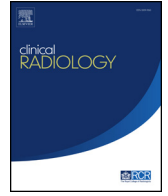




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MRI safety, imaging artefacts, and grid distortion evaluated for FFP3 respiratory masks worn throughout the COVID-19 pandemic



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AIM: To determine which filtering face piece (FFP3) respirators worn throughout the COVID-19 pandemic are safe for magnetic resonance imaging (MRI).

MATERIALS AND METHODS: Three clinical MRI sequences were performed to assess imaging artefacts, grid distortion, and local heating for eight commercially available FFP3 respirators. All examinations were performed at Cardiff University Brain Research Imaging Centre using a 3 T Siemens Magnetom Prisma with a 64-channel head and neck coil. Each FFP3 mask was positioned on a custom-developed three-dimensional (3D) head phantom for testing.

RESULTS: Five of the eight FFP3 masks contained ferromagnetic components and were regarded as “MRI unsafe”. One mask was considered “MRI conditional” and only two masks were deemed “MRI safe” for both MRI staff and patients. Temperature strips positioned at the nasal bridge of the phantom did not exhibit local heating. A maximum grid distortion of 5 mm was seen in the anterior portion of the head of the ferromagnetic FFP3 masks.

CONCLUSION: This study has demonstrated the importance of assessing respiratory FFP3 masks for use in and around MRI machines. Future research involving FFP3 masks can be conducted safely by following the procedures laid out in this study.

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Introduction

Since the onset of the COVID-19 pandemic, personal protective equipment (PPE) has become an important topic in healthcare. The role of respiratory masks in infection control has been widely recognised, but many frontline healthcare workers have experienced skin and soft-tissue

injuries as a result of wearing respiratory PPE for prolonged periods of time. This has been exacerbated for those individuals who have been required to wear a mask that has not correctly fitted their face shape and size.¹ Although in certain clinical settings, (such as intensive care units and operating theatres) staff have always been required to wear surgical masks, this has not been the case for patients or staff in an magnetic resonance imaging (MRI) setting;

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however, this all changed in 2020, when it became mandatory for MRI staff, patients, and healthcare workers (accompanying patients to their MRI examination) to wear a respirator or facemask. As a result, hospital staff may not be aware of the potential hazards these masks could pose and that MRI safety documentation does not exist.

Over the past two years, there has been a significant increase in the range of commercially available FFP2/FFP3/N95/N99/KN95/KN99 respirator masks. To protect the user effectively from infection, these masks rely on a tight-fitting seal around the nose and mouth. Many of these masks, however, contain metallic components, both visible and hidden, which in the MRI environment poses a potential risk. Some facemasks have metal nose strips, clips, or wires to help shape the mask to the face of the user. Others have metal staples to hold the elastic straps in place or antimicrobial coating containing metal (typically silver or copper). It is therefore important to not assume that the mask is safe prior to an MRI examination, and to conduct a safety evaluation to determine which components are made of ferromagnetic metals (such as steel) and which are non-ferromagnetic metal (such as aluminium). Materials such as austenitic stainless steel that are not generally considered ferromagnetic may exhibit paramagnetic behaviour when exposed to strong magnetic fields in MRI. Furthermore, not all masks are labelled appropriately, and the user may be completely unaware that their mask may contain potentially hazardous metal components.

The presence of metallic components in facemasks can cause one or all of the following to occur: (a) artefacts on the MRI, (b) deflection or displacement of the mask, creating a gap between the mask and face, thus reducing effectiveness, (c) risk of the projectile effect, and (d) radiofrequency (RF)-induced heating, with one incident already reported of a facemask burn during a scan of a patient's neck with a 3 T MRI machine in the USA.²

