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Original Article

Magnetic resonance imaging respirators: a randomized crossover trial to assess respiratory protection, usability, and comfort

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Abstract

Objective: Many available facepiece filtering respirators contain ferromagnetic components, which may cause significant problems in the magnetic resonance imaging (MRI) environment. We conducted a randomized crossover trial to assess the effectiveness, usability, and comfort of 3 types of respirators, judged to be "conditionally MRI safe" with an aluminum nosepiece (Halyard 46727 duckbill-type respirators and Care Essentials MSK-002 bifold cup-type respirators) or "MRI safe" completely metal free (Eagle AG2200 semirigid cup-type respirators).

Design and setting: We recruited 120 participants to undergo a quantitative fit test (QNFT) on each of the 3 respirators in a randomized order. Participants then completed a usability and comfort assessment of each respirator.

Results: There were significant differences in the QNFT pass rates (51% for Halyard 46727, 73% for Care Essentials MSK-002, and 86% for Eagle AG2200, $P < .001$). The first-time fit test pass rate and overall fit factor were significantly higher for Eagle AG2200 compared with the other 2 respirators. Eagle AG2200 scored the lowest ratings in the ease of use and overall comfort. There were no significant differences in other modalities, including the seal rating, breathability, firmness, and overall assessment.

Conclusions: Our study supports the utility of the Eagle AG2200 and Care Essentials MSK-002 respirators for healthcare professionals working in an MRI environment, based on their high QNFT pass rates and reasonably good overall usability and comfort scores. Eagle AG2200 is unique because of its metal-free construction. However, its comparatively lower usability and comfort ratings raise questions about practicality, which may be improved by greater user training.

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Introduction

Tight-fitting disposable respirators are the commonest respiratory protective equipment used by healthcare workers to protect against airborne pathogens and concurrently provide source control. Many available facepiece filtering respirators (FFRs) contain ferromagnetic components, such as metal nose strips and metal staples that hold the elastic straps in place.[1] The presence of ferromagnetic components in face masks may cause a variety of potential problems in the magnetic resonance imaging (MRI) environment, such as artifacts in the imaging,[1,2] deflection or displacement of FFRs resulting in reduced seal effectiveness,[1–3] and radiofrequency-induced heating.[1]

A recent safety advisory by the US Food and Drug Administration (FDA) followed a case report that a patient's face was burned by the metal in a face mask worn during an MRI.[4] Consequently, a number of international bodies have recommended that consumers and health professionals should not wear face masks with metal parts or coatings during an MRI examination.[4,5] However, there are only a few commercially available face masks that are completely devoid of metal parts and classified as "MRI safe." Many commonly available face masks contain metal parts that are non-ferromagnetic, like aluminum. They are considered "conditionally MRI safe" because aluminum, while being non-ferromagnetic, may theoretically induce currents and cause local heating in specific circumstances.[2] Many face masks are not labeled appropriately. Therefore, it is vital to conduct a safety evaluation to determine which mask components are made of ferromagnetic or non-ferromagnetic metal. MRI staff are also advised, by the American College of Radiology guidance on MRI-safe practice, to test face masks with a strong handheld magnet.[6]

It is important to acknowledge that apart from MRI safety, other factors, such as respirator availability, individual respirator fit, usability, comfort, and local work practices, including proximity to the magnet, are also important when selecting the most appropriate respirators for healthcare workers frequently working in the MRI environment.[7,8] There is currently limited

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published data on the respirator fit, usability, and comfort assessment of MRI-safe FFRs.

In this study, we examined 3 types of N95/P2 respirators: the commonly available Halyard 46727 duckbill-type N95 respirators and Care Essentials MSK-002 bifold cup-type P2 respirators, which are judged to be "conditionally MRI safe" with an aluminum nosepiece, and the newly available Eagle AG2200 semirigid cup/cone-type P2 respirators, which are completely metal free and "MRI safe." We conducted a randomized crossover trial to compare their effectiveness, usability, and comfort.

Methods

This prospective randomized crossover study was conducted through the Respiratory Protection Program (RPP) at the Royal Melbourne Hospital, which is a tertiary-care hospital with a recently expanded MRI department.[9] There are in total 7 MRI machines within the institution, including 1 intraoperative MRI used mainly for neurosurgical procedures.

Ethics approval was obtained through the Melbourne Health Human Research Ethics Committee (QA 202017) as part of our RPP implementation and improvement. We invited healthcare workers who were participating in the RPP at the Royal Melbourne Hospital and frequently worked at the MRI department to take part in this study. Details of the study were provided, and participation was voluntary. Verbal consent was obtained before the inclusion of the study.

