Introduction

Ferromagnetic materials are considered as contraindications for MRI because there is a potential for them to move or become displaced[1]. In 1986, Kelly et al. first reported a case where a patient who had a clinically occult 2.0 × 3.5 mm metallic intra-ocular foreign body (IOFB) underwent an MRI examination which subsequently resulted in a vitreous haemorrhage and unilateral blindness[2].

Since then, radiographic examinations of the orbit are used as a screening test prior to MRI examinations to rule out possible IOFBs in patients who are deemed high risk following completion of screening questionnaires. Previous studies have concluded that radiographic examinations are a useful method to exclude ferromagnetic IOFBs prior to MRI[3]. However, Bryden et al.[4] and Bray, & Griffiths[5] found the sensitivity of film/screen for detecting metallic IOFBs to be 69% and 90%, respectively. Furthermore case reports of ocular injury despite apparently normal orbit radiographs have led to concerns regarding the sensitivity and specificity of film/screen radiographs used for this purpose[6].

The aim of this study was to determine the accuracy of orbital X-rays, when using computed radiography (CR), in detecting ferromagnetic IOFBs prior to Magnetic Resonance Imaging (MRI).

Materials and methods

Image acquisition

An adult anthropomorphic head phantom was positioned for a posteroanterior (PA) projection of the orbits in keeping with key radiographic positioning texts[7,8]. The phantom's chin was then raised in order to lower the petrous ridge below the inferior aspect of the orbit. A Wolverson Acroma X-ray unit (high frequency generator with VARIAN 130 HS standard X-ray tube, total filtration of 3 mm Aluminum equivalent and a 0.6 mm focal spot) was used to acquire the images. The tube voltage and mAs were manually selected (70kVp and 20mAs) as this mimicked local clinical practice. The source-to-image distance was fixed at 100 centimetres and the primary X-ray beam was collimated to include the lateral skull margins and the whole of the orbits (21.5 x 8.5 cm). This also followed recommendations within the literature[7,8].

Images were acquired using the same 18 x 24cm Agfa CR image receptor (IR) which was placed in the vertical Bucky. Acquisitions made use of a secondary radiation grid and images were processed using an Agfa 35-X digitizer (Agfa-Gavaert Corp, Mortsel, Belgium) using a skull look up table.

IOFB simulation

A preliminary study was conducted to select suitable sizes and compositions of ferromagnetic materials in order to mimic IOFBs. Four large (>1.0 to 0.6 mm) sized IOFBs, four mid-sized (0.5 to 0.1 mm) IOFBs and four small (iron filing) IOFBs were subsequently selected. For each image it was planned to have 1, 2, 3, or 4 IOFBs in either the left or right orbit across the four quadrants (**Fig 1**). The IOFBs were fixed to the anterior surface of the orbit with a random distribution but with a minimum of 20% distribution for each size per quadrant (**Table 1**). Across the 24 images with IOFBs present there was a dedicated image with small, medium and large IOFBs for each of the eight eye quadrants. All of the 24 acquired images with an IOFB were duplicated in order to increase the sample size. A further 16 normal images (no IOFB) were also included in the sample; this gave a total of 64 images (**Fig 1**).

Image assessment

Ten observers (four radiographers, four reporting radiographers and two consultant radiologists) reviewed each of the images independently. Observers were provided with 64 diagrams of the orbits and asked to place a cross on the diagram to indicate the location of any IOFB they identified on the corresponding image (**Fig 2**). The same instructions were provided to each observer and images were randomised but presented to each participant in the same order. Observers had no prior knowledge of the IOFB simulations.

Images were viewed on a 24 inch NEC MultiSync EA243WM monitor (NEC Corp, Tokyo, Japan). Each display had been previously calibrated to digital imaging and communications in medicine (DICOM) grayscale standard display function (GSDF) and had a resolution of 2.3 megapixels. The LCD luminance was consistently above 170cd m^{-2} which satisfied the minimum specification for primary diagnostic display devices used for image interpretation. The ambient lighting conditions were dimmed and kept constant for all observers in order to standardise the viewing conditions. Observers were permitted to manually magnify and window the images to detect any IOFBs present on each image.

