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Lockwood, P., Pittock, L., Lockwood, C., Jeffery, C. and Piper, K. (2015) Intraorbital foreign body detection and localisation by radiographers: a preliminary JAFROC observer performance study. Radiography, 2015. pp. 1-5. ISSN 1078-8174.

Link to official URL (if available):

http://dx.doi.org/10.1016/j.radi.2015.06.005

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# Intraorbital foreign body detection and localisation by radiographers: a preliminary JAFROC observer performance study

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#### Key words

Radiographer, Intra Orbital Foreign Body, Jackknife free-response receiver operating characteristic, Observer Performance, Magnetic Resonance Imaging.

Word count 2656

#### Abstract

Introduction - The purpose of this study was to run a preliminary investigation to establish if a short course of learning would increase radiographers' performance in intraorbital foreign body (IOFB) detection and localisation on pre-magnetic resonance imaging (MRI) orbital computed radiographs (CR).

Method - A multi-reader multi-case (MRMC) human observer study was performed. Fifteen radiographers from 5 hospitals participated. Each radiographer reviewed a pre- and post-training image bank and was instructed to identify the presence or absence of IOFBs, indicating the lesion location on each case whilst scoring the detection using a confidence index on a 5-point scale, for 30 orbital radiographs. The results were analysed using a Jackknife free-response receiver operating characteristic (JAFROC2 equal weighted) methodology.

Results -The performance of the radiographers demonstrated a statistically significant difference after a short period of training in the detection of IOFBs on orbital radiographs (F (1,14)= 12.99, df = 14.0, p = 0.0029). The JAFROC2 analysis averaged figure of merit (FOM) for the radiographers was 0.818 (95% CI 0.769, 0.867) pre-training and 0.920 (95% CI 0.891, 0.950) post-training.

Conclusion - These results suggest that with a short programme of learning in image interpretation for IOFBs in orbital radiographs, radiographers should be able to achieve a high level of accuracy in the identification and localisation of IOFBs prior to MRI examination.

#### Highlights

- Using a MRMC study of 15 radiographers from 5 hospitals
- We evaluated radiographers' performance in IOFB detection and localisation
- The examination incorporated a pre- and post- image bank of IOFB examples
- The exam reports were analysed using JAFROC2 methodology
- Radiographers after a short course of learning achieved high levels of accuracy

#### Introduction

Since the first reported cases of serious eye injuries from metallic intraorbital foreign bodies (IOFBs) by Kelly et al<sup>1</sup>. The risk from injuries such as rupture, haemorrhage or blindness have formed the basis for stringent screening protocols for pre- magnetic resonance imaging (MRI) examinations. There has since been numerous reported cases<sup>2, 3, 4, 5</sup> that have helped develop health and safety protocols to screen patients with suspected metallic IOFBs before they enter the controlled area of the MRI department. Current policies applied in National Health Service (NHS) practice conform to recent guidelines by the Society and College of Radiographers (SCoR) and the British Association of Magnetic Resonance Radiographers (BAMRR)<sup>6</sup>, the Medicines and Healthcare products Regulatory Agency(MHRA)<sup>7</sup>, the European Union Physical Agents Directive (EUPAD)<sup>8</sup> and the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R Schedule 1<sup>9,10</sup>. All of which aim to ensure no individual (patient, staff, or visitor) enters an MRI controlled area with a metallic IOFB. This process involves verbal screening, written questionnaires, review of previous imaging (if available) and in uncertain cases pre-MRI orbital radiographes.

