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Repeated vaporised hydrogen peroxide disinfection of 3M 1860 N95 mask respirators does not degrade quantitative fit performance

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Editor—We describe our mask recycling and repeated National Institute for Occupational Safety and Health (NIOSH) quantitative fit testing as performed by a multidisciplinary collaboration of clinicians and materials science experts to address the current shortages of appropriate personal protective equipment (PPE) caused by the current coronavirus disease 2019 pandemic.

Disposable filtering face-piece respirators (FFRs), including N95 masks, are mainstays of PPE designed to prevent the spread of aerosolised infections. Worldwide demand because of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has outstretched worldwide N95 FFR supplies.^{1–3} To mitigate these shortages, extended use or limited reuse of N95 FFRs in healthcare settings is under investigation; the US Centers for Disease Control and Prevention (CDC) currently recommends isolating used FFRs in a paper bag and allowing 72 h for any residual virus to deactivate.⁴ Other decontamination techniques (ultraviolet light, vaporised

hydrogen peroxide, and moist heat) have been suggested, but not currently endorsed by the CDC.⁴

Our health system addressed shortages of N95 FFRs by instituting a vaporised hydrogen-peroxide-based system to disinfect the most abundant commercially available N95 FFR currently in use at our institution: the 3M[®] model 1860 dome-type N95 FFR. We chose to reprocess these FFRs for reuse to expand our stockpiles for use by healthcare workers and remove the need to isolate masks for 72 h. Previously published results on decontamination of N95 masks (including the same 3M 1860 N95 FFR) using vaporised hydrogen peroxide have focused on the results of this sterilisation technique and the performance of the decontaminated mask material only.^{5–8} There are no studies using the NIOSH quantitative fit testing of decontaminated masks to assess both the fit and function of a full mask after repeated decontamination using 35% vaporised hydrogen peroxide (35% VHP).

The NIOSH quantitative fit testing allows evaluation of both the mask filter media and fit. This dynamic evaluation provides insight into specific activities of a healthcare worker and portions of a mask that may fail (e.g. fit around nose, seal around face, and dynamic movement). The complete mask system, including filter media, nose wires, straps, and resultant fit to the wearer’s face, is challenged during a series of four activities (bending over, talking, head moving side to side, and head moving up and down) representative of healthcare worker wear of the mask. Quantitative fit testing offers a superior numerical assessment for fit factor of masks up to 200 for each individual test activity, rather than solely utilising an overall pass/fail score, as used in NIOSH qualitative testing. Quantitative fit testing was utilised to assure, to the highest

possible standard, that disinfected masks would retain sufficient protection for an individual before returning the masks for use in emergency departments and inpatient wards.

Our mask reprocessing and testing programme included a rigorous quality assurance protocol. Each used mask was inspected by staff within the Prisma Health Office of Occupational and Environmental Safety who received specialised training in all aspects of mask reprocessing, including the proper inspection of masks before decontamination and the maintenance and operation of the commercial device we utilised to deliver the 35% VHP for decontamination of the masks. The staff inspected and removed masks that (i) contained cellulose or exhalation valves, (ii) were visibly soiled (e.g. blood, bodily fluids, and facial cosmetics), or (iii) contained

