LANDMARK INDEPENDENT STUDY BY UCLA SCHOOL OF MEDICINE

MR Spondylography™* Study is the First to Quantify the "Miss Rate" of Static MRI

4 Reports Compare Dynamic™ MRI in the UPRIGHT® Position With Static MRI in the UPRIGHT® Position in More Than 1,000 Patients (1,302)

IS THE UCLA STUDY ESTABLISHING A NEW STANDARD OF CARE FOR SPINE MEDICINE?

Key Findings

Static MRI "Miss Rate" at the Critical L4-5 Segment is 35.1%

Static MRI "Miss Rate" at L3-4 is even higher at 38.7%

Static MRI Overall "Miss Rate" is 18.1%

Spinal Stenosis Measured in Flexion and Extension with High Precision

Potential for Greater Precision in Optimizing Decompression

Review of UCLA Findings

At the 22nd Annual Meeting of the North American Spine Society (NASS), the University of California, Los Angeles, (**UCLA**) School of Medicine reported the results of a study of 1,302 patients imaged in the **FONAR UPRIGHT® Multi-Position™ MRI** [*The Spine Journal* 7 (2007) 1S-163S, October 23-27, 2007, Austin, Texas]. Four scientific papers were reported, comparing the visualization of spine pathology by Dynamic™ Multi-Position™ MRI to images obtained by Static MRI.[1] The studies were performed utilizing image analysis software developed by **True MRI** for the Fonar UPRIGHT® MRI. The software provides comprehensive **quantitative** measurements of spinal structures in both the Dynamic™ and Static positions.

"MISSED SPONDYLOLISTHESIS IN STATIC MRIs BUT FOUND IN DYNAMIC MRIs IN THE PATIENTS WITH LOW BACK PAIN" (PAPER 145)

The **UCLA** study reported the rate at which Static MRI **missed spondylolistheses** when compared to Dynamic™ MRI (Table 1).

Table 1

% Spondylolistheses **"Missed"** by Static MRI 40º Flexion					Overall **"Miss Rate"** 40º Flexion
Minimum Slip	L2-3	L3-4	L4-5	L5-S1	L1-2 to L5-S1
3 mm	30.8%	**38.7%**	**35.1%**	4%	**18.1%**
4 mm	33.3%	**53.8%**	17.9%	3.5%	12.3%
10º Extension					10º Extension
	L2-3	L3-4	L4-5	L5-S1	L1-2 to L5-S1
3 mm	25%	20.8%	14%	3.2%	8.9%
4 mm	33.3%	25%	4.2%	2.4%	5.0%

Static MRI "Miss Rate" at the Critical L4-5 Segment is 35.1%

At L4-5, the vertebral level responsible for 49.8% of lumbar disc herniations,[2] 35.1% of the spondylolistheses visualized by Dynamic™ MRI were missed by Static MRI (Table 1). Since this segment is responsible for the majority of all disc herniations,[2] the finding may well reveal a principal cause of failed back surgeries.

*Spondylography™; definition: The name for FONAR UPRIGHT® Multi-Position™ MRI
Spondylometrics™; definition: The precise measurement of spinal dimensions from Spondylographic™ MR images
Spondylometry™; definition: The discipline of measuring spinal dimensions from Spondylographic™ MR images

Corrective surgical fusion for 35.1% of patients with spondylolistheses at L4-5 – and the relief it could have provided them – could not be undertaken for lack of knowledge that they existed.

Static MRI "Miss Rate" at L3-4 is even higher at 38.7%

An even more marked spondylolisthesis **"miss rate"** by Static MRI was observed at vertebral segment **L3-4**. **38.7% of 3 mm spondylolistheses went undetected by Static MRI and 53.8% of 4 mm spondylolistheses went undetected by Static MRI (Table 1)**.

This important finding raises the question whether co-existent instability at L3-4 should be excluded by **FONAR Upright® Multi-Position™ MRI** imaging before the decision to perform surgical fusions at L4-5 and L5-S1 (e.g. L4-S1 fusion) is made.

Static MRI Overall "Miss Rate" is 18.1%

As the UCLA study states, "In the patients with back pain, missed spondylolistheses in neutral MRIs, but found in flexion MRIs, is 18.1% for all levels"[3] when the minimum condition for designating a segmental slip as a spondylolisthesis is a 3 mm translation.

"KINEMATIC ANALYSIS OF THE RELATIONSHIP BETWEEN THE GRADE OF DISC DEGENERATION AND THE MOTION UNIT IN THE CERVICAL SPINE" (PAPER 111)

The role of cervical spinal instability in the genesis of spinal cord injury (cervical **myelopathy**) and the complete extent of that instability over the full range of flexion and extension positions that a patient's cervical spine occupies can now be measured in the FONAR UPRIGHT® Multi-Position™ MRI. Additionally, the measurements can be performed in the FONAR UPRIGHT® Multi-Position™ MRI with the patient in the UPRIGHT® position where the spine is supporting its full weight load.

