

## Original Article

# Adapting re-usable elastomeric respirators to utilise anaesthesia circuit filters using a 3D-printed adaptor - a potential alternative to address N95 shortages during the COVID-19 pandemic

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## Summary

The COVID-19 pandemic has increased the demand for disposable N95 respirators. Re-usable elastomeric respirators may provide a suitable alternative. Proprietary elastomeric respirator filters may become depleted as demand increases. An alternative may be the virus/bacterial filters used in anaesthesia circuits, if they can be adequately fitted onto the elastomeric respirators. In addition, many re-usable elastomeric respirators do not filter exhaled breaths. If used for sterile procedures, this would also require modification. We designed a 3D-printed adaptor that permits elastomeric respirators to interface with anaesthesia circuit filters and created a simple modification to divert exhaled breaths through the filter. We conducted a feasibility study evaluating the performance of our modified elastomeric respirators. A convenience sample of eight volunteers was recruited. Quantitative fit testing, respiratory rate and end-tidal carbon dioxide were recorded during fit testing exercises and after 1 h of wear. All eight volunteers obtained excellent quantitative fit testing throughout the trial. The mean (SD) end-tidal carbon dioxide was 4.5 (0.5) kPa and 4.6 (0.4) kPa at baseline and after 1 h of wear ( $p = 0.148$ ). The mean (SD) respiratory rate was 17 (4) breaths.min<sup>-1</sup> and 17 (3) breaths.min<sup>-1</sup> at baseline and after 1 h of wear ( $p = 0.435$ ). Four out of eight subjects self-reported discomfort; two reported facial pressure, one reported exhalation resistance and one reported transient dizziness on exertion. Re-usable elastomeric respirators to utilise anaesthesia circuit filters through a 3D-printed adaptor may be a potential alternative to disposable N95 respirators during the COVID-19 pandemic.

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## Introduction

The COVID-19 pandemic has caused a worldwide surge in the consumption of personal protective equipment including disposable N95 or equivalent respirators. These

respirators are recommended when performing aerosol generating procedures including tracheal intubation and extubation [1, 2]. For anaesthetists who perform aerosol generating procedures, the critical shortage of these

respirators is a pressing issue. National Institute for Occupational Safety and Health (NIOSH)-approved elastomeric respirators may be suitable alternatives when used with compatible NIOSH or European Certification (CE)-approved filters such as P100 and P3 [1, 3]. Healthcare personnel can be rapidly fit tested and trained to use them [4]. During the COVID-19 pandemic, the supply of elastomeric respirator filters may also be depleted. In addition, many re-usable elastomeric respirators do not filter exhaled breaths [1], but simply have an expiratory one-way valve. Therefore, elastomeric respirators also require modification when respiratory protection from the user to the patient is also required (e.g. sterile procedures).

High-efficiency filters routinely used in anaesthesia circuits are designed to filter viruses and bacteria [5]. There are two types of filters; electrostatic and mechanical (also known as pleated hydrophobic). Advantages of electrostatic filters include: low resistance; light weight; small size; and low cost. Disadvantages of electrostatic filters include lower filtration efficiency and vulnerability to liquids (and any microbe contained in the liquid) [5]. Mechanical filters generally have higher filtration efficiency compared with electrostatic filters and are more resistant to liquids. Disadvantages of mechanical filters include higher resistance, heavier weight, larger size and higher cost [6].

Applications of 3D printing in the field of anaesthesia have included: creating airway models for pre-operative planning [7, 8]; producing airway stents [9, 10]; facial prosthetics [11]; and creating spinal column [12] and bronchial tree [13, 14] education models. Facing the shortage of oxygen delivery devices and personal protective equipment in the COVID-19 pandemic, 3D printing has been used to convert snorkel masks into CPAP masks for patients [15] and full-face respirators for healthcare workers [16, 17]. Venturi valves [18] and ventilator splitting devices [19] are also being tested and produced.

