

Standalone Validation of Fracture AI

Standalone algorithm testing

Radiographs, CT

Multi-site validation cohort

Challenge

Before its fracture detection algorithm could be marketed, the developer needed standalone performance evidence on a dataset entirely independent of the algorithm's training data. Regulatory reviewers required the validation cohort to reflect real-world acquisition variability—multiple scanner manufacturers, imaging protocols, and patient demographics—and demanded confidence intervals tight enough to support the intended-use claims. Assembling such a cohort, with rigorously adjudicated truth for every examination, exceeded the developer's internal capacity.

Our Solution

Intrinsic Imaging curated a multi-site validation cohort drawn from geographically distinct institutions, deliberately balancing scanner vendors, protocols, and patient populations to mirror deployment conditions. Fellowship-trained musculoskeletal radiologists established the reference standard for every examination through independent dual review with adjudication, documenting fracture presence, location, and subtype. The algorithm's outputs were then compared against this standard under a pre-specified statistical analysis plan, with subgroup analyses by anatomical region and acquisition parameters.

Results

- Validation cohort of 4,800 examinations delivered
- Sensitivity and specificity claims substantiated
- 510(k) clearance received on first review cycle

Read the full study online: <https://www.intrinsicimaging.com/case-studies/ai-fracture-detection>

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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 750 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.

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