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Biomechanical VMA

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Disclosure

Research Funding

- Aesculap
- Alphatec Spine
- Globus
- Medtronic
- Ortho Kinematics
- Ratchiotek
- Stryker Spine

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Comparison Metric

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Quality of Motion
How you get there…

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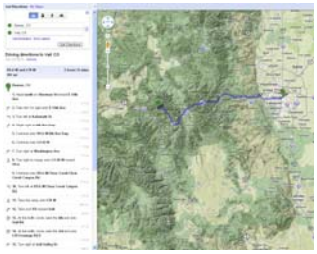
Quantity and Quality of Motion



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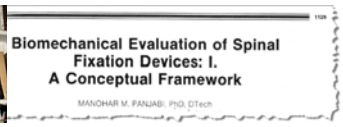
Spine Biomechanical Testing

- Method of *Comparative* Testing
  - Flexion extension and lateral bending (pure moment testing – *flexibility protocol*)
  - Axial torsion and axial compression (are also important)



Panjabi, 1988

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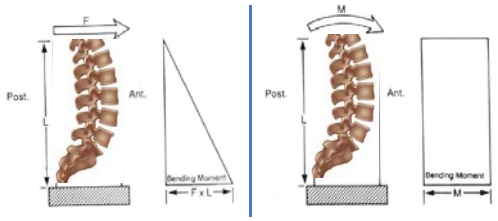
"Pure Moment" Testing

What bending moment does each intervertebral level see?



L5 > L1

Modified without permission from Panjabi, 1988

L5 = L1

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Stability

White and Panjabi define ***clinical stability of the spine*** as the ability of the spine under physiologic loads to limit patterns of displacement so as not to damage or irritate the spinal cord or nerve roots and, in addition to prevent incapacitating deformity or pain caused by structural changes.

Instability

Easier to define than stability

Lends itself to quantification

Rotational

Translational

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Radiographic Instability (rotational) / Radiographic non-union of a fused level Limits

Diagnostic criteria for surgery, in conjunction with results from physical findings and other studies:

- Radiographic Instability (rotational) as an indication for fusion surgery:
  - InterQual: > 22 degrees
  - AMA Guides (5th Ed.):
    - L1/L2 – L3/L4: >15 degrees
    - L4/L5: > 20 degrees
    - L5/S1: > 25 degrees
- Non-union of a fused level as an indication for revision surgery
  - FDA: ≥ 5 degrees

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Problems with traditional flexion-extension films

- Variable extent of motion (voluntary bend angle)
- Unable to separate muscular and skeletal effects
- Only end-point data

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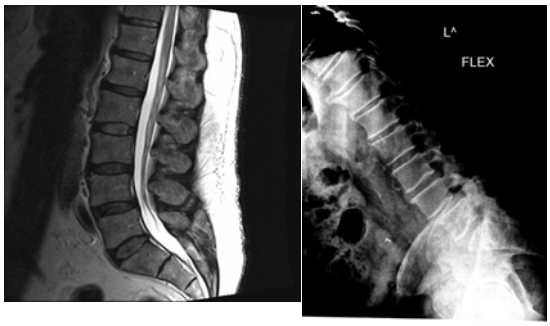
Static and Dynamic Radiographic Studies



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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 • EKG • Stress testing • Labs • Echo • Others
Surgical Success	74%	95%+

Today's standard for spine functional testing is highly variable and largely ineffective

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Patient Quality of Motion

Standardized Bending

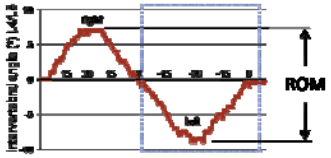

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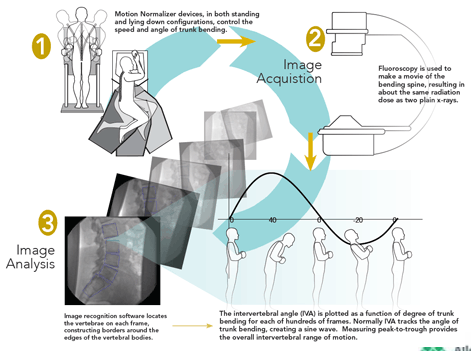
Image and Analysis



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KineGraph VMA System

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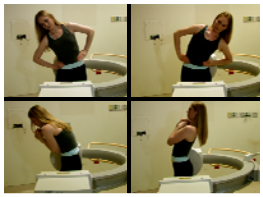
Image Acquisition

Stills



Cines

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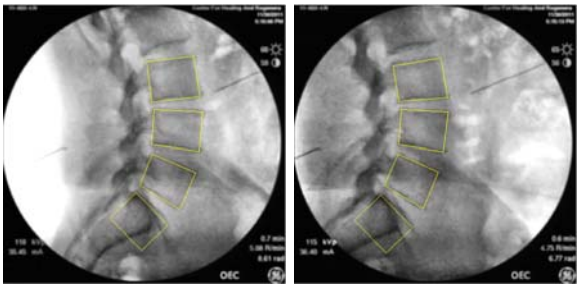
Cine Fluoroscopy



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Orthokinematics VMA Study

Study to establish the accuracy, safety, and repeatability of VMA analysis

Seven centers enrolling

Initial cohort of asymptomatic normals as well as patients with a variety of pathologies

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Enrollment Report

Subjects Imaged as of October 25, 2011			
Site	**Patients**	**Normals**	**Withdrawn**
Pittsburgh	27	0	1
Austin	0	8	0
Bristol	16	29	1
LA	16	24	1
Tampa	19	37	4
Baltimore	10	16	1
Totals	**88**	**114**	**8**

NOTE: Patients with multiple testing events are only counted once.

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Analysis of Patient population

	Count of Levels	% of all 314 Levels with Standing Lateral Data	Levels with Head-to-Head MVBA Data (count)
Radiographicallly-Confirmable Conditions			
Anterior Fusion	4	1.3%	3
Posterior Fusion	17	5.4%	13
TDR (Total Disc)	3 (2 are same pt)	1.0%	2 (same pt)
Posterior Motion Preserving	4	1.3%	3
ISP (Inter-Spinous)	0	0.0%	0
Radiographicallly-Confirmable Conditions			
Spondylolisthesis	15	4.8%	7
Scoliosis	32	10.2%	26
Collapsed Disc	10	3.2%	6
Longitudinal Data Series (enrollment in surgical outcomes study)			
Longitudinal-Baseline	34	10.8%	19
Longitudinal-Follow-up	32	10.2%	29

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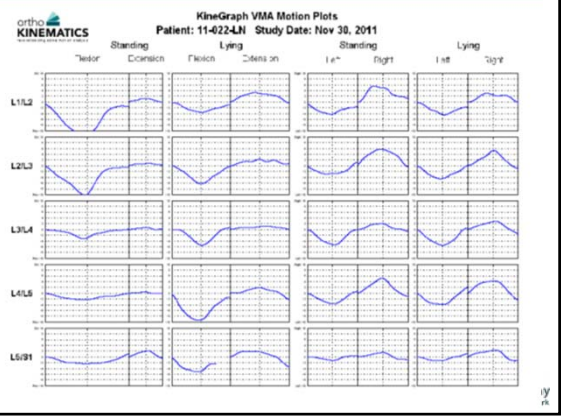

Chart Report

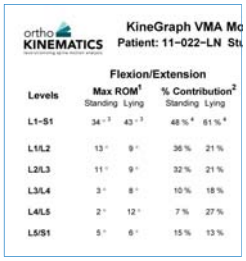

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Image Acquisition

Stills

- •Uncontrolled Bending
- •Image captured at end range & neutral
- •End range used to calculate Maximum Voluntary Bending Angle (MVBA)
- •Used as current "gold standard"

Cines

- Controlled bending
- Weighted and un-weighted
- ± 30 degrees FE and LB
- Processed with fully automated tracking algorithms
- Aim to replace standard FE x-rays with VMA

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Radiation Dose Risk Comparison

- KineGraph VMA testing exposures of 8 consecutive patients were compared to standard end-range x-rays in 8 consecutive patients

Table 2: Radiation dose equivalents (DRL_q) for the KineGraph VMA and end-range x-rays for different test protocols and bending configurations

Protocol	Single bend (either lying or standing)			Both lying and standing		
	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q
Flexion/ extension	0.38 mSv	0.50 – 0.75 mSv	51-76 %	0.76 mSv	1.0 – 1.5 mSv	51-76 %
Side bending	0.49 mSv	0.70 – 1.05 mSv	47-70 %	0.98 mSv	1.4 – 2.1 mSv	47-70 %
Both flexion/ extension and side bending	0.87 mSv	1.2 – 1.8 mSv	48-73 %	1.74 mSv	2.4 – 3.6 mSv	48-73 %

- No increased risk compared to traditional weighted FE and LB x-rays
- VMA exposure significantly less than an equivalent standing and lying end-range x-ray series

