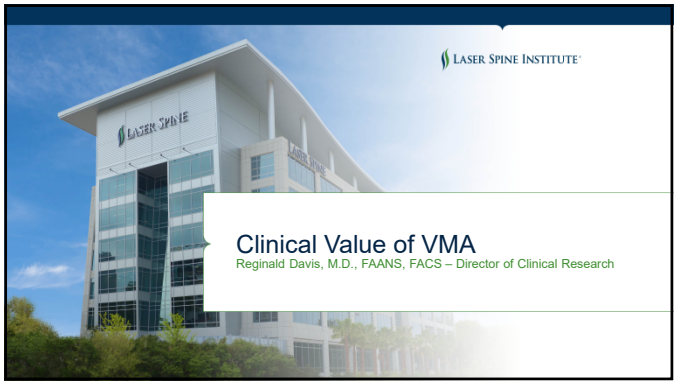

Disclosure

- Zimmer/Biomet/LDR: Consultant, Royalties
- Ortho Kinematics: Consultant
- Paradigm Spine: Consultant
- Titan Spine: Consultant

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Functional Tests Lacking in Spine

	Spine	Cardiovascular
Diagnostic Challenge	Non-Specific SPINE Pain	Non-Specific CHEST Pain
Assessing Anatomy	X-ray (bones); MRI (soft tissue)	X-ray (tissue features); CT (vasculature)
Assessing Function	GAP	• Angiography • Stress testing • Echo • EKG • Labs • Others
Surgical Success[1]	74%	95%+

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The Flex/ex has Significant Limitations

5 Million Flex/Ex studies/year. Impact 1.9m Surgeries

Positive test: indicates patient for fusion - 500k per year

Negative test: Decompression 600k / yr Pain Injections – 800k / yr

However, there are **significant issues with the 1940s-era flex/ex**

- Highly variable and subjective results
- *"We believe that **no useful information can be derived from [the flex/ex]** procedure, especially in relation to the need for surgical fusion."*
  – Dvorak & Panjabi, 1991

The continued use of flex/ex demonstrates how important functional testing is in the workup of patients for spine surgery

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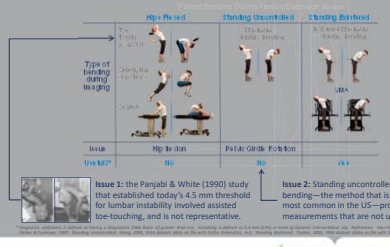
Issues with Current Instability Thresholds

There are no scientifically-valid thresholds for instability in use today.
Panjabi & White's 4.5 mm threshold for lumbar instability is equally unsupportable as NASS's recent recommendation of 2.0 mm.



Issue 1: the Panjabi & White (1990) study that established today's 4.5 mm threshold for lumbar instability involved assisted toe-touching, and is not representative.

Issue 2: Standing uncontrolled bending—the method that is by far most common in the US—produces measurements that are not useful.

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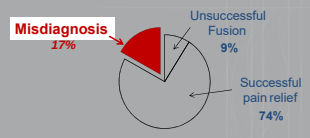
Misdiagnosis in Spine

Lumbar Fusion Outcomes (1)



- Biggest need is better diagnostics, not improved fusion technology
- <5 companies focused on developing next-gen diagnostics
- Of these, OKI is the most commercially mature

(1) From Meta-analysis of Medical Literature. Data on file at OKI.

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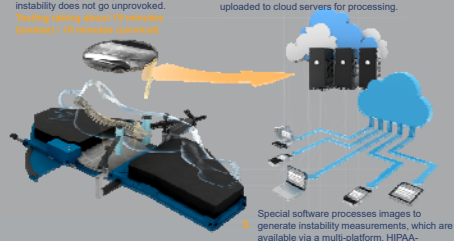
VMA Advanced Functional Imaging

1. VMA device controls patient bending during imaging, ensuring instability does not go unprovoked. Testing takes about 10 minutes (lumbar) / 14 minutes (cervical)

2. Standard imaging machines (C-arm fluoroscopes) capture video x-rays of the spine as it bends, which are then uploaded to cloud servers for processing.



3. Special software processes images to generate instability measurements, which are available via a multi-platform, HIPAA-compliant cloud application in 12-24 hours.

