VMA: Spine's New Standard for Instability Testing
Game-Changing Technology: VMA Advanced Functional Imaging

- 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
The Flex/ex has Significant Limitations

The flex/ex is prescribed 5 million times per year (US)
- Higher volume than spine MRI + CT combined

The flex/ex impacts decisions for 1.9 million surgeries / year
- A positive test indicate a patient for fusion surgery (500K/year, US)
- A negative test qualify a patient to potentially receive decompression surgery (600K/year) or spine pain injections (800K/year)

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.”

The continued use of flex/ex demonstrates how important functional testing is in the workup of patients for spine surgery
VMA is an Attractive Alternative to the Flex/Ex

Helps identify more patients with lumbar radiographic instability
More informed decision making & patient selection
Online tools that make a surgeon’s job easier

Device-Assisted Bending During Imaging + Enterprise Software and Big Data

✅ See FDA-cleared lumbar and cervical indications for use
✅ Uses standard C-arms (fluoroscopes) to generate images
✅ Covered under existing category I CPT codes*

* Ortho Kinematics, Inc. does not provide coding advice, however customers have reported receiving reimbursement for VMA testing under current Category I CPT codes.
How VMA Works
• Motion summary clearly shows at C3/C4 the patient had no measurement result (nr) in a voluntary bend.

• Controlled bend using the VMA, motion increased up to 27 degrees.

• Had the patient just received a standard Flex/Ex, no trigger would be alerted for meeting minimum threshold.
Flex/Ex vs. VMA for Detecting Radiographic Instability

**Flex/ex:**
X-rays of **Uncontrolled Bending**

- **Devices assure sufficient bending in both standing and lying postures to maximize the chance that existing instability is provoked.**
- **5.5% prevalence of lumbar radiographic instability** (1).

**VMA:**
**Devices Control Bending** **During X-rays**

- **Easy for patients to avoid painful positions, and therefore avoid provoking instability.**
- **11.5% prevalence of lumbar radiographic instability** (1).

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(1) Lumbar radiographic instability is defined as 5.3 millimeters or more of translation on flexion/extension radiographs.
Spine Surgeons Lack Reliable Function Tests Critical to Other Surgeons

<table>
<thead>
<tr>
<th>Non-Specific Spine Pain</th>
<th>Non-Specific Chest Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONE</strong> option: the 1940s-era <strong>flex/ex</strong></td>
<td><strong>MULTIPLE</strong> advanced technologies</td>
</tr>
<tr>
<td>Functional Tests Used to Select Surgery Patients</td>
<td>Stress EKG, Echocardiogram, Angiography</td>
</tr>
<tr>
<td>Related Surgeries</td>
<td><strong>1.1 million</strong></td>
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<tr>
<td>1.1 million</td>
<td><strong>1.1 million</strong></td>
</tr>
<tr>
<td>Fusion surgery, decompression surgery</td>
<td>Stent, Coronary Artery Bypass Graft (CABG)</td>
</tr>
<tr>
<td>Surgical Success Rate</td>
<td>74%</td>
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</table>

Rev. 1095-1.0 (9/2016)
Misdiagnosis in Spine

Lumbar Fusion Outcomes

Misdiagnosis 17%

Unsuccessful Fusion 9%

Successful pain relief 74%

Biggest need is better diagnostics, not improved fusion technology
<5 companies focused on developing next-gen diagnostics

(1) From Meta-analysis of Medical Literature. Data on file at OKI.
Case Study: Fusion Assessment

CASE STUDY: Assess Cervical Fusion Status
Role of Instability in Spine Surgery

For more than 50% of spine surgeries, pre-existing instability at a target or adjacent level can directly drive the decision to fuse vs. decompress.

Spine Surgery Indications (% of all spine surgeries), Ranked by % Fusion vs. Decompression

- Fracture / trauma (4%)
- Spondylolisthesis (12%)
- Disc Pathology (9%)
- Deformity (5%)
- Surgery Revision (4%)
- Spondylosis (13%)
- Stenosis (12%)
- Displaced Disc (18%)
- Tumor (<1%)
- All Other (10%)
- Pain / Neuro Symptoms (13%)

Indications in which instability can drive decision to fuse vs. decompress.

