old standard of care: a widely used process with well-known problems that is ripe for innovation. The end-range x-ray method was first described in the 1940s and remains the most widely used method of measuring the motion between vertebrae. However, the usefulness of this method has been debunked by multiple studies.^{2,3,4,5,6}

The literature points to two major problems with end-range x-rays:^{2,3,4,5,6}

**Problem #1:
Unreliable Measurement**
High variability makes the numeric output unreliable and practically useless.



**Problem #2:
Not a True Functional Test**
Two static x-rays cannot accurately capture the complexities of spine motion. Mid-range instabilities are impossible to assess.

Weak link in back pain diagnosis and treatment

Despite these problems, the end-range x-ray method is a fixture in evaluating back and neck pain patients, triggering diagnoses and treatments.

Diagnosis: Patients are evaluated using a combination of 3 tests:
MRI (soft tissues) + plain x-rays (bony structures) + end-range x-rays (motion)
Only 15% of back pain patients get a definitive anatomic diagnosis.^{7,8}

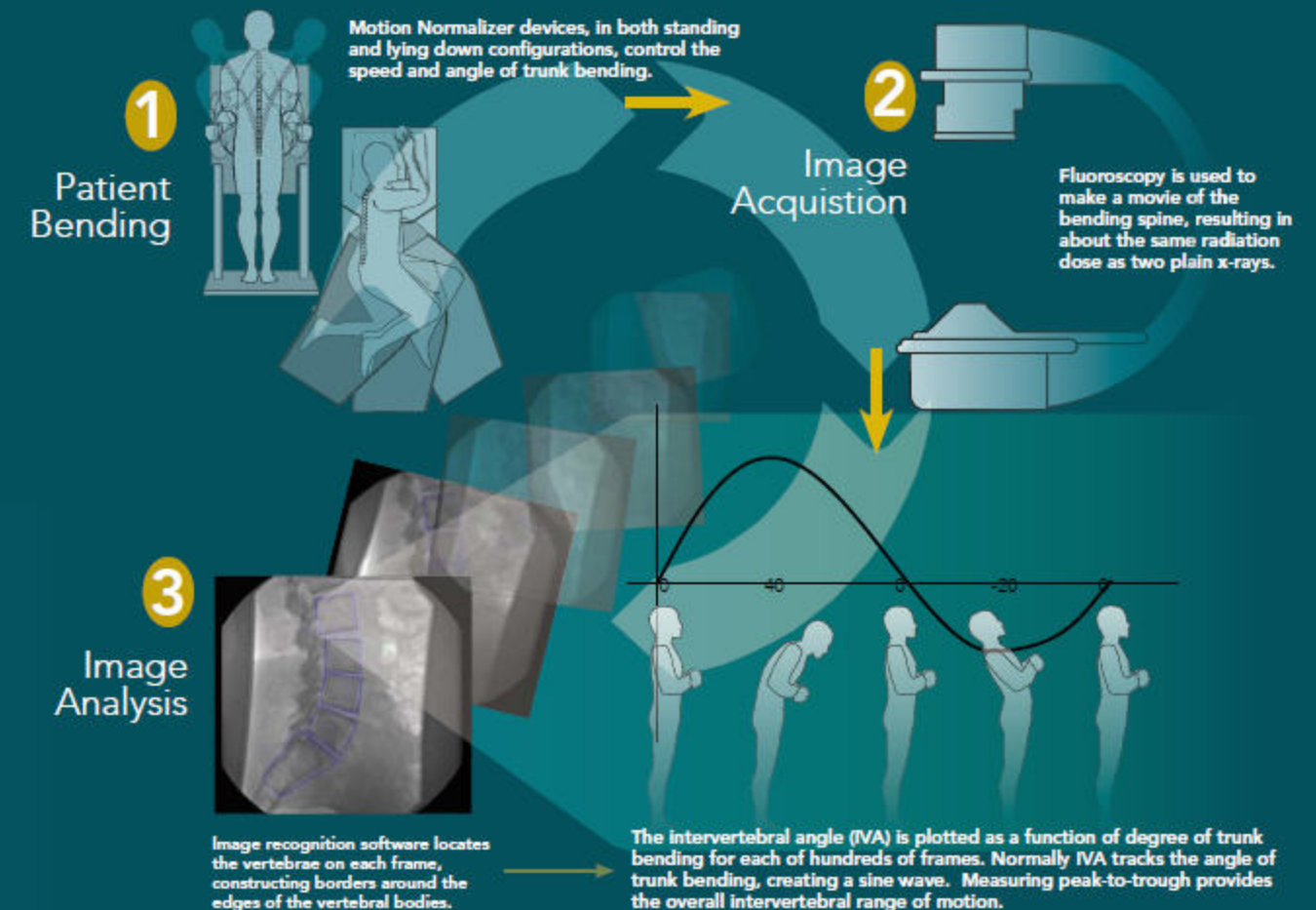
Treatment: There are 400,000+ lumbar and cervical fusions per year in the U.S.⁹
Over 90% of fusions are technically successful, but only 60-70% are effective at relieving pain.^{10,11,12}
This gap in fusion outcomes highlights a major failure in spine diagnostics.