In this feasibility study, we designed a 3D-printed adaptor that allowed 3M™ (St Paul, MN, USA) elastomeric respirators to interface with anaesthesia circuit filters and made a simple modification to the elastomeric respirators to divert exhaled breaths through the filter as well. Fit testing of respirators used during aerosol generating procedures is required. Therefore, it seems reasonable to use both qualitative and quantitative fit testing to evaluate the performance and safety of elastomeric respirators that have undergone the modifications we propose.

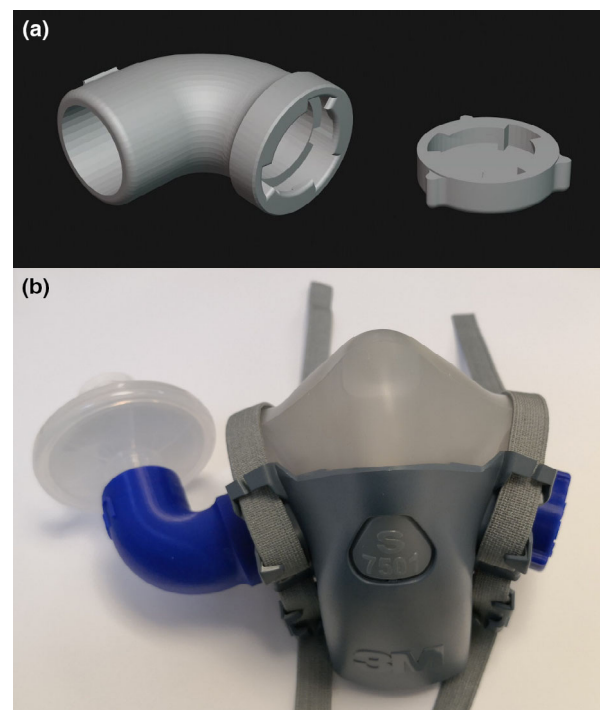
## Methods

After ethical approval by the Hospital Authority Research Ethics Committee, we recruited eight volunteers who

provided their written informed consent. As this was a feasibility study with no comparator group, no power calculation was performed. Primary outcomes were quantitative and qualitative fit testing. Secondary outcomes were end-tidal carbon dioxide, respiratory rate and volunteer self-reporting of discomfort.

Due to their widespread use and availability, we chose to design a 3D-printed adaptor for the 3M 7501 (small) and 3M 6200 (medium) elastomeric respirators. The design of both respirators is comprised of two inhalation limbs on the left and right sides, and an exhalation valve on the front of the respirator. Normally, two filters are placed on the inhalation limbs via bayonet connectors. The 3D-printed adaptor was designed to fit between the 3M inspiratory limb bayonet connector and a standard 22-mm outer diameter connector [20] (Fig. 1a). Two of these can be printed for both left and right bayonet connectors, or one side can be closed using a 3D-printed cap (Fig. 1b). Should the respirator be used for sterile procedures, the expiratory valve can be sealed such that user inhalation and exhalation is via the anaesthesia circuit filter.

The inspiratory limb adaptor and a cap were designed using SolidWorks software (Dassault Systèmes, Vélizy-Villacoublay, France) and printed with an Ultimaker S5 3D



**Figure 1** Design of the adaptor and cap. (a) 3D rendering of the 3D-printed adaptor; (b) Configuration 1: 3D printed and attached to a 3M 7501 respirator and an Undis BVF-02 anaesthesia circuit filter.

printer (Utrecht, Netherlands) using polylactic acid (Premium PLA, Formfutura BV, Nijmegen, Netherlands). Printing instructions and a web link to the stereolithography files for the adaptor and cap can be found in online Appendix S1. Polylactic acid was chosen as it is biodegradable, non-toxic and has a long history of being used for food storage [21] and medical implants [22].

Two configurations were tested. Configuration 1 consisted of inhalation through a single anaesthesia circuit filter and exhalation through the elastomeric respirator exhalation valve (Fig. 1b). Configuration 1 could be used for non-sterile procedures. Configuration 2 consisted of both inhalation and exhalation through a single anaesthesia circuit filter attached to one inspiratory limb with the exhalation valve occluded. For configuration 2, the inhalation valves were removed and the exhalation valve was occluded by wedging a piece of plastic cut out from a zipper storage bag between the exhalation valve and the head harness assembly (Fig. 2).

