Radiation Exposure Comparison
VMA™ versus end-range x-rays

Radiation dose was measured for 8 consecutive patients undergoing VMA testing. Dose data from those tests was used to compare the radiation exposure associated with the VMA to that of end-range x-rays. The VMA protocol involves 47-76% of the radiation dose associated with an equivalent set of end-range x-ray films, depending on the test configuration. This level of radiation exposure is considered to have very low risk and is well below the levels associated with other commonly-used diagnostic procedures.

Introduction
When evaluating back and neck pain patients, clinicians consider the spine’s bony structures, soft tissue, and range of motion to make a diagnosis. Back and neck pain patients are currently diagnosed using a combination of MRI, neutral x-rays, and x-rays taken at the end-range of trunk bending—the latter to evaluate spine motion. By comparing the two films taken at the extremes of bending, the relative change in position between two vertebrae is manually measured. The range of motion is then expressed as the resulting intervertebral angle (IVA).

The VMA addresses the technical shortcomings of the end-range x-ray method, reducing variability and providing a detailed set of in vivo spine motion data during bending. The system uses a powered Motion Normalizer™ device to bend the patient's trunk through a standardized range of motion while hundreds of digital fluoroscopic frames are collected. To find the relative motion of the vertebrae from one frame to the next, image recognition software locates the vertebrae on each frame, constructing borders around the edges of the vertebral bodies. Then, a geometric algorithm uses these constructions to calculate the intervertebral angle frame-to-frame. The output from the VMA is the intervertebral motion plot, in which intervertebral angle is plotted as a function of degree of trunk bending for each frame.

Like the current standard of care (end-range x-rays), fluoroscopy is a type of radiological imaging. The purpose of this paper is to compare the radiation exposure associated with the VMA to that of end-range x-rays.

Method
Radiation dose was measured for 8 consecutive patients undergoing VMA testing at the Anglo European College of Chiropractic (Bournemouth, United Kingdom) from March through September 2009. A mobile Siemens Arcadis Avantic VC10A fluoroscopy unit was used, and dose was recorded using the resident dosimetry equipment on that fluoroscopy system. Of these 8 patients, usable dose data was obtained for all 8 patients in Anterior/Posterior (A/P) imaging and for 7 patients in lateral imaging.

The dose equivalent (H) is the measure used to compare the overall risk to the patient associated with different medical procedures that involve radiation. Dose equivalent is a derived quantity that is calculated as shown in the box titled “Calculating Dose Equivalent.” In assessing the risks associated with the VMA, it is necessary to first determine the DRL dose equivalent (DRL<sub>H</sub>) for end range x-rays, then use that as the basis for making a comparison with the DRL dose equivalent associated with the VMA. The DRL dose equivalent (DRL<sub>H</sub>) for a single plain x-ray is given in Table 1 below.

Table 1: Radiation dose values for plain lumbar x-rays

<table>
<thead>
<tr>
<th>Imaging configuration</th>
<th>A/P (for side-bending)</th>
<th>Lateral (for flexion/extension)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRL&lt;sub&gt;exp&lt;/sub&gt; (cGy*cm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>2.5&lt;sup&gt;5&lt;/sup&gt;</td>
<td>1.6&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>W&lt;sub&gt;f&lt;/sub&gt; (mSv/Gy*cm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>0.22&lt;sup&gt;6&lt;/sup&gt;</td>
<td>0.1&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>DRL&lt;sub&gt;H&lt;/sub&gt; (mSv)</td>
<td>0.35</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Calculating Dose Equivalent

DRL<sub>H</sub> = DRL<sub>DAP</sub> * W<sub>f</sub>

Dose equivalent (H): Measure of the overall risk to the patient associated with an applied radiation dose; used to make an “apples to apples” comparison of the dose associated with different medical procedures; takes into account the type of tissue being irradiated (e.g., irradiating thyroid tissue is much more risky for the patient than irradiating hair tissue, and dose equivalent takes this difference into account); expressed in Sieverts (Sv)

Dose-area product (DAP): Measure of the radiation dose and the volume of tissue irradiated; dependent upon patient size, muscle-to-fat ratio, and other factors affecting the amount of radiation required to penetrate the patient’s body; is directly measured and recorded by most imaging equipment; expressed in R*cm<sup>2</sup> (cGy*cm<sup>2</sup>)

Dose reference level (DRL): A statistical assessment of radiation dose-related measurements for a given medical procedure, calculated as the 3rd quartile value of actual recorded dose measurements taken from a representative set of patients undergoing that particular medical procedure; DRLs may refer to dose-area product (DRL<sub>DAP</sub>) expressed in R*cm<sup>2</sup> (cGy*cm<sup>2</sup>) and may also refer to dose equivalent (DRL<sub>H</sub>) expressed in Sieverts (Sv)

Tissue weighting factor (W<sub>f</sub>): A normalization factor applied to DAP values to account for the different radiation sensitivities among various tissues and organs; expressed in mSv/Gy*cm<sup>2</sup>.

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Results

For the 8 patients in the VMA study, the third quartile of the dose equivalent data DRLVMA collected was measured to be no greater than 0.38 mSv for lateral imaging (120° of flexion/extension bending) and 0.49 mSv for A/P Imaging (120° of side bending). For a typical flexion/extension series of end-range x-rays, 2 or 3 lateral plain x-ray images are collected (3 if there is a neutral view, 2 if not). Thus, the comparator DRLA/P for flexion/extension end-range x-rays is 0.50-0.75 mSv. Similarly, for a typical side bending series of end-range x-rays, 2 or 3 A/P plain x-ray images are collected. Thus, the comparator DRLS for side bending end-range x-rays is 0.70-1.05 mSv.

Therefore, the VMA involves 51-76% of the dose equivalent associated with an equivalent set of plain films collected in flexion/extension and 47-70% of that collected in side bending. Table 1 summarizes these results, along with comparisons for the different possible protocols and configurations for VMA testing.

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

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Single bend (either lying or standing)</th>
<th>Both lying and standing</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>VMA@ 120° of bending</td>
<td>End-range x-rays</td>
</tr>
<tr>
<td>Flexion/extension</td>
<td>0.38 mSv</td>
<td>0.50 – 0.75 mSv</td>
</tr>
<tr>
<td>Side bending</td>
<td>0.49 mSv</td>
<td>0.70 – 1.05 mSv</td>
</tr>
<tr>
<td>Both flexion/extension and side bending</td>
<td>0.87 mSv</td>
<td>1.2 – 1.8 mSv</td>
</tr>
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</table>

Discussion

Taking into account the most expansive VMA protocol, in which both flexion/extension and side bending are measured in both standing and lying postures, the third quartile dose equivalent (DRLVMA) is 1.74 mSv. Assuming that the natural background radiation exposure for a person is about 2.5 mSv/ 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:

- 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. 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. 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.

Conclusion

The 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 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.

References:

5. Hart D, et al. Doses to Patients from Radiographic and Fluoroscopic X-Ray Imaging Procedures in the UK—2005 Review. Health Protection Agency, Centre for Radiation, Chemical, and Environmental Hazards, Radiation Protection Division. p65 (Table 29) [This 2005 survey by the UK government of British hospitals reported the DRLs (third quartile) taken from measurements across over 115 X-ray rooms as 2.3 Gy*cm² and 1.6 Gy*cm² for the A/P and lateral views, respectively. The U.K. is the only country that mandates widespread collection of dose data, making the data from this survey the best available data for doses measured directly during radiological procedures.]
8. Ibid, Table 2b.
11. 10 CFR 20.120