Article:
Desai, N., Naveed, H., Koenig, M. et al. (4 more authors) (2021) Fit and filter integrity of a respirator mask after multiple cycles of autoclave. BMJ Innovations, 7 (3). pp. 532-538. ISSN 2055-8074

https://doi.org/10.1136/bmjinnov-2020-000521

Fit and filter integrity of a respirator mask after multiple cycles of autoclave

Nidhi Desai BMBS[1], Hasan Naveed MBBS[1,3], Michael Koenig MD[1,3], Nik Kapur PhD[2], Mahmood Bhutta DPhil[1,3], Saul Rajak PhD[1,3]

[1]Brighton and Sussex University Hospitals NHS Trust, United Kingdom,

[2]School of Mechanical Engineering, University of Leeds, United Kingdom

[3]Brighton and Sussex Medical School

Abstract

Background

The COVID-19 pandemic has led to profound shortages in personal protective equipment worldwide. The availability of filtering facepiece class 3 (FFP3) respirators could be greatly increased if they could be reused after sterilisation

Aims

This study aims to determine the effects of repeated cycles of autoclave on the fit and filter function of the 3M 1863 FFP3 disposable respirator.

Methods

Participants underwent fit tests with 3M 1863 FFP3 respirators. Respirators were subjected to autoclave cycles and a repeat fit test was conducted after each cycle until failure. The filter function of both unused and autoclaved respirators was determined by quantitatively assessing the differential pressures and filter penetration of aerosolised sodium chloride particles. Mask structural inspection was also carried out by light microscopy.

Results

A total of 38 participants were recruited. Repeat fit testing with a new respirator was passed by 30 of 38 (79%) participants in comparison with 31 of 38 (82%) of participants after the respirator had undergone one autoclave cycle. There was fit test failure with further rounds of autoclave. There was no evidence of structural changes after one autoclave cycle, but the nose foam began to separate from the mask following further cycles. Filter efficiency of all 15

autoclaved respirators that underwent filter testing was 97.40% or more. Differential pressure (breathability) of respirators was unaffected by autoclaving.

Conclusions

3M 1863 FFP3 respirator retains good fit and filter function after a single autoclave cycle. Addressing nose foam separation and further testing to EN149 standards would be required before respirators could be considered for reuse.

Introduction

Filtering facepiece (FFP) respirators are an essential component of respiratory protective equipment. They protect wearers against airborne infection, including the novel SARS-CoV2 virus which is predominantly spread via droplet and aerosol inhalation.[1] Healthcare workers (HCW) are advised to wear respirators in high risk encounters, such as close contact with patients and when performing aerosol generating procedures (AGPs).[2] The COVID-19 pandemic has led to profound PPE shortages in almost all healthcare sectors which may be exacerbated as respirator use becomes widespread in the general population. Therefore, extended use, reuse and sterilisation of respirators is being explored.[3]

Respirators are regulated against strict standards such as the USA National Institute for Occupational Safety and Health standard NIOSH 42CFR84 for N95 (specifying 95% filter efficiency) or the European standard EN 149:2001 for FFP3 respirators (specifying 99% filter efficiency).[4] Respirator performance is assessed by specific tests measuring particulate filtration efficiency and breathing resistance. There are three categories of FFP respirators: FFP1, FFP2 and FFP3 are tight fitting respirators with minimum filter efficiencies of 80%, 94% and 99% respectively.[5] There is wide variability in availability and usage of these respirators, but typically FFP3 respirators are used in higher risk settings such as operating theatres or wards designated for patients with respiratory infections such as COVID-19,

Optimal function of respirators is dependent on fit, whereby an airtight seal is formed around the mouth and nose of the wearer; and filter efficiency of the respirator which reflects the barrier capability against particles. Effective respirator function also depends on its breathability (resistance to air flow), which must be balanced with the conflicting requirement for non-penetration of particles. Successful reprocessing of respirators requires elimination of viable infective particles, without compromising respirator seal, filter efficiency or breathability. Sterilisation methods utilising chemicals or radiation are effective at destroying pathogens but can cause damage to filter integrity.[6-9] There is still a relative paucity of research on the effect of autoclave on respirator masks.