Revolutionizing spine motion analysis

Evolutionary upgrades to the current standard of care process provide revolutionary advancements in spine motion analysis. The KineGraph VMA standardizes and automates each of the basic steps of the spine motion analysis process. These upgrades address the main shortcomings of end-range x-rays: Measurements are unreliable and not taken during bending.

	1 Patient Bending	2 Image Acquisition	3 Image Analysis
End-range X-rays	Patient bends spine to maximum voluntary bending angle—flexion and extension; left and right	Plain x-rays taken at the extremes of motion—2 films in each plane	Relative motion between the vertebrae measured manually
KineGraph VMA	Powered Motion Normalizer™ devices assist patients through controlled spine bending	Video fluoroscopy captures hundreds of frames at standardized spine bending angles	Automated image analysis software finds relative motion of the vertebrae for each frame angles
KineGraph VMA intended advantage	Controlled movement means more reliable measurement ^{15,16}	Captures spine motion, thus a true functional test	Automation reduces observer-related variability ^{15,16}



Breakthrough diagnostic capabilities

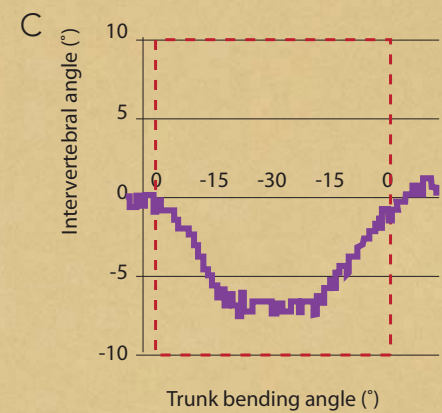
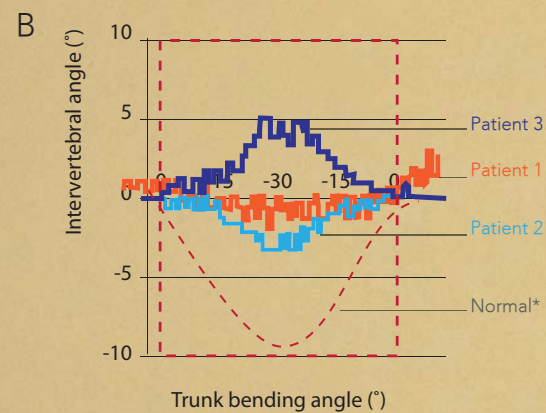
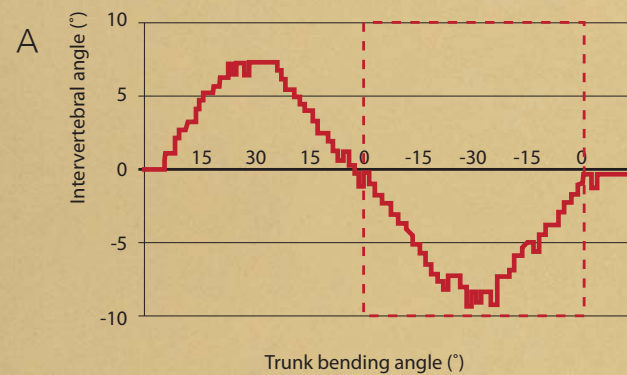
Provides breakthrough diagnostic capabilities proven out in pilot studies

Results demonstrate that the KineGraph VMA delivers capabilities that were previously impossible.