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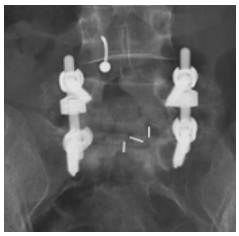
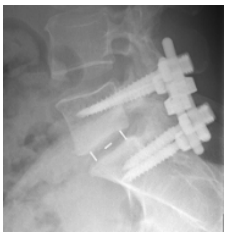
Single Level Dynamic Fusion (Patient 01)

Anterior Posterior



Lateral



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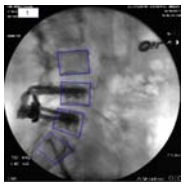
OrthoKinematics

Extension (Unweighted)

Flexion (Unweighted)



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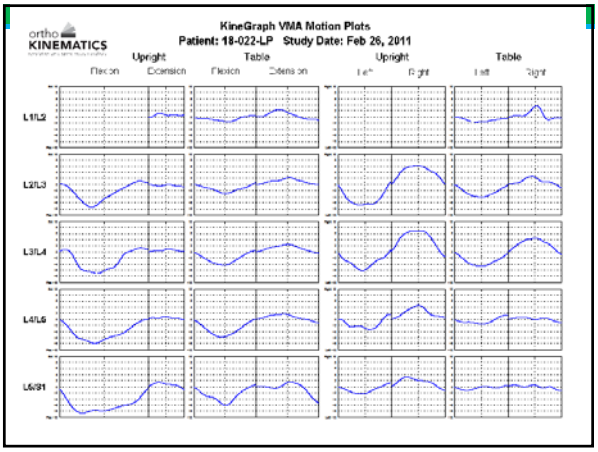


Conclusions

- A standardized technique that may help in the evaluation and treatment of patients with back pain
- The decision-making tree with respect to specific disease processes will take studied application in a controlled setting

Technology Overview

FDA-cleared in lumbar, label expansions in process

Lumbar: December 2011
Cervical, cloud operations: 510K submitted this week

Broad patent protection

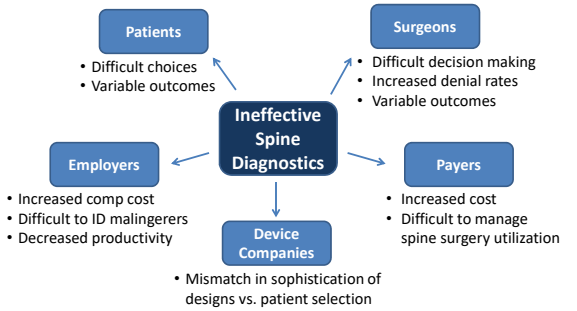
Key foundational patent already issued
Multiple fortress patents in prosecution

Key benefits already validated in clinical studies

Improved diagnostic outcomes
Reduced radiation exposure

1,000+ patients tested to date / has been operational in 10+ clinical sites

Big Effects Across the Board



OKI has a business line focused on each party

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Worker's Compensation

What it is:

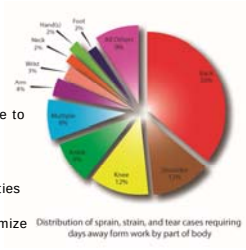
- Post Offer Employment Testing
- Functional Capacity Evaluations
- Injury Prevention
- Post Injury Management

Who is the customer:

- Worker's Compensation Payer
- Self-insured employers with workforce prone to back injury

How we add value

- Identify workers at risk of mechanical back injury for re-assignment to lower risk activities and injury prevention
- Provide objective evidence of injury to minimize expense due to malingerers



Why it is important

- Employers pay ~$1 billion per week for direct Worker's Compensation costs alone
- ***A single spine injury can cost an employer over $500K in claims***

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The VMA Vision

Replace today's 1940's era standard for functional testing of the spine <u>based on already-validated clinical benefits</u>

- More accuracy and reliable measurements
- Avoid false positives and false negatives
- Reduced radiation exposure to patient

<u>A NEW DIAGNOSTIC STANDARD OF CARE:</u>
Drive 100% adoption, similar to MRI in spine surgery, via the development of better spine instability & fusion criteria to improve pain relief success rates.

- SCENIC project is providing this this data
- Key clinical proof of concept already validated
- Results expected in the 2014-2015 timeframe

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Current 1940s-Era Standard of Care for Spine Functional Testing

"Flex/Ext": Flexion/Extension X-rays of the Spine

Standard X-rays taken at the end ranges of lumbar bending

Manual ruler & protractor measurements of vertebral motion

- 4MM per year ordered in US (2MM by spine surgeons; 2MM by others)
- Quantitative measurements of inter-vertebral motion, taken by measuring the motion between images, are used to detect spinal instability
- Spinal instability is the #1 most common primary diagnosis for fusion

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Issue: High Measurement Variability

Patients bend very differently from one another

A patient's bend can vary over time depending on many things, especially pain

The way flex/ex images are captured introduces highly problematic variability. Because patients can bend in highly variable ways, the resulting measurements taken from the flex/ex images of that bending is highly variable as well

Bending Variability = Measurement too variable

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Problems with Today's Standard

High bending variability leads to big diagnostic problems:

- Very high inconclusive rate (95%)—Can't Rule OUT problems
- Picks up ONLY the most obvious of problems, like grossly slipped discs
- High rates of false negatives (missed treatment opportunities)
- High rates of false positives (ineffective surgeries)

Because of this, spine surgeons face serious challenges

- Important questions go unanswered (can functional problems explain the pain?)
- Patient selection and patient outcomes can be highly variable

Ubiquitous today because it provides important information and there is no alternative

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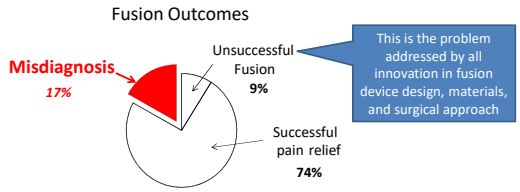
Misdiagnosis in Spine



- **Biggest need is better diagnostics**, not improved fusion technology.
- **Only ~5 companies** are focused on improving diagnostic technology.
- Of these, **OKI is the most commercially mature**

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Simple, Patented Fix

Our device (green) rests on the floor or on top of a standard imaging table.

To address bending variability, our patented patient handling device **controls and standardizes the bending of the subject during imaging**

- Our issued patent: Device to control the bending of a joint during imaging
- Ensures consistent bending effort, dramatically reducing variability
- Variability can ONLY be brought under control via our patented approach

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The VMA (Vertebral Motion Analysis)

Our Approach:	**Controlled Bending** +	**Video X-rays** +	**Computer Processing**
Instead of:	Variable bending	X-ray snapshots	Ruler & Protractor
Dramatic Improvements vs. Flex/Ext:	■ **68% better accuracy** ■ **79% better precision** ■ **46% less variability** ■ **29% less radiation dose**		

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How it Works

Hardware-enabled <u>services</u> model

Patented patient handling device	Standard C-Arm (fluoroscope)	Service: Derive diagnostic measurements from images
• MUST be used to control variability • We make & sell	• Widely available • VMA works with any C-arm • Images uploaded to us	• Image processing service • done by our staff using our proprietary software • Reports delivered to prescriber

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Easy to Adopt

Testing Workflow:

1. Capture uncontrolled "old school" static bending images:
   (*surgeons don't have to give up the old test to adopt the VMA)*
2. Do controlled motion + video fluoro imaging
3. Output files for upload to the cloud

Imaging: 30 minutes per test, vs. 20 for standard flex/ex

Results processed centrally at Ortho Kinematics
Current system: 24-48 hours
With current cloud implementation: 1 hour

Results streamed online via HIPPA-compliant cloud (browser, smartphone, or iPad)

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Well-Established Diagnostic Concept

	Controlled Input	Motion Imaging	Output
KineGraph VMA			• Reliable numeric data • Confirmable patient input • **Avoids missing treatable disease** • **Detects disease earlier in progression**
Cardiac Stress Test			

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Case Studies

See video case studies of the following cases:

- 17-049: Normal spine function
- 12-012, 16-002, 18-002: False negatives for Instability (2 cases)
- 16-041: False positives for instability
- 16-012: Post-Op Lumbar Disc Replacement

Summary of Benefits to Surgeon

Better diagnostic outcomes

- Picks up treatable disease that flex/ext misses
- Avoids "false positives"
- Better pinpoint mechanical sources of pain (i.e. which level)

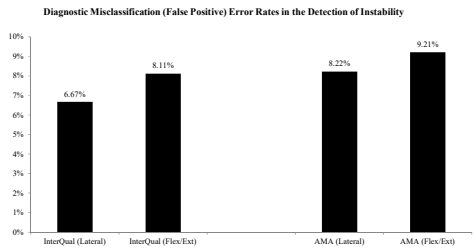
Much more valuable diagnostic information for surgeons

- Can rule problems OUT, not just rule problems in
- Provides definitive results on all patients
- Provides valuable patient consult tool

Adoption involves no surgeon risk-taking

- "Old Style" results are provided along with more reliable data
- Explicitly allowed under current guidelines

Misclassification in the Detection of Instability



*submitted for publication

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Failure is NOT *Uncommon*

- Gary Hart (Gary Warren Hartpence)
  - Senator from CO
  - 1975-1987
- Hart officially declares his candidacy on April 13, 1987.
- 1988 Democratic Party Presidential Nominee
  - 20 pt lead prior to picture
  - 'Monkey Business'

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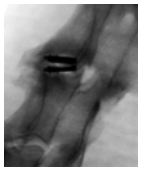
Sheep #387
6mm cTDR @ 6 mos.



