Radiobotics
Augmented Radiology

RBfracture™ improves the diagnostic accuracy of Emergency Care professionals

A publication by Radiobotics
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Radiobotics has shown that its tool, **RBfracture™**, can reduce the number of missed hip fractures for Emergency Care staff by 47%. This represents significant potential to improve patient care when deployed in a clinical setting.

What is RBfracture™?

RBfracture™ is a clinical support tool which includes a binary classification of femoral fractures in plain radiographs. This product has been trained on more than 26,000 images (from 10,000 patients) and has been tested on more than 3,000 unseen images (1,000 patients), which is one of the largest datasets to train an AI model for this specific application. **RBfracture™** can currently analyse acquired hip X-ray images and provides a visual overlay identifying where a fracture is located. In the near future, **RBfracture™** will provide automated analysis of suspected fracture cases in all extremities.

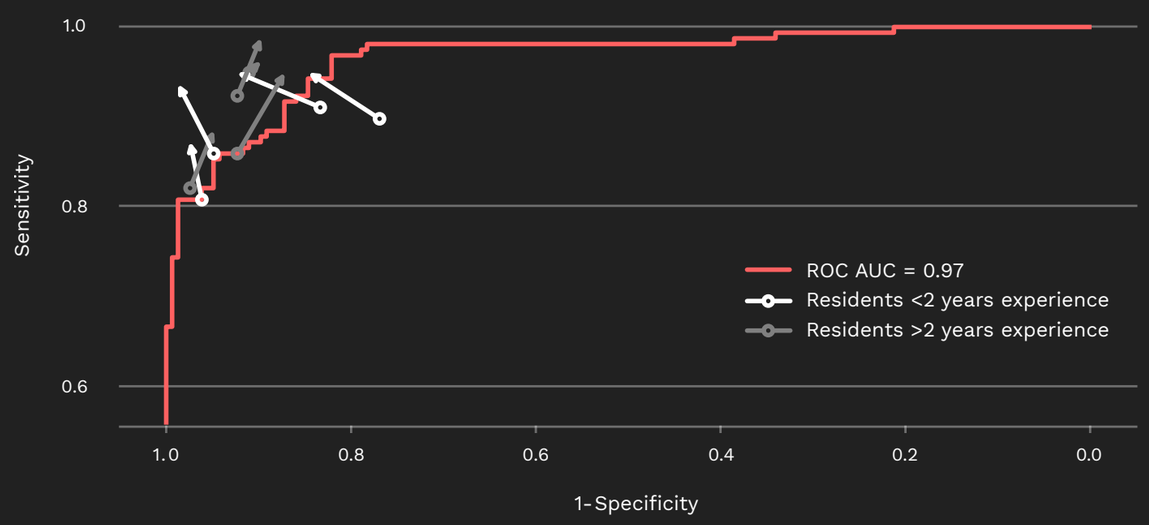
Hip fractures are the most common disabling injury and cause of accidental death in older people. Hip fractures are a frequent source of morbidity and mortality in elderly osteoporotic patients with a 1-year mortality rate of 22% for women and 33% for men. The incidence and the public health and economic consequences of this injury have risen as the population has aged, and this is expected to continue for the foreseeable future. (Parker & Johansen, 2006). This type of fracture is often caused by a ground-level fall and the incidence is almost doubled in women as compared to men. In the United States, hip fractures result in approximately 300,000 hospitalizations per year (Ross et al., 2019). With an aging population, the incidence of hip fractures and associated medical costs will continue to rise.
Rapid diagnosis and treatment of hip fractures is critical since delays in diagnosis and treatment are associated with increased short- and long-term mortality as well as increased medical cost, complication rate and length of hospital stay (Ross et al., 2019).

It can often be difficult to diagnose hip fractures in the Emergency Department, especially during stressful working conditions. It is estimated that between 2-9% of hip fracture cases are missed (Oka & Monu, 2004). Fractures may be missed due to factors like perception errors, the experience level of the readers, patient age, or image interpretation under stressful conditions in the emergency room or by an on-call radiologist after office hours (Oka & Monu, 2004). Misdiagnosis of hip fractures are associated with increased cost, complication rate, length of hospital stay, and shortened long-term mortality. Therefore, accurate diagnosis of hip fractures in a timely manner is critical. Hip fractures cannot be reliably diagnosed or excluded on the basis of physical examination alone; therefore, imaging plays a key role in early and accurate diagnosis with x-ray being the initial imaging modality of choice for assessment (American College of Radiology, 2018). A recent retrospective observational study demonstrated a direct correlation between a surgical delay of more than 12 hours and the increased adjusted risk of 30-day mortality (Nyholm et al. 2015). Additionally, it demonstrated a surgical delay of more than 24 hours significantly increased the adjusted risk of 90-day mortality (Donegan et al., 2021). Getting it right first time for patients is therefore of upmost importance and time critical.

