

Evaluating the impact of artificial intelligence-assisted image analysis on the diagnostic accuracy of front-line clinicians in detecting fractures on plain X-rays (FRACT-AI): A multicase multireader study

Statistical analysis plan

Sample size and power calculation

The study sample size of 500 images, evenly split between normal and selected abnormal cases, was determined using the Multi-Reader Sample Size Program for Diagnostic Studies.¹⁸ This tool, developed by Hillis, was specifically designed for MCMRS power calculations. Based on parameters derived from a previous MCMRS on pneumothorax detection, the program calculated that with 18 readers and 500 cases, the study would achieve 85% power to detect a 10% difference in accuracy between unassisted and AI-assisted readings, with a 5% type 1 error rate.

Statistical analyses

The performance of the algorithm was compared with the ground truth generated by the musculoskeletal radiologist panel. Sensitivity and specificity of readers with and without AI were tested based on the Obuchowski-Rockette model for MCMRS analysis, which modelled the data using a two-way mixed-effects analysis of variance (ANOVA) model, treating readers and cases (images) as random effects and the effect of AI as a fixed effect with recommended adjustment to degrees of freedom by Hillis.

The main analysis was performed as a single pooled analysis, including all groups and sites. Per-case sensitivity was defined as the proportion of reads in which a true fracture was marked out of all the reads having at least one fracture. Per-case specificity was defined as the proportion of reads in which no fracture was marked by the reader as a proportion of the reads that did not show a fracture. To account for correlated errors arising from readers interpreting the same images with and without AI, the Obuchowski-Rockette, Dorfman-Berbaum-Metz procedure was

used for estimation. Subgroup analyses utilised the same approach. Analyses were carried out using R and the MRMCAov library.¹⁸