Research paper

A randomised crossover trial of two flat-fold cup respirators: BYD DE2322 N95 versus Care Essentials MSK-002 P2

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Abstract

Background: The use of respiratory protection remains important in protecting health care workers from airborne pathogens such as viruses. Respirator supply is constantly changing with new models regularly becoming available. Health services should consider a broad range of factors when procuring respirators, including the results of quantitative fit testing in a representative sample of the workforce. Subjective comfort factors and compatibility with a variety of workplace tasks, such as suitability for staff use near magnetic resonance imaging (MRI) environments where relevant, should also be considered. This article compares the quantitative fit factors and user assessments for two styles of flat-fold cup respirators, Care Essentials (CE) MSK-002 P2 and BYD DE2322 N95.

Methods: Quantitative fit tests (QNFT) were performed on 300 participants on each model of respirator in this randomised crossover trial. Participants then completed a questionnaire on their assessments of each respirator.

Results: The Care Essentials MSK-002 had a significantly higher quantitative fit test pass rate than the BYD DE2322 (57% vs 18%, p < 0.001). There was no concordance between fit test pass rates for each model. Additionally, the Care Essentials MSK-002 achieved significantly higher scores on each of the responses in the subjective usability survey.

Conclusion: It is recommended that the Care Essentials MSK-002 be made available for health care use due to higher QNFT pass rates, higher subjective usability assessment scores, plus its potential for use in MRI environments when compared to the BYD DE2322.

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Highlights

- Care Essentials MSK-002 P2 respirator achieves higher quantitative fit test pass rates than the BYD DE2322 N95 respirator.
- CE MSK-002 is rated as more comfortable, easier to use and has higher overall user ratings compared to BYD DE2322.
- CE MSK-002 does not have any ferro-magnetic components and may be suitable for use by MRI clinical staff.
- Quantitative fit test results and user assessments should be considered when providing respirators to healthcare workers.

Introduction

As the COVID-19 pandemic continues impacting health care systems across the globe, the use of respiratory protective equipment remains an important tool in preventing exposure to airborne hazards for health care workers (HCWs) [1]. Facepiece filtering respirators (FFRs) are the commonest respirators in the health care industry due to worker familiarity with disposable masks and the fact that FFRs provide both respiratory protection and source control. The BYD DE2322 (BYD Care, Los Angeles, CA, USA) N95 FFR was procured in large volumes internationally early in the pandemic and it remains a commonly available FFR.

It has previously been demonstrated that the BYD vertical flat-fold cup has a quantitative fit test (QNFT) pass rate of approximately 30% in large cohorts of HCWs and is subjectively less preferred compared to other respirators such as the 3M Aura 3-panel flat-fold FFR [2,3].

Care Essentials (CE) MSK-002 FFR, is another vertical flat-fold cup respirator that has recently been designed and manufactured in North Geelong, Australia. It is registered and approved by the Australian Therapeutic Goods Administration (TGA) as a medical P2 respirator under standard AS/NZS 1716:2012, which is a similar standard to the NIOSH N95 certification but additionally requires an assessment of inward leak of particulate aerosols on users [4].

The BYD DE2322 was widely available during the early stages of the COVID-19 pandemic. The CE MSK-002 became available during the second half of 2021. The filtering material for both models of respirator consists of non-woven polypropylene, and the straps for both are the braided elastic style, with similar donning and doffing techniques.

Differences of note between the models include

- the presence of a strip of polyurethane foam in the CE MSK-002 model at the skin-respirator sealing surface across the nose and cheeks (this strip is absent in the BYD DE2322);
- the absence of ferro-magnetic components in the CE MSK-002 model, potentially making it suitable for use in magnetic resonance imaging (MRI) environments, where the presence of ferro-magnetic components typically preclude the use of many models of disposable respirators; and
- differences in strap tension - on average the straps for the BYD DE2322 model required 40% more force to extend the strap an equivalent distance (Supplementary material A).

Various international bodies recommend that respirators undergo a thorough assessment prior to broad-based procurement, including an assessment of safety, usability and comfort [5]. We hypothesise that the addition of the total inward leak assessment required under standard AS/NZS 1716:2012 and the presence of a polyurethane nasal strip could improve the seal and comfort of the CE MSK-002 vertical flat-fold cup FFR compared to the BYD DE2322. This study aims to compare two flat-fold cup style FFRs, the BYD DE2322 N95 and CE MSK-002 P2 with respect to objective QNFT performance and subjective user assessments in HCWs.

Method & materials

Design

This prospective randomized crossover study was conducted through the Respiratory Protection Program (RPP) at the Royal Melbourne Hospital (RMH), which was a tertiary-care COVID-19 streaming hospital when this study was conducted in the second half of 2021 in Melbourne, Australia. Ethics approval was obtained through the Melbourne Health Human Research Ethics Committee (QA 2020174) as part of our RPP implementation and improvement.

Participants

Healthcare workers or employees who were participating in the RPP of the Royal Melbourne Hospital were invited to take part in this study. As part of the RPP, participants completed a standardised online respiratory protection training program. Details of the study were provided before commencement of the quantitative fit test. Participation was voluntary and verbal consent was obtained before inclusion to the study.