To the authors' knowledge, there have only been two studies to date which have assessed the safety implications of FFP2 and FFP3 masks in an MRI environment. These studies have only assessed a limited number of products. Murray *et al.*, tested four commercially available masks (3M Aura 1863, Kolmi FFP2 and FP3, Halyard FFP2 and a Dahlhausen surgical mask) using a 1.5 T Siemens Avanto system and found that the three respiratory masks were "MRI unsafe".³ The University Hospitals Birmingham NHS Foundation Trust conducted MRI on three masks using both 1.5 T and 3 T Siemens Skyra and found the 3M 8833 and 3M Aura 1863 mask "MRI conditional" for staff positioning patients, but could not verify safety for patients wearing the mask. The Easimask FSM18 is the only mask to be reported as "MRI safe" for both patients and staff with no ferromagnetic components or detectable forces present.⁴ Yet, caution is still required for the Easimask FSM16 due to weak magnetism of the nose strip.⁴

As the present study focuses on MRI safety, it is important to acknowledge the effect of wearing a facemask during an MRI examination, whereby the mask will combine expired air with the subject's inspired air stream. This can elevate the concentration of inspired carbon dioxide (CO₂),

resulting in mild hypercapnia. A recent study by Law *et al.* investigated the effect of wearing a surgical mask during a gradient-echo fMRI examination in a group of healthy participants ($n=8$). The results found that the mask increased the blood oxygen dependent (BOLD) baseline signal by 30% with the grey matter across the brain showing an evident deactivation in the group activation maps.⁵ The measured end tidal CO₂ showed an average increase of 7.4%, confirming the predicted rise in inspired CO₂ concentration with mask use. Another study compared the effects with both an FFP2 mask (RM101 FFP2 NR, Zhejiang Yinghua Technology, China) and surgical mask, and reported statistically significant changes in the cerebral haemodynamics (cerebral blood flow [CBF]) and oxygenation (blood/tissue oxygen saturation [StO₂]) in healthy young subjects at rest for both masks.⁶ The respiratory rate was found to decrease significantly for the FFP2 mask by 3.2 breaths/min (95% CI: -5.4, -1.1 breaths/min). Whilst this study used non-invasive functional near-infrared spectroscopy (fNIRS), it further highlights the importance in understanding the environment created by wearing a facemask and the potential implications this will have on the participant undergoing an MRI examination.

This preliminary study therefore forms the basis for a future project where participants are recruited to undergo a series of MRI examinations with different types of FFP3 masks; however, it will also aid further MRI research studies conducting examinations with an FFP2 or FFP3 mask. Therefore, in order to conduct prospective research safely, the masks must first undergo an MRI safety evaluation. Thus, the purpose of this study was (1) to design and manufacture an MRI-compatible head phantom based on an average human head (incorporating an internal lattice structure to measure grid distortion); (2) identify any metal components in each of the commercially available FFP3 masks; and (3) run a series of MRI sequences to determine which masks are "MRI safe" for both staff and patients using a 3T MRI system.

MATERIALS and METHODS

This study was reviewed and approved by the Cardiff University School of Psychology Ethics Committee (EC.21.01.12.6256A). Although ethical approval is not typically required when examining a phantom, the results of this study are to be directly used to determine which masks are safe for participants undergoing a head and neck examination, and therefore, was included in the ethics application.

Development of head phantom

The National Institute for Occupational safety and Health (NIOSH) ISO digital head forms were used to develop a physical head and neck phantom.⁷ Each head form is symmetric and represents the facial size and shape distribution of a current USA respirator user.^{7,8} For the present study, the small and medium size head forms were modified and printed three dimensionally. The initial design incorporated

an internal lattice structure to measure distortion from the MRI examiner; face and head ribs for support; internal tubes from the nose and mouth to allow filtration; and a crown to balance the head upside down when filling the phantom with water. The design stages for the head phantom are shown in Fig 1.