Statistical analysis

All data were transferred to Excel 2013 (Microsoft Corp, Redmond, WA) for statistical analysis. Sensitivity, specificity, and accuracy values were calculated for each observer. According to Altman (1999) the sensitivity of a test can be calculated $a/(a + c)$ by the number of cases with a true IOFB correctly detected by CR (*a*) divided by the sum of this number combined with any true cases of IOFBs missed by CR (*c*)[9]. The specificity of the test was calculated in a similar manner $d/(b + d)$ where (*d*) is the number of cases without an IOFB correctly identified by CR and (*b*) is the number of positive IOFB cases determined by CR which were in fact not present. Accuracy refers to the true positives plus the true negatives divided by the true and false positives and the true and false negatives. For sensitivity, specificity and accuracy values generated using the above equations were multiplied by one hundred in order to provide percentage values. Sub-analyses were undertaken to evaluate the diagnostic accuracy of CR for different IOFB sizes and locations. In order to achieve this, IOFBs were graded as small, medium and large and the eye was split into four quadrants as previously demonstrated. Performance data were expressed as mean values plus and minus their respective standard deviations (SD). Data was also assessed according to observer type (radiographer, reporting radiographer or radiologist).

Results

In this study, a total of ten observers evaluated 64 images and confirmed the presence or absence of an IOFB. The overall performance for all of the participants is summarised in **Table 2**.

The mean sensitivity for confirming the presence of an IOFB was 72.1%, indicating that when using CR IOFBs can be demonstrated in around three quarters of patients when present. When confirming the absence of metallic IOFBs the specificity was higher at 99.2%. When combining the evaluation of the presence and absence of IOFBs the diagnostic accuracy was 93.1%.

The diagnostic performance of CR in relation to IOFB size is summarised in **Table 3**. Unsurprisingly, sensitivity rates fell from 92.6% to 45.8% when decreasing the IOFB size (large to small). Specificity rates remain relatively unaffected by the size of the IOFB; accuracy did show a reduction when decreasing the IOFB size and reflects the changes in the sensitivity of the test (ability to detect pathology).

In terms of IOFB location there were a number of diagnostic performance trends identified from this research (**Table 4**). Metallic IOFBs located in the lateral quadrants were more likely to be missed. Overall, the lower lateral quadrant had the lowest sensitivity (mean 53.0 SD 7.8%) followed by the upper lateral quadrant (mean 76.9 SD 5.0%) and then the lower medial quadrant (mean 77.1 SD 9.4%). The upper medial quadrant had the highest sensitivity (mean 87.8 SD 5.9%).

Our sample of participants included four (40%) radiographers, four (40%) reporting radiographers and two (20%) consultant radiologists. **Table 5** indicates that there was minimal difference in the accuracy in detecting metallic IOFBs between the different observer types.

Discussion

The aim of the current study was to determine the accuracy of CR orbital x-rays in detecting ferromagnetic IOFBs prior to MRI. The overall accuracy was found to be 93.1%. Previously, Bryden et al.[4] and Bray & Griffiths[5] quantified the value of conventional film/screen radiography for detecting metallic IOFBs. Although the aim of these studies was not to specifically determine the accuracy of film/screen radiography for detecting metallic IOFBs prior to MRI, they do highlight the importance of detecting IOFBs to prevent complications. However, the conclusions drawn by these authors are based on the use of film/screen systems and our study is based on the use of CR systems.

Observers correctly identified the absence of a metallic IOFB in 99.2% of cases. However, this suggests that in approximately 0.8% of normal cases, the radiographic findings might incorrectly identify a patient as contraindicated for MRI which could potentially hinder MRI examinations thus delaying patient diagnosis or treatment. In addition, patients may be referred for further imaging examinations such as CT to more precisely locate the IOFB[3, 10, 11]. This could further delay the MRI examination and potentially result in the patient receiving an unnecessary radiation dose. However, in a clinical setting, in accordance with local imaging protocols, more than one radiographic projection of the orbits may be acquired for each patient (e.g. one with the patient's eyes in upward gaze and a second with the eyes in downward gaze) and, therefore, the accuracy may be higher than that found in this study.

Importantly, the overall sensitivity of 72.1% in our study suggests that in approximately 28% of cases, where an individual has a ferromagnetic IOFB, a CR image will fail to detect the IOFB. Our results indicate that nearly half of the small ferromagnetic IOFBs used in this investigation will not be detected by CR. Our results are slightly higher than those of Bryden et al.[4] who found the sensitivity of film/screen images for detecting metallic IOFBs to be 69%. However, this may be due to higher image quality resulting from CR systems as opposed to the use of film/screen. In suggesting that image quality may be higher for CR this would result from an increase in contrast resolution and the ability to optimise the image using post-processing features on the CR system. Our sensitivity value (72.1%) can be viewed as being a lot lower than the 90% sensitivity value found by Bray, & Griffiths[5]. A possible explanation for this higher value may be that in their study, all 1137 patients included in the retrospective analysis, had a modified occipitomental projection (with chin elevated 35°) and a lateral projection with exposure for soft tissues. The lateral projection may have increased the sensitivity but would also include an additional radiation dose. Newman[10] in 1999 reported on the use of the lateral projection for IOFB detection and described a case where a foreign body located on the eyelid failed to be identified. Additionally, it is our experience that lateral orbital radiographs are rarely undertaken but we accept that they may have some utility for some patients.

