CASE STUDY · MEDICAL DEVICE

Cervical Disc Replacement IDE Trial With Range-of-Motion Analysis

25 sites · Flexion-extension radiographs, CT · Range of motion, heterotopic ossification and adjacent segments

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. A cervical total disc replacement is intended to do what a fusion cannot: preserve motion at the treated level. The pivotal IDE trial for this device therefore had to demonstrate two things on imaging: that the implant maintained a functional range of motion through 24 months, and that it did not produce the complications that can defeat that purpose, chiefly heterotopic ossification that bridges and immobilizes the segment, device migration or subsidence, and accelerated degeneration at adjacent levels. Because the device was compared with anterior cervical discectomy and fusion, the control arm required fusion assessment as well.

Range of motion measured on flexion-extension radiographs is sensitive to patient effort, positioning and the method of angular measurement. Manual measurements vary by several degrees between observers, a large fraction of the motion being measured. Inadequate effort is especially common at 24 months, when asymptomatic participants have little incentive to flex fully. With 25 sites and 24-month follow-up, the sponsor needed a quantitative method whose repeatability was documented, a quality-control process capable of recovering otherwise-unevaluable timepoints, and results that would withstand the scrutiny of a premarket approval review.

Intrinsic Imaging’s Solution

Intrinsic Imaging defined a radiographic protocol specifying neutral, flexion and extension lateral views with standardized positioning instructions and a calibration marker in every image, and qualified each site's radiology staff on the acquisition before enrollment. Every incoming series was quality-checked for adequacy of effort and visibility of the relevant vertebral landmarks. Images with inadequate flexion or extension effort were flagged at quality control and the site asked to repeat the view while the participant was still present, which recovered most otherwise-unevaluable timepoints.

Central analysis used validated quantitative motion-analysis software in which trained analysts identified vertebral landmarks and the software computed angular range of motion and translation at the index and adjacent levels, with physician review of every case. Heterotopic ossification was graded by musculoskeletal radiologists using a published classification scale, and device position, subsidence and radiolucency were assessed against baseline at each follow-up. In the control arm, fusion status was determined from flexion-extension motion and bridging bone on CT at 24 months.

Analyst and reader repeatability for range of motion was established on a test set before the study began and documented in the charter. Because radiographic success was a composite in this trial, each imaging component was reported both individually and as a per-participant success determination according to the protocol definition, which the sponsor's statisticians could use directly without further derivation.

Intrinsic Imaging’s Results

- Within one degree: range-of-motion measurement repeatability on the test set, established before enrollment and documented in the charter for the premarket approval submission
- 100% of evaluable 24-month visits received dual-review assessment of heterotopic ossification, device position, subsidence, radiolucency and adjacent-segment degeneration against baseline
- Zero imaging-related deficiencies raised against the dataset supporting the sponsor's 24-month primary endpoint analysis and PMA filing, including fusion assessment in the control arm
- 25 sites held to a calibrated three-view radiographic protocol, with same-visit repeat acquisition recovering most timepoints compromised by inadequate flexion or extension effort

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

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 50 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