The MRI compatible head phantom was manufactured using selective laser sintering (SLS) polyamide 12 powder (nylon) at the Additive Manufacturing Laboratory at Cardiff University School of Engineering. The dimensions of the head phantom were as follows: the lattice grid structure was 15×3 mm (pitch and diameter), the internal diameter of the channels through the nose and mouth was 10 mm, and the ribs in the face, neck and head were 3 mm thick. The height of the first two ribs in the neck was 15 mm, with the next 15 at a height of 3.5 mm. The second design did not include the crown due to leaks at the line where it met the head. This was rectified by increasing the wall thickness of the phantom from 1 mm to 2.5 mm and using waterproof polyvinyl acetate glue to seal the surface. An Avery Berkel Model HL 206–31 electronic scale was used to weigh the medium head phantom when full of water. The weight of the phantom was 4.60 kg, which is consistent with the weight of an adult human cadaver dissected around the C3 vertebra, with no hair at approximately 4.5–5 kg.⁹

FFP3 respiratory mask samples

Eight commercially available facemasks worn by clinicians during the COVID-19 pandemic were tested in the present study (Fig 2). Each mask was brand new at the time of testing. The masks consisted of bifold, trifold, duckbill, and cone designs, with almost all containing metal components. The masks selected for testing were GVS Segre



Figure 2 A selection of FFP3 masks used by the NHS during the COVID-19 pandemic.

F31000 (bifold), 3M Aura 9320+ (trifold), 3M Aura 9330+ (trifold), Handanhy 9330 (trifold) Handanhy 9632 (cone), Easimask FSM 18 (cone), Cardinal Health (duckbill) and Valmy Spireor (duckbill).

Mask positioning and MRI test set-up

All facemasks were initially inspected for any manufacturing defects prior to testing. Each mask was then taken one by one into the MRI examination room to assess the ferromagnetic attraction of any metallic components present. The MRI operator handheld the mask at the entrance to the bore of the machine. As the study by Murray *et al.*,³ had reported three of the respirator masks lifting from the table top at 1,000 Gauss, it was decided that at 3 T, the mask should be securely fitted to the head phantom to avoid it becoming a potential projectile. The mask was fitted to the phantom as a user would typically wear the mask,

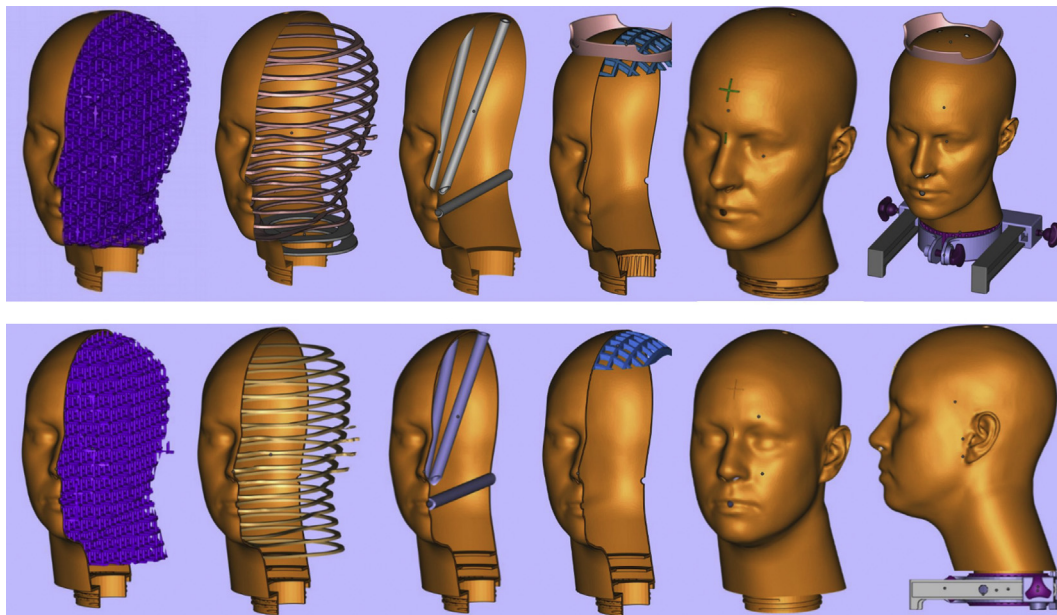


Figure 1 Modified phantom design of NIOSH head forms. Small and medium size head form on top and bottom row, respectively. From left to right: internal lattice structure, internal face and neck ribs, nose and mouth channels, head ribs (with crown on small size), MRI face markings, and final design with upright stand.

