



Assessing the Spine using MRI, CT, and X-Ray

Intervertebral Disc Degeneration (commonly referred to as Degenerative Disc Disease or DDD) is one of the most common forms of lower back pain and is generally related to changes in disc morphology or disc hydration in the lumbar and lumbosacral discs. Different strategies exist to treat DDD, ranging from novel treatments that address the health of the disc all the way through spinal fusion. Depending upon the treatment strategy, several different imaging techniques may be utilized to determine the success of the treatment.

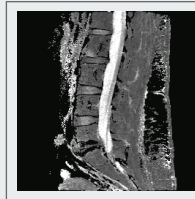
Intervertebral Disc Repair:

VirtualScopics has multiple capabilities when it comes to assessing DDD and intervertebral disc repair. We provide standard structural measurements as well as compositional endpoints related to the makeup and function of the disc or vertebral body.

Structural Measurements:

- Disc height
- Disc volume
- Degree of disc herniation
- Presence of annular fissures

Compositional Endpoints:



- T2 relaxation time (related to disc hydration)

- Presence of intradiscal gas or calcium

- Edema volume or fatty marrow deposits in the vertebral bodies – relative health of the surrounding vertebral bodies



- Apparent diffusion coefficient (ADC – related to hydration and health of disc)

Spinal Fusion:

VirtualScopics can evaluate all of the radiographic endpoints outlined in the *FDA Guidance Document for the Preparation of IDEs for Spinal Systems* (2000) including:

- Evidence of bridging bone
- Disc degeneration
- Osteophyte formation

- Disc height
- Vertebral height
- Radiolucent lines
- Disc herniation
- Facet joint changes
- Stability (horizontal translation as well as angulation)

Scoring Options

In addition to the aforementioned assessments, there are many scoring systems that have been published that focus on a single aspect of disc and vertebral health. At VirtualScopics, we have combined many of these scoring systems together, along with the presence or absence of certain features, to provide a complete assessment of the disc and vertebral bodies. This unique combination of scoring systems can be used to assist in screening potential subjects, or to track changes to specific features.

- Modic – degenerative changes to vertebral body bone plate and marrow adjacent to disc space
- Pfirrmann – degenerative changes in the intervertebral discs
- Grogan – facet arthrosis
- Fujiwara – facet osteophytes
- Grogan – facet sclerosis
- Meyerding – degree of spondylolisthesis
- Spondylolysis
- Vertebral Osteophytes
- Disc Collapse
- Disc Extrusion
- Non-contained Herniated Nucleus Pulposus
- Intradiscal Gas or Calcium

Reliable, Compliant Systems

Regardless of the assessments performed, VirtualScopics utilizes a **21 CFR Part 11 compliant** system to analyze images of the spine. For the structural and compositional measurements, algorithm-based technology is used to assist the analyst in determining the regions of interest. This leads to improved reproducibility, which is crucial when assessing the impact a sponsor's drug or device is having upon the treatment of a disc or vertebra.

With extensive imaging knowledge and experience with spine and other musculoskeletal studies, our ability to minimize data variability across multi-center trials, our global reach and a strong, proactive project management team, VirtualScopics provides the most comprehensive imaging solution for your spinal therapy studies.

Additional VirtualScopics Imaging Services to support your spinal compound and device studies:

Pre-Study Services

- Modality selection - CT, MRI, X-Ray, DEXA
- Standardization across global imaging sites
- Clinical protocol design support, including image-based biomarker and image modality selection
- Independent review charter development (Imaging charter)
- Special protocol assessment (SPA) development
- Statistical analysis plan development support
- Imaging site qualification, initiation and training
- Method, proof-of-concept and pilot studies
- Support at regulatory meetings

Study Services

- Ongoing image site management
- Image data quality control and inspection
- Regulatory-compliant image data management processes
- State-of-the-art image analysis techniques
- Traditional image-based biomarkers
- Novel quantitative biomarkers
- Image data results delivered to your specifications
- Medical and scientific reports

Post-Study Services

- Secure image data management and archiving
- Statistical analysis and mining of image data
- 3D & 4D visualization of results
- Image data regulatory submissions

For more information on how we can accelerate your clinical trials with our industry-leading technology, Call us at 585.249.6231. Or visit www.virtualscopics.com.