Randomisation

The sequence of the two respirators tested, BYD DE2322 N95 and CE MSK-002 P2, was allocated randomly using a computer generated method, in order to minimise any training affect, with participants stratified into male and female groups.

Intervention

Each participant completed a baseline demographic survey as part of the RPP requirement. They were then required to
complete the QNFT on both the BYD DE2322 N95 and CE MSK-002 P2 respirators. Each of these respirators comes vertically folded flat and both require a similar donning method, in which the respirator is placed onto the face and held in position whilst the straps are lifted over the head. The malleable nose piece is subsequently moulded to fit the individual’s face. Prior to the fit test, each individual performed a fit check. This was a user self-assessment of the perceived fit of the respirator. The respirator was adjusted until the individual was satisfied that it fit satisfactorily, at which point the fit test proceeded.

The fit of each respirator was assessed using a PortaCount Pro+ 8048 (TSI Inc., St. Paul, Minnesota, USA) employing the Occupational Safety and Health Administration (OSHA) modified fast filtering facepiece protocol [6]. 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 (i.e. repeating a fit test until a pass is recorded) was prevented by limiting participants to a maximum of three attempts per respirator.

The RNH RPP fit testers who participated in the study completed an initiation seminar and followed the standard operating procedure for flat fold cup fit testing. All of the qualified fit testers had previously completed a training course endorsed by the Victorian Department of Health and the Australian Institute of Occupational Hygienists. They had also completed a period of supervised practice before completing a comprehensive workplace assessment.

Guidance from the qualified fit tester during the fit test was limited to general guidance that is normally available in the workplace. To assist with this limitation, use of the PortaCount’s real time fit test mode was not permitted, in order to ensure that the fit test environment resembled standard workplace practices as closely as possible.

At the completion of the fit test, each participant was asked to complete a survey (Supplementary material B) canvassing their opinion of several usability and comfort factors for each respirator.

Blinding

The participants and fit testers were not able to blinded to the group allocation. The statistician was blind to the group allocation until full analysis was complete.

Outcomes

The primary outcome was to compare the QNFT pass rate, defined as a harmonic mean fit factor of ≥100, between the two respirators. Secondary outcomes included the overall fit factor, the individual fit factor for each exercise, the concordance of passing the QNFT between the two models, and the self-rating usability and comfort assessment results.

Sample size

Power analysis was performed based on a baseline QNFT pass rate of BYD DE2322 of approximately 30% [2]. To demonstrate a clinically significant improvement by 15%–45% with the CE MSK-002 model, we required at least 180 participants per group, for a power of 0.8. We recruited a total of 300 participants for this crossover study, to account for potential underestimation of the BYD fit test pass rate and also potential missing data.

Statistical analysis

Basic demographic information and the usability and comfort assessments were collected from the RPP survey via REDCap 10.5.2 (Vanderbilt University, Nashville, Tennessee, USA). The QNFT results were recorded on the PortaCount machine and uploaded onto the REDCap system. Descriptive statistics such as means, medians and percentages were used to present the demographic data, and QNFT scores and pass rates. McNemar test was used to compare categorical data, such as the pass rate. Wilcoxon sign-rank test was used to compare the fit factors and five-point Likert scale results from the user assessment between the two respirators. A p-value of <0.05 was considered statistically significant. Kappa statistics were used to examine the concordance between the two respirators. The kappa value was interpreted to indicate consistency between the two models, as follows: <0.21 was “poor”, 0.21 to 0.40 was “fair”, 0.41–0.60 was “moderate”, 0.61–0.8 was “good” and 0.81–1.0 was “very good”. Statistical analysis was performed using Stata 13.0 (Statacorp, College Station, Texas, USA).

Results

A total of 300 participants were recruited. We deleted eight records because of incomplete data. Therefore, a total of 292 sets of data were analysed in the study. A summary of participant demographics is shown in Table 1. Of the participants, 70% identified as female. The BYD DE2322 respirator was randomized to be tested first for 46% of the participants.

The CE MSK-002 had a significantly higher quantitative fit pass rate than the BYD DE2322 (57% vs 18%, p < 0.001). The CE MSK-002 also demonstrated significantly higher fit factors than the BYD DE2322 in both the overall fit factor and individual exercises (Fig. 1). BMI and randomisation order did not affect the likelihood of passing BYD or Care Essentials, however males were less likely to pass the CE MSK-002 than females, with odds ratio (OR) of 0.58 (95% CI: 0.35–0.97). Overall, there was poor concordance between the two vertical flat-fold N95 FFRs with a Kappa value of 0.07. In the subjective usability and comfort survey, a significantly higher proportion of participants found that the firmness of the CE MSK-002 was ‘about right’ when

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<th>Table 1: Participants’ baseline characteristics. Values are expressed as mean ± S.D. or number (percentage).</th>
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compared to the BYD (59% vs 36%, p < 0.001). The CE MSK-002 also achieved significantly higher subjective ratings than the BYD for ease of use, respirator seal and breathability (Fig. 2). The overall comfort and overall assessment ratings were also significantly higher for the CE MSK-002 than the BYD (median 4 [IQR 3–4] vs median 3 [IQR 2–4], and median 4 [IQR 3–4] vs median 3 [IQR 2–3] respectively, Fig. 3).