ensuring the straps were not twisted and the nose strip fitted snugly over the nose. Where ferromagnetic components were not enclosed within the material, micropore tape was used (e.g. to secure the staples on the 3M masks) to reduce projectile risk. A self-adhesive non-reversible temperature sensitive label, 40–71°C (RS Pro, Corby, Northants, UK) was placed over the nose of the phantom (and directly below the metal nose strip) to record the temperature at the nose bridge–phantom interface. The temperature test strip recorded the highest bracketed temperature reached by the label with an accuracy of $\pm 1^\circ\text{C}$.

The phantom was then placed inside a 3T Siemens Magnetom Prisma (Siemens Healthineers, Erlangen, Germany) machine with a 64-channel head and neck coil (Fig 3). Care was taken to ensure the phantom was positioned as straight as possible using both the cross-hair line from the phantom and the scanner laser system. The scanner isocentre was then set to the head and neck coil markings (as per routine practice). The temperature in the MRI room throughout the testing period was 22°C. All masks were tested on the same day by the same MRI operators at the Cardiff University Brain Research Imaging Centre.

The phantom was initially examined in the prone and supine position to obtain reference data. All subsequent masks were examined with the phantom supine as per a typical MRI head and neck examination.

MRI protocol

Three MRI sequences were run to assess imaging artefacts, grid distortion, and local heating. A three-dimensional (3D) susceptibility-weighted imaging (SWI) sequence with an acquisition time of 5 min, 1.5 mm section thickness, 27 ms repetition time, 20 ms echo time and a 15° flip angle was used to assess how any metal compounds that have paramagnetic, diamagnetic, or ferromagnetic properties interact with the local magnetic field, and consequently, distort it. A two-dimensional (2D) echo-planar imaging (EPI) sequence with an acquisition time of <1 min, a 2,000 ms repetition time, 30 ms echo time, 70° flip angle, and high specific absorption rate (SAR) was used to assess local heating. Finally, a 3D magnetisation-prepared rapid gradient echo (MPRAGE) sequence with an acquisition time of ~10 min, a

section thickness 0.7 mm isotropic, 2,100 ms repetition time, 3.94 ms echo time, and an 8° flip angle was also included, as this is a typical sequence used to obtain structural data of a participant.

Measurement of grid distortion

The MPRAGE examination of the phantom without a mask was imported into the image processing software, Synopsys Simpleware ScanIP N-2021.6-SP1. A mask of the phantom volume was extracted in order to focus the registration to the intensity values within this region of interest (ROI) only. Image registration was performed using the open-source software, 3D Slicer with a non-rigid registration toolbox Elastix.^{10,11} The phantom with and without a mask was selected as the “moving” and “fixed” image, respectively.

In Elastix, the transform is defined from the “fixed” image to the “moving” image. The similarity metric (the degree of similarity between the moving and fixed image) was chosen as the mean squared difference. The nrrd transform displacement file was exported and opened using custom MATLAB code with the displacement of each voxel (x,y,z) plotted.

RESULTS

The MRI conditionality of the masks was assessed based on (i) presence of ferromagnetic material components, (ii) presence of metallic material, (iii) a measurable deflection at the bore of the MRI machine ($\sim 1\text{ T}$), and (iv) a temperature measurement of $>40^\circ\text{C}$ during testing. Five of the eight commercially available FFP3 masks contained ferromagnetic components and were thus classified as “MRI unsafe” (Table 1). The Easimask FSM18 and Handanhy 9632 contained no metal components and were deemed “MRI safe”. The GVS Segre F31000 mask has a non-ferromagnetic aluminium nose strip on the external edge of the mask. This was deemed “MRI conditional” due to the potential risk of local heating if imaging with higher specific absorption

Table 1

Masks deemed MRI safe, MRI unsafe or MRI conditional with their corresponding ferromagnetic components.