Other indications

Source: National Hospital Discharge Survey, National Ambulatory Medical Care Survey, National Hospital Ambulatory Care Survey. All published by US Centers for Disease Control & Population, 2010
<table>
<thead>
<tr>
<th>Topic</th>
<th>Summary</th>
<th>References</th>
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<tr>
<td><strong>Sensitivity &amp; Specificity</strong></td>
<td>A Level I evidence study of 509 patients and 73 asymptomatic controls. VMA demonstrated no less than a 41% increase in the sensitivity of detecting lumbar radiographic instability, with the same 98%+ specificity. This study used a .3 mm threshold for instability.</td>
<td>Davis, RJ, et. al. “Measurement Performance of a Computer Assisted Vertebral Motion Analysis System.” <em>International Journal of Spine Surgery</em> (2015). Vol. 9. Article 36.</td>
</tr>
<tr>
<td>Radiation dose</td>
<td>The radiation exposure from 74 VMA studies was directly compared to the radiation exposure from 27 flex/ex* studies. After accounting for differences between the two groups with respect to age, weight, and height, VMA resulted in a 17% reduced radiation exposure (Dose Area Product) as compared to flex/ex*.</td>
<td>Mellor, F, et.al. “Moving back: The radiation dose received from lumbar spine quantitative fluoroscopy compared to lumbar spine radiographs with suggestions for dose reduction.” <em>Radiography</em>. Vol. 20, Issue 3, pp. 251-257, Aug. 2014.</td>
</tr>
<tr>
<td>Measurement accuracy</td>
<td>In studies submitted to the FDA, VMA measurements were demonstrated to be accurate to within 0.2-0.4° (angulation) and 0.5-0.7 mm (translation). This is comparable to what was reported a prior peer-reviewed accuracy study of the VMA software.</td>
<td>See <a href="http://www.orthokinematics.com/pubs/vmaindications-for-use.html">www.orthokinematics.com/pubs/vmaindications-for-use.html</a>. Also see Breen, AC, et. al. “An objective spinal motion imaging assessment: reliability, accuracy, and exposure data.” <em>BMC Musculoskeletal Disorders</em>. 7:1 (2006).</td>
</tr>
<tr>
<td>Decompression vs. fusion for “stable spondy”</td>
<td>Decompression has better results than decompression + fusion for stable spondy and unilateral side leg pain.</td>
<td>Rampersaud, YR, et. al. “Health-related quality of life following decompression compared to decompression and fusion for degenerative lumbar spondylolisthesis.” The Journal of the Canadian Chiropractic Association, 57(4), 2014.</td>
</tr>
<tr>
<td>Performance of the flex/ex* (for comparison)</td>
<td>The definitive study cited by virtually all US payers regarding the use of a 4.5 mm threshold for lumbar instability was a Level III study involving 142 patients. This study found the test was not diagnostically useful in the selection of patients for fusion surgery, however this finding has been largely overlooked.</td>
<td>Dvorak, J., et. al. “Clinical validation of functional flexion-extension roentgenograms of the lumbar spine”. <em>Spine</em> (1991), 16:8, 943-950.</td>
</tr>
</tbody>
</table>

* Plain x-rays with flexion and extension views.
Clinical Validation (1 of 5)

VMA vs. Flex/ex: “Markedly reduced variability”

Details:
• 84 patients
• Coefficient of repeatability (CR), limits of agreement (LOA), intraclass correlation coefficient
• Measured twice by three physicians using the KineGraph vertebral motion analysis (VMA) system and twice by three different physicians using a digitized manual technique.
• VMA measurements demonstrated substantially more precision compared with the manual technique.
Clinical Validation (2 of 5)

VMA vs. Flex/ex: 44% increase in sensitivity, same high 98%+ specificity. NPV increase of 33-47%.