RBfracture™ was shown to improve sensitivity by 5.6% as well as showing a 47% reduction in false negatives when using the tool. This study was carried out with medical professionals in Denmark and the UK.
For more information, see Appendix 1: Study Design and Methodology.

Potential of this innovation[1]
As demonstrated by this study, **RBfracture™** offers significant improvement in detection rates of hip fractures for patients.
Diagnosing these patients quickly and minimising missed fracture cases can unlock several benefits in healthcare including:

1. Reduce errors in diagnosis
2. Reduce time to diagnosis for hip fracture patients
3. Reduce time to treatment for hip fracture patients due to reduced time to diagnosis
4. Reduce mortality and morbidity due to decreased time to treatment
5. Increase confidence for practitioners in Emergency Care



Benefits to Radiology Departments
Radiologists may experience a reduced workload as reporting is increasingly automated and standardised, requiring only review and additional observations added where clinically appropriate.

Benefits to Hospitals
Emergency Care staff will be provided with tools which will enable them to more accurately diagnose hip fractures, which can be difficult to diagnose, particularly in busy A&E departments.

Waiting times in A&E may be reduced as patients can be diagnosed and treated faster than levels today.

Length of stay in hospitals can be reduced as early diagnosis can prevent more complex surgery.

Orthopaedic surgeons may get earlier visibility of hip fracture patients who may otherwise be missed and sent home as they will be diagnosed using RBfracture™, which enables faster time for these practitioners to operate.

Benefits to Social Care
Those involved in community care, occupational therapists as well as unpaid carers will have a reduced burden as patients will be diagnosed and treated in a more timely manner. This will cause less care burden.

1: To be confirmed in future clinical studies

RBfracture™ has shown very promising results and represents a real game changer for use when reviewing hip fracture X-rays. This technology can generate value for a wide range of healthcare professionals in the hospital and social care environment, not least for emergency care professionals to have a second pair of eyes when reviewing fracture images.

Appendix 1:
Study design and methodology

The purpose of our study was to investigate how the use of RBfracture™ affects the diagnostic performance of the reader to detect hip fractures. Here, we define hip fractures as fractures occurring on the proximal femur, including the femoral neck and head.

The primary objective of this study was to determine whether the diagnostic accuracy of readers aided by the medical device, RBfracture™, is superior to the diagnostic accuracy of readers unaided by RBfracture™. This was assessed in terms of the mean patient-wise sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) with and without aid.

The study was conducted as a multireader, multicase (MRMC) study, where readers assessed radiographic examinations in two different modes; aided and unaided by RBfracture™. In the unaided mode, only the original radiographs were available for the assessment of the fracture status. In the aided mode, the original radiographs were available together with the output from RBfracture™ that included a copy of the original radiographs with the text “No Hip Fracture Detected” or “Hip Fracture Detected” depending the assessment made by RBfracture™. A bounding box encompassing the fracture site was automatically drawn by RBfracture™ on images with “Hip Fracture Detected”.

The radiographs for this study were originally acquired during normal clinical practice in clinical sites in both USA and Denmark, and contained 312 patients with a balanced distribution of fracture (50%) and no-fracture (50%). The data used for this study was not used during development of the device. The eligibility criteria for the data was considered on both a patient level and an image level, and included patients aged 21 years or above referred to diagnostic workup with a suspicion of acute hip fracture. Patients with implants or other hardware in the proximal femur of the symptomatic side were excluded. Patient examinations showing only obvious fractures (multi-fragment, displaced or dislocated) and images that were of too poor quality precluding human interpretation were excluded.

Reference standard
The Reference Standard was established by two radiologists with more than 4 years of musculoskeletal experience by independently reviewing all images. The original radiological reports from the hospitals reporting system were available for the experts during labelling. Any disagreements were resolved by a reporting radiographer with 11 years of experience, specialized in MSK-reporting. All examinations included in the study sample were assigned a binary label indicating the presence or absence of fractures in any of the radiographs included in the examination.