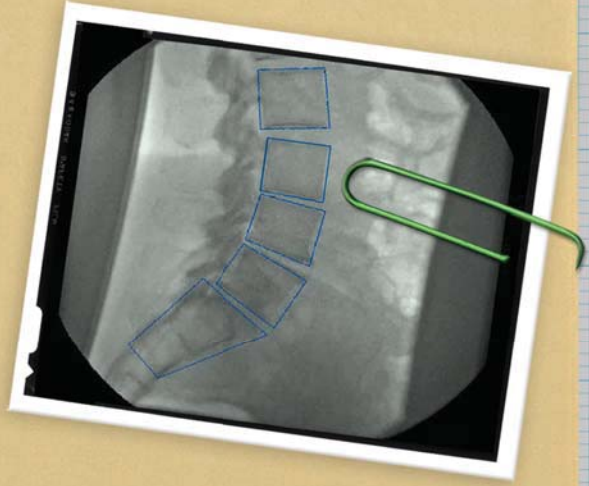
Study subjects
Asymptomatic (n=30; mean age=32.5)¹³
Degenerative disc disease patients (DDD) (n=10)¹⁴

Capability ^{13,14}	KineGraph VMA	End-range X-rays
Measure overall range of motion ¹³	X	X
Identify gross instabilities ¹³	X	X
Discern normal* from abnormal	X	
Discern stiffness from immobility ¹³	X	
Correlate motion abnormalities to pain ¹⁸	X	
Capture mid-range instabilities (e.g. laxity) ¹⁸	X	
Assess kinematics of motion preserving devices ¹⁴	X	

KineGraph plots from pilot studies



*The term "normal" as used here refers to the statistical norm among a population of asymptomatic subjects.



KineGraph plots of intervertebral angle (IVA)

A Case example from asymptomatic cohort. All 30 asymptomatics had a smooth sinusoidal curve where the IVA tracked trunk bending angle, representative of normal* motion. (L4/L5 left/right bending)¹³

B Case examples from pre-surgical DDD cohort (L4/L5 right bending)¹⁴

Patient 1 - Apparent immobility: IVA remains close to zero degrees across the range of trunk bending.

Patient 2 - Apparent hypomobility (stiffness): IVA is much reduced compared to the normal* plot.

Patient 3 - Apparent paradoxical motion: IVA tracks in the opposite direction from trunk bending angle, creating a mirror-image of the normal* plot.

C Case example of pre-surgical DDD patient. (Plot of L3/L4 in right bending; operated level was L4/L5) Apparent laxity: Evidenced by steeper-than-normal sides and a flattened bottom.¹⁴

Improved diagnostics = Improved outcomes

Offers immense promise for improving diagnosis and subsequent clinical outcomes.

Improve measurement reliability and capture spine motion

Potential for better diagnostic decisions

Potential for improved patient outcomes

Addresses a broad patient population

Target of on-going clinical trials

Patient Population	Potential Clinical Impact
Instability and spondylolisthesis	Detection of subtle instabilities → New treatment indications
Stenosis	Avoiding intra-op decisions regarding decompression alone vs. decompression and fusion
Degenerative disc disease	Address fusion outcomes gap
Discography	Non-invasive and less costly method to determine level to fuse
All fusion patients	Observe adjacent level laxity before it becomes painful
Non-surgical back/neck pain	New ways to diagnose/manage

Motion-preserving device design

Provides a tool for evaluating and selecting motion preserving device designs.

The KineGraph VMA™ provides the level of kinematic detail necessary to compare different spine implants *in vivo*, which is impossible with the currently used technology.¹⁴

Are these devices performing in patients as they do *in vitro*? The KineGraph VMA allows this question to be addressed for the first time.

1944 End-range x-ray method introduced¹⁹

1950s Anterior discectomy introduced

1960s Instrumented lumbar fusion introduced

1970s Fluoroscopy used to assess cardiac function

1980s MRI used in spine diagnosis
DDD fusion volume takes off

1990s Artificial disc introduced in U.S.

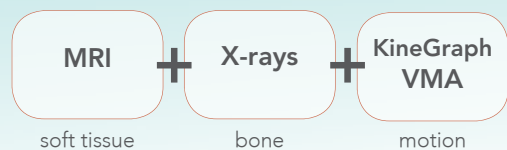
Motion-preserving device category takes off

2000s KineGraph VMA building blocks fall into place:
- Digital videofluoroscopy gains traction
- Science behind motion normalization published^{16,17}
- Necessary computing power readily available

2007 Ortho Kinematics founded

Future KineGraph VMA becomes an integral part of the diagnostic process for back and neck pain patients—providing, for the first time, a complete picture of spine structures and function.

New standard of care in spine diagnostics



Ortho Kinematics is a diagnostics company committed to the idea that spine motion matters. We are partnered with leading surgeons and scientists to revolutionize spine motion analysis and improve spine care. Our aim is to improve functional diagnostics of the spine and ultimately contribute to improved outcomes for back and neck pain sufferers.



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