As part of the RPP requirement, participants completed an online basic demographic survey and a standardized respiratory protection online training program. Each participant was then required to complete a quantitative fit test (QNFT) on all 3 respirators: Halyard 46727, Care Essentials MSK-002, and Eagle AG2200. The sequence of the 3 respirators tested was allocated randomly to minimize any training effect, using a computer-generated randomization method,[10] with participants stratified into male and female groups. All male participants were clean-shaven.

Prior to the fit testing, each participant was reminded of the standard donning, user seal check, and doffing techniques, according to the manufacturer's instructions, for each of the 3 respirators. They were also given the opportunity to practice on the Eagle AG2200 respirator, which is a relatively newly available FFR with a slightly different donning and doffing method compared with other commonly used FFRs. It has an adjustable buckle that can be used to tighten the respirator rather than molding a metal strip over the nose.

The QNFT was performed outside the MRI environment; however, all 3 respirators were tested for the absence of ferromagnetic attraction using a strong handheld magnet (>1,000 Gauss). Each participant completed a QNFT for all 3 respirators according to the allocated randomization order. They performed a user seal check and were allowed to adjust the respirator until satisfied before commencing the QNFT for each respirator.

The fit of each respirator was assessed using a PortaCount Pro+ 8048 (TSI, St. Paul, Minnesota, USA) employing the Occupational Safety and Health Administration (OSHA) modified fast-filtering facepiece protocol.[11] All of the qualified fit testers completed a training course endorsed by the Victorian Department of Health and the Australian Institute of Occupational Hygienists. An overall fit factor (defined as the harmonic mean of each individual exercise) of 100 or more was considered a pass in accordance with OSHA guidelines. The practice of force fit testing (ie, repeating a fit test until a pass is recorded) was prevented by limiting participants to no more than 3 attempts per respirator. A standard operating procedure was followed. Guidance from the qualified fit tester during the fit test was limited to general guidance that is normally available in the workplace. The use of the PortaCount's real-time fit test mode was not permitted, to ensure that the fit test environment resembled standard workplace practices as closely as possible. Upon completion of the QNFT, participants were asked to complete a usability and comfort assessment for each of the 3 respirators (Appendix 1).

The primary outcome was to compare the QNFT pass rate among the 3 respirators. Secondary outcomes included the overall fit factor, pass rate at the first attempt, and the self-rating usability and comfort assessment results.

Statistical analysis

Based on our previous study,[12] the QNFT pass rate of the Halyard respirators was approximately 60%. To demonstrate a clinically significant change, that is, a 20% difference in the QNFT pass rate, we required at least 114 participants per group, for a power of 0.8 and alpha of 0.02 (to account for 3 possible pairwise comparisons among 3 arms). We recruited a total of 120 participants for this crossover study, to account for potential missing data.

Descriptive statistics such as means, medians, and percentages were used to present the demographic data, QNFT pass rates, overall fit factors, and usability and comfort assessment results. Cochran's Q test was used to compare QNFT pass rates among the 3 respirators, followed by the McNemar test to compare each of the 3 possible pairs, with Bonferroni-adjusted $P < .02$ deemed statistically significant. Friedman's test was used to compare the fit factors and 5-point Likert scale results from the usability and comfort assessment among the 3 respirators. Each of the 3 possible pairs was then compared using the Wilcoxon signed ranks test, with Bonferroni-adjusted $P < .02$ considered statistically significant. Statistical analysis was performed using Stata 13.0 (StataCorp, College Station, Texas, USA).

Results

A total of 120 participants were recruited. We excluded 7 cases because of deviation from protocol or missing data (details shown in the CONSORT diagram in Figure 1). Therefore, a total of 113 sets of data were analyzed in the study. A summary of participant demographics is shown in Table 1. Most of the participants were female nursing staff.

There were significant differences in the QNFT pass rates among the 3 types of respirators, with the Eagle AG2200 achieving the highest pass rate, followed by Care Essentials MSK-002, and then Halyard 46727 (Table 2). The Eagle AG2200 also demonstrated a significantly higher first-time fit test pass rate and overall fit factor compared with the other 2 respirators (Table 2).