FFP3 mask	Ferromagnetic component	MRI safe	MRI unsafe	MRI conditional
GVS Segre F31000	None			X ^a
3M Aura 9320+	Staples		X	
3M Aura 9330+	Staples		X	
Handanhy 9330	Nose strip		X	
Handanhy 9632	None	X		
Easimask FSM 18	None	X		
Cardinal Health	Nose strip		X	
Valmy Spireor	Nose strip		X	

^a MR conditions: Not to be placed in the RF coil during scanning.

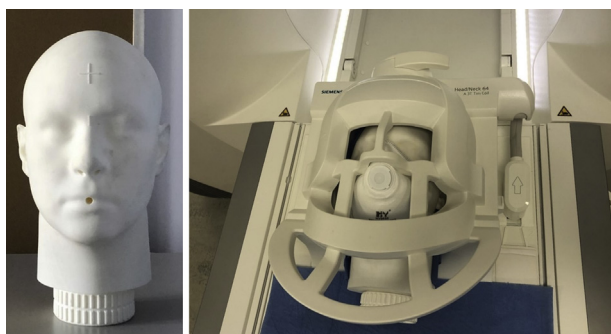


Figure 3 3D printed head phantom and MRI set-up of head phantom with HY9632 mask.

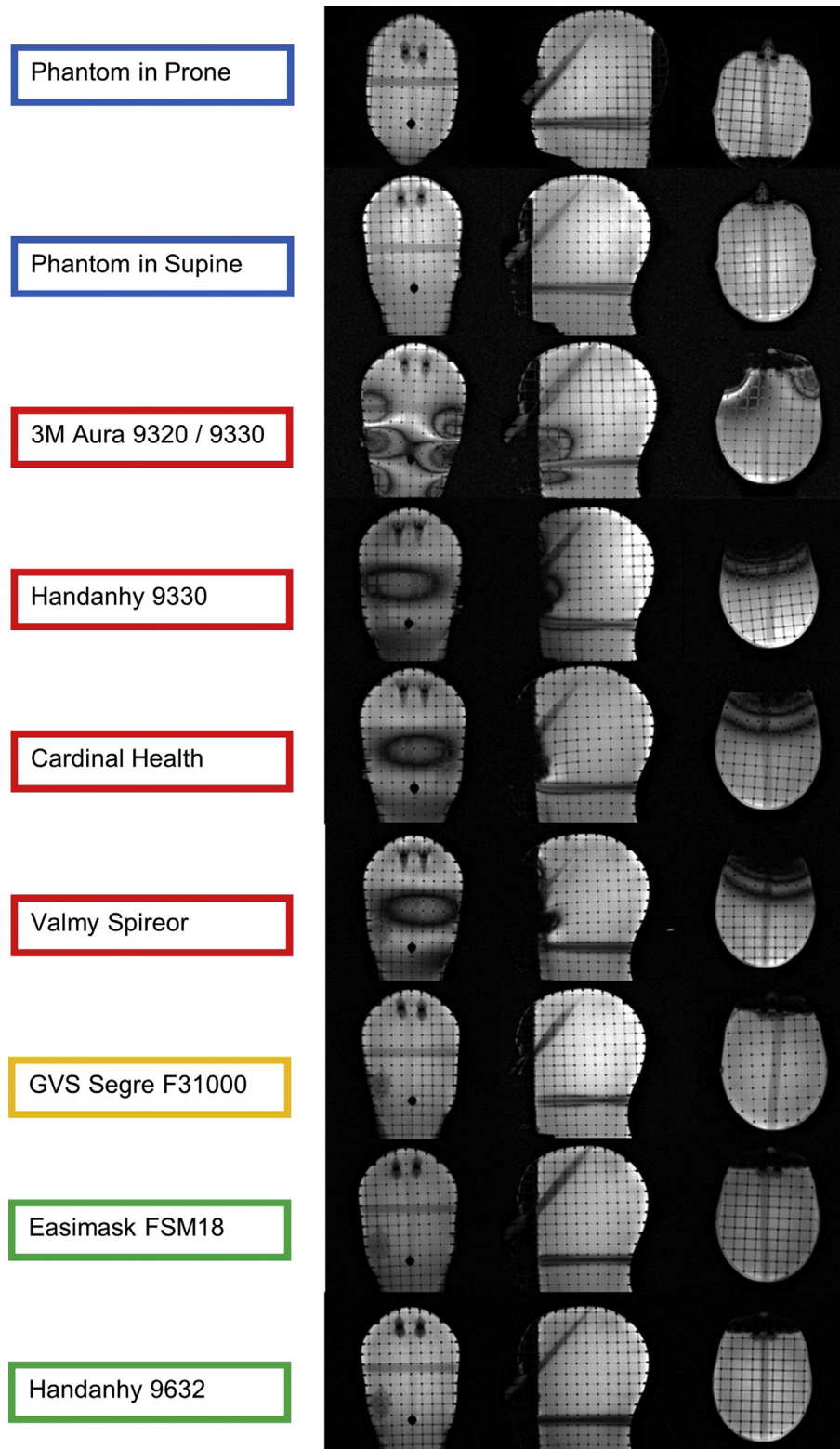


Figure 4 MRI images showing image artefacts caused by ferromagnetic components. Green represents MRI safe; orange, MRI conditional; and red, MRI unsafe.

rate (SAR) sequences or using a coil, such as the head and neck coil, where the proximity of the nose strip to the soft tissues at the bridge of the nose could result in a burn when examined. This device is therefore “conditional”, whereby

the conditions include “no RF irradiation”. None of the masks displayed a temperature of $\geq 40^{\circ}\text{C}$ at the nasal bridge. As this was the lowest the temperature labels recorded, the only conclusion is that the metal nose strip did not heat to 40°C .

Fig 4 shows the gradient-echo images acquired when imaging a custom-developed head phantom with different types of respiratory FFP3 masks. It is clear to see the substantial image artefacts caused by the MRI unsafe masks, particularly for the 3M Aura masks where there is bilateral artefact from the four large steel staples. Note that the three 10 mm channels through the nose and mouth can be seen on the phantom and must not be mistaken for artefacts.