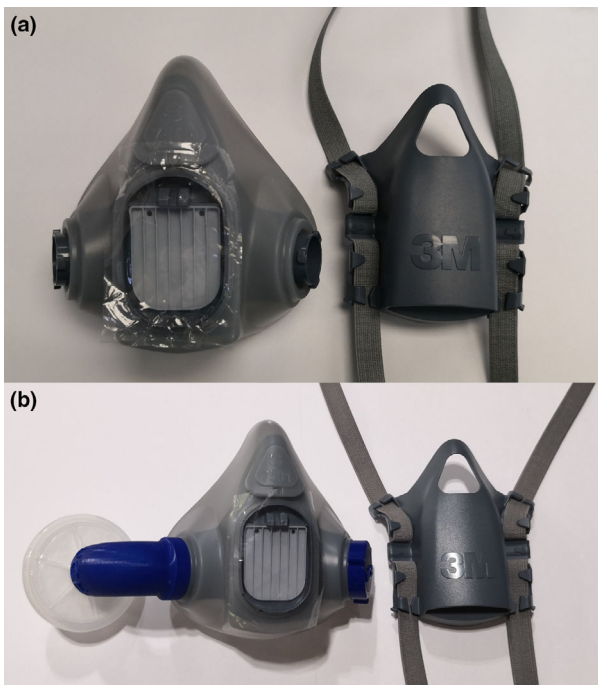
Qualitative negative and positive pressure leak tests were performed by the eight volunteers. The negative pressure leak test was performed by inhaling with the anaesthesia circuit filter covered by the volunteer's hand. The positive pressure seal check was performed by exhaling with either the respirator exhalation valve (configuration 1)

or anaesthesia circuit filter (configuration 2) covered by the volunteer's hand. Adequacy of negative and positive qualitative leak tests were self-reported by the volunteers.

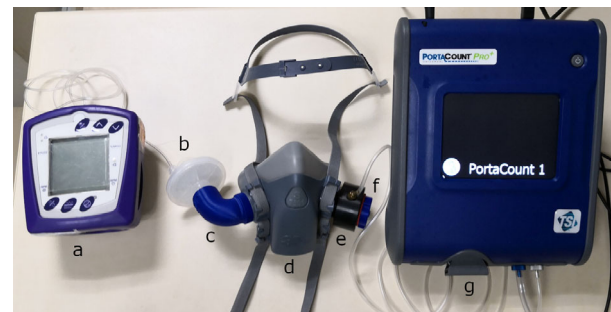
Quantitative fit testing was performed using the PortaCount Pro + 8038 fit tester (TSI Incorporated, Shoreview, MN, USA). The PortaCount N95-companion mode tests respirators with < 99% filtration efficiency and was used in this feasibility study. The Portacount fit tester measures the concentration of particles 55 nm in size, which carry a negative charge in both ambient air and the respirator. As penetration of these particles through electrostatic filters is insignificant, any 55 nm particles detected inside the respirator must have come from a leak [23]. The fit factor is a ratio of these concentrations. A fit factor in the range of 1 to 200+ is calculated with  $\geq 100$  constituting a pass [24].

Being the most commonly available anaesthesia circuit filter in our department, we tested the Undis BVF-02 [25] (Shaoxing, Zhejiang, China) electrostatic filter (without a heat and moisture exchanger). It has a viral and bacterial filtration efficiency of > 99.99%. As most electrostatic filters have a filtration efficiency of < 99% [6], therefore the PortaCount N95-companion mode was chosen.