The extent to which disc degeneration and the occurrence of spondylolistheses are correlated and the full extent of the spondylolistheses that occur when cervical flexion and extension occur in the UPRIGHT® body position was measured in 168 patients suffering from neck pain.

To evaluate the degree to which cervical vertebral slippage was a candidate for inflicting cervical cord injury, UCLA scientists measured the extent to which cervical vertebra slippage (spondylolisthesis) increased as a function of disc degeneration. The extent to which slippage increases as a consequence of disc degeneration is the first step in evaluating the potential of a patient's spine pathology for causing cervical cord impingement, cervical cord injury and ultimately cervical **myelopathy**.

Muhle, et al.,[4] for example, in a flexion-extension recumbent MRI study of patients with neck pain concluded that **"cervical spinal motion may contribute to the development of cervical spondylitic myelopathy."** Their conclusion was the result of their data that showed **"at flexion and extension, the prevalence of spinal stenosis and cervical cord impingement increased as the stage of degenerative disease progressed."**

Additionally, Muhle, et al. described the possibility of a **"PINCER CONDITION"** arising with respect to the patient's cervical cord wherein cervical disc degeneration and the consequent loss of disc height results in spinal cord pinching from intervertebral disc bulging anteriorly and cord pinching from infolding of the ligmentum flavum posteriorly.

The Muhle, et al. study is compelling regarding the prospect of serious injury to the spinal cord when the cervical spine with degenerative pathology engages in its normal range of flexion and extension motion.

The Muhle, et al. study, however, necessarily underestimates the injury potential of such degenerative pathology since the study was performed with the patients recumbent when the full extent of the compressive forces of weight loading were not engaged.

The UCLA study using the FONAR UPRIGHT® Multi-Position™ MRI evaluated the potential for cervical instability to induce cord injury with the patients fully UPRIGHT® with the cervical spine subjected to its normal compressive gravitational forces of body weight.

The study established that cervical spine translational and rotational instabilities increase as disc degeneration increases finally reaching an ankylosing stage where translational and rotational mobility is reduced relative to normal. In their paper "Multilevel cervical spondylosis: laminoplasty versus anterior decompression" Hirabyashi and Bohlmon report that **"cervical spondylosis is the most common cause of cervical spinal cord dysfunction in individuals older then 55."**[5]

The full range of motion analysis of the cervical spine made possible by the FONAR UPRIGHT® Multi-position™ MRI further enables the future implementation of clinical treatments that limit cervical motion to positions that do not encroach on the cord and cause injury. The FONAR UPRIGHT® MRI also now makes possible post-operative image analysis to verify that cord impinging and cord injuring conditions have been successfully eliminated by surgery.

The study by UCLA of patients with neck pain was the first demonstration in the fully UPRIGHT® patient of the degree to

which the cervical spinal cord can be exposed to injury from spondylolithesis secondary to cervical disc degeneration. The study proved that potential cord injuring cervical spine instability increased as a function of cervical disc degeneration, consistent with the conclusion of Muhle, et al. that cervical spinal **motion** may be a contributor to the development of cervical spondylitic **myelopathy**. The FONAR UPRIGHT® Multi-Position™ MRI technology was shown to be capable of quantifying existing spondylolistheses and assessing the cord injuring potential of degenerative spine changes that exist in the neck pain patient so the prospect of **myelopathy** can be assessed and surgical (or non-surgical) treatments implemented to prevent injury.

"POSITIONAL MRI: A VALUABLE TOOL IN THE ASSESSMENT OF CERVICAL DISC BULGE" (PAPER 80)

UCLA scientists further assessed another major component of cervical spondylosis, namely the cervical disc degenerative pathology manifest as disc bulges and the variation of these bulges with flexion and extension, when the criterion for designating a disc prolapse as a bulge was a visible bulge 2 mm or greater.

The UCLA studies concluded that 25.08% of the time there was a failure to see disc bulges in the neutral sitting position that became evident when these 163 patients with radicular signs and symptoms were additionally imaged in the flexion and extension positions. 18.18% exhibited a bulge 2 mm or greater in flexion that was less than 2 mm in the neutral sit position and 23.75% exhibited a bulge 2 mm or greater on extension that was less than 2 mm in the neutral sit position (Table 2).

"Miss Rate" of Cervical Disc Bulges 2 mm or Greater Seen in Flexion and Extension Positions But Not Seen in the Neutral Sitting Position

Table 2

Position Eliciting Disc Bulge	% of Cervical Disc Bulges Greater Than or Equal to 2 mm That Were **"Missed"** in the Neutral Sit Position But Seen on Flexion or Extension
Flexion	**18.18%**
Extension	**23.75%**

The UCLA study concluded that flexion and extension imaging with the cervical spine in the UPRIGHT® position might help resolve those cases where the extent of MRI pathology visualized by static (recumbent) MRI studies does not match the extent of "spinal cord dysfunction" exhibited by the patient's clinical signs and symptoms.