All ferromagnetic masks were found to distort the internal lattice grid structure in the anterior portion of the head phantom. The geometric distortion was greatest for the Cardinal Health mask and Valmy Spireor masks, whereby the lattice grid was shown to distort by 5 mm. The Handanhy 9330, 3M Aura 9320+ and 9330+ were shown to distort by 3.095, 1.354, and 2.725 mm, respectively. The GVS Segre F31000, Handanhy 9632 and Easimask FSM18 showed little to no distortion (Table 2).

Discussion

This study has demonstrated the importance of assessing respiratory facemasks for use in and around MRI examinations. Only the Easimask FSM18 and Handanhy 9632 masks can be considered “MRI safe” for both patients and MRI operators. This echoes the results reported by the University of Birmingham Hospitals Foundation Trust for the Easimask FSM18 mask.⁴ The FFP3 masks that were deemed “MRI unsafe” were different to the make and models previously reported by Murray *et al.*,³ and no direct comparison can be made.

It is necessary to remove the metal nose strip from the GVS Segre F31000 mask for operators, and either modify or not use this mask for patients, particularly at high SAR sequences, high gradient fields, or protocols involving the brain, head, and neck; however, it is important to highlight here that any modifications to the masks would reduce the seal at the nose bridge and allow leakage, so that the mask would no longer conform to the relevant standards, and hence, this practice is potentially dangerous. It is also worth mentioning here that significant artefacts have been reported on a patient who had undergone a coronal T2, axial T2, axial T2 fluid-attenuated inversion recovery (FLAIR), axial T1 FLAIR, and an axial 3D gradient echo sequence with a surgical facemask, further highlighting the necessity to remove all metal from a mask.¹² The MRI conditionality of