Quantitative fit testing can be seen in Figure 3. A 3M 601 fit test adaptor was installed between the elastomeric respirator and the 3D-printed cap. Initial fit testing was determined as satisfactory if no leaks were detected during pressure seal checks and stable fit factors were obtained during the real-time display function on the PortaCount Pro + 8038 tester. The real-time display allows a test subject to experiment with strap tension and other adjustments while watching the effect in real-time [24]. If the initial tests were unsatisfactory, the volunteers were fitted with an alternate sized respirator and retested.



**Figure 2** Sealing the exhalation valve. (a) 3M 7501 with a piece of 5 × 7 cm plastic; (b) Configuration 2 with attached adaptor, filter and cap cover (expiratory cover is replaced but is removed for the purpose of clarity).



**Figure 3** Quantitative fit testing set-up. (a) Capnostream-2 carbon dioxide detector; (b) Undis BVF-02 anaesthesia circuit filter; (c) 3D-printed adaptor; (d) 3M 7501 respirator; (e) 3M 601 fit test adaptor; (f) 3D-printed cap; (g) PortaCount Pro + 8038 fit tester.

Following satisfactory initial fit testing, the volunteers performed full standardised quantitative fit testing [26]. The volunteers performed test exercises consisting including normal breathing; deep breathing; head side to side; head up and down; talking out loud; grimace; and bending with touching toes. Fit testing was performed three times: using configuration 1; using configuration 2; and using configuration 2 after wearing the respirator for 1 h.

End-tidal carbon dioxide and respiratory rate were measured in configuration 2 at baseline and after 1 h of wear using a Capnograph-2 carbon dioxide detector (Smiths Medical, Minneapolis, MN, USA) connected to the anaesthesia circuit filter via its Luer-lock connector. Volunteers were asked to wear configuration 2 for 1 h as configuration 2 permits inspiration and expiration of tidal volumes only through the anaesthesia circuit filter, potentially requiring a higher work of breathing.

The paired t-test was used to compare the mean end-tidal carbon dioxide and respiratory rate. Data were analysed with SPSS 26.0 (IBM Corp, Armonk, NY, USA).

## Results

Eight volunteers (five men, three women) completed the study (Table 1). None of the volunteers suffered from cardiorespiratory disease, had a history of smoking, or facial hair or facial abnormalities that may impede fitting of the respirators.

All volunteers passed qualitative positive and negative pressure leak testing. Four out of five men failed the real-time quantitative fit testing wearing 3M 6200 (medium) respirators, with the seal becoming unstable during head movement. They were subsequently fitted with 3M 7501 (small) respirators. All three women were fitted with 3M 7501 (small) respirators. All eight volunteers obtained fit factors of 200+ in all three fit tests (range of testing 1 to 200+ with  $\geq 100$  constituting a pass)[24].

The mean (SD) end-tidal carbon dioxide was 4.5 (0.5) kPa and 4.6 (0.4) kPa at baseline and after 1 h of wear

respectively ( $p = 0.148$ ). The mean (SD) respiratory rate was 17 (4) breaths.min<sup>-1</sup> and 17 (3) breaths.min<sup>-1</sup> at baseline and after 1 h of wear respectively ( $p = 0.435$ ). Four out of eight subjects self-reported discomfort; two reported pressure on the face, one reported exhalation resistance and one reported transient dizziness with exertion.

## Discussion

This study demonstrated that interfacing an anaesthesia circuit filter with re-usable elastomeric respirators may be a feasible alternative to disposable N95 respirators for healthcare providers undertaking aerosol generating procedures in patients with COVID-19 disease. Quantitative fit testing should be mandatory before using re-usable elastomeric respirators as a significant proportion of volunteers failed the real-time fit factor test despite having satisfactory qualitative negative and positive pressure seal checks, in line with published guidelines [3, 26]. Once the four volunteers were refitted with a smaller-sized respirator, quantitative fit testing was excellent for all eight volunteers. Exhalation through the anaesthesia circuit filter was well tolerated with no significant change in end-tidal carbon dioxide or respiratory rate. Given this is a feasibility study with a convenience sample of only eight volunteers, firm conclusions cannot be drawn.