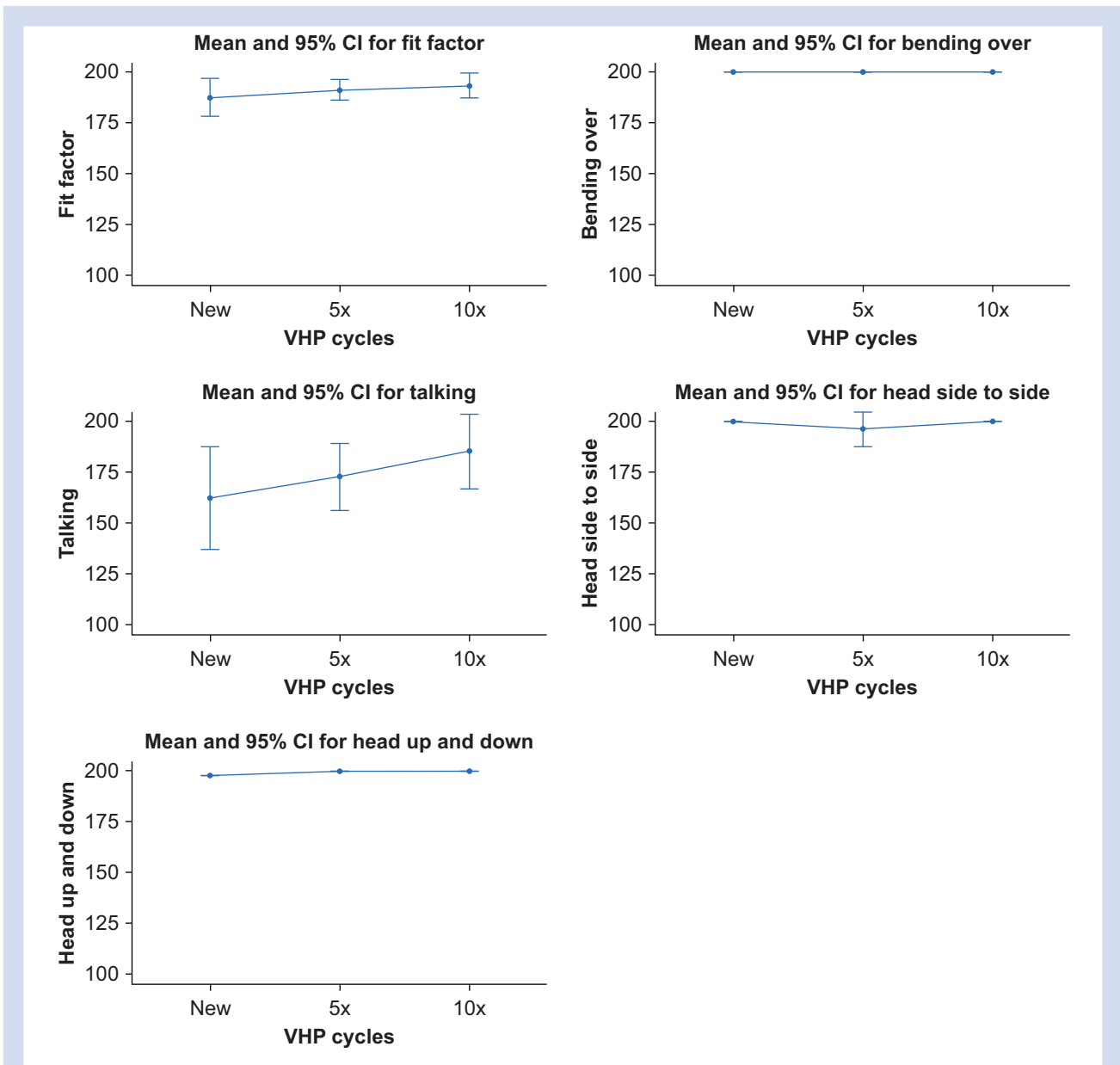


Fig 1. Quantitative fit testing. The mean scores for overall fit factor and each activity as part of quantitative fit testing are reported as means with 95% confidence interval (CI). Maximum score is 200 (N=30, with 10 per cohort). VHP, vaporised hydrogen peroxide.

visibly damaged mask materials or elastic straps. Remaining masks were disinfected with immersion in 35% VHP using a Bioquell® BQ-50 machine (Bioquell UK Ltd, Andover, UK). Control biological indicator (BI) release of 6-log *Geobacillus stearothermophilus* spores was performed with every load of masks disinfected and incubated for 7 days. Processed masks were held in quarantine until final culture and BI results were obtained. No mask loads demonstrated any pathogen or BI growth. These standard tests only verified the sterility of a mask and did not verify that the masks would protect a healthcare worker from a viral challenge, such as SARS-CoV-2.

We tested the widely available 3M model 1860 N95 FFR. Our protocol was modelled after testing used for certification of all new N95 mask designs, but built on certification protocols by using the more robust quantitative NIOSH fit testing in accordance with 29 Code of Federal Regulations 1910.134, utilising a TSI PortaCount® Pro (TSI Incorporated, 500 Cardigan Road, Shoreview, Minnesota, 55126, USA) with an 8026 aerosol generator, to produce 40–70 nm NaCl aerosol challenge particles (approximately the size of SARS-CoV-2). The independent fit testing was performed using a single-volunteer repeated-measures design to remove the variability of fit attributable to various head sizes and shapes. We evaluated 30 masks: one cohort of 10 randomly selected new masks and two cohorts of 10 randomly selected masks taken from our mask reprocessing programme, where each cohort was subjected to either five or 10 repeated cycles of disinfection using immersion in VHP. Figure 1 shows the means and 95% confidence interval of the mask cohorts on the overall fit factor and each activity, as analysed using R Core Team (2019). All masks (both new and recycled) passed testing with the raw data and pictures of fit testing supplied in Supplementary Table 1 and Supplementary Figure 1.

These results are the first to demonstrate that repeated vaporised hydrogen peroxide processing does not degrade the fit and function of this N95 mask. Based on these results, our institution has reprocessed and stockpiled approximately 200 000 3M 1860 N95 FFRs. Further analysis and testing with repeated wear cycles and on various other types of masks from other manufacturers are ongoing.

Declarations of interest

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.bja.2020.12.021>.

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Association between inflammation, angiotensin, and disease severity in critically ill COVID-19 patients: a prospective study

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