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Guidance for Sponsors
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Complex Spinal Deformities: Medical Imaging in Clinical Trials

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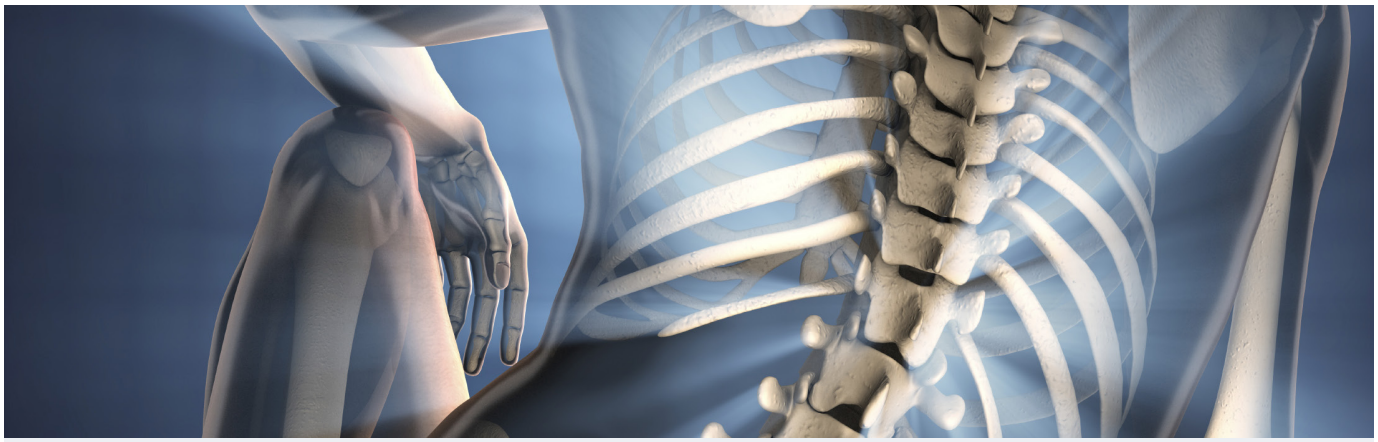

Scoliosis affects two to three percent of adolescents, and degenerative adult spinal deformity is far more common than once thought, with radiographic prevalence reported as high as 68 percent in volunteers over 60.[1] Deformity surgery has become one of the most complex and heavily instrumented fields in orthopedics, and the devices, growth-modulating implants and surgical strategies it uses are tested in trials whose primary endpoints are radiographic. This issue reviews how spinal deformity is classified and measured, how imaging technology has changed, and what sponsors need from an imaging core lab.

Classifying the Deformity

Spinal deformity is described in three planes. In the coronal plane, the Cobb angle, the angle between the superior endplate of the most tilted vertebra above the curve apex and the inferior endplate of the most tilted vertebra below, has defined scoliosis for more than 75 years; a curve of 10 degrees or more is scoliosis. For adolescent idiopathic scoliosis, the Lenke classification of 2001 combines curve type, a lumbar modifier and a sagittal thoracic modifier to guide which curves should be fused, and it remains the standard surgical classification.[2]

For adults the emphasis has shifted to the sagittal plane. The SRS-Schwab classification, published in 2012, added three sagittal modifiers to the coronal curve type: pelvic incidence minus lumbar lordosis (PI-LL), pelvic tilt and sagittal vertical axis.[3] These parameters correlate with pain and disability far better than coronal Cobb angle does, and they define the realignment goals of adult deformity surgery. The Global Alignment and Proportion (GAP) score of 2017 goes further, expressing alignment relative to each patient's own pelvic incidence and predicting mechanical complications after surgery.[4]

Imaging Technology Has Changed

Standing full-spine radiographs, posteroanterior and lateral, remain the foundation of deformity assessment because alignment must be measured under load. Two developments have transformed how they are acquired. Low-dose biplanar slot-scanning systems acquire simultaneous orthogonal images of the entire skeleton at a fraction of conventional radiographic dose and allow three-dimensional reconstruction of the spine and pelvis, which is particularly important in children who will be imaged dozens of times during growth.[5] Standard digital radiography has also improved, with automatic stitching of long-cassette images that preserves measurement accuracy.

CT remains the reference for bone detail, fusion assessment and surgical planning; MRI evaluates the cord, discs and neural elements. Both are used selectively in trials because of dose and cost, and their protocols must be defined in the imaging charter so that measurements are comparable across sites.

Measurement Variability and AI

The limiting factor in deformity trials is measurement error. Manual Cobb angle measurement has an inter-observer variability of about five to seven degrees, which is of the same order as the change a trial may be trying to detect. Sources of error include endplate selection, radiograph quality and the measurement tool. Trials reduce this by having a small group of trained central readers use the same software with predefined vertebral levels. The FDA has cleared software that automatically measures Cobb angles and sagittal parameters from spine radiographs.[6] These tools improve reproducibility, but in a trial they should be validated against expert readers and used

under reader supervision rather than as a substitute for one.

Devices, Growth Modulation and Endpoints

The regulatory landscape has broadened. In August 2019 the FDA approved the first vertebral body tethering system under a humanitarian device exemption, allowing a non-fusion, growth-modulating alternative to spinal fusion for selected skeletally immature patients.[7] Magnetically controlled growing rods, pedicle screw systems, interbody cages and osteobiologics all reach the market through trials whose endpoints are radiographic: curve correction and maintenance, fusion status, implant integrity and the absence of proximal junctional kyphosis or rod fracture. Patient-reported outcomes such as the SRS-22r and Oswestry Disability Index complement, but do not replace, these imaging endpoints.

Large prospective studies such as Scoli-RISK-1 have shown how frequently complications, including neurologic deficits, follow complex adult deformity surgery, which makes consistent imaging surveillance for mechanical failure a safety requirement as well as an efficacy measure.[8]

Guidance for Sponsors

Imaging a spinal deformity trial

- **Define the measurements.** Specify Cobb levels, sagittal parameters and the software to be used in the imaging charter.[3]
- **Standardize positioning.** Standing full-spine PA and lateral radiographs with a fixed protocol for arm position and fists-on-clavicles.
- **Minimize dose in children.** Use low-dose biplanar imaging where available and define the number of exposures in the protocol.[5]
- **Limit and train readers.** A small central reader pool with documented reproducibility beats many local readers.
- **Validate any AI tool.** Compare automated measurements with expert reads before relying on them.[6]
- **Capture mechanical complications.** Assess implant integrity, junctional kyphosis and fusion at every imaging visit.[8]

Summary

Spinal deformity trials live and die by radiographic measurements that are notoriously variable. Modern classification systems, low-dose three-dimensional imaging and validated software have given sponsors better tools, but the fundamentals remain: define the measurement, standardize the acquisition and read centrally.

About the Author

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