Interestingly, nearly half of all patients who have small ferromagnetic IOFBs may have undergone MRI examinations. The risk of an adverse effect is likely to be dependent on a number of factors including the strength of MR scanner, location and the size of the ferromagnetic object. It is, therefore, important to highlight that large and medium-sized IOFBs will go undetected in nearly 7% and 24% of cases, respectively. These findings concur those of Bryden et al[4] who concluded that it is not only the small IOFBs that escape detection. Patients will therefore undergo the MRI examination even though they harbour a ferromagnetic material that is potentially hazardous in an MR environment. This also supports the conclusions of Williamson et al.[12] and Seidenwurm et al.[13] who have stated that several patients with ferromagnetic IOFBs may have undergone MRI examinations unharmed.

More recently, Zhang et al.[14] reported two cases where patients with tiny ferromagnetic IOFBs (0.375x0.3x0.15mm and 0.5x0.4x0.2mm) underwent MRI examinations with no apparent resultant MR-induced damage. In both cases, plain X-ray films failed to allow the visualisation of the IOFBs. The authors therefore concluded that such small ferromagnetic IOFBs, which are too small to detect on plain film X-rays and CT, may not be large enough to result in MR-induced intra-ocular damage using MR scanners of magnetic field strengths below 1.0T. However, the risk of an MR-induced injury is dependent on several factors including the shape, location, composition, and orientation of the ferromagnetic objects[15, 16]. If a foreign body is located near important neural or vascular structures or other soft tissues, MR examinations must be avoided[14]. Approximately one-third of the orbit is occupied by the globe while the rest of the orbit is composed of fat, nerves, muscles, and vasculature[17]. Nevertheless, regardless of whether such small ferromagnetic IOFBs might result in MR-induced ocular injury, it is vital that they are visualised because misdiagnosis could result in ocular toxicity, and retinal inflammation, discolouration of the iris, siderosis and cataract formation[18, 19]. Failure to identify metallic IOFBs depending on the location of the IOFB may result from dense anatomical structures overlying the orbital region. It is therefore important to achieve optimal patient positioning to ensure the petrous ridges do not overly the orbits.

Limitations

Although our findings support the conclusions of previous authors which indicate that conventional X-rays fail to detect metallic IOFBs in 100% of cases, as this is a phantom-based *ex-vivo* study, factors including positioning, non-IOFB pathology and variations in anatomy were not taken into consideration. Furthermore, it is acknowledged that variations exist in the imaging protocols between different centers and in our study we only acquired one PA projection of the orbits without any control of visual gaze.

Recommendations for further work

Future work should extend this study to include more observers across a range of study sites, particularly radiologists and radiographers trained to assess orbital X-rays for detecting metallic IOFBs prior to MRI. As there was little difference between the results of radiographers and reporting radiographers, it would be worth investigating the effect of training on the observers' performance. An *in-vivo* study using cadavers may provide more valid results, however there was logistical and ethical challenges with such an approach. Furthermore, the accuracy of different radiographic projections of the orbits to detect metallic IOFBs should be determined. Finally, with dose optimization high on the agenda it is important to consider the effect of individual examination parameters on diagnostic accuracy. To the authors' knowledge, there have been no such studies which have sought to optimise orbital radiographs using CR and DR systems.

Conclusion

Findings from this study using CR support previous conclusions that conventional X-rays fail to detect metallic IOFBs in all cases. Diagnostic performance is governed by IOFB size and location but appears to be independent of observer type. Further investigations into the accuracy of different radiographic projections and examination parameters should be undertaken including those based on DR technologies.

LEGENDS FOR FIGURES

Figure 1. Image with a no IOFB(**A**), small IOFB(**B**), medium IOFB(**C**) and a large IOFB(**D**).

Figure 2. An illustration of the data collection tool used to indicate the presence or absence of an IOFB on each of the 64 images.

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