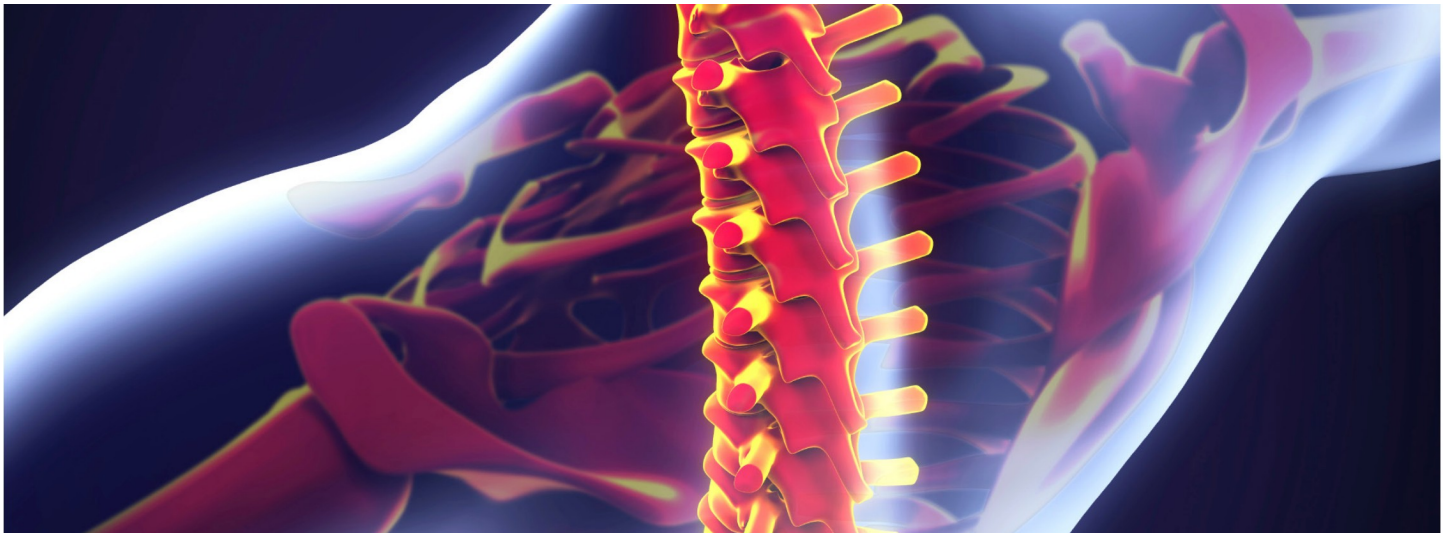
Orthopedic Device Assessments: Medical Imaging Challenges in Clinical Trials

By Jack Clement, M.D., Ph.D., Medical Director, Musculoskeletal Imaging · Updated for 2026 by Intrinsic Imaging



Orthopedic research spans joint reconstruction, spinal fusion and motion preservation, and biologics for cartilage, tendon and ligament repair. Regulators and payers expect rigorous quantitative and qualitative evidence of efficacy, safety and longevity, and imaging supplies much of it. Because investigational devices are often unlike anything imaged before, protocols must be built around the device itself: its engineering, materials, surgical technique and position. Advances in CT, metal-artifact-reduction MRI and radiostereometric analysis now allow earlier and more precise answers than ever.

Orthopedic Device Assessments

An aging and increasingly active population continues to drive refinement of existing orthopedic devices and development of new ones. Clinical research ranges from improved joint reconstruction hardware, spinal fusion and motion-preserving spinal devices to biologics for articular and fibrocartilage repair and for tendon and ligament reconstruction. Regulatory and market acceptance of these therapies requires rigorous assessment of efficacy, safety and longevity, and imaging endpoints are central to that evidence.

Orthopedic investigational devices are often novel. Designing an imaging protocol requires an intimate understanding of the device's engineering, material composition, surgical placement and expected position. Musculoskeletal radiologists with experience in longitudinal device assessment are best placed to design protocols and interpret the data, because they can translate their expertise with established hardware to devices that have frequently never been imaged before.

Dynamic and Static Evaluations

Imaging assessment of devices and biologics falls broadly into dynamic and static evaluation. Orthopedic devices are, by definition, subject to motion and stress. **Dynamic assessment** is most common for spinal devices, using flexion–extension radiographs or dynamic fluoroscopy. Dedicated software processes these images into quantitative measures of motion and alignment, including disc height, angular motion and change in spondylolisthesis, with reproducibility to less than 1 degree and 1 mm. Metallic hardware does not usually prevent identification of the landmarks these measurements require. CT and MRI are rarely used for dynamic analysis, because patients remain in one position during acquisition.