The 3M 1863 FFP3 respirator (3M, Bracknell) is commonly used in the UK National Health System. It is a valve-less mask that consists of three panels of non-woven material with a nose clip in the top panel allowing the wearer to mould the respirator for a better fit. This study evaluates the effect of multiple rounds of autoclave sterilisation at 121°C on seal integrity (assessed via qualitative fit testing) and microscopic filter integrity (assessed via filter aerosol penetration) of the 3M 1863 FFP3 respirator

Materials & Methods

Ethics

The HRA ethics decision tool determined that formal ethical review was not required for this study.

Participants

Participants were a convenience sample of consenting healthcare workers recruited from the Ear Nose and Throat and Ophthalmology departments of Brighton and Sussex University Hospital. Participants were excluded if they failed an initial fit test on an unused 3M model 1863 respirator, or if they had symptoms consistent with COVID-19. Participants were only ever fit-tested on an unused respirator, or one that they personally had worn previously.

Autoclave

3M model 1863 respirators went through one or more cycles of autoclave treatment using a B type vacuum autoclave (Eschmann Little Sister SES3000B, UK), which has a 17-litre chamber suitable for processing porous materials. A standardised, pre-programmed cycle to the requirements of EN13060 (standard for small steam sterilisers) was used with a total duration of approximately 60 minutes, comprising an initial air removal stage, a heat to sterilisation stage, a sterilisation hold stage of 121-124°C at absolute pressure of 205-225kPa for 15 minutes, with a subsequent discharge and vacuum drying phase.[10]

Assessment of seal integrity

The integrity of the respirator seal was assessed through both visual inspection and qualitative fit testing.[11]

Visual inspection comprised inspection of: (1) the outer and inner respirator surfaces for damage or deformity, (2) the attachment and elasticity of the elastomeric headbands, (3) the shape of the nose clip area. Participants were also asked to comment on the comfort and fit of respirators.

Fit testing was conducted by a single certified fit testing practitioner in accordance with the Occupational Safety and Health Administration (OSHA) protocol. In brief, a plastic hood (3M FT30 kit) was placed over the participant's head. Participants initially underwent a sensitivity test which involves a nebulised bitter (Bitrex, 3M FT31) or sweet (saccharin, 3M FT11) solution

sprayed through a hole in the hood. If participants could not detect the taste, they were excluded from the study. Those remaining in the study donned the respirator and the plastic hood, and performed seven different repeated head exercises for one minute each, with a Bitrex (3M FT32) or saccharin (3M FT12) solution of higher concentration than used for sensitivity testing sprayed into the hood at the beginning of each exercise. If the participant tasted the solution at any point, the fit test was classed as failed.

Anecdotally, it is recognised that fit testing is not entirely reliable, and reliability is likely specific to each model of respirator. Therefore 30 participants underwent consecutive fit testing on two unused respirators to establish a benchmark for test-retest variation. Results of fit testing after autoclave were compared to this benchmark (McNemar's test, $p<0.05$ significance threshold).

Light microscopy

One respirator that had been autoclaved at 121°C and one new respirator were examined by a histopathologist using a conventional light microscope (Olympus BR-40), who was blind to which respirator was which. The filter was separated into its three component layers, each layer inserted between two glass slides, and examined at low and high magnification under polarised and non-polarised light for structural degradation or distortion.

Assessment of filter performance

Filter efficiency and breathability was assessed in a commercial filter testing laboratory (Filter Integrity, Sedgefield, United Kingdom). Efficiency was tested on a sample of respirators in the study (three each after 1-4 cycles of autoclave and three new respirators) using an aerosol of solid sodium chloride particles generated from solution.

The respirator was secured to a holder using hot melt and tape along its perimeter and placed inside a controlled test chamber, comprising a sealable metal cabinet with inlet and outlet connections. A dispersion bar was fitted on the inlet port to prevent aerosol jetting onto the filter during testing. An aerosol of solid sodium chloride (NaCl) was generated from 1-2% NaCl solution and passed through the test chamber. Temperature and humidity levels inside the chamber were maintained in accordance with standard requirements (<40% relative humidity, 22°C +/- 3°C). The full area of the mask was exposed to the aerosol flow and the domed adaptor spread the mask in a similar fashion to when it is on the face.