"THE EFFECT OF LUMBAR FLEXION AND EXTENSION ON THE CENTRAL CANAL WITH DYNAMIC MRI" (PAPER 79)

Spinal Stenosis Measured in Flexion and Extension with High Precision

Additionally, in the UCLA study of patients with low back pain, **"The Effect of Lumbar Flexion and Extension on the Central Canal with Dynamic MRI" (Paper 79),** Wei, et al. assessed the capability of the FONAR UPRIGHT® Multi-Position™ MRI to quantify spinal stenosis**, the most common reason for spinal surgery in patients older than 65 (Katz, J., et al., Rheum Dis Clin North Am 1994:20:471)**. In their study of 461 patients with low back pain, UCLA scientists reported that they were able to measure spinal canal diameter in the vertical patient and **quantify** its changes with flexion and extension **"with high precision"** using the FONAR UPRIGHT® MRI. They further reported the ability to measure the flexion and extension changes in the spinal canal cross-sectional area **"with the highest accuracy**."

Lumbar spinal canal **stenosis** and the entrapment of the cauda equina roots, which is a consequence of the constriction of spinal canal dimensions produced by stenosis, results in the symptom complex **intermittent neurogenic claudication** – manifest as debilitating pain in the back and lower extremities, weakness and difficulties in ambulation, and leg paresthesias. The ability of the FONAR UPRIGHT® Multi-Position™ MRI to quantify key spinal canal dimensions with **"high precision"** in all the UPRIGHT® body positions brings to the highly skilled and specialized craft of spine surgery a new and much needed technology for quantifying the full extent of spinal stenosis in patients.

Additionally, the power of FONAR's new UPRIGHT® Multi-Position™ MRI to **measure** spinal canal dimensions with the body in its UPRIGHT® position and the spine fully weight-loaded, with the gravitational compressive forces responsible for back pain fully engaged, means that FONAR's new technology is now available to surgeons to **quantify the full extent of stenosis** responsible for claudication symptoms in their patients and to do so with their patients fully UPRIGHT® and

occupying the full range of body positions they do normally.

It is self-evident that measurements of canal stenosis made in a conventional MRI with the patient lying down are an underestimate of the full extent of the stenosis that exists when the patient is UPRIGHT® with his spine subject to the full extent of gravitational forces that normally compress the spine.

Indeed, when conventional recumbent MRI scans do not visualize pathology that corresponds in severity with the intensity of claudication symptoms, the likelihood is that recumbent MRI is not seeing the full extent of the stenosis the patient is experiencing UPRIGHT® with his/her spine subjected to its full weight-load and occupying its normal flexion and extension positions.

Potential for Greater Precision in Optimizing Decompression

Moreover, current procedures for decompressing spinal stenosis can, from the surgeon's perspective, be limited by the expected impact of the procedure on spinal stability. It is likely that a full quantitative multi-position assessment of **central canal stenosis** measured **simultaneously** with quantitative multi-position analysis of **spinal stability –** a combination that is now possible using FONAR's new UPRIGHT® Multi-Position™ MRI technology – will enable surgeons to achieve greater precision in optimizing decompression while at the same time minimizing spinal instability.

IMPROVED SURGICAL OUTCOMES

DYNAMIC DIAGNOSIS OF THE SPINE TOTALLY WEIGHT-LOADED, UPRIGHT AND OCCUPYING ITS FULL RANGE OF NORMAL PHYSIOLOGICAL POSITIONS MEANS A MORE ACCURATE DIAGNOSIS, IMPROVED SURGICAL OUTCOMES AND, AS A RESULT, INCREASED PATIENT REFERRALS.

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[1]The Static position was defined by UCLA scientists as the UPRIGHT® neutral sitting position and the Dynamic position as the flexion and extension sitting positions.

[2]Hsu K., Zucherman J., Shea W., Kaiser J., White A., Schofferman J., and Amelon C., *Spine*, Vol. 15, No. 7, July 1990: Spangfort EV: *Acta Orthop. Scand. (Suppl)* 142:40-44, 1972 back

[3]Soon-Woo Hong, M.D., et al., “Missed Spondylolisthesis in Static MRIs but Found in Dynamic MRIs in the Patients with Low Back Pain” (UCLA Study: Paper 145)

[4]Muhle C., Metzner J., Weinert D., Falliner A., Brinkmann G, Mehdorn Maximillian H., Heller M., and Resnick D., *Am. J. Neuroradiol.* 19:1763, Oct. 1998

[5]Hirabyashi K., Bohlmon H. "Multilevel cervical spondylosis: laminoplasty versus anterior decompression" *Spine* 1995;20:1732-1734