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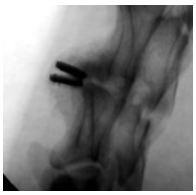
Sheep #398
7mm cTDR @ 6mos.



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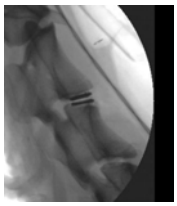
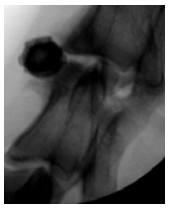
Sheep #388
7mm cTDR @ 6 mos.

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Sheep #396
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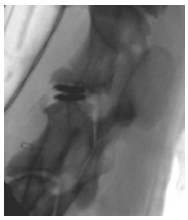

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Failure is NOT *Uncommon*

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Important Considerations:

Must understand anatomical function
- Normal
- Pathologic

Medical Device/ Engineering Principles
- Function of Implant – Design Intent
- Effect on Treated Tissue

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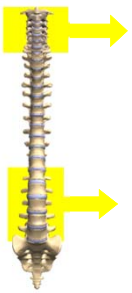
Spinal Anatomy:
Three Segments of the Spine



- Cervical Segment
  - 7 vertebrae
- Thoracic Spine
  - 12 vertebrae
- Lumbar Spine
  - 5 vertebrae

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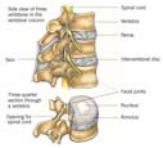
Functional Spinal Unit

- Basic building block of a spinal segment - Functional Spinal Unit (FSU)
  - Two Vertebral Bodies
  - Osteoligamentous Structures and Intervertebral Disc
- Three Joint Complex
  - Intervertebral Disc
  - Two Facet Joints



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Functional Spinal Unit

- Basic building block of each spinal segment: Functional Spinal Unit (FSU)
- Interdependent

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Treatments

- Nonsurgical
  - Physical therapy
  - Pain management
- Surgical
  - Functional Neurosurgery (spinal cord stimulation)
  - Decompression of offended nerve structures
    - Direct vs. Indirect
  - "Fixation" or "Re-stabilization"
    - Approaches
      - Posterior vs. Anterior vs. Lateral
      - Depending on the level of the spine, the anatomical structures targeted and the anatomical structures at risk in the procedure
    - Implants
      - Enormous variety, but they serve one of two purposes
        - Stabilize the spine while the vertebrae fuse together (by a new bony mass connecting them) – "Fusion"
        - Stabilize the spine without a fusion mass usually with the objective of allowing "near normal" amounts of motion – "Motion Preservation"

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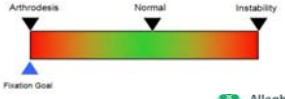
Biomechanical Goal: Rigid Fixation

- Fixation design rational
  - Provides immediate stabilization and fixation
  - Adjunct to fusion, i.e. "stiffens" FSU
- Clinical relevance
  - Reduce instability of pathologic FSU (< ROM)
  - correlated clinical outcomes to stiffness
- Metric
  - ROM



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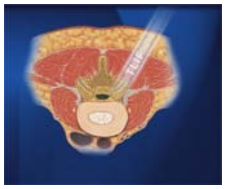
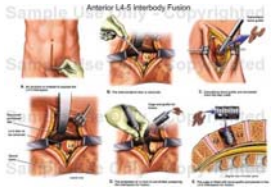
Fixation - Approaches





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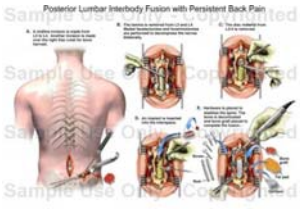
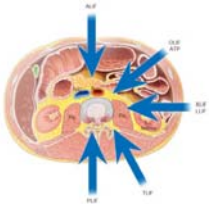
Fixation - Approaches





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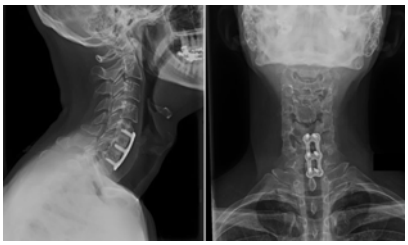
Implants – Pedicle Screw

Interbody Spacers

Cervical Plates

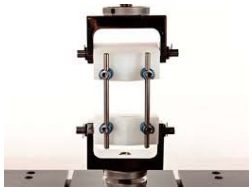


Cervical Fusion – Example At Follow Up

HOW?

- Benchtop studies
- In vitro biomechanics
- Clinical Studies – for another day

Benchtop Test



Background – *in vitro* testing

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M. M. Panjabi

"Pure Moment" in vitro biomechanical tests
- Simplifying assumption appropriate and very useful in comparative tests.

"Hybrid" test protocol for motion preserving devices
- Because pure moment should not be able to detect ALE

Neutral Zone
- Instability Hypothesis [2]

Many other studies and significant contributions through a long career pioneering the field of spine biomechanics

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Spine Biomechanical Testing

- Method of *Comparative* Testing
  - Flexion extension and lateral bending (pure moment testing – *flexibility protocol*)
  - Axial torsion and axial compression (are also important)

Biomechanical Evaluation of Spinal Fixation Devices: I. A Conceptual Framework

MANOHAR M. PANJABI, PhD, DTech

Panjabi, 1988

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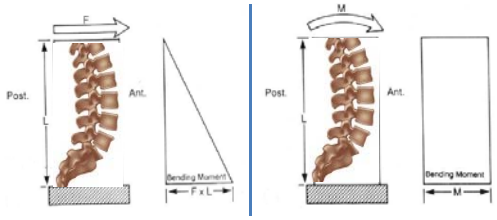
"Pure Moment" Testing

What bending moment does each intervertebral level see?



L5 > L1

Modified without permission from Panjabi, 1988

L5 = L1

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Manual Weight Hanging

- Discrete weights
- Pure moment bending
- 3D kinematic response
- Perfectly valid and still in use
- Fundamentally different from what we do

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University of Pittsburgh
Department of Orthopedic Surgery

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Spine Biomechanics Lab

- Bose 6DOF Spine Tester (Bad Boy)
- Optotrak (Certus) Motion Capture System
- Patient Imaging
  - Fluoroscopy, CT, DEXA
- Cadaveric biomechanical testing for the evaluation of spine implants

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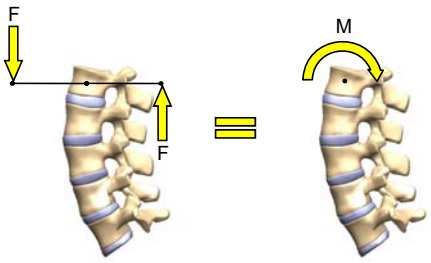
Equivalent Pure Moment Test Protocols



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Electromechanical System

- Automated continuous loading
- FE, LB, AT, AC or any combination thereof

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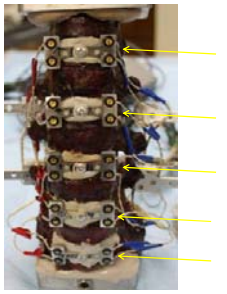
Vertebral Motion Tracking



- Traditionally, motion tracking has focused on the vertebrae with fixation typically on the vertebral bodies
- Rotational ROM has been the standard comparative metric

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Outcome Measures

- Fusion
  - ROM
    - relative change with optimum near 0
  - Load Sharing
  - Fusion Mass (animal and clinical only)
  - Clinical Outcomes (pain, quality of life)
- Non-Fusion
  - ROM
    - optimum unknown but assumed "near normal"
  - Measures of Laxity
    - Neutral Zone (Lax Zone)
    - Max Slope
    - Nonlinearity
  - Facet Articulation

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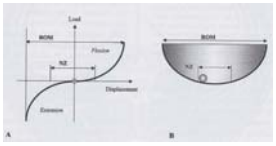
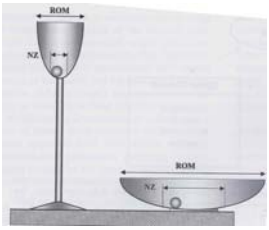
Measures of Laxity - Neutral Zone



The zone of extreme laxity around neutral posture



Reproduced without permission from Panjabi, 2003

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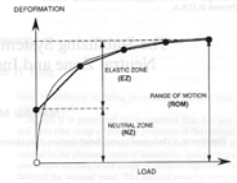
Neutral Zone



Reproduced without permission from Panjabi, 1992

- In these labs discrete weights are hung from a pulley system

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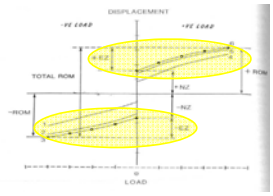
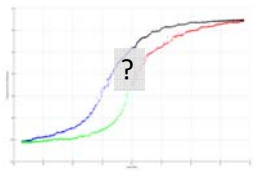
Neutral and Elastic Zones?