Upstream aerosol distribution was measured using a Palas U-SMPS (an 'electrical mobility method') according to BS EN 13274-7-2019 standard specifications. Filter efficiency was

measured over a 0.2-10µm range using a Palas Promo 3000 aerosol spectrometer fitted with a single sensor located downstream of the test filter.

A benchmark reading was taken prior to respirator attachment to measure upstream aerosol samples. After sealing the respirator to the holder five downstream samples were taken at flow rates of 30 and 55L min^{-1}. A further test run was carried out using U-SMPS in classifier mode to assess specific number efficiency at 0.1µm at 55 L min^{-1}. Both the challenge and the penetrating fractions were measured.

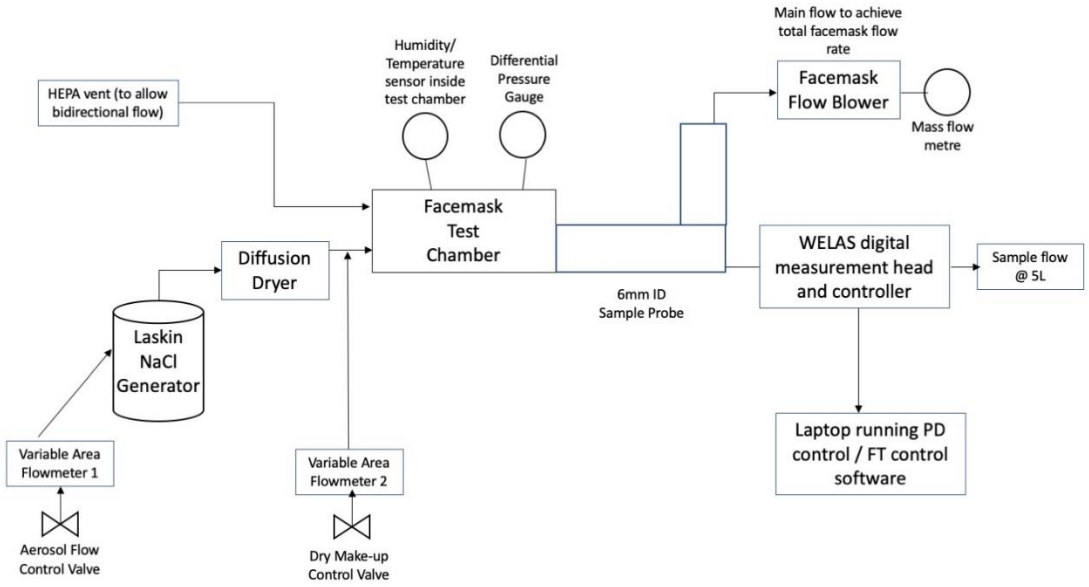

Figure 1. Schematic example of Sodium Chloride aerosol test apparatus.

Results

We recruited 38 participants. Their average age was 41 (range 19-65) and 22 participants were female. One participant was insensitive to Bitrex solution but was sensitive to saccharin solution which was used instead for fit testing.

The test-retest reliability of new 3M 1863 respirators was 30/38 (79%). After one cycle of autoclave, 31/38 (82%) participants passed fit testing (p=0.743). Of the 31 respirators that had passed one cycle, 12/26 (46%), 4/10 (40%) and 0/3 participants passed fit testing after two, three and four autoclave cycles respectively (fig 2) with 5, 2 and 1 participants being lost to follow up after each autoclave cycle.