Measurement Performance of a Computer Assisted Vertebral Motion Analysis System

Reginald J. Davis, MD,1 David C. Lee, MD,2 Chip Wade, PhD,3 Boyle Cheng, PhD4

1Department of Neurosurgery, Greater Baltimore Medical Center, Baltimore, MD, 2Southern Neurologic and Spinal Institute, Hattiesburg MS, 3Department of Industrial and Systems Engineering, Auburn University, Auburn, AL, 4Department of Neurosurgery, Drexel University College of Medicine, Pittsburgh, PA

Details:
• 582 patient study
• Level 1 evidence
• Direct comparison vs. flex/ex
• Sensitivity, Specificity, Negative Predictive Value
Clinical Validation (3 of 5)

VMA vs. Flex/ex: Reduced radiation dose.

Details:
- 101 patients
- Level 3 evidence
- Direct comparison vs. flex/ex
Clinical Validation (4 of 5)

VMA: Cage Placement (July 2015)

Effect of TLIF Cage Placement on In Vivo Kinematics

Alejandro D. Castellvi, MD, Shankar K. Thampi, BS, Daniel J. Cook, MS, Matthew S. Yeager, BS, Yuan Yao, MD, Qing Zou, MD, Donald M. Whiting, MD, Michael Y. Oh, MD, Edward R. Prostko, MD, and Boyle C. Cheng, PhD

Details:

- 13 patients
- Capstone (Medtronic, Memphis, TN) polyetheretherketone (PEEK) TLIF straight cages
- Statistically significant correlations were noted between sagittal cage position and lying LB
- Statistically significant correlations were noted between coronal cage positioning with both and lying LB
Clinical Validation (5 of 5)

VMA : Cage Placement (July 2015)

Variability in Flexion Extension Radiographs of the Lumbar Spine: A Comparison of Uncontrolled and Controlled Bending
Boyle Cheng, Ph.D.,1 Anthony E. Castellvi, MD,2 Reginald J. Davis, MD,3 David C. Lee, MD,4 Morgan P. Lorio, MD,5 Richard E. Prostko, MD,6 Chip Wade, Ph.D.6

Details:
• 109 patients
• (57 asymptomatic, 52 symptomatic)
• Measurement variability was determined by the mean and standard deviation of intervertebral rotation when evaluated by 5 independent observers
• 26% to 46% decrease in measurement variability under VMA compared to FE
Static versus dynamic bending flexion extension radiographs: The influence on reduction in patient reported pain post lumbar fusion.

- 414 Patients (138 per group)
- Compared standing VMA to standing FE
- Known thresholds of 15% intervertebral translation (IVT, equivalent to 5.3mm assuming a 35mm vertebral body
- Group 1-the VMA was positive while the FE were negative
- Group 2- the VMA was positive and the FE was positive
- Group 3-the VMA was negative while the FE were positive.
- Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) pre and post 12-months.

- Group 1- 52% improvement in the VAS and a 43% improvement in the ODI
- Group 2- 35% improvement in the VAS and a 34% improvement in the ODI
- Group 3 showed insignificant improvements of 11% and 18% in VAS and ODI scores, respectively.
All Measurements & Equations

\( (\alpha A) = \text{Sacral Slope} \)

\( (\alpha B) = \text{Pelvic Tilt} \)

\( (\alpha C) = \text{Pelvic Incidence} \)

\( (\alpha D) = \text{Lumbar Lordosis} \)

\( (\alpha A) + (\alpha B) = \text{Pelvic Incidence} \)

\( (\alpha C) - (\alpha D) = \text{Target} \)
Lumbar Sagittal Alignment Parameters

\[ \text{PI} = \text{SS} + \text{PT} \]

Any Retroversion?

These two track the same issue—The correlate very closely with each other

- SVA < 50 mm
- PT < 20°
- Spino-Pelvic Harmony
  \[ \text{LL} = \text{PI} \pm 9° \]
Significance of PI-LL Mismatch

This study is the first to find that PI-LL mismatch influences postoperative residual symptoms, such as LBP, lower extremity pain and numbness. The importance of maintaining spinopelvic alignment is Emphasized... surgeons should pay attention to sagittal spinopelvic alignment and avoid post-operative PI-LL mismatch even when treating patients with short-segment lumbar interbody fusion.