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Evidence

The VMA was validated in the largest Level 1 Evidence study of its kind

VMA Improvement Relative to Today's Test	Quality of Evidence Level I (best) – V (worst)	Study Size (# of patients)
Detects double the rate of lumbar radiographic instability* • Instability rates increased to **11.5%** (VMA) vs. **5.5%** (flex/ex) • Very high specificity (**99.5%**)	**Level I**	**1,112 ***
68% more repeatable	Level III	84
79% more accurate	n/a	2
Lower dose of radiation	n/a	101
Comparator: Most often-cited study to support the use of the flex/ex (Pearcy & White, 1991)	Level III	142

VMA advantages

** VMA's key performance benefits were validated in a recently-completed "head-to-head" study of the VMA vs. the flex/ex in **878 consecutive spine surgery clinic patients** and **234 pain-free healthy volunteers**. Lumbar radiographic instability was defined as slippage of 5.3 mm (15%) or more between lateral views.*

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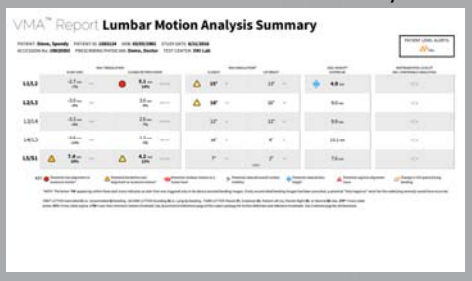
VMA Lumbar Motion Summary


VMA™ Report: **Lumbar Motion Analysis Summary**

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"Win-Win" Economic Profile – Additive to all Constituents

Earlier identification of spine instability leads has the benefit of driving fusion volume while lowering overall costs. Patients, however, stand to benefit the most.

Patients	• Higher quality diagnostic data at a lower radiation dose • Much lower odds to suffer prolonged pain due to undiagnosed instability
Surgeons	• More complete, higher quality data to make surgical decision easier • Net increase to overall surgery and fusion volumes
Hospitals	• Increase in overall surgery and fusion volumes • Service line differentiation and profit driver for radiology departments
Payors	• Earlier diagnosis reduces costs related to pain management • Correct procedure ID reduces surgery failure and re-operation rates
Implant Company	• Net Increase in overall fusion volume • Improving the risk/benefit profile of elective spine surgery

VMA delivers benefits to all economic stakeholders.
Non-economic and time-savings benefits accrue to everyone.

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Significant Impact

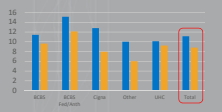
ID's More Fusion Patients

The Following Statistics Were Observed Across Sites:

35% Changed Decisions → New Fusion +25%
35% Changed Decisions → Fusion Decom-pression -10%
= +15% Net Effect on Fusion Volume

Reduces Fusion Approval Time

Average Days to Fusion Approval Before and After VMA



21% Reduction

- VMA avoids the need for 6 months of conservative care
- VMA reduces the amount of time surgeons and insurance companies spend

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Sagittal Alignment

Spine Surgeons ARE Deformity Surgeons
- Ignoring it
- Addressing it
- Creating it
- Correcting it

"Life is a kyphosing event"

Dave Polly, M.D.

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Sagittal Alignment Clinical Value Proposition

In the recently published studies, the following has been investigated:

- **Rothenfluh**: **10X chance** of revision surgery @ 49 months post-op following 1- or 2-level fusions when PI-LL mismatch > 10deg.
- **Akoi: Increased VAS Pain scores** in patients w/o Sagittal Alignment following 1- or 2-level MIS TLIF fusions.

Other important study:

- **Schwab**: Found that PI-LL has roughly the same predictive power as Sagittal Vertical Axis (SVA) and Pelvic Tilt (PT) in predicting disability in adult deformity patients.

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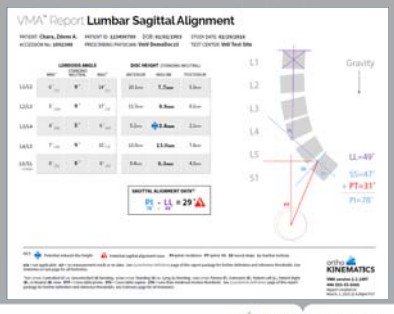
Sagittal Alignment Measurements from VMA



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Case Studies

1. Reversal of Insurance Denials
2. False Negative Impact to Surgical Decisions
3. Impact of the VMA to Broaden Customer Relationships

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PAYER ISSUES

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

Pierce D. Nunley, MD[1] · John Small, MD[2] · Kelly Frank, MS[1] · Marcus B. Stone, PhD[1]
[1]Spine Institute of Louisiana, Shreveport, LA · [2]Florida Orthopedic Institute, Tampa, FL

- Surgeons reported 24.6% of cases are denied in the pre-authorization process, with 58.5% of denials occurring ≤ 3 days prior to the scheduled surgery.