MRI radiographers have the potential to role extend and develop their clinical practice in a service improvement capacity to streamline their diagnostic imaging pathways. Under IR(ME)R<sup>10</sup> legislation MRI practitioners have the capacity through local level agreement to develop a scope of entitlement to identify themselves through departmental protocols, referral criteria, job descriptions and appropriate continuing profession development (CPD) training and audit activities to be recognised as the referrer for pre-MRI orbital radiographs. The relevant skills and knowledge to extend radiographers' scope of practice for the rationale to refer patients for orbital radiographs and the interpretation of imaging for the purposes of excluding the presence of metallic IOFBs are contained as part of the protocols in the employers' procedures under IR(ME)R<sup>10</sup>. The demonstrable knowledge would need to show an awareness of the circumstances leading to a penetrating injury resulting in a retained IOFB, with regular audit of the suitability and impact of referrals<sup>11</sup>. Whilst documenting a record of a sufficient amount of test film viewings from a bank of suitable radiographs, and a period of clinical image interpretations to demonstrate a level of competence. Specifically IR(ME)R<sup>10</sup> advises that each medical exposure has a clinical evaluation of the image, which is recorded for audit purposes.

Radiographers have previously evidenced the ability to interpret a wide range of current radiographic investigations<sup>12, 13, 14, 15, 16, 17, 18</sup>. Role extension into referral and interpretation of pre-MRI orbital radiographic imaging would benefit the workflow practice of busy MRI departments and waiting time initiatives, as well increasing radiographer responsibilities in a modern radiology service.

#### **Aims and Objectives**

The purpose of this study was to run a preliminary investigation to establish if a short one day intensive course of lectures, question and answer sessions and interactive case reviews would increase radiographers' performance in IOFB detection and localisation on pre-MRI orbital computed radiographs. The training reviewed orbital and facial bone anatomy, physiology, pathology, image interpretation and search strategies. Whilst reviewing published cases of IOFB injuries, and discussing the current legal perspectives and NHS polices and guidelines to prevent IOFB injuries.

#### Methodology

The study followed a multiple reader multiple case (MRMC) retrospective preliminary study of 15 radiographers from 5 hospitals using a Jackknife free-response receiver operating characteristic

(JAFROC2) methodology<sup>19</sup>. The observers reviewed a pre- and post-training image bank and were instructed to identify the presence or absence of IOFBs, recording the lesion location (LL) on each case and scoring the detection using a confidence index on a 5-point scale for 30 orbital radiographs. The study was approved by an ethics and governance panel, and all observers gave informed written consent.

The sample of participants recruited conformed to the criteria of band 5 and 6 radiographers working within MRI departments of southern United Kingdom (UK) hospitals, all had MRI experience ranging from 3 to 9 years, and some had previous postgraduate training in MRI, but no radiographers had any plain film reporting experience. The sample size for this preliminary study followed Obuchowski<sup>21, 22</sup> tables for receiver operating characteristic (ROC) studies of observers sampled in medical imaging studies, and for external validity purposes<sup>23</sup> would not be representative of being proportional to the general population.

The images were obtained by permission of local NHS trusts from an anonymised retrospective digital teaching library (DTL) used by the university for research and teaching that conformed to section 33 of the UK Data Protection Act<sup>24</sup>, the Cosson and Willis<sup>25</sup> guidance from the National Information Governance Board for Health and Social Care, and the General Medical Council<sup>26</sup>.

Orbital radiographs used included letter box collimated under tilted occipito-mental (OM) with orbitomeatal baseline raised 10 degrees less than for a standard OM (to provide a circular appearance of the orbits, unlike the oval OM standard view). Some of the images used included secondary supplementary views of eyes up or down or lateral side to side.

Images rejected from the study bank included those with the petrous ridge superimpositioned upon the lower orbital margin, poor positioning or rotation of the facial bones, over tilted projections, and the presence of artefacts on the imaging plate.

A sampling bias of pathology was reduced as near as possibly by using an appropriately wide range, amount and size of IOFBs as was feasible that conformed to textbook examples and conspicuity. A suitable range of subtle IOFBs as discriminatory examples ensured a fair process of image interpretation<sup>22, 27</sup>. Where there were multiple IOFBs on an image each lesion was given equal weighting factor for the JAFROC2 analysis, as each lesion was deemed to have an equal importance and risk factor for potential injury. JAFROC2 methodology compares the performance of readers interpreting the same bank of cases at two different intervals (pre-testing was at the start of the study day, post-testing at the end of the study day). The methodology was intended to investigate questions such as whether or not teaching image interpretation improves diagnostic performance in the detection and localisation of IOFBs on orbital radiographs.