In regard to the usability and comfort assessment, Eagle AG2200 scored a significantly lower rating in the ease of use and overall comfort assessment than the other 2 respirators (Figure 2 and Figure 3). There were no significant differences found in other modalities, including the seal rating, breathability, firmness of the fit, and the overall assessment rating among the 3 respirators (Figure 2, Table 3, and Figure 4). A few participants commented that the Eagle AG2200 was not compatible with their spectacles.

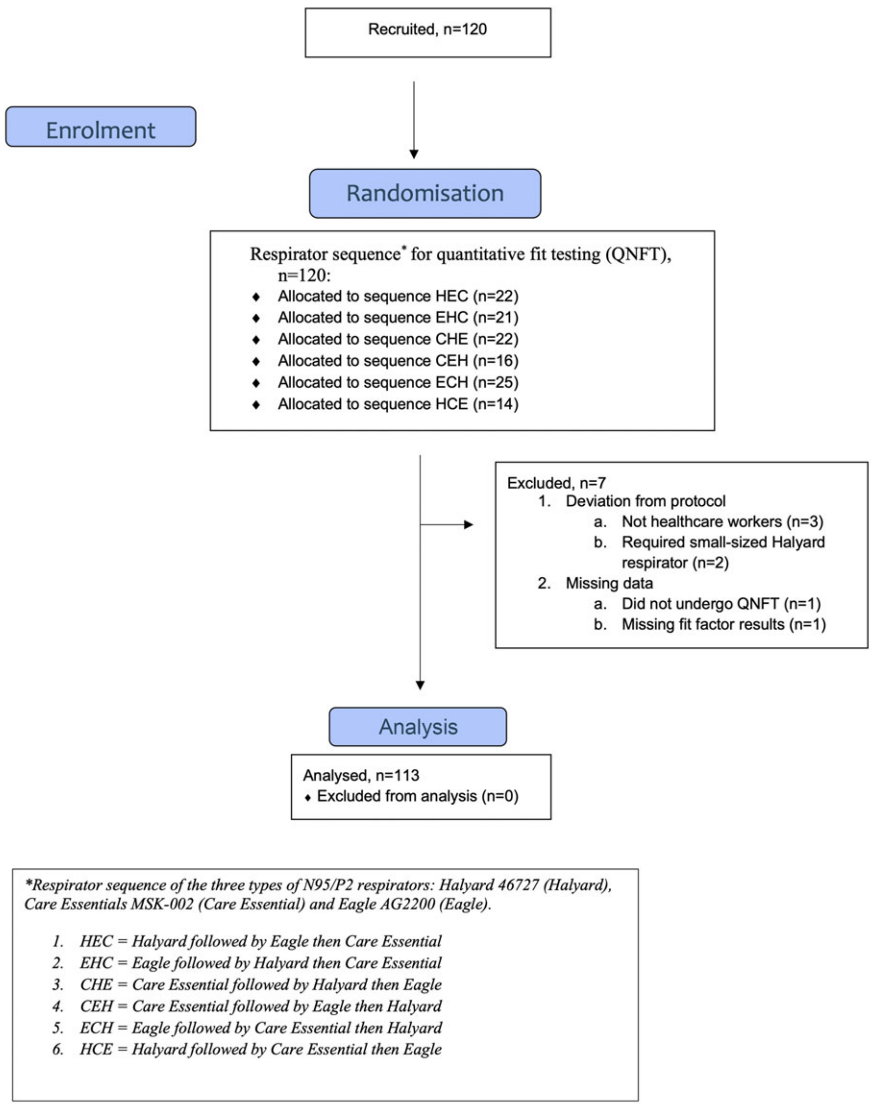

Figure 1. CONSORT diagram.

Discussion

This study is unique in its exploration of respirator fit, usability, and comfort characteristics of 3 separate MRI-compatible FFRs. Furthermore, we believe it to be the first published report of these characteristics in a representative sample of healthcare workers for the Eagle AG2200 respirator, which has no metallic components and therefore is unconditionally MRI safe.[7] The emphasis on both quantitative fit testing and usability and comfort factors in an MRI context distinguishes this study from laboratory-based respirator assessments in that it has practical significance for healthcare workers located in an MRI suite.

The study's QNFT results reveal a notable disparity in pass rates among the 3 respirators. The Halyard 46727 respirators, with a pass rate of 51%, fall significantly behind the Care Essentials MSK-002 respirators at 73% and the Eagle AG2200 respirators at a high rate of 86%. This statistically significant difference in pass rates is important, particularly in the context of the respirators' metal content. It is noteworthy that the Eagle AG2200, the only respirator among the 3 with no metallic components, demonstrates the highest pass rate.