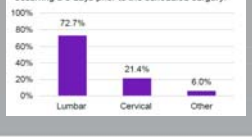

Figure 4: Case Denial Type

- Despite pre-authorizations
  - 24% of cases yield reduced payments
  - 9.4% result in no payment

Economic Impact

Annual Case Volume	Reported Denial Rate	Lost Cases
300	25%	75

Total Potential Lost Revenue*
$191,250

* Based on Medicare reimbursement for instrumented and non-instrumented cases

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Reversal of Insurance Denials

- Patient 1

31 YO WF with 2 year history of mechanical LBP and left greater than right radiculopathy
She had been treated with PT, Lumbar traction, LESI's, facet blocks, narcotics and NSAIDS without success
She had to quit working due to the back pain
She had a MRI with DDD and disc protrusions at L4-5 and L5-S1
Her discogram was positive for concondant pain at both levels with abnormal nucleograms at both levels.
Her EMG was positive for L5 mild left acute radiculopathy.
We submitted for a L4-5, L5-S1 TLIF that was denied

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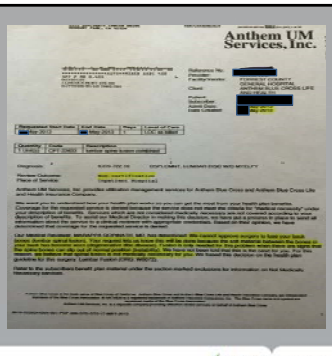

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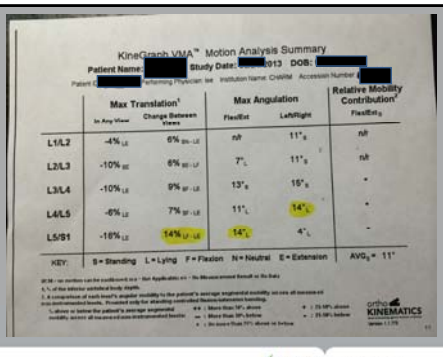

KineGraph VMA™ Motion Analysis Summary

Patient Name: [redacted] Study Date: [redacted]2013 DOB: [redacted]

	Max Translation[1]		Max Angulation		Relative Mobility Contribution[2]
	In Any View	Change Between Views	Flex/Ext	Left/Right	Flex/Ext
L1/L2	-4%	6%	nft	11°	nft
L2/L3	-10%	6%	7°	11°	nft
L3/L4	-10%	9%	13°	15°	-
L4/L5	-6%	7%	11°	14°	-
L5/S1	-18%	14%	14°	4°	-

KEY: S = Standing L = Lying F = Flexion N = Neutral E = Extension AVG = 11°

orthoKINEMATICS

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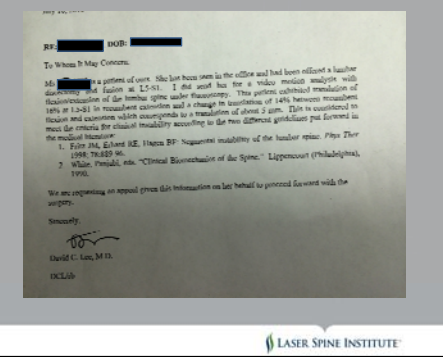

RE: [redacted] DOB: [redacted]

To Whom It May Concern,

Ms. [redacted] is a patient of ours. She has been seen in the office and had been offered a lumbar discectomy and fusion at L5-S1. I did send her for a video motion analysis with flexion/extension of the lumbar spine under fluoroscopy. This patient exhibited translation of 16% at L5-S1 in recumbent extension and a change in translation of 14% between recumbent flexion and extension which corresponds to a translation of about 3 mm. This is considered to meet the criteria for clinical instability according to the two different guidelines put forward in the medical literature:

1. Fritz JM, Erhard RE, Hagen BF: Segmental instability of the lumbar spine. Phys Ther 1998; 78:889-96.
2. White, Panjabi, eds. "Clinical Biomechanics of the Spine." Lippencourt (Philadelphia), 1990.

We are requesting an appeal given this information on my behalf to proceed forward with the surgery.

Sincerely,

David C. Lee, M.D.

DCL/ab

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DAVID LEE
[redacted] LINCOLN PKWY #303
HATTIESBURG MS 39420

Reference No: [redacted]
Provider: DAVID LEE
Facility/Vendor: FORREST COUNTY GENERAL HOSPITAL
Client: ANTHEM BLUE CROSS LIFE AND HEALTH
Patient: [redacted]
Subscriber:
Admit Date: [redacted]-Jul-2013
Date Created:

Service	Date	Quantity	Code	Description	Charges
Surgical	[redacted]-May-2013	1 Unit(s)	63047	remove spine lamina 1 intv	
Surgical	[redacted]-May-2013	1 Unit(s)	22851	apply spine prosth device	

Review Outcome: Certification
Place of Service: Hospital - Additional IP Procedure

Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company.

The services listed above have been certified as medically necessary. We have informed your health care provider of this decision.

Your provider may be part of our network in this state, but not in other states. This matters because using a provider who is not in our network may cost you a lot more than using one who is in-network. You must tell us if something changes related to the care you are going to receive. This includes the date or location of the care and the provider you choose.