Quasistatic / Discrete loading



Continuous loading



Load vs. Angular Displacement (Blue=0-Flexion; Green=Flexion-0; Red=0-Extension; Black=Extension-0)

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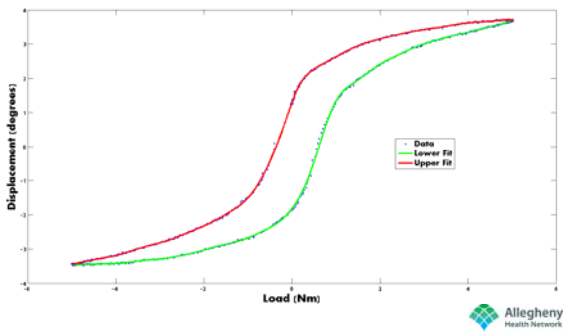
Hysteresis



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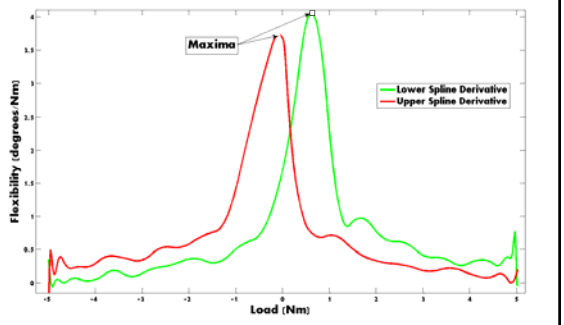
Derivative



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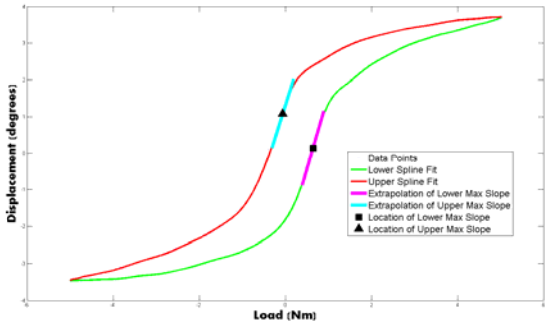
Max Slope Example



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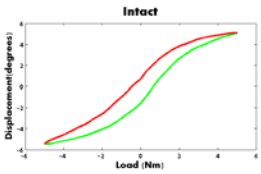
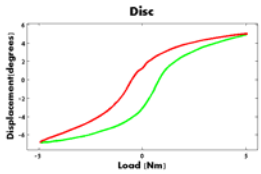
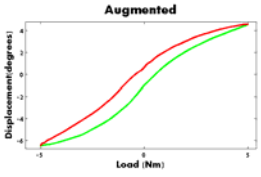
Hysteresis over Treatments

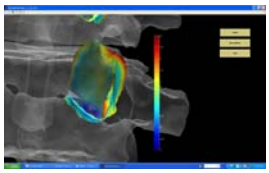




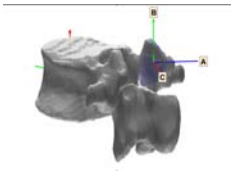


Analysis of Facet Articulation

Facet Distance Mapping



Facet Translation Analysis



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Biomechanical Flexibility Testing

- Baseline (Intact) parameters are obtained (ROM, NZ, etc.)
- Surgical Decompression is performed and Flexibility test is repeated
- Subsequent surgical interventions are performed and the testing is repeated
- Because of rarity and expense of samples, studies are small in sample size (n=6-10 for fusion), and paired analysis allows specimens to serve as their own control.

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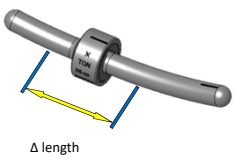
Posterior Dynamic Stabilization



Δ length

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Posterior Dynamic Stabilization

Next Gen PEEK

PEEK

Titanium

Dynesys

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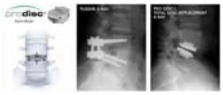
Disc Replacements



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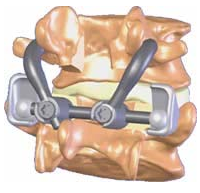
Facet Replacement



The Acadia Facet Replacement System

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Motion Analysis in the Lumbar Spine

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OKI Study Team

Dr Boyle Cheng
Daniel Cook MS
Matthew Yeager BS
Diane Cantella RN
Dorothy Packer RN

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Lumbar Instability and Post-Fusion Pseudarthrosis: Diagnostic Misclassification in Standard Bending Radiographs

October 2013
North American Spine Society

Boyle C. Cheng, PhD
Chip Wade, Ph.D.
Michael Oh, MD
Donald Whiting, MD
Richard Prostko, MD

Sunset Sail

D-C

Pre-op

46 yo male, Ht. 187cm, Wt. 101kg
Progressive LBP, numbness and tingling in buttocks and both legs R>L
Can only walk 5-7 min before needing to rest
Steroids & PT – no relief
MRI – congenitally narrow canal, R T11 disc herniation, disc bulge at L3-4 w lig hypertrophy causing spinal stenosis at that level. Bit of facet hypertrophy at L4-5.
VAS scores pre-op R leg =67 L leg =4 Back =27
Zurich Claudication Symptoms =3.28
Zurich Claudication Phys. Func. =2.6
Oswestry Score =56/100

D-C
6 months post-op

VAS scores R=2 L=0 Back = 1
Zurich Claudication Symptoms =1.57
Zurich Claudication Phys. Func. =1
Oswestry Score =20/100

D-C
2 years post-op

Doing well, minimal pain in foot intermittently

Quantity and Quality of Motion

Biomechanical metrics have been primarily based on fixation technology

Additional clinically relevant parameters would facilitate device design and be better suited for qualifying new technologies

Critical thinking skills are needed in defining quality of motion for spinal technologies

Everything looks like a nail…
Square peg and round hole…

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Significance

Standard of care (standing flex/ex X-Rays)
- introduced more than a half century ago
- functional testing of the spine

Radiographic diagnostic and outcome studies
- Segmental instability of the lumbar spine is suggested to be a major cause of low back pain
- Post-operative to a fusion, pseudarthrosis is a primary indication for revision surgery

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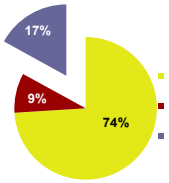
Diagnostic Inefficiencies in Spine Surgery



- *Misclassification* errors resulting from the methodology and reporting of radiological examinations are common place across radiographic modalities

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Investigational Objective

Investigate the rate of diagnostic misclassification errors (false positives and false negatives)

Specifically, misclassifications comparison between

- diagnosed using measurements of intervertebral motion taken from SBR
- radiographs measured throughout a range of continuous controlled motion

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Study Metrics

Diagnostic false positives and false negatives

- False positives were identified when the SBR measurement was above the disease threshold and the VMA measurements were below.
- False negatives were identified when the SBR measurement for a patient (either pre-op or post-op) was below the disease threshold and the VMA measurement was above.

Threshold Standards

- InterQual: 22° at any level
- AMA: (L1-L2 through L3-L4: 15º; L4-L5: 20º; L5-S1: 25º)
- FDA (pseudoarthrosis): < 5º

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Study Design

- Patients (n=202)
  - 47 asymptomatic volunteers
  - 45 symptomatic subjects being considered for spine surgery
  - 26 patients post-operative to fusion surgery
- Controlled continuous bending radiographs were conducted via vertebral motion analysis (VMA) (Ortho Kinematics, Inc; Austin, TX)

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Results

Conclusions

Current standard of care for detecting lumbar instability using standard bending radiographs results in both false positive and false negative type diagnostic misclassification errors.

Continuous controlled bending incorporating videoflouroscopy yields invaluable data focusing on not just the magnitude of the motion but the nature of the motion as well.

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Perfect Storm

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What is stability?