Elastomeric respirators are designed to undergo repeated disinfection. The cost to print an adaptor and a cap using the recommended polylactic acid as a material is approximately £3 sterling (\$3.73 US, 3.5 Euros). We recommend, should these items be required for use, they should be treated as single-use, disposable items as their integrity and safety after disinfection cannot be guaranteed. Other materials may be suitable for 3D printing the adaptor if they are airtight and biocompatible; however, such use requires communication with regulatory bodies within the country before use as stringent standards must be followed [27–31].

**Table 1** Baseline characteristics of the volunteers.

No.	Age; y	Sex	Weight; kg	Height; m	BMI; kg.m <sup>-2</sup>
1	38	F	55	1.58	22.0
2	47	F	54	1.64	20.1
3	51	F	47	1.64	17.5
4	34	M	67	1.67	24.0
5	35	M	78	1.78	24.6
6	41	M	75	1.7	26.0
7	49	M	68	1.71	23.3
8	58	M	70	1.73	23.4

We sealed the exhalation valve with a piece of plastic in configuration 2 forcing exhalation through the anaesthesia circuit filter. For convenience, we cut a piece of plastic from a zipper storage bag and placed it between the exhalation valve and the head harness assembly (Fig. 2). This may not be a very reliable method for clinical use. Although the elastomeric respirators were well tolerated, four of our volunteers reported some discomfort. Similar complaints of discomfort are often reported when using different types of respiratory protective equipment including surgical masks, disposable N95 respirators, elastomeric respirators and even powered air-purifying respirators [32–34]. We found subjectively that wearing these well-fitted, tightly sealed respirators resulted in the user's voice being mumbled and lower in volume. This may affect communication, especially when the exhalation valve is sealed. It was possible to understand the user's speech in a quiet environment; however, in noisy environments such as during resuscitation or trauma, the risk of miscommunication may be increased.

Before resorting to using the anaesthesia circuit filter from one's hospital, it is important to know its specifications. Many filters have filtration efficiencies of < 95% and are therefore inferior to N95 respirators [6]. Most manufacturers recommend that their filters can be used for up to 24 h, but, due to the accumulation of moisture, resistance will increase with prolonged use. Filters with a heat and moisture exchanger demonstrate a greater increase in resistance compared with those without [6]. Filter specifications have important implications in terms of comfort and safety. Sudden blockage of filters is known to occur [35] and elastomeric respirators may be challenging to doff without adequate training.

When contemplating the clinical use of a modified elastomeric respirator, adherence to appropriate regulatory standards is essential. Regulatory organisations such as the Medicines and Healthcare products Regulatory Agency in the United Kingdom [36], Food and Drug Administration in the United States [37] and Health Canada [38] have released guidance on the manufacturing and usage of personal protective equipment including improvised equipment during the COVID-19 pandemic. It is important that the safety of healthcare providers be maintained by following the guidelines and protocols from the appropriate regulatory agencies.

Limitations of our study include our small sample size, short duration of respirator usage and that only one model of anaesthesia circuit filter was tested. Other limitations include the highest BMI of our eight volunteers was 26 kg.m<sup>-2</sup>, with the greatest weight being 78 kg. The use of our modification by larger users requires further

investigation to assess resistance through the anaesthesia circuit filter to both inspiration and expiration with increased minute ventilation.

This study was designed to be a feasibility study with descriptive outcome measures and no power analysis was done beforehand. We chose to test the respirators for 1 h as most aerosol generating procedures can be completed within this timeframe.

In conclusion, we have modified a NIOSH-approved elastomeric respirator not intended for medical use to function as an N95 respirator by interfacing with a standard electrostatic anaesthesia circuit filter with and without occluding the built-in expiratory valve. If N95 or equivalent respirators and NIOSH-approved filters become difficult to source, anaesthesia circuit filters when combined with well-fitted NIOSH-approved elastomeric respirators using an interposed 3D-printed connector may be a potential solution.

## Acknowledgements

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## Supporting Information

Additional supporting information may be found online via the journal website.

**Appendix S1.** Printing instructions and stereolithography files for the adaptor and cap.