– Akoi, et al, 2015

Patients with [PI-LL > 10 degree or more] mismatch exhibit a 10-times higher risk for undergoing revision surgery than controls if sagittal malalignment is maintained after lumbar fusion surgery.

New Literature: Deformity → Degenerative

“[Using] PI-LL mismatch brings the deformity world into the degenerative lumbar spine…”

## Sagittal Alignment Measurements from VMA

### Lumbar Sagittal Alignment

**Patient:** Chara, Zdeno A.  
**Patient ID:** 123456789  
**DOB:** 01/01/1953  
**Accession No:** 1092348  
**Prescribing Physician:** VmV DemoDoc15  
**Test Center:** VmV Test Site  
**Study Date:** 02/29/2016

<table>
<thead>
<tr>
<th>Level</th>
<th>Lordosis Angle</th>
<th>Disc Height (Standing Neutral)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Min.</td>
<td>Max.</td>
</tr>
<tr>
<td>L1/L2</td>
<td>6°</td>
<td>14°</td>
</tr>
<tr>
<td>L2/L3</td>
<td>5°</td>
<td>17°</td>
</tr>
<tr>
<td>L3/L4</td>
<td>4°</td>
<td>6°</td>
</tr>
<tr>
<td>L4/L5</td>
<td>7°</td>
<td>15°</td>
</tr>
<tr>
<td>L5/S1 Fusion</td>
<td>8°</td>
<td>18°</td>
</tr>
</tbody>
</table>

**Sagittal Alignment Data**

\[
\text{PI} - \text{LL} = 29^\circ
\]

**Notes:**
- **PI:** Pelvic incidence. **LL:** Lumbar lordosis.
- **SS:** Sacral slope.
- **PT:** Pelvic tilt.

**Key:**

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**Ortho Kinematics**

VMA version 2.2.1007  
444-555-55-6666  
Report created on March 1, 2016 @ 4:09 pm PST
Use of PI-LL Mismatch in Clinical Decision Making

Provide PI-LL mismatch data to support more nuanced surgical decision making.

A surgeon can decide between standard treatment options, including:

1. Proceed with **planned surgery**, but with extra patient education.
2. Proceed with a **different surgery**:
   - Try to correct imbalance by adding lordosis
   - Extend the fusion construct to incorporate adjacent levels
   - Change from fusion to decompression
3. Decide **against surgery**.
Different Surgical Approaches Based on PI-LL Mismatch

- OKI has detected a **prevalence of 37%** of PI-LL > 10 degrees

- **If Decompression candidate:**
  - PI-LL > 10: avoid 10x chance of adjacent level disease.
  - PI-LL < 10: no change

- **If Fusion candidate:**
  - If PI-LL > 10: Consider
    - MIS TLIF: Expandable cages
    - Lateral approaches: Hyperlordotic cages
    - 2 level fusion vs. 1 level (to get additional lordosis)
    - Smith Pete Osteotomy + fusion
  - If PI-LL < 10: No Change
VMA-Align™: Sagittal Alignment Measurements from VMA*

Key Features & Benefits

**Automated**
VMA* automates the process for obtaining established spinopelvic alignment parameters from fluoroscopic images collected during VMA testing.

**Complete**
Pelvic incidence, lumbar lordosis, pelvic tilt, and sacral slope are included in the VMA report, along with assessments of spinal motion and instability.

**Easy to Use**
VMA provides a “red-light” alert when PI-LL mismatch exceeds the physician-set threshold (e.g. 10°).

**Lower Dose**
Fluoroscopic imaging is lower dose for the patient.

* The PI, LL, SS, and PT measurements included in VMA reports are generated via the Ortho Kinematics, Inc. image processing service using FDA-cleared, off the shelf software (OrthoView, K063327).
Assess *spinal motion* and *sagittal alignment* with one straightforward test.

Vertebral Motion Analysis (VMA) reports now include sagittal alignment measurements.

Entirely **no-touch**. No long-film x-rays. **No manual mark-ups**.

Fluoroscopic imaging means **reduced radiation exposure**.
Thank you!

VMA: Spine’s New Standard for Instability Testing