- Definition
- Theories

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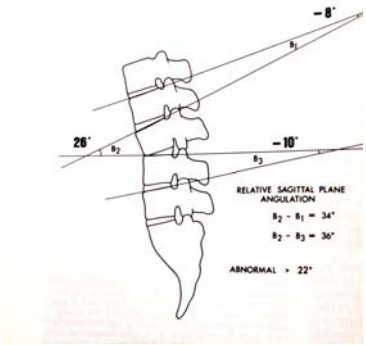
Rotational



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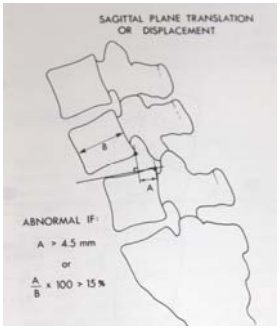
Translational



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Categories of Instability

- Acute
  - Overt
    - Limited
- Chronic
  - Glacial
    - Dysfunctional segmental motion

Does it really matter?

Appropriate initial diagnosis
Assist in logical design of treatment strategy
Tracking outcomes

Patient assessment

History and Physical
Testing
MRI
Myelo/CT
EMG
Bone scan
Xrays

Patient assessment

History and Physical
Testing
MRI
Myelo/CT
EMG
Bone scan
Xrays

Patient assessment

History and Physical
Testing
MRI
Myelo/CT
EMG
Bone scan
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Patient assessment

History and Physical
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Patient assessment

History and Physical
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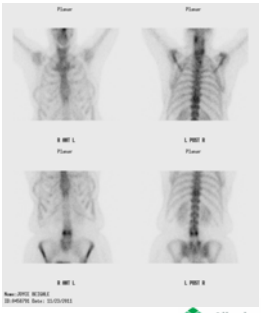
MRI
Myelo/CT
EMG
Bone scan
Xrays



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Patient assessment

History and Physical
Testing
MRI
Myelo/CT
EMG
Bone scan
Xrays

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Xrays
Static
Supine
Upright
Dynamic

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Problems with traditional flexion-extension films

- Variable extent of motion
- Unable to separate muscular and skeletal effects
- Only end-point data

Orthokinematics VMA Study

- Study to establish the accuracy, safety, and repeatability of VMA analysis
- Seven centers enrolling
- Initial cohort of asymptomatic normals as well as patients with a variety of pathologies

Enrollment Report

Subjects Imaged as of October 25, 2011			
Site	Patients	Normals	Withdrawn
Pittsburgh	27	0	1
Austin	0	8	0
Bristol	16	29	1
LA	16	24	1
Tampa	19	37	4
Baltimore	10	16	1
Totals	**88**	**114**	**8**

NOTE: Patients with multiple testing events are only counted once.

Analysis of Patient population

	Count of Levels	% of all 314 Levels with Standing Lateral Data	Levels with Head-to-Head MVBA Data (count)
Radiographicallly-Confirmable Conditions			
Anterior Fusion	4	1.3%	3
Posterior Fusion	17	5.4%	13
TDR (Total Disc)	3 (2 are same pt)	1.0%	2 (same pt)
Posterior Motion Preserving	4	1.3%	3
ISP (Inter-Spinous)	0	0.0%	0
Radiographicallly-Confirmable Conditions			
Spondylolisthesis	15	4.8%	7
Scoliosis	32	10.2%	26
Collapsed Disc	10	3.2%	6
Longitudinal Data Series (enrollment in surgical outcomes study)			
Longitudinal-Baseline	34	10.8%	19
Longitudinal-Follow-up	32	10.2%	29

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KineGraph VMA System

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KineGraph VMA System

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Image and Analysis

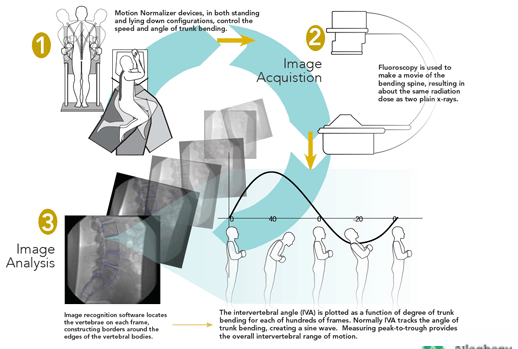

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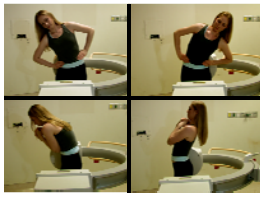
Image Acquisition

Stills



Cines

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Normal Video

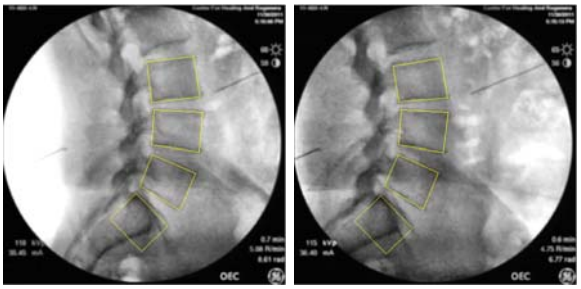

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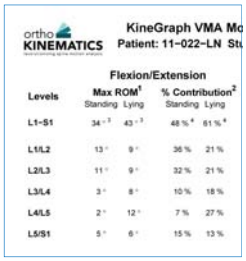
Chart Report



ortho KINEMATICS

KineGraph VMA Mo
Patient: 11-022-LN St

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	34 ° [3]	43 ° [3]	48 % [4]	61 % [4]
L1/L2	13 °	9 °	36 %	21 %
L2/L3	11 °	9 °	32 %	21 %
L3/L4	3 °	8 °	10 %	18 %
L4/L5	2 °	12 °	7 %	27 %
L5/S1	5 °	6 °	15 %	13 %

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Image Acquisition

Stills	Cines
•Uncontrolled Bending	• Controlled bending
•Image captured at end range & neutral	• Weighted and un-weighted
•End range used to calculate Maximum Voluntary Bending Angle (MVBA)	• ± 30 degrees FE and LB
•Used as current "gold standard"	• Processed with fully automated tracking algorithms
	• Aim to replace standard FE x-rays with VMA

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Radiation Dose Risk Comparison

- KineGraph VMA testing exposures of 8 consecutive patients were compared to standard end-range x-rays in 8 consecutive patients

Table 2: Radiation dose equivalents (DRL_q) for the KineGraph VMA and end-range x-rays for different test protocols and bending configurations

Protocol	Single bend (either lying or standing)			Both lying and standing		
	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q
Flexion/ extension	0.38 mSv	0.50 – 0.75 mSv	51-76 %	0.76 mSv	1.0 – 1.5 mSv	51-76 %
Side bending	0.49 mSv	0.70 – 1.05 mSv	47-70 %	0.98 mSv	1.4 – 2.1 mSv	47-70 %
Both flexion/ extension and side bending	0.87 mSv	1.2 – 1.8 mSv	48-73 %	1.74 mSv	2.4 – 3.6 mSv	48-73 %

- No increased risk compared to traditional weighted FE and LB x-rays
- VMA exposure significantly less than an equivalent standing and lying end-range x-ray series

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Radiation Dose Comparison

Summary table

Table 2: Radiation dose equivalents (DRL_q) for the KineGraph VMA and end-range x-rays for different test protocols and bending configurations

Protocol	Single bend (either lying or standing)			Both lying and standing		
	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q	KineGraph VMA® 120° of bending	End-range x-rays	KineGraph DRL_q as % of end-range x-ray DRL_q
Flexion/ extension	0.38 mSv	0.50 – 0.75 mSv	51-76 %	0.76 mSv	1.0 – 1.5 mSv	51-76 %
Side bending	0.49 mSv	0.70 – 1.05 mSv	47-70 %	0.98 mSv	1.4 – 2.1 mSv	47-70 %
Both flexion/ extension and side bending	0.87 mSv	1.2 – 1.8 mSv	48-73 %	1.74 mSv	2.4 – 3.6 mSv	48-73 %

Discussion

Taking into account the most expansive KineGraph VMA protocol, in which both flexion/extension and side bending are measured in both standing and lying postures, the third quartile dose equivalent (DRL_q) is 1.74 mSv. Assuming that the natural background radiation exposure for a person is about 2.5 mSv[7] per year, this equates to about 8 months of background radiation exposure. This is well below the radiation exposure associated with other commonly prescribed diagnostic procedures, as listed below[7]:

- CT of abdomen or pelvis: 10 mSv
- CT of chest: 8 mSv
- Barium enema: 7 mSv

The risk associated with an exposure of around 1 mSv is associated with an increased risk of developing cancer of between 1 in 10,000 and 1 in 100,000[8]. This risk is considered by the International Commission on Radiological Protection as "Very Low," especially when considering that the overall lifetime risk for the general population of developing cancer is 1 in 3 and of dying from cancer is 1 in 4. Note that this increased cancer risk was calculated using a theoretical model, not based on actual observations. There is currently no consensus regarding whether these theoretical models are meaningful, but an excess of fatal cancers have never been detected in lab animals or humans for doses below 100 mSv[9,10]. Further, in the U.S., the maximum allowable radiation dose for professionals who work with radiation (e.g. x-ray technologists and radiologists) is 50 mSv.[11]

Conclusion

The KineGraph VMA provides a significant upgrade to the current standard of care. Hundreds of fluoroscopic images of the moving spine are collected and analyzed, as opposed to the 2 or 3 static images in the end-range x-ray method. This gives surgeons a more comprehensive picture of spine motion and more reliable, actionable measurements of spine function. Yet, the KineGraph VMA involves less radiation than the current standard of care for conducting end-range x-rays of the lumbar spine. This level of radiation is well below that associated with other commonly-prescribed diagnostic procedures, and the risk associated with radiation in this range is considered very low.