Each case had a triple reader retrospective approach of interpretation by three independent and blinded reviewers<sup>27</sup> (a consultant radiologist and two reporting radiographers) to determine concordance for the reference standard, and reduce potential bias (internal validity) of inter-rater disagreement of same case reviews <sup>28, 29, 30</sup>.

The images were evaluated on Liquid Crystal Display (LCD) image monitors with a resolution of 1280 x 1024, calibrated to the Digital Imaging and Communications in Medicine (DICOM) part 14 Greyscale Standard Display Function (GSDF) with VeriLUM software<sup>32</sup>. Quality checks were performed on the monitors prior to each test with a standard diagnostic imaging Society of Motion Picture and Television Engineers (SMPTE) reference pattern for spatial uniformity of luminance and temporal luminance stability complying with Royal College of Radiologists (RCR) guidelines<sup>31</sup>. The cases were viewed using commercially available software (K-PACS<sup>33</sup>) intended for displaying DICOM

images. This allowed the observers to alter the computed radiograph (CR) window width and window level, pan and zoom the image, and measure region of interests (ROI) with the ability to display multiple images from a case for comparison views. An observing environment was chosen specifically for this study that reduced the possibility of disturbance of concentration, by controlling the lighting, noise and interruptions<sup>27</sup>.

The JAFROC2 (equal weighted) methodology allowed the readers to make as many or as few responses per images, and the paradigm allowed multiple IOFBs per case if required. When the observer reviewed each case they labelled the LL ROI (or quadrants in JAFROC2 terminology) and rated the degree of suspicion using a confidence index score, in this study 1-5. A score of 1 equated to high confidence that the ROI in question did not have a lesion (normal), with grading up to a score of 5 inferred the reader was highly confident the ROI in question did have a lesion (similar to a Likert scale).

The reader's scores were marked as either LL i.e. the mark of a lesion was within an acceptance region to the real lesion, or a non-lesion location (NLL). Acceptance regions of lesions are varied in peer review literature, this study has followed the Chakraboty<sup>34</sup> recommendation of a maximum diameter of a lesion or 3 mm. Acceptance radiuses are a controversial topic in observer performance studies and Chakraborty<sup>34, 35</sup> considers the question of what is the maximum inaccuracy with no clinical impact that would be acceptable in a study scenario.

The JAFROC2 (equal weighted)<sup>19</sup> analysis produces a figure of merit (FOM) metric which determines the measure of the observer's detectability, using the number of LLs compared to the total known number of lesions (lesion localisation fraction (LLF), and NLLs relative to the total number of cases in the image bank (non-lesion localisation fraction (NLF). Specifically JAFROC2 (equal weighted)<sup>20</sup> methodology was used as NLL on non-diseased cases are counted towards false positives factor (FPF), which takes into account satisfaction of search errors (the amount of NLL marks on diseased cases).

With all statistical reasoning of data there is a need to estimate the variability of the results, in this study the JAFROC2<sup>19</sup> variance component uses analysis of variance (ANOVA) with the results displayed as 95% confidence intervals (95% CI) which JAFROC2 uses to qualify each statistic as the trapezoidal area under the curve (AUC). This is a non-parametric bootstrapping method to obtain the FOM<sup>35</sup> to bench mark the performance of the observational task. Although the reader performance in decision making is subjective, the FOM is an objective measure of performance which rewards correct answers and penalizes incorrect answers using a scalar unidirectional measure of 0-1 (0 as an incorrect decision and 1 as a correct measure against the reference standard of case answers). The FOM is equal to a Wilcoxon test statistic<sup>36</sup> for two samples (pre- and post-training image bank results) and JAFROC2 determines if the difference is sufficiently bigger evaluated against the statistical variability of chance<sup>35</sup>. JAFROC2 also calculates an *F* statistic,  $n_N$  (numerator) and  $n_D$  (denominator) degrees of freedom (*df*), at the desired probability level<sup>38</sup> used in small sample size studies, and the *p* value determines the quantified degree of unlikelihood<sup>37</sup>.