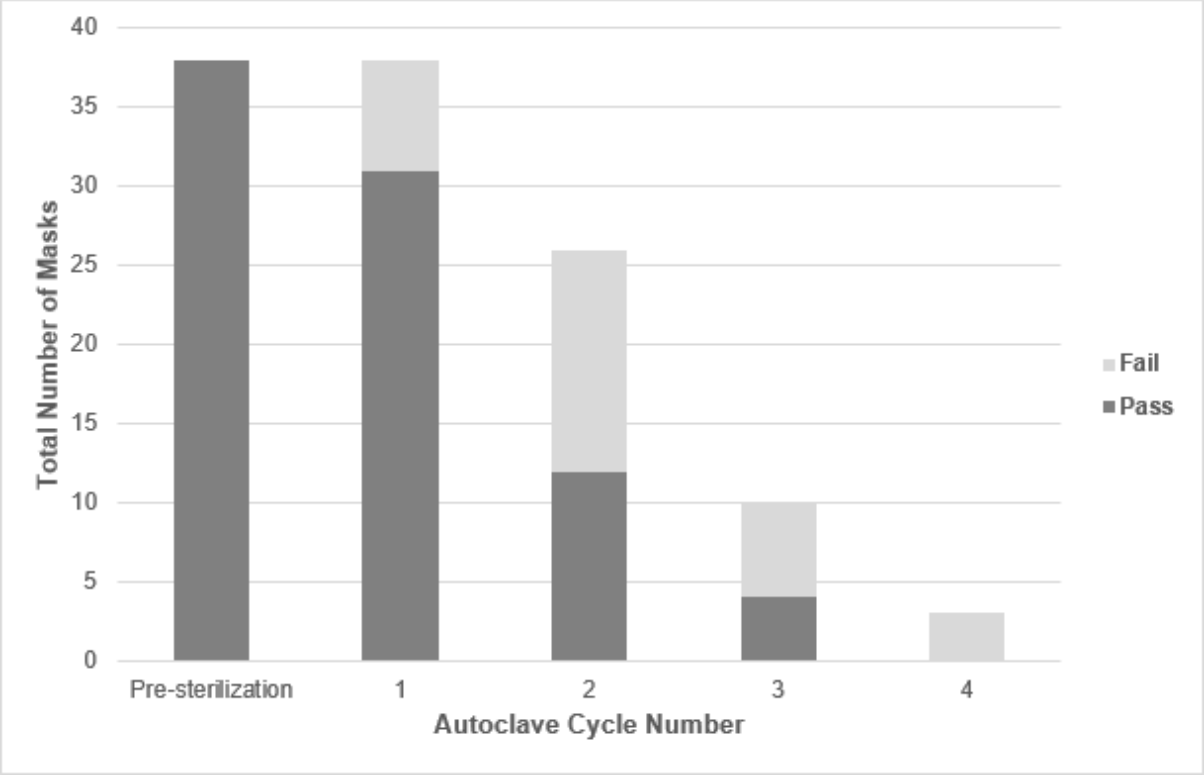

Fig 2: the number of respirators passing/failing fit testing after 1-4 cycles of autoclave

On visual inspection before and after autoclave, a variable degree of separation between the grey nose foam and the respirator fabric layers was observed (***Figure 3***). There was no evidence of other macroscopic changes or deformities after autoclave. 7/38 (18%) of participants reported that material felt less tight around the nasal bridge in post-autoclave respirators, with no other subjective changes noted.

Figure 3: A 3M 1863 respirator mask before (left) and after (right) one autoclave cycle, with arrow marking the separation of nose foam.

On light microscopy, the interlacing material patterns in all layers of the respirator materials were visually identical, and there was no difference in the refractile patterns of the middle layer under polarised light (fig 4).