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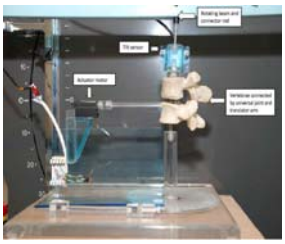
Accuracy Study



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Accuracy Results

Measure-ment	Descriptive Statistic Used in Zhao	Comparator: Target to achieve to be no worse than the standard of care:	Measured Value for KineGraph VMA	Pass
IVR (Sagittal) from null motion	Mean error ± std. dev, and max	Equal to or less than:: 1.2° ± 0.9° (max: 4.0°)	0.1° ± 0.0° (max: 0.1°)	Yes
IVR (Sagittal) from known motion	95% CI of the mean error	Equal to or less than: 1.7° - 2.7°	0.4° - 0.9° (max: 1.4°)	Yes
IVT (Sagittal) from known motion	Mean error ± std. dev	Comparable to: 0.5 mm ± 0.3 mm	0.5 mm ± 0.4 mm	Yes
IVR (Coronal) from null motion	Mean error ± std. dev, and max	Comparable to: 0.1° ± 0.0° (max: 0.1°)	0.1° ± 0.0° (max: 0.1°)	Yes
IVR (Coronal) from known motion	Mean error ± std. dev, and max	No higher than: 0.7° ± 0.4° (max: 1.4°)	0.2° ± 0.2° (max: 0.5°)	Yes

Comparator: Ruler & Protractor method

Comparator: Automated software

KIMAX QMA, Medical Metrics.

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Accuracy Results

- **No less accurate than Ruler and Protractor method**
- **No less accurate than Medical Metrics KIMAX QMA**

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Repeatability Testing Methodology

Question: *How much disagreement between different measurements taken from the same images?*

APPROACH:

Three MDs analyze the same input image set in three ways

1.ruler & protractor,

2.Using our software in "manual" mode

3.In "Automatic" Mode

Component	Description	Shorthand "build" of the analyses conducted
Input image set	A set of retrospectively-acquired images from 62 patients representative of the KineGraph VMA expected clinical population	$1_{\text{input set}}$
Three measurement systems (i –iii)	i. KineGraph VMA automated tracking measurements ii. KineGraph VMA manual templating measurements iii. Standard of care (ruler and protractor) measurements	$1_{\text{input set}} \times 3_{\text{systems}}$
Observers	Three observers conduct measurements for each of the three measurement systems (not the same three observers across all three measurement systems)	$1_{\text{input set}} \times 3_{\text{systems}} \times 3_{\text{observers}}$
Multiple Analyses (1-2)	Each observer does each analysis twice, at least two weeks apart	$1_{\text{input set}} \times 3_{\text{systems}} \times 3_{\text{observers}} \times 2_{\text{analyses}}$
TOTAL	Input image set is analyzed a total of 18 times	1 x 3 x 3 x 2 = 18 individual analyses of the input image set by an observer
	Image input set contains images from 62 patients	18 x 62 = 1,116 individual patient analyses
	205 levels of IVR and IVT data across the 62 patients	18 x 205 = 3,690 patient levels of IVR and IVT data

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Repeatability Results

	VMA	Ruler & Prot.
	Mean Error	Mean Error
Rotation (degrees)		
Inter-Observer	0.7	3.3
Intra-Observer	0.4	3.1
Translation (% VBD)		
Inter-Observer	1.1 %	4.9 %
Intra-Observer	0.6 %	4.2 %

- **Mean error lower than Ruler and Protractor method in rotation and translation**

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Repeatability Results

General Study Population (n = 62)

	KineGraph VMA Automated Tracking Measurement			KineGraph VMA Manual Templating Measurements			Standard of Care Ruler & Protractor Method		
	Lower 95% CI	Mean Abs. Error	Upper 95% CI	Lower 95% CI	Mean Abs. Error	Upper 95% CI	Lower 95% CI	Mean Abs. Error	Upper 95% CI
Rotation (degrees)									
Inter-Observer	0.6	0.7	0.8	2.3	2.4	2.5	3.2	3.3	3.5
Intra-Observer	0.3	0.4	0.4	1.9	2.1	2.2	2.8	3.1	3.3
Translation (% VBD)									
Inter-Observer	1.1%	1.1%	1.2%	3.2%	3.4%	3.5%	4.6%	4.9%	5.2%
Intra-Observer	0.6%	0.6%	0.7%	2.8%	3.0%	3.2%	3.8%	4.2%	4.6%

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MVBA: Literature vs VMA

- **MVBAs compared to reported values in literature***

	From Literature		From OKI-103 (MVBA)	
	Mean	Std Dev	Mean	Std Dev
L2-L1	10.6	3.8	7.5	4.2
L3-L2	11.6	4.4	11.3	4.8
L4-L3	11.8	5.1	10.2	5.2
L5-L4	13.8	6.0	12.0	7.0
S1-L5	11.9	6.4	8.0	6.1
Avg.	**11.9**	**5.1**	**9.8**	**5.5**

The values obtained for uncontrolled flex/ext were not significantly different

* Deitz AK, Breen AC, Mellor FE, Teyhen DS, Wong KWN, Panjabi MM. Kinematics of the aging spine: A Review of Past Knowledge and Survey of Recent Developments, with a Focus on Patient-Management Implications for the Clinical Practitioner, In The Comprehensive Treatment of the Aging Spine: Minimally Invasive and Advanced Techniques (eds. by Yue, Guyer, Johnson, Khoo, Hochschuler) Elsevier, in press.

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Inter-Subject Variability: Flex/Ext

	Uncontrolled Flex/Ext MVBA			KineGraph VMA: Standing Lateral			KineGraph VMA: Lying Lateral		
	Mean	Std Dev	Count	Mean	Std Dev	Count	Mean	Std Dev	Count
L2-L1	7.5	4.2	55	8.6	3.5	34	5.9	2.3	61
L3-L2	11.3	4.8	55	10.2	3.7	57	6.9	2.3	74
L4-L3	10.2	5.2	55	9.0	4.0	65	7.6	2.5	78
L5-L4	12.0	7.0	55	8.3	4.4	59	9.1	3.3	75
S1-L5	8.0	6.1	55	10.4	4.7	49	8.5	4.2	62
Avg.	**9.8**	**5.5**	**55**	**9.3**	**4.1**	**53**	**7.6**	**2.9**	**70**

- Inter-Subject Variability reduced for lying KGVMA vs. Standing uncontrolled MVBA

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Inter-Subject Variability: Left/Right

	Uncontrolled Left/Right MVBA			KineGraph VMA: Standing A/P			KineGraph VMA: Lying A/P		
	Mean	Std Dev	Count	Mean	Std Dev	Count	Mean	Std Dev	Count
L2-L1	6.5	4.2	55	8.0	2.9	69	6.3	2.3	77
L3-L2	9.7	4.6	55	9.6	2.8	72	8.9	2.2	79
L4-L3	10.1	4.5	55	10.0	3.1	75	9.9	2.8	80
L5-L4	7.1	4.0	55	8.6	3.8	75	9.3	3.1	79
S1-L5	1.8	1.5	50	3.0	1.5	75	3.8	2.1	78
Avg.	**7.0**	**3.7**	**54**	**7.8**	**2.8**	**73**	**7.6**	**2.5**	**79**
% Change (vs. MVBA)				**11%**	**-25%**		**8%**	**-33%**	

- Inter-Subject Variability reduced for lying KGVMA vs. Standing uncontrolled MVBA

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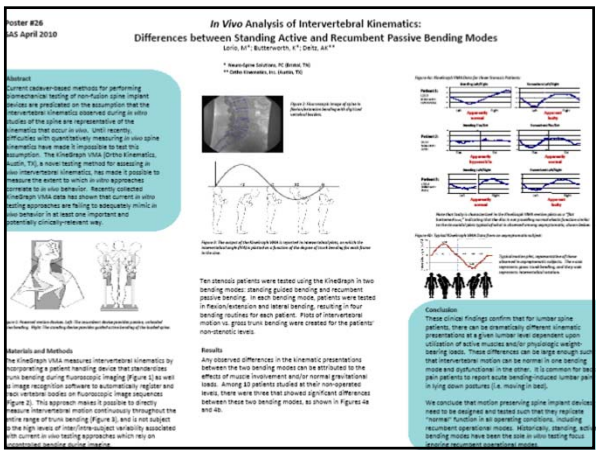

Poster #26
SAS April 2010

In Vivo Analysis of Intervertebral Kinematics:
Differences between Standing Active and Recumbent Passive Bending Modes

Lorio, M.*; Butterworth, K.*; Deitz, AK.**

* Neuro-Spine Solutions, PC (Bristol, TN)
** Ortho Kinematics, Inc. (Austin, TX)

Abstract

Current cadaver-based methods for performing biomechanical testing of non-fusion spine implant devices are predicated on the assumption that the intervertebral kinematics observed during in vitro studies of the spine are representative of the kinematics that occur in vivo. Until recently, difficulties with quantitatively measuring in vivo spine kinematics have made it impossible to test this assumption. The KineGraph VMA (Ortho Kinematics, Austin, TX), a novel testing method for assessing in vivo intervertebral kinematics, has made it possible to measure the extent to which in vitro approaches correlate to in vivo behavior. Recently collected KineGraph VMA data has shown that current in vitro testing approaches are failing to adequately mimic in vivo behavior in at least one important and potentially clinically-relevant way.