#### Results

The performance of the radiographers demonstrated a statistically significant difference after a short period of training. The detection of IOFBs in CR images demonstrated an increased performance after training (F (1,14) = 12.99, df = 14.0, p = 0.0029, Table 1, 2,and 3). The JAFROC2 analysis average FOM for the radiographers was 0.818 (95% CI 0.769,0.867) pre-training and 0.920 (95% CI 0.891,0.950) post-training.

The overall observer's performance improved with training, showing 11 radiographers increased the amount of correct LL IOFBs recorded from the pre-training bank to the post-training bank, and 4 radiographers scored the same amount of LLs in the pre- and post-training image banks. The variation of the observed distribution of NLL scores between the pre- and post-training banks ranged from an increase of NLLs for 6 radiographers, no difference for 7 radiographers and 2 radiographers reduced their NLL scores with training (Table 1).

#### Discussion

The results are consistent to previous studies showing the ability of radiographers to improve their performance of interpretation after a short course of formal training<sup>39, 40</sup>. The radiographers in this study produced a mean FOM of 0.920 (standard error 0.013, *df* 14, 95% CI 0.891,0.950). A literature search to find similar studies of radiographers' abilities in the accuracy of IOFB identification and localisation found no comparable figures. Historic studies have shown a range of predicated observer sensitivity scores of plain film radiographs to identify IOFB's. Bryden et al<sup>41</sup> have shown that observers able to identify IOFBs using radiographic (not CR) images to a 69% sensitivity on x-rays.

The appearance of an IOFB radiographically is a debatable issue. The question of IOFBs to be detectable on CR must take into consideration the size and shape of the metallic IOFB. It has been shown in previous studies<sup>11</sup> that metallic fragments as small as 0.5x0.2mm are not visible on radiographs to observers, and additionally glass and wooden IOFBs have poorer sensitivity on radiographs<sup>44, 45</sup>.

Other additional examinations have been shown as alternative non-ionising examinations of the orbits prior to MRI scanning, ultrasound has proven to be exceptionally sensitive (93%) to IOFBs in screening<sup>41, 44</sup>, although orbital cavity fat has shown to produce reflective artefacts that impact the evaluation of retained intra and extra ocular particles<sup>41</sup>. Additionally there are multiple studies that have researched computed tomography (CT) as highly accurate in determining IOFBs<sup>43, 46</sup>, with sensitivity for metallic IOFB detection at  $100\%^{43, 47}$  (65% sensitivity <0.06mm<sup>3</sup>, 100% sensitivity >0.06mm<sup>3, 48</sup>). Although the increased radiation dose to the radiosensitive orbital contents must be considered before imaging.

It could be argued that there is substantial controversy regarding the necessity of screening patients prior to MR procedures. Various studies have questioned the adequacy of the screening process including the questions asked within pre-MRI questionnaires<sup>11</sup>, and have implied that some clinical sites do not use orbital radiographs when screening patients. The implications for this variation in practice are that some centres may deem the subjection of ionising radiation unjustified, whereas others might see this as an unsafe practice according to their safety protocols and guidance from other countries<sup>49</sup>.

