CASE STUDY · MEDICAL DEVICE

Spinal Fusion Device Trial With Fusion Review

28 sites · CT, flexion-extension radiographs · 24-month fusion endpoint

Challenge

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. Evaluating the effectiveness of a spinal fusion device requires reproducible imaging evidence of fusion and implant stability across longitudinal follow-up. Fusion status and subsidence had to be assessed consistently across 24 months of post-surgical imaging at 28 sites, with measurements reproducible enough to support the trial's fusion endpoint. Given the well-documented subjectivity of radiographic fusion assessment, the sponsor needed a central methodology that would withstand scrutiny in an IDE final report.

Image acquisition presented additional obstacles. Flexion-extension radiographs depend on adequate patient effort, positioning and calibration, while CT assessment of bridging bone can be affected by implant artifact and slice orientation. Sites differed in equipment and technique. The sponsor required standardized dynamic radiography and CT, explicit integration of biomechanical and morphological findings, and consistency in measurement landmarks and interpretation sufficient to evaluate both fusion and implant stability, with each determination traceable to its source examinations and documented criteria so that the evidence supporting the effectiveness endpoint could be reconstructed during review. A functional motion assessment and morphological evidence of bridging bone describe complementary aspects of fusion rather than interchangeable observations.

Intrinsic Imaging’s Solution

Intrinsic Imaging provided sites with detailed guidance for radiographic positioning, calibration and CT acquisition, supported by training before enrollment. Submissions were reviewed for technical adequacy, and sites received prompt feedback when examinations could not support reliable fusion or subsidence assessment. Project managers monitored follow-up imaging to help sites keep the 24-month longitudinal record complete.

Our musculoskeletal radiologists employed calibrated measurement tools to quantify angular and translational motion on flexion-extension radiographs, providing an objective biomechanical complement to morphological assessment. CT examinations were reviewed for bridging bone formation under standardized criteria, and the two lines of evidence were integrated into a single documented fusion determination for each timepoint. Readers were trained and calibrated on the fusion criteria and measurement definitions before reading began, and uniform methods applied across the full follow-up period ensured that longitudinal comparisons rested on a stable measurement foundation.

Adjudication was invoked when readers disagreed on fusion status or measured motion. Adjudicators reviewed the complete radiographic and CT record under the same criteria, and their decisions were documented in detail, giving the sponsor a transparent account of how each determination had been reached. Motion measurement on dynamic radiographs and bridging bone assessment on CT address complementary aspects of fusion; integrating them under a documented framework provided a consistent basis for every determination and a traceable rationale the sponsor could apply to future spinal device programs.

Intrinsic Imaging’s Results

- Reader agreement above 0.90 on fusion status, sustained across 28 sites and the full 24-month post-surgical follow-up period under a single calibrated methodology
- Complete 24-month imaging dataset, with follow-up monitored so that no longitudinal timepoint was lost to missed visits or technically inadequate acquisition
- Core laboratory findings included in the IDE final report, each fusion determination supported by integrated biomechanical motion data and CT evidence of bridging bone
- Calibrated motion measurement and standardized CT criteria combined into one documented fusion methodology the sponsor can apply across future spinal device programs

---

Read the full study online: https://intrinsicimaging.com/case-studies/device-orthopedic

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 St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com