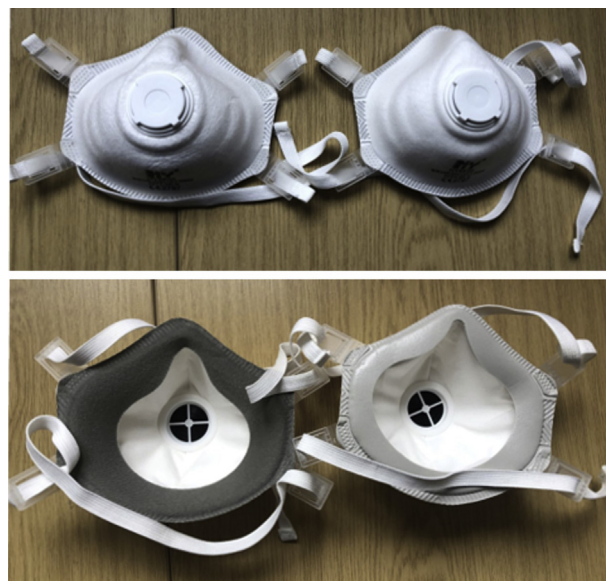


Figure 5 Differences in the inner seal of the same FFP3 Handanhy 9632 mask.

the GVS Segre F31000 was defined as “Not to be placed in the RF coil during examining”. Further testing would be required to define this as a limiting RF transmit field, $B1_{+rms}$.

Where possible, surgical masks should be ordered in a separate colour to distinguish between an “MRI safe” surgical mask and the one a patient may be wearing to their appointment on the day.

Although heating and image distortion were tested for, the effect of CO₂ levels on fMRI sequences, such as BOLD, were not evaluated, which have previously been reported to increase when a patient wears a mask.⁵ There is limited information available regarding the implication of wearing a facemask on other types of MRI sequences, and as such, care must be taken when conducting any study where these types of masks are used. It is also important to note that the MRI sequences used within the present study are typical of those used clinically. Therefore, the duration of exposure and its possible effect were not assessed, but an increased acquisition time may worsen the results, e.g., cause induced local heating.

A limitation of the present study is that a large number of FFP2 and FFP3 masks are currently available and it was therefore not possible to assess all of them; however, all the masks tested in this study have been used by NHS Wales and NHS England at some point throughout the pandemic and include bifold, trifold, duckbill, and cone shaped masks. The medium-size head phantom was able to fit within the 64-channel head and neck coil with each of the masks tested. This is the maximum head size (in terms of depth) that would comfortably allow all masks to be tested without the coil pushing directly on the mask. A further limitation was that some air was trapped in the phantom, but this would not have significantly affected the results. Any future designs will look to rectify this.

Table 2

Maximum geometric distortion of FFP3 masks using a 3 T Siemens magnetic resonance imaging system.

FFP3 mask	Max distortion (mm)
Cardinal Health	5.102
Valmy Spireor	4.931
Handanhy 9330	3.095
3M Aura 9330+	2.725
3M Aura 9320+	1.354
GVS Segre F31000	0.132
Handanhy 9632	0
Easimask FSM 18	0

As part of the current study, the Handanhy 9632 masks were ordered from two independent suppliers. Despite the mask being the same make and model, the inner seal was completely different for each mask (Fig 5). Although this particular mask did not pose a safety risk and was still deemed “MRI safe”, it is possible that other changes to materials could pose a risk. The authors therefore emphasise that caution must be taken even when using a mask that has been reported as “MRI safe”.

In conclusion, the Handanhy 9632 and Easimask FSM18 FFP3 masks are “MRI safe”. Image artefacts have been shown to distort the grid by 5 mm in the anterior portion of the head of the ferromagnetic masks. Future research involving participants wearing an FFP3 mask can be conducted safely, whereby any additional masks not assessed in the present study will undergo the same safety procedure.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Bethany Keenan reports financial support was provided by the Engineering and Physical Sciences Research Council.

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