Eight independent readers with varying levels of experience were included. All readers had experience with assessing trauma radiographs in Acute and Emergency (A&E) departments. Each reader received training in using RBfracture™ prior to starting the study and were blinded to one another's readings and the reference standard defined by the experts.

Study design
The images were divided into two blocks, where half of readers read block 1 in the aided mode and block 2 in the unaided mode. The other half of the readers read block 1 in the aided mode and block 2 in the aided mode. Readers were assigned to either of the reading schemes so that a homogenous distribution of experience was present across groups. The readers read all images and the order of images to be read aided/unaided was randomised at a patient level.

Outcome Observations
To resemble the natural workflow in the clinic, the evaluation was done on a patient-level, i.e. all radiographs from the radiographic hip examination. Each patient examination was, after processing, classified into one of four categories:

True positive (TP) Any patient identified by a reader as having a fracture, in which at least one fracture is present as defined by the Reference Standard.
True negative (TN) Any patient identified by a reader as having no fracture, in which no fracture is present in any of the radiographs as defined by the Reference Standard.
False positive (FP) Any patient identified by a reader as having a fracture, but in which no fracture is present in any of the radiographs as defined by the Reference Standard.
False negative (FN) Any patient identified by a reader as having no fracture, but in which at least one fracture is present as defined by the Reference Standard.

Evaluation of the readers
The mean patient-wise sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) was used to assess the difference in diagnostic accuracy in the aided and unaided mode. The success of the primary analysis requires demonstration of both the superiority of the patient-wise sensitivity in aided mode to that in unaided mode and the noninferiority of the patient-wise specificity in aided mode to that in unaided mode with a non-inferiority margin of 3%.

This corresponds to use in clinical practice. The first clinical review of hip fracture X-ray cases is usually performed by non-Radiology staff who have less training in image interpretation compared to their Radiology peers. These cases are subsequently reviewed by their Radiology counterparts where there can be delays in reporting times due to Radiology capacity constraints. Between 2-9% of cases are reported to be missed (Oka & Monu, 2004). This is confirmed by the Royal College of Radiologists who report that more than half of hospital bosses say that they do not have enough Radiologists to keep patients safe (The Royal College of Radiologists, 2021). It is common for Xx-ray reports to be delayed by over 24 hours in the UK and this has direct implications to patient outcome (The Royal College of Radiologists, 2016).

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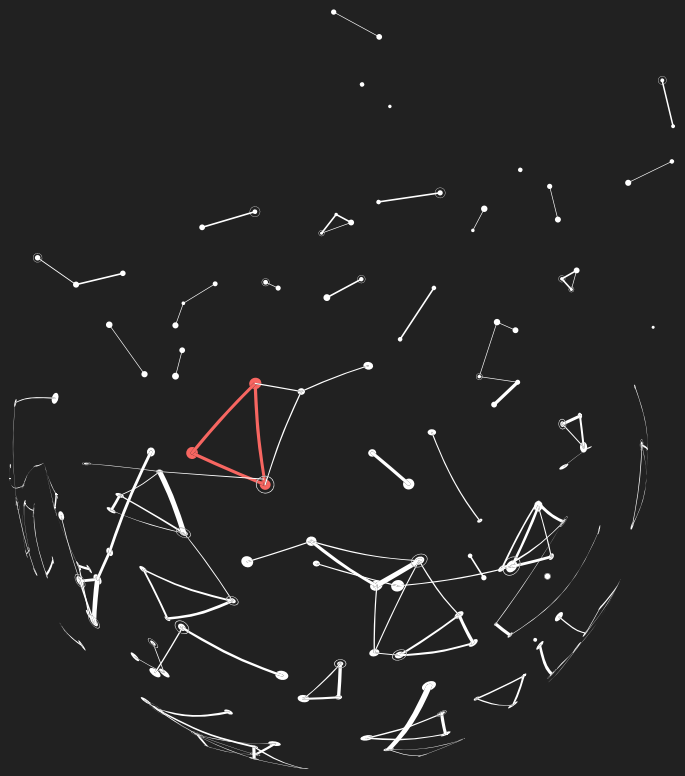

About Radiobotics

Radiobotics is a multiple award-winning health tech company having their HQ in Denmark and with an office in Texas, US. The company has build an innovative AI technology specialized in x-ray analysis with focus on musculo-skeletal radiology. Based on advanced computer vision and machine learning methods, Radiobotics' algorithms generate fully automated, objective text and visual reports.

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