This certification is part of our utilization management program to enable our subscribers to receive medically necessary care in the medically appropriate setting. The utilization management program assures our subscribers of lower out-of-pocket expenses when they use participating facilities and providers. You have chosen to receive services from a provider that is a non-participating network provider. Your services could result in significant out-of-pocket expenses.

THIS CERTIFICATION IS BASED ON THE INFORMATION PROVIDED, AND IS A CERTIFICATION OF MEDICAL

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Case Study: Impact of False Negatives

22%

"False Negative" Rate

% of VMA scans that detect anomalies missed by today's current instability test

VMA results routinely changes surgical decisions, and has lead to significant new fusion volume at all sites where it is in use.

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Case 1

- 63 year old female
- Left leg radicular pain with weakness
- Severe Low Back Pain
- L3/4 slip not moving on F/E but clearly 5 mm (13°) on VMA and well documented.
- VMA conducted following failed treatment
  - Dr. Lynch began using the VMA following the initial visits
- Following 18-month conservative care, VMA imaging contributed to TLIF surgery

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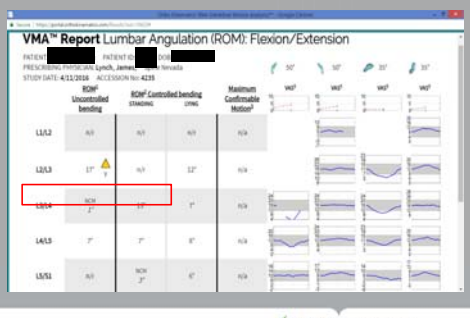
Case 1 Report



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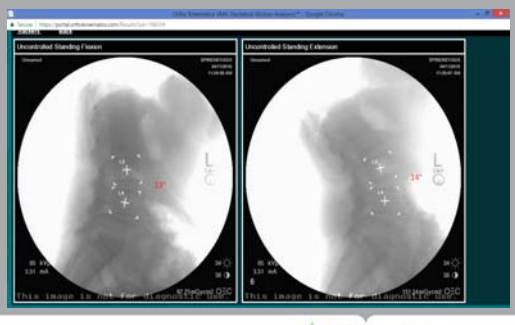
Uncontrolled Flexion Extension



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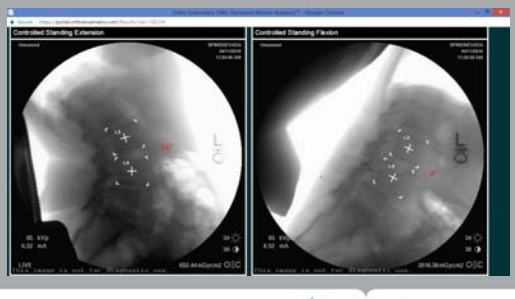
VMA Imaging



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Case 2

- 64 Female
- Non-Smoker
- L2/L3 slip not moving on F/E but clearly 5.3 mm (15°) on VMA and well documented.
- Grade 2 Spondy seen greatly on standing VMA, possible grade 3
- No confirmable motion under static flexion extension series

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Case 2 Report

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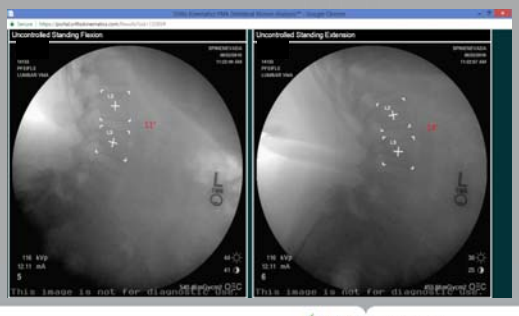
Uncontrolled Flexion Extension



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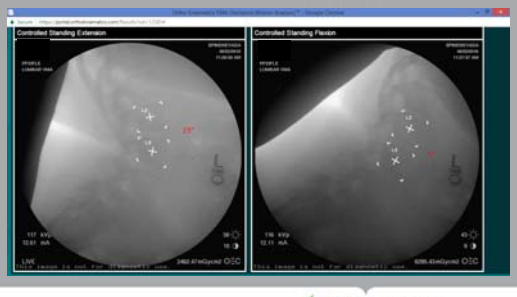
VMA Imaging



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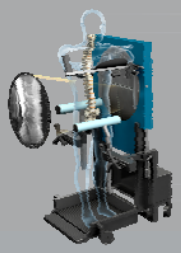
Advanced Functional Imaging



VMA

- Detects instability at higher rates
- Helps surgeons reverse denials
- Easy to integrate into clinical workflow
- Stronger science than today's test
- Lower radiation exposure to patient

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