Discussion

The CE MSK-002 was superior to the BYD DE2322 with respect to face seal as demonstrated by higher QNFT pass rates. Participants also preferred the CE MSK-002 over the BYD DE2322 respirator for subjective measures such as firmness of fit, breathability and overall comfort.

The CE MSK-002 vertical flat-fold cup QNFT pass rate was 57%, which is similar to other collapsible flat fold respirators reported in the literature, such as the BSN ProShield and Halyard Fluidshield duckbill style FFRs [7], albeit below the class-leading three-panel flat-fold respirators, such as 3M Aura (9320A+, 1870+) and Industree Trident [2,8]. The lower QNFT pass rate for the BYD DE2322 of 18% supports the findings in other published research [2,3,9].

The procurement of respirators for HCWs should take into consideration effectiveness, integration with workplace tasks, comfort, regulatory compliance and logistical factors, such as cost and availability [5]. Respirators should be comprehensively assessed prior to healthcare deployment, with many models reported as performing poorly in fit testing, despite being N95 approved [9]. As many workplaces become more ethnically diverse, staff have a variety of facial features, some of which may not fit the N95/P2 respirators that are typically designed for Europeans or North Americans. Additionally, in times of poor supply, novel approaches have been proposed to improve the fit of respirators, including the use of external frames, which have been found to significantly improve the fit of the BYD DE2322 from a very low pass rate of 13% [10]. The suitability and efficacy of such modifications must be assessed and considered thoroughly prior to wide-spread deployment.

In 2009, a multi-agency working group in the USA named Project BREATHE, recommended that a multi-faceted assessment of respirators should be conducted for healthcare workers [5]. Under Project BREATHE, there are four categories of desirable characteristics of RPE. It was recommended that respirators be: safe and effective; compatible with work activities; comfortable and tolerable for the duration of wear; and compliant with relevant standards, guidelines and policies as part of a comprehensive RPP.

Furthermore, the overall vetting procedure for new respirators should include the use of respirators in the wide variety of clinical settings encountered in healthcare. Amongst the diverse work groups and departments in a hospital setting, this should incorporate medical imaging, which has its own particular safety challenges when considering respiratory protection. It is commonly
Figure 2  Violin plots comparing user assessments on ease of use, seal of respirator and breathability between BYD and Care Essentials.

Figure 3  Violin plots comparing overall comfort and overall assessment ratings between BYD and Care Essentials.
understood that there are potential implications for MRI image quality when patients wear metal-containing items, including the nose piece in surgical masks or respirators [11]. An important point of difference between the respirators studied is that the CE MSK-002 respirator does not have any metal staples and the nasal bar is an aluminium construction (i.e. no ferro-magnetic components). Therefore, the CE MSK-002 may be suitable for use by clinical staff in close proximity to MRI scanners. Whilst the TGA and Centers for Disease Control and Prevention recommend respirators should be free of any metal to minimise any heating or magnetic attraction [12,13], there are very few FFRs that meet this criteria.

A limitation of our study is that FFRs were tested in controlled conditions with participants given time to don and doff the respirators without any external pressures or workplace demands. The user assessments with respect to comfort and tolerability may change over longer periods of repeated use. Secondly, our study was performed in Melbourne Australia, in a hospital setting where 70% of participants were female, and therefore our results may not necessarily be applicable to different industries and different jurisdictions.

Conclusions

The CE MSK-002 demonstrated higher QNFT pass rates and higher subjective user assessments than the BYD DE2322. Given the overall QNFT pass rates, subjective usability scores, and potential safe use in MRI settings, it is recommended that the CE MSK-002 be considered in the suite of FFRs available for use in the healthcare sector.

Authorship statement

Mr Charles R Bodas: conceptualization, methodology, project administration, resources, data acquisition and interpretation, writing — original draft, review and editing.
Dr Irene Ng: obtained ethics approval, conceptualization, data analysis and interpretation writing — original draft, review and editing.
Dr Benjamin Kave: conceptualization, methodology, resources, writing — original draft, review and editing.
Ms Fiona Begg: conceptualization, methodology, project administration, resources, writing — review and editing.
Professor Daryl L Williams: obtained ethics approval, conceptualization, methodology, project administration, resources, data acquisition and interpretation, validation, writing — original draft, review and editing.

Conflict of interest

There are no competing interests or conflict of interest declared.

Data sharing 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 five years after publication.

Funding

There was no external funding provided for this study.

Ethics

Ethics approval was obtained through the Melbourne Health Human Research Ethics Committee (QA 2020174) as part of our RPP implementation and improvement.

Provenance and peer review

Not commissioned; externally peer reviewed.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.idh.2022.08.002.

References