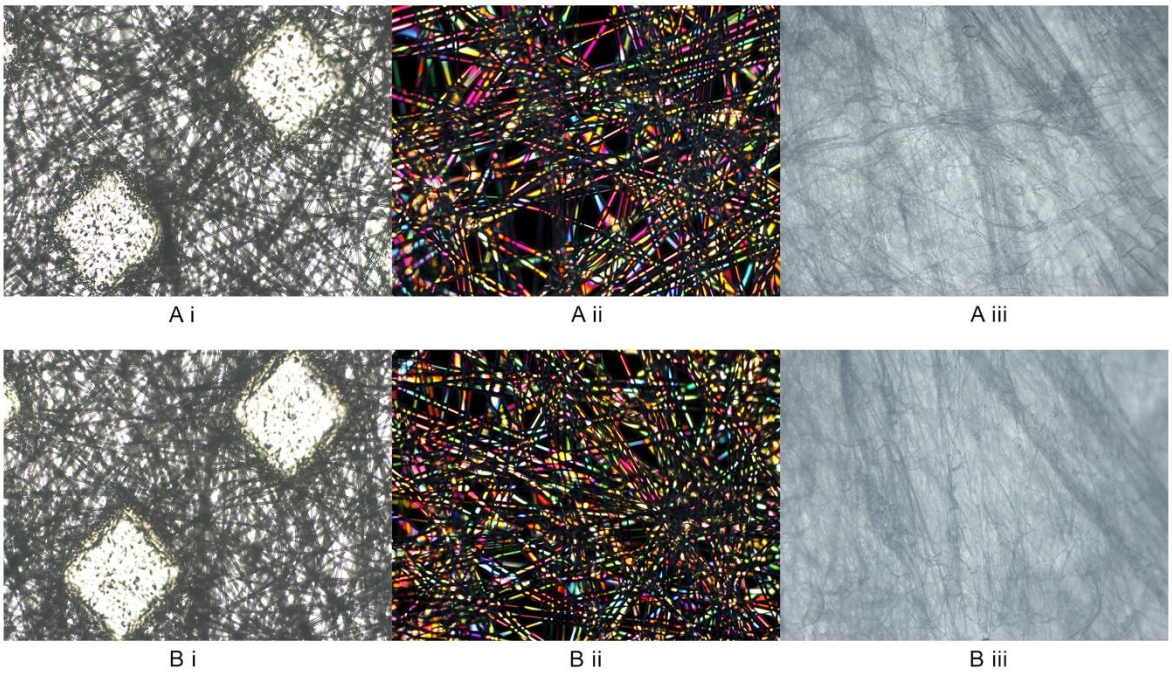

Figure 4: Light microscopy at 40x magnification of the individual layers of a new respirator (A) and a respirator after one autoclave cycle (B): (i) Outer layer, (ii) middle layer, (iii) inner layer

Filter Integrity Testing

The filter efficiency for particles of 0.3um and 0.1um in size at flow rates of 55 L min^{-1} and 30 L min^{-1} is shown in table 1. There was a trend towards slightly lower efficiency with repeated autoclave cycles, but the lowest recorded efficiency was 97.4%. The operating differential pressure at 30 L min^{-1} did not exceed 35.1Pa (table1), which is below the maximum breathing resistance allowance (1mbar/100Pa) defined by the EN 149 standard.

Number of autoclave cycles	Number of respirators tested	Mean (range) efficiency of penetration of 0.3um particles at 55 L min^{-1}	Mean (range) efficiency of penetration of 0.1um particles at 30 L min^{-1}	Mean (range) of differential pressure at 55L min
0	3	99.66 (99.20 - 99.99)	99.92 (99.80 – 99.98)	52.13 (51.50 – 52.80)
1	3	99.26 (97.90 - 99.97)	99.72 (99.30 – 99.94)	60.03 (57.70 – 62.80)
2	3	99.23 (99.20 – 99.30)	98.60 (98.20 – 99.00)	55.90 (52.80 – 60.50)
3	3	99.13 (98.0 – 99.80)	98.40 (97.40 -99.69)	58.90 (56.50 – 60.50)
4	3	99.27 (98.85 - 99.75)	98.96 (98.60 - 99.69)	55.57 (53.70 – 57.10)

Table 1: filter testing results of 15 respirators (3 each of 1 – 4 autoclave cycles and 3 new respirators)

Discussion

The COVID-19 pandemic has led to large scale depletions in single use respirators. In low income countries, respirator availability is restricted, and therefore re-use may be the only option. Furthermore, the environmental harms could be significant: it has been estimated that daily respirator use by the UK population could generate over 128,000 tonnes of unrecyclable waste, putting extreme strain on waste disposal services and potentially exposing disposal workers to infection risk.[12] Strategies for increasing re-use of respirators are urgently required.