Static assessment uses radiography, CT and MRI, each offering distinct information about bone, soft tissue and the device. Radiography provides a broad view of the device and its complications: migration, subsidence, disassembly, and bone changes such as fracture, remodeling, hypertrophic bone formation or ankylosis.

For hip and knee arthroplasty, **radiostereometric analysis (RSA)** adds precision that conventional radiographs cannot. RSA uses calibrated stereo radiographs and small marker beads to measure implant migration at submillimeter scale. A systematic review identified RSA and EBRA migration and wear measurements as validated surrogate markers of long-term outcome in primary hip arthroplasty and recommended RSA in premarket testing of new implants.[1] RSA is the foundation of the phased, evidence-based introduction of new joint implants that leading investigators have advocated.[2]

CT performs a role similar to radiography but with much greater sensitivity and specificity, often revealing complications hidden by superimposed anatomy. It allows accurate measurement of the device and adjacent bone in any plane and an improved, though still limited, assessment of soft tissue. CT protocols must be optimized for each device, especially those with metal components. Higher kilovoltage and tube current reduce beam hardening and streak artifact; thin, overlapping slices produce a robust data set that clearly depicts the bone–device interface; and multidetector scanners allow greater overlap and better image quality around hardware. Modern iterative metal artifact reduction algorithms and dual-energy techniques further improve visualization.

MRI is the modality of choice for soft-tissue changes and complications near hardware, including synovitis, periarticular fluid collections, particle disease, arthrofibrosis, muscle injury, bone stress changes and changes in cartilage morphology and quality. It is also the optimal modality for biologic cartilage and soft-tissue reconstruction, showing graft position, integrity and incorporation and changes in adjacent bone. In the spine, MRI detects marrow changes adjacent to the device as well as disc degeneration, herniation, epidural hematoma, infection and cerebrospinal fluid leaks.

Metal once made MRI near implants unusable. Metal artifact reduction sequences changed that, and multispectral techniques such as SEMAC and MAVRIC now substantially reduce in-plane and through-plane distortion, allowing assessment of anatomy close to hardware in both clinical practice and research.[3] Any trial that scans implanted devices must also respect the device's MR safety labeling, which FDA addresses in its 2023 guidance on testing and labeling medical devices for safety in the MR environment.[4]

Guidance for Sponsors

Imaging an orthopedic device trial

- **Design the protocol around the device.** Involve musculoskeletal radiologists early, with full knowledge of materials, geometry and surgical technique.
- **Match the modality to the question.** Radiography and RSA for migration and wear; CT for the bone–device interface; MRI for soft tissue, biologics and complications.[1]
- **Measure motion quantitatively.** For spinal devices, use standardized flexion–extension imaging with validated software analysis.
- **Plan for metal.** Specify CT and MRI metal artifact reduction techniques in the imaging charter.[3]
- **Confirm MR conditional status.** Align MRI protocols with each device's MR safety labeling.[4]
- **Read centrally and longitudinally.** Compare every time point with baseline, using the same readers and methods throughout.

Summary

As novel orthopedic devices enter clinical evaluation, imaging modality, acquisition and analysis must be tailored to each trial. Each modality provides different but complementary qualitative and quantitative data. Advances in CT and MRI give these modalities a growing role in precise device evaluation, while software analysis of radiographs and radiostereometry provide some of the earliest and most reliable signals of long-term device performance.

About the Author

Dr. Jack Clement wrote the original edition of this issue as Medical Director, Musculoskeletal Imaging, at Intrinsic Imaging. A graduate of Tulane University in New Orleans, he completed M.D. and Ph.D. degrees at Baylor College of Medicine in Houston, where his training was sponsored by the National Institutes of Health. He has coauthored peer-reviewed original research in *Science*, the *New England Journal of Medicine* and *Neuron*. He completed a diagnostic radiology residency at Baylor College of Medicine and subspecialized in musculoskeletal radiology at Harvard Medical School's Massachusetts General Hospital in Boston. He is a board-certified radiologist with specialized training in orthopedic radiology and interventional pain management.

References

1. Surrogate markers of long-term outcome in primary total hip arthroplasty: a systematic review. ncbi.nlm.nih.gov/pmc/articles/PMC4921042

2. Nelissen RGHH, et al. The era of phased introduction of new implants. pmc.ncbi.nlm.nih.gov/articles/PMC4921053

3. Managing hardware-related metal artifacts in MRI: current and future approaches. *Skeletal Radiol.* 2024. pmc.ncbi.nlm.nih.gov/articles/PMC11303499

4. U.S. FDA. Testing and labeling medical devices for safety in the magnetic resonance (MR) environment. October 2023. fda.gov

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

Contact

Intrinsic Imaging, LLC
580 Main Street, Suite 210
Bolton, MA 01740
Tel: +1 978-616-4650
Contact@IntrinsicImaging.com
www.IntrinsicImaging.com