The identification of a respirator, such as the Eagle AG2200, that is both MRI safe and highly effective may challenge existing norms in respirator design.[1] This may prompt a reconsideration of the materials used in the manufacturing of FFRs so that more respirators can be manufactured without metal components and therefore be deemed as MRI safe.

The study's twin focus on both QNFT results and usability and comfort assessment adds a second layer of complexity to our findings. The fact that 34% of the participants found the Eagle AG2200 "difficult or very difficult" to use, compared to only 10% for the other 2 respirators, introduces a crucial consideration. This statistically significant difference poses the potential challenges associated with the practical application of the Eagle AG2200 respirator. Although the Eagle excels in fit testing, its usability concerns suggest that a successful implementation strategy should include comprehensive training and familiarization programs for users, especially within the relatively small pool of MRI workers.[13]

Although the overall comfort rating of the Eagle AG2200 was significantly lower than the Care Essentials MSK-002 respirators, it was similar to the Halyard 46727 respirators. The recognition of the usability and comfort challenges with the Eagle AG2200 doesn't necessarily negate its value, but it highlights the need for a targeted approach to its adoption. Training can play a pivotal role

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Table 1. Participants' baseline characteristics. Values are expressed as mean+/– SD, number (percentage), and median (IQR [range])

Baseline characteristics	n = 113
Age, years	37 +/– 11
Sex, male:female:missing	35:74:4
BMI, kgm^{-2}	24.5 +/– 6.7
Professional group	
Allied health	22 (19.5%)
Medical imaging professional	30 (26.5%)
Medical practitioner	8 (7%)
Non-clinical role	2 (1.8%)
Nursing	37 (32.7%)
Other healthcare worker	14 (12.5%)
Years of healthcare experience	9 (4–16 [1–40])

Note. BMI, body mass index; SD, standard deviation; IQR, interquartile range.

Table 2. Quantitative fit test results of the 3 types of respirators: Halyard 46727 (Halyard), Care Essentials MSK-002 (MSK), and Eagle AG2200 (Eagle) N95/P2 respirators. Values are expressed as number (percentage), median (IQR [range])

	Halyard (n = 113)	MSK (n = 113)	Eagle (n = 113)	*P*-value
Pass fit test	58 (51%)	83 (73%)	97 (86%)	<.001[a]
Overall fit factor	101 (49–171 [5–201])	146 (96–193 [3–201])	201 (162–201 [2–201])	<.001[b]
Pass at first attempt	47 (42%)	71 (63%)	88 (78%)	< .001[c]

[a]Cochran's *Q* test shows a significant difference among the 3 groups ($P < .001$). Pairwise comparisons using the McNemar test show significant differences between Halyard and MSK ($P < .001$) and between Halyard and Eagle ($P < .001$).
[b]Friedman's test shows a significant difference among the 3 groups ($P < .005$). Pairwise comparisons using the Wilcoxon signed ranks test show significant differences between Halyard and MSK ($P < .001$), between MSK and Eagle ($P < .001$), and between Halyard and Eagle ($P < .001$).
[c]Cochran's *Q* test shows a significant difference among the 3 groups ($P < .001$). Pairwise comparisons using the McNemar test show significant differences between Halyard and MSK ($P < .001$), between MSK and Eagle ($P = .013$), and between Halyard and Eagle ($P < .001$).