Indeed a study by Williamson et al<sup>50</sup> discussed the risk of injury from an MRI scan to patients with a history of a metallic IOFB, and suggested a figure of one in several thousand will actually incur an injury, and thus routine screening of at risk patients would seem unnecessary. A balanced argument would state that although it has been shown that a questionnaire may not provide an adequate patient history to reduce the risk of harm<sup>11, 51</sup>, and that there are many factors that impact on the level of risk from ferromagnetic IOFB movements (location, size, geometry, metallic properties, MRI field strength, and period of time the IOFB has been in situ<sup>50</sup>), a proven risk has been demonstrated in peer reviewed papers <sup>1, 2, 3, 4, 5</sup>. The majority of NHS facilities have established strict screening criteria for possible intraocular and IOFBs in line with current guideline recommendations<sup>6</sup>.

Radiographic imaging appears to be the acceptable technique<sup>6</sup> for identifying or excluding an intraocular or peri-orbital metallic foreign body that may present a potential hazard to the patient entering the MRI environment.

The value of short training courses for radiographers appears appropriate in this setting to compliment continuous professional development requirements of radiographer's registration to the Health and Care Professions Council and the SCoR. Furthermore it supports research and initial modelling of future role extension and development of radiographer's ability in service improvement within MRI departments. The efficacy of running short courses has the ability to produce change and has been shown to be beneficial in improving radiographic interpretation<sup>52, 53</sup>.

The results of this research, although significant in findings, constitute a small sample and are unrepresentative of the population of radiographers. Further research is recommended and using the preliminary study's JAFROC2<sup>19</sup> data analysis allowed an Obuchowski-Rockette Dorfman-Berbaum-Metz (OR-DBM) method to perform sample size estimation for a future phase 2 study. The OR-DBM method is considered the standard to reasonably calculate how many readers and how many cases are needed to get a 0.05 Alpha, with a desired power of .80 (1-beta). The variance component covariance estimates for sample size ANOVA estimated a future study of 30 observers and 45 cases would give a prediction of observer performance at 0.8.

#### Conclusions

These results suggest that with a short programme of learning in image interpretation for IOFBs in orbital radiographs, radiographers were able to achieve a high level of accuracy (0.920 FOM (95% CI 0.891,0.950) in the identification and localisation of IOFBs prior to MRI examination. A significance of p = 0.0029 was demonstrated between the pre and post-training bank results signifying a potential for inexperienced radiographers to improve image interpretation with training. Further study in this field of training radiographers in the interpretation of pre-MRI orbital radiograph should be completed.

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#### Acknowledgements

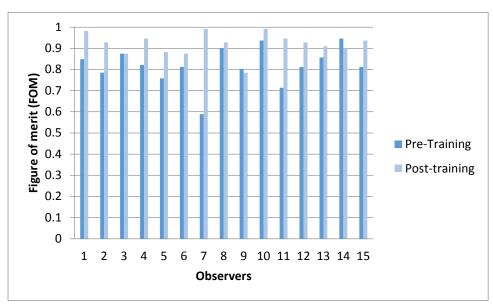
The authors would like to thank all the radiographers that participated in the study.

#### Funding

There were no financial conflicts of interest.

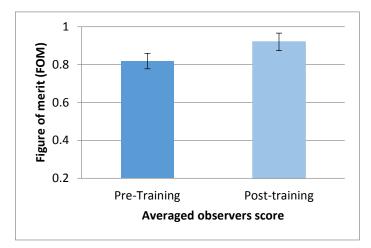
#### **Conflicts of Interest / Affiliations**

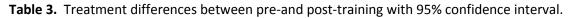
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**Table 1.** JAFROC FOM for pre-training (dark blue bars) and post-training (light blue bars) for each observer.

**Table 2.** Observer averaged pre-training (dark blue bar) and post-training (light blue bar) with 95% confidence intervals.





	Statistical	Radiographer Mean	Radiographer Mean
Analysis	significance	Pre-training	Post-training
		FOM (95% CI)	FOM (95% CI)
JAFROC2	F (1,14) = 12.99	0.818	0.920
Equal Weighting	<i>P</i> < 0.0029	(0.769,0.867)	(0.891,0.950)