Materials and Methods

The KineGraph VMA measures intervertebral kinematics by incorporating a patient handling device that standardizes trunk bending during fluoroscopic imaging (Figure 1) as well as image recognition software to automatically register and track vertebral bodies on fluoroscopic image sequences (Figure 2). This approach makes it possible to directly measure intervertebral motion continuously throughout the entire range of trunk bending (Figure 3), and is not subject to the high levels of inter/intra-subject variability associated with current in vivo testing approaches which rely on

Ten stenosis patients were tested using the KineGraph in two bending modes: standing guided bending and recumbent passive bending. In each bending mode, patients were tested in flexion/extension and lateral bending, resulting in four bending routines for each patient. Plots of intervertebral motion vs. gross trunk bending were created for the patients' non-stenotic levels.

Results

Any observed differences in the kinematic presentations between the two bending modes can be attributed to the effects of muscle involvement and/or normal gravitational loads. Among 10 patients studied at their non-operated levels, there were three that showed significant differences between these two bending modes, as shown in Figures 4a and 4b.

Conclusion

These clinical findings confirm that for lumbar spine patients, there can be dramatically different kinematic presentations at a given lumbar level dependent upon utilization of active muscles and/or physiologic weight-bearing loads. These differences can be large enough such that intervertebral motion can be normal in one bending mode and dysfunctional in the other. It is common for back pain patients to report acute bending-induced lumbar pain in lying down postures (i.e. moving in bed).

We conclude that motion preserving spine implant devices need to be designed and tested such that they replicate "normal" function in all operating conditions, including recumbent operational modes. Historically, standing, active bending modes have been the sole in vitro testing focus

Discussion Cases

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18-007 LBJ

73 y/o homemaker w hx of multiple spinal surgeries
1st seen 9/2009 w LBP, bil LE pain
10/09 L3-4 laminectomy
10/10 pain recurred
Radiographic studies
- MRI
- orthoKinematic

Refused surgery, responded to ESI

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MRI - X-Ray

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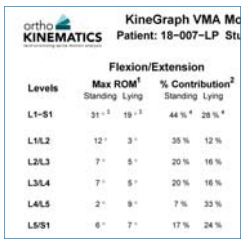
KineGraph VMA Motion Report
Patient: 18–007–LP Study Date: Oct 16, 2010

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1–S1	31 ° [3]	19 ° [3]	44 % [4]	28 % [4]
L1/L2	12 °	3 °	35 %	12 %
L2/L3	7 °	5 °	20 %	16 %
L3/L4	7 °	5 °	20 %	16 %
L4/L5	2 °	9 °	7 %	33 %
L5/S1	6 °	7 °	17 %	24 %



KineGraph VMA Mo
Patient: 18–007–LP St

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1–S1	31 ° [3]	19 ° [3]	44 % [4]	28 % [4]
L1/L2	12 °	3 °	35 %	12 %
L2/L3	7 °	5 °	20 %	16 %
L3/L4	7 °	5 °	20 %	16 %
L4/L5	2 °	9 °	7 %	33 %
L5/S1	6 °	7 °	17 %	24 %

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18-019 AMW

80 y/o retired
Back and Bil. LE pain
Surgical History
- 6/2002 L4-5 laminectomy
- 9/2009 L4-5 discectomy
- 11/2011 L3-4-5 fusion

Imaging
- orthoKinematic 1/2011

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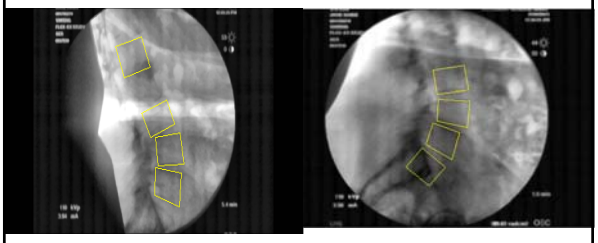
18-019



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18-019

KineGraph VMA Motion Report
Patient: 18-019-LP Study Date: Jan 08, 2011

Flexion/Extension — Left/Right

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	N/R [3]	N/R [3]	N/R [4]	N/R [4]
L1/L2	N/R	N/R	N/R	N/R
L2/L3	N/R	N/R	N/R	N/R
L3/L4	N/R	5 °	N/R	N/R
L4/L5	N/R	N/R	N/R	N/R
L5/S1	N/R	N/R	N/R	N/R

Slip[3] — MVBA[4]

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18-022 ELH

66 y/o retired w 2 yr hx LBP and leg pain
Conservative Rx w some relief
- Chiropractor
- TENS, VAX-D

MRI- L4-5 stenosis w Gr 1 spondy
L4-5 laminectomy with Total Facet Arthroplasty in 1/2009
2/2011 orthoKinematics imaging

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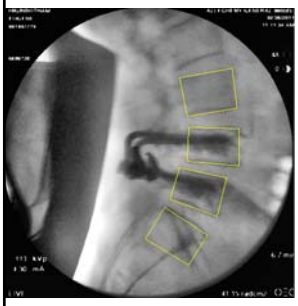
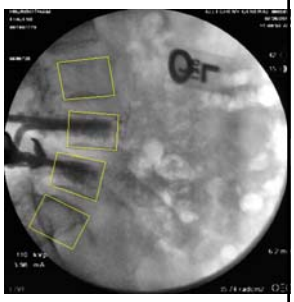
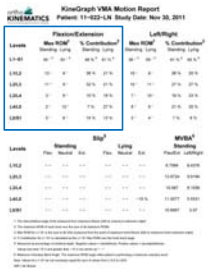
ALLEGHENY GENERAL
ALLEGHENY GENERAL

L
EXTENSION
UPRIGHT
ALLEGHENY GENERAL
ALLEGHENY GENERAL

FLEXION
UPRIGHT
ALLEGHENY GENERAL
ALLEGHENY GENERAL





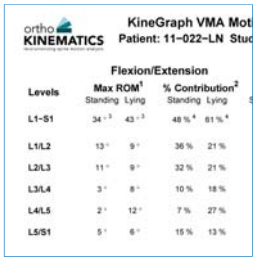


KineGraph VMA Motion Report
Patient: 11-022-LN Study Date: Nov 30, 2011

Flexion/Extension — Left/Right

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	34 °[3]	43 °[3]	48 %[4]	61 %[4]
L1/L2	13 °	9 °	36 %	21 %
L2/L3	11 °	9 °	32 %	21 %
L3/L4	3 °	8 °	10 %	18 %
L4/L5	2 °	12 °	7 %	27 %
L5/S1	5 °	6 °	15 %	13 %

Slip[5] — MVBA[6]



KineGraph VMA Mot
Patient: 11-022-LN Stud

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	34 °[3]	43 °[3]	48 %[4]	61 %[4]
L1/L2	13 °	9 °	36 %	21 %
L2/L3	11 °	9 °	32 %	21 %
L3/L4	3 °	8 °	10 %	18 %
L4/L5	2 °	12 °	7 %	27 %
L5/S1	5 °	6 °	15 %	13 %

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JLB 18-025

58 y/o
L4 stenosis and HNP since 2006
Conservative Rx
Total Facet Arthroplasty 10/2008
orthoKinematics imaging 05/2011
Recently 6 month Hx of S-I pain
OK re-imaging 12/2011

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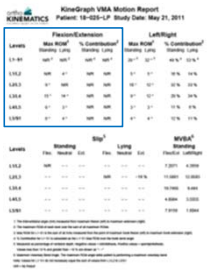
Post Op