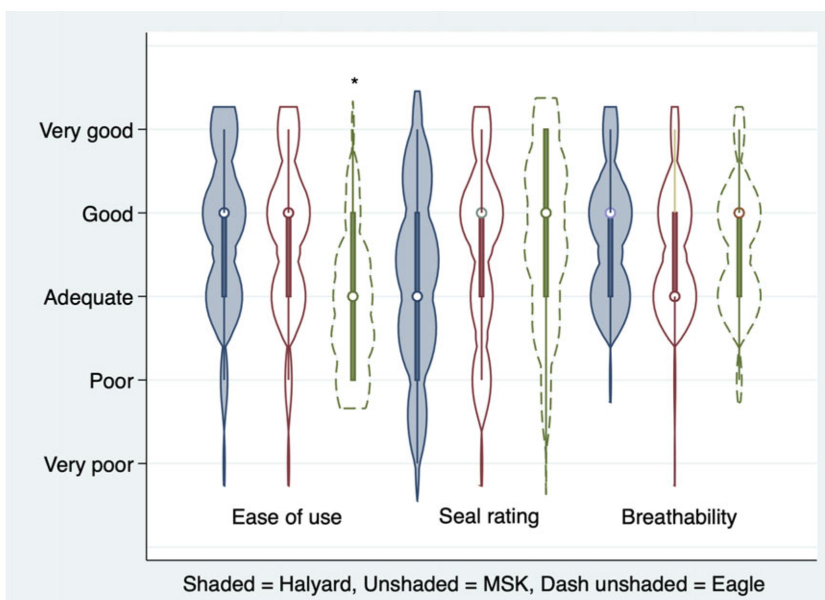

Figure 2. Violin plots to show the ease of use, seal rating, and breathability among the 3 types of respirators: Halyard 46727 (Halyard), Care Essentials MSK-002 (MSK) and Eagle AG2200 (Eagle) N95/P2 respirators. *Friedman's test shows significant differences among the 3 groups ($P < .001$). Pairwise comparisons show significant differences between Eagle and Halyard ($P < .001$) and between Eagle and MSK ($P < .001$) in the ease-of-use rating. (Violin plot is a combination of a box plot, which shows the summary statistics, and a kernel density plot, which shows the distribution of the data).

by providing MRI workers with the knowledge and skills, which may enhance their comfort and confidence when wearing the respirators.[14] A reasonable alternative is to provide a "conditionally MRI-safe" respirator for those who either fail the QNFT on the Eagle AG2200 or do not find the Eagle AG2200 comfortable. This study showed that the Care Essentials MSK-002 could potentially be a good alternative given its reasonably high QNFT pass rate and usability and comfort rating scores.

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Table 3. Participants' firmness of fit ratings for each of the three types of respirators: Halyard 46727 (Halyard), Care Essentials MSK-002 (MSK), and Eagle AG2200 (Eagle) N95/P2 respirators

	Halyard (n = 95)	MSK (n = 94)	Eagle (n = 94)	*P*-value
Firmness of fit				.835
Too tight	3 (3%)	4 (4%)	5 (5.5%)	
Slightly tight	11 (12%)	22 (23%)	20 (21%)	
About right	52 (55%)	55 (59%)	54 (57%)	
Slightly loose	21 (22%)	13 (14%)	14 (15%)	
Too loose	8 (8%)	0 (0%)	1 (1.5%)	

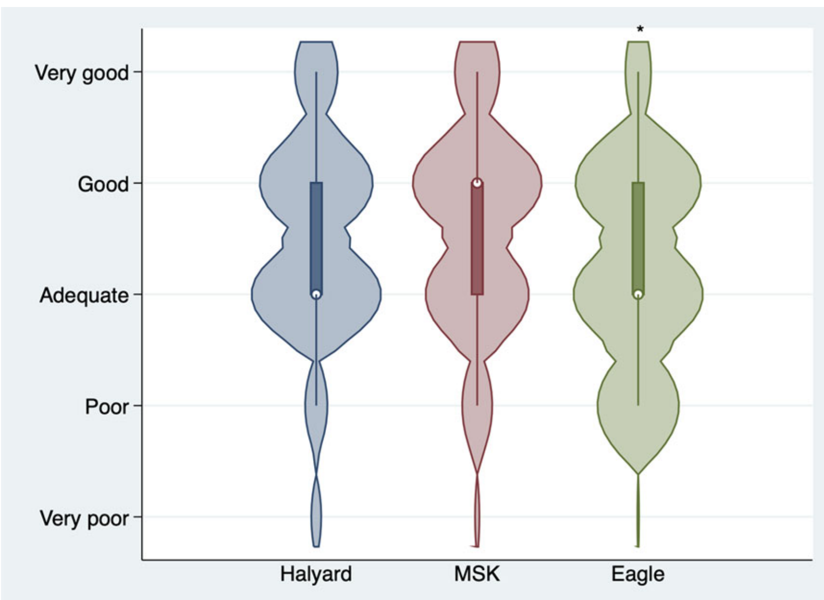

Figure 3. Violin plot to show the overall comfort rating for the 3 types of respirators: Halyard 46727 (Halyard), Care Essentials MSK-002 (MSK), and Eagle AG2200 (Eagle) N95/P2 respirators. *Friedman's test shows a significant difference among the 3 groups ($P = .007$). Pairwise comparisons show a significant difference between Eagle and MSK ($P < .012$) only.

