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A crossover study assessing the protective efficacy of improvised snorkel-based improvised respirators

Paul R Greig[1,2], James Bradshaw[3], Clarissa Carvalho[1], Luke Iwaszko[4], Suniel Ramessur[1], Jan Schumacher[1] and Kariem El-Boghdadly[1,5]

Abstract

Introduction: This study was designed to determine whether improvised respirators based on modified full-face snorkel masks are able to pass a standard qualitative fit test.

Methods: This is a prospective crossover study conducted in 16 staff. Fit-tests were conducted on masks mated to (1) an anaesthetic breathing circuit heat and moisture exchange filter and (2) a CE-marked P3 grade filter. P3 filters were mounted using both epoxy-coated and uncoated adaptors.

Results: None of the tests using anaesthetic filters passed. Only one overall pass was observed using the P3-rated filter mated to the snorkel mask.

Conclusions: These data suggest that improvised PPE designs cannot provide reliable protection against aerosols. Failures are likely due to poor fit, but the suitability of 3D printed materials is also uncertain as fused-filament manufacturing yields parts that are not reliably gas-tight. Improvised PPE cannot be recommended as a substitute for purpose designed systems.

Keywords

Personal protective equipment, COVID-19

Introduction

Clinicians performing aerosol-generating procedures on potential COVID patients require adequate personal protective equipment (PPE), including a class-3 filtering face piece (FFP3 mask).[1] Several unconventional PPE designs were made available online early in the pandemic, when supply chains were at their most stretched.

One widely-shared design involves repurposing a full-face snorkel mask as an FFP3 respirator, using a 3D-printed connector to mount a heat and moisture exchange (HME) filter in place of the snorkel.

We conducted this study to explore the extent to which such devices can pass standard quantitative fit-testing (QNFT).

Methods

Decathlon Easybreath snorkel masks (Decathlon, Villeneuve d'Ascq, France) were modified in three iterations:

- an online-sourced design[2] mated to an HME filter (Filta-Guard, Intersurgical, Wokingham, UK), printed using a Prusa i3-Mk2 (Pruza Research, Praha, Czech Republic)
- a redesigned adaptor mounting a P3 filter (Scott Pro2000-PF10, Scott Safety, Skelmersdale, UK), printed using a Stratasys Dimension SST 1200es (Stratasys Europe, Rheinmünster, Germany)
- an epoxy-resin coated version of the redesigned P3 adaptor.

A convenience sample of 16 was drawn from clinical staff at our institution. Participants underwent

[1]Department of Anaesthetics, Guy's and St Thomas' NHS Foundation Trust, St Thomas' Hospital, London, UK
[2]Nuffield Department of Clinical Neurosciences, University of Oxford, John Radcliffe Hospital, Oxford, UK
[3]Formula 1, Sapphire House, Kent, UK
[4]Formula 1, Product Design Engineering, Formula 1, Sapphire House, Kent, UK
[5]School of Medicine, King's College London, London, UK

Corresponding author:
Paul Greig, Department of Anaesthetics, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH, UK.
Email: Paul.greig@gstt.nhs.uk

Table 1. Summary of unsuccessful fit-tests by stage of failure.

Point of failure	HME filter Uncoated adaptor	P3 filter Uncoated adaptor	P3 filter Coated adaptor	Total
Stage 1: Normal breathing	16	7	8	31
Stage 2: Deep breathing	0	1	0	1
Stage 3: Head side-to-side	0	2	1	3
Stage 4: Head up-and-down	0	2	4	6
Stage 5: Talking	0	1	1	2
Stage 6: Bending forward	0	2	2	4
Stage 7: Normal breathing	0	0	0	0

QNFT, using each of the three mask-adaptor combinations, on a TSI PortaCount Pro 8030 (TSI UK, High Wycombe, UK) according to standard British procedures.[3] Overall fit-factors above 100 are demanded of half-masks,[4] but full-face designs must achieve 500–2000 depending on jurisdiction.[5]

Proportional outcomes were compared using Chi-squared tests. Fit-test scores were not normally distributed, so comparisons were drawn using the Wilcoxon signed rank test.

Results

Seven males and nine females participated; five were white, one black, and eight Asian. One participant was of 'other' ethnicity, and one of mixed-ethnicity.

All were tested on a Sundstrom SR-100 (Sundstrom Safety AG, Lagan, Sweden) mask for comparison. Only two participants failed, both at test-stage four of seven (head movement up-and-down).

All failed QNFT using the HME-mated combination during the first phase ('normal breathing'; median (IQR) fit-factor = 8 (3–23)).

Only a single user passed QNFT with the P3 filter mounted. This was using the uncoated adaptor, achieving a fit factor of 564 overall (Table 1). No users passed using the coated adaptor.

To compare the performance of the coated and uncoated P3 adaptors, comparison was made of the stage 1 scores from each participant who passed the phase. Coated adaptors performed significantly better ($p = 0{\cdot}018$): median (IQR) fit-factor 349 (169–462) versus 899 (350–1396).

Discussion

Only one combination of participant and adaptor passed out of 48 tests, and no users passed on the original internet-sourced design. The degree of protection these designs offer is therefore doubtful.

Filters can be discounted as the source of failure by the inclusion of the P3 filter in testing. This leaves either the mask or the adaptor as failure points. The mask is designed to be used in an aquatic environment where a positive pressure exists outside the mask, pressing it to the user's face. Out of the water only the force exerted by the fabric straps holds the mask in place. A poor seal at ambient pressure is therefore plausible.

The adaptor may also contribute significantly to leakage. Engineers generally consider parts constructed using fused deposition modelling (FDM) or fused filament fabrication (FFF) to be porous. This reflects a limitation of 3D printing as a manufacturing method, as parts are built up as a series of layers of filament bonded together by heat. Adhesion between layers can differ during the process causing inconsistent bonding. Variations in nozzle temperatures, filament type, and filament quality all contribute to irregularity. Microscopic examination of printed parts usually reveals gaps, particularly in areas where the extruder has changed direction during printing.

We considered porosity to be a risk, hence testing an epoxy-coated version of the adaptor. It is noteworthy that this performed better than the than the uncoated equivalent, but did not overcome the poor fit of the mask.

QNFT failures are to be expected, even with purpose-designed equipment.[6,7] Given the limitations of even purpose-designed equipment, the safety implications of using improvised systems based on consumer-grade parts used in ways for which they were never designed (and using a manufacturing method that may be unsuited to the task) must be questioned.

Although the sample size is relatively small, it exceeds the sample of masks required to be tested for inward leakage in order for a mask system to receive kite-marking.[8] These data combined with our assessment of the respiratory safety of these masks[9] lead us to conclude that improvised systems offer little protection, and in some cases may present an active hazard.

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ORCID iD

Paul R Greig https://orcid.org/0000-0003-3161-5641

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