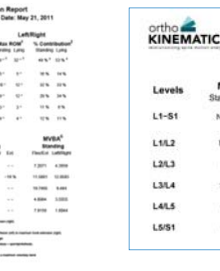
Initial Post-Op

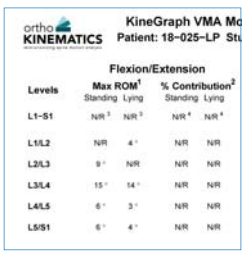


KineGraph VMA Motion Report
Patient: 18-025-LP Study Date: May 21, 2011

Levels	Flexion/Extension Max ROM[1] Standing	Flexion/Extension Max ROM[1] Lying	Flexion/Extension % Contribution[2] Standing	Flexion/Extension % Contribution[2] Lying	Left/Right Max ROM[1] Standing	Left/Right Max ROM[1] Lying	Left/Right % Contribution[2] Standing	Left/Right % Contribution[2] Lying
L1-S1	N/R [3]	N/R [3]	N/R [4]	N/R [4]				
L1/L2	N/R	4°	N/R	N/R				
L2/L3	9°	N/R	N/R	N/R				
L3/L4	15°	14°	N/R	N/R				
L4/L5	6°	3°	N/R	N/R				
L5/S1	6°	4°	N/R	N/R				

Levels	Slip[3] Standing Flex.	Slip[3] Standing Neutral	Slip[3] Standing Ext.	Slip[3] Lying Flex.	Slip[3] Lying Neutral	Slip[3] Lying Ext.	MVBA[4] Standing Flex/Ext	MVBA[4] Standing Left/Right
L1/L2	N/R	---	---	---	---	---	7.3771	4.3556
L2/L3	---	---	---	N/R	---	19 %	11.0881	12.6040
L3/L4	---	---	---	---	---	---	19.7455	9.4441
L4/L5	---	---	---	---	---	---	4.5884	3.5555
L5/S1	---	---	---	---	---	---	7.9155	1.6944





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Recent X-Ray

Allegheny Health Network

Late Post-Op

ortho KINEMATICS

KineGraph VMA Motion Report
Patient: 18-025-LP Study Date: Dec 10, 2011

Flexion/Extension — Left/Right

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	N/R [3]	26 ° [3]	N/R [4]	36 % [4]	30 ° [3]	27 ° [3]	44 % [4]	32 % [4]
L1/L2	N/R	5 °	N/R	17 %	12 °	4 °	35 %	15 %
L2/L3	10 °	8 °	N/R	28 %	9 °	10 °	35 %	33 %
L3/L4	9 °	8 °	N/R	29 %	4 °	10 °	15 %	33 %
L4/L5	5 °	3 °	N/R	11 %	4 °	2 °	11 %	7 %
L5/S1	5 °	4 °	N/R	15 %	6 °	5 °	16 %	15 %

Slip[1]

Levels	Standing Flex.	Standing Neutral	Standing Ext.	Lying Flex.	Lying Neutral	Lying Ext.
L1/L2	---	---	N/R	-15 %	---	---
L2/L3	---	---	-10 %	---	-16 %	-27 %
L3/L4	---	---	-27 %	-27 %	---	---
L4/L5	---	---	---	---	---	---
L5/S1	---	---	---	---	---	---

MVSA[2]

Levels	Standing Flex/Ext	Standing Left/Right
L1/L2	0.000	7.2865
L2/L3	10.0000	5.0001
L3/L4	11.7216	9.6707
L4/L5	0.0625	2.5001
L5/S1	4.0312	1.443

[1] The Instantaneous angle of the measured from maximum flexion with to maximum extension angle.
[2] Contribution for L1-S1 is calculated as the L1-S1 Max ROM over the total same angle.
[3] Data N/A for L1-L2 is the sum of all the measured from the point of maximum flexion with to maximum extension angle.
[4] % Contribution for L1-S1 is calculated as the L1-S1 Max ROM over the total same angle.
Values less than 1 % and greater than -1 % are shown as 0 °.
A maximum Vertebral Body Slip. The maximum VSA angle value pattern is performing a maximum vertebral body.
N/R = No Result

ortho KINEMATICS

KineGraph VMA Mo
Patient: 18-025-LP Stu

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	N/R [3]	26 ° [3]	N/R [4]	38 % [4]
L1/L2	N/R	5 °	N/R	17 %
L2/L3	10 °	8 °	N/R	28 %
L3/L4	9 °	8 °	N/R	29 %
L4/L5	5 °	3 °	N/R	11 %
L5/S1	5 °	4 °	N/R	15 %

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18-020 N-T

- 58 y/o realtor
- Hx of LBP and leg pain since 2007
- Imaging showed spondy
- Treated conservatively for several years
- orthoKinematics 02/05/10
- L4-5 fusion 02/2011
- Repeat orthoKinematics imaging 7/2011

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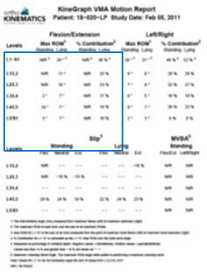
Allegheny Health Network



ortho KINEMATICS

KineGraph VMA Motion Report
Patient: 18-020-LP Study Date: Feb 08, 2011

Flexion/Extension — Left/Right

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	N/R [3]	26 ° [3]	N/R [4]	36 % [4]	30 ° [3]	31 ° [3]	44 % [4]	32 % [4]
L1/L2	N/R	11 °	N/R	25 %	9 °	9 °	35 %	29 %
L2/L3	N/R	10 °	N/R	23 %	7 °	4 °	23 %	27 %
L3/L4	2 °	7 °	N/R	17 %	6 °	5 °	19 %	19 %
L4/L5	10 °	7 °	N/R	18 %	6 °	3 °	26 %	23 %
L5/S1	3 °	7 °	N/R	16 %	2 °	3 °	8 %	8 %

Slip[1]

Levels	Standing Flex.	Standing Neutral	Standing Ext.	Lying Flex.	Lying Neutral	Lying Ext.
L1/L2	N/R	---	---	---	---	-15 %
L2/L3	N/R	-16 %	-10 %	---	---	---
L3/L4	---	---	---	---	---	---
L4/L5	25 %	24 %	19 %	22 %	24 %	23 %
L5/S1	---	---	---	---	---	---

MVSA[2]

Levels	Standing Flex/Ext	Standing Left/Right
L1/L2	N/R	N/R
L2/L3	N/R	N/R
L3/L4	N/R	N/R
L4/L5	N/R	N/R
L5/S1	N/R	N/R

[1] The Instantaneous angle of the measured from maximum flexion with to maximum extension angle.
[2] Contribution for L1-S1 is calculated as the L1-S1 Max ROM over the total same angle.
[3] Data N/A for L1-L2 is the sum of all the measured from the point of maximum flexion with to maximum extension angle.
[4] % Contribution for L1-S1 is calculated as the L1-S1 Max ROM over the total same angle.
Values less than 1 % and greater than -1 % are shown as 0 °.
A maximum Vertebral Body Slip. The maximum VSA angle value pattern is performing a maximum vertebral body.
N/R = No Result

ortho KINEMATICS

KineGraph VMA Mo
Patient: 18-020-LP Stu

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	N/R [3]	26 ° [3]	N/R [4]	36 % [4]
L1/L2	N/R	11 °	N/R	25 %
L2/L3	N/R	10 °	N/R	23 %
L3/L4	2 °	7 °	N/R	17 %
L4/L5	10 °	7 °	N/R	18 %
L5/S1	3 °	7 °	N/R	16 %

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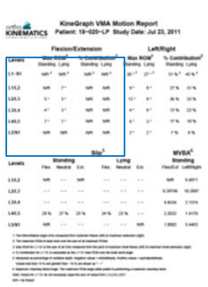

ortho KINEMATICS

KineGraph VMA Mo
Patient: 18-020-LP Stu

Flexion/Extension

Levels	Max ROM[1] Standing	Max ROM[1] Lying	% Contribution[2] Standing	% Contribution[2] Lying
L1-S1	NR [3]	NR [3]	NR [4]	NR [4]
L1/L2	NR	7 °	NR	NR
L2/L3	5 °	3 °	NR	NR
L3/L4	4 °	3 °	NR	NR
L4/L5	7 °	7 °	NR	NR
L5/S1	NR	NR	NR	NR

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Radiographic Instability (rotational) / Radiographic non-union of a fused level Limits

Diagnostic criteria for surgery, in conjunction with results from physical findings and other studies:

- Radiographic Instability (rotational) as an indication for fusion surgery:
  - InterQual: > 22 degrees
  - AMA Guides (5th Ed.):
    - L1/L2 – L3/L4: >15 degrees
    - L4/L5: > 20 degrees
    - L5/S1: > 25 degrees
- Non-union of a fused level as an indication for revision surgery
  - FDA: ≥ 5 degrees

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Conclusions

A new technique that may help in the evaluation and treatment of patients with back pain

The decision-making tree with respect to specific disease processes will take studied application in a controlled setting

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Sunset Sail

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