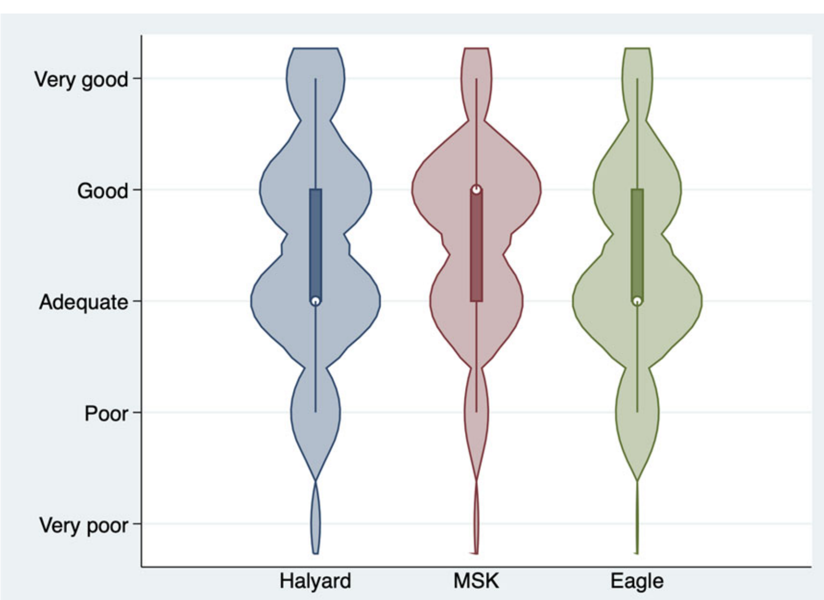

Figure 4. Overall assessment rating for the 3 types of respirators: Halyard 46727 (Halyard), Care Essentials MSK-002 (MSK), and Eagle AG2200 (Eagle) N95/P2 respirators.

Our study's strengths are that it incorporates both quantitative and qualitative assessments, providing a holistic view of respirator performance. Bias has been minimized by the randomized crossover design, and the study addresses a practical concern around MRI compatibility, which has been previously raised by regulatory authorities, such as the FDA.

We acknowledge several limitations to the study. First, the sample size was small. However, a statistical significance was shown in the QNFT pass rate and ease of use among the respirators. The respirator fit may vary among different populations. Further tests on a larger group of subjects, preferably with diverse ethnicity backgrounds may be helpful. Second, we did not assess heat production and respirator distortion of the "conditionally MRI-safe" respirators under MRI conditions, thereby limiting the potential applicability of results in the MRI suite. However, the previous study showed only minimal grid distortion with the "conditionally MRI-safe" respirators.[1] Third, the study's focus on a specific set of respirators may restrict the generalizability of its findings to healthcare settings with a different range of respirator types.

In conclusion, our study supports the utility of the Eagle AG2200 and Care Essentials MSK-002 respirators for healthcare professionals working in MRI suites, based on their high QNFT pass rates and reasonably good usability and comfort rating scores. The unique metal-free construction of the Eagle AG2200 respirator enhances its preferred suitability for use in the MRI environment, both for source control in patients undergoing MRI procedures and respiratory protection for healthcare workers who are in close proximity to the magnet. The lower usability rating for the Eagle AG2200 raises questions about practicality, especially for staff members. This may be mitigated by training and a selection of back-up respirator models. We recommend future studies to evaluate other types of MRI-safe or "conditionally safe" respirators and also investigate their performance in the MRI environment to further validate these findings.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/ash.2024.50.

Data availability statement. All the individual de-identified data that support the findings of this study are available upon request from the corresponding author. Study protocol and statistical analysis are also available. Information will be available immediately following publication until 5 years after publication.

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Author contribution. Prof Daryl Williams: Obtained ethics approval, Conceptualization, Data curation, Methodology, Investigation, Project administration, Resources, Supervision, Validation, Writing—original draft, review, and editing.

Mr Charles Bodas: Conceptualization, Data curation, Methodology, Investigation, Project administration, Resources, Validation, Writing—original draft, review, and editing.

Dr Benjamin Kave: Conceptualization, Methodology, Investigation, Validation, Writing—original draft, review, and editing.

Ms Megan Roberts: Conceptualization, Data curation, Formal analysis, Methodology, Investigation, Project administration, Resources, Validation, Writing—review and editing.

Dr Irene Ng: Obtained ethics approval, Conceptualization, Data curation, Formal analysis, Methodology, Investigation, Validation, Writing—original draft, review, and editing.

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