Autoclaves are widely utilised for equipment reuse in a variety of healthcare settings, and should ensure a six log (99.9999%) reduction in microorganisms if saturated steam is held at a temperature of a minimum 121°C for at least 15 minutes .[10] Previous research suggests that a single cycle of autoclaving should destroy influenza viral particles on a respirator mask.[9]

Our study indicates that the filter function of the 3M 1863 respirator is materially unaffected by up to four cycles of autoclave sterilisation, Throughout testing, all of the respirators retained breathability of 3.0 mbar or lower and 9% or greater efficiency for 100nm (0.1um) and 300nm (0.3um) diameter particles. Whereas 300nm particles are the size tested for when certifying to the EN149 standard, 100nm particles are thought to be the most penetrative for this type of filter, and representative of the SARS CoV2 virus which is 50-200nm in size.[13] Although, FFP3 respirators should have a minimum efficiency of 99%, a drop-off to 98% will not place the user at materially increased risk, and FFP2 or N95 respirators with 95-96% efficiency, are already deemed acceptable for use in high risk settings.[5] However, we did find that the 3M 1863

respirator seal was reliably maintained for only one cycle of autoclave, with an increasing proportion of masks failing on fit testing after further cycles. We suspect this derives from adhesive failure leading to the separation we noted between the nose foam and fabric layers.

Several previous studies have investigated the effect of autoclaving on the integrity of respirators, but have used a variety of autoclave protocols and respirators, which may explain varying outcomes.[6-9] Vicusi et al report a marked worsening of fit of the 3M 8210/MHI and the Moldex 2200 respirator after 30 minutes of 60°C moist heat treatment.[8] Lore et al reported that 3M model 1860 and 3M model 1870 respirators retained at least 95% efficiency for 300nm sized particles after being treated with moist heat reaching up to 65+/-5°C for three hours but did not assess respirator fit after treatment.[9] Lin et al reported a marked change in physical appearance and rise in particle penetration in a N95 respirator (model not specified) after a 15 minute 121°C autoclave cycle.[6] A further non-peer reviewed report of the 3M NR D 8822d FFP2 respirator reported marked deformation of the mask after 90°C autoclave cycles such that fit testing was not attempted, and no deformation after a 60°C, but failure of fit testing.[14] However, in contrast, de Man et al recently reported that the 'functionality' of the 3M 1862 FFP2 mask was unaffected by a 15 minutes autoclave cycle and Kumar et al's as yet non peer reviewed manuscript reports that there was no loss of structural or functional integrity of four different models of N95 mask (3M Aura 1870, 3M VFlex 1804S, 3M 9210 and AO Safety 1054S) after ten cycles of autoclave sterilisation (121°C for 15 minutes) but failure of the 3M 1860 and 8210 respirators after the first cycle.[15,16]

For the 3M 1863 we found that the limiting step to reuse was a failure of the seal integrity rather than of the filter. Two differing and potentially complementary strategies may overcome this limitation: use of different parameters for autoclave, or a change in materials used in the respirator. Whereas here we found no evidence that a temperature of 121°C materially affected filter function at up to four cycles of autoclave, other have reported that heating non-woven polypropylene materials above 100°C can cause irreversible filter damage and lead to loss of electret charge thought to be important in repelling micro-organisms.[17] Many micro-organisms are destroyed at temperatures lower that 100°C: for example exposure of the SARS-CoV-2 virus to 56°C for 20 minutes leads to inactivation.[18] A lower temperature may therefore lead to better preservation of the materials of the mask without compromising sterilisation. We have conducted preliminary testing of the the 3M 1863 masks with autoclave temperatures of 85°C and 110°C (data not presented), and found that it does not appear to cause the same degradation of adhesive around the nose foam. It is also possible that altering the position of the mask during autoclave (for example straightening the mouldable nosepiece)

may reduce stress on the join between the nose piece foam and the fabric, and also prevent failure.

Nevertheless, most autoclaves run on pre-programmed cycles, and adjustment to such cycles may not be possible or feasible at scale. A better solution may lie in a change in materials in the manufacture of respirators, to those resistant to higher temperature autoclave. To date we are not aware that any manufacturer has attempted such an endeavour.

The respirator used in this study was designed, manufactured and certified for single use only. Whilst the present study provides promising data on respirator fit and filter function after autoclave that may assist respirator manufacturers and policy makers, there are limitations of this study and further important considerations and potential differences between new and sterilised respirators: (1) All the respirators autoclaved in this study had not been worn by the user other than for fit testing and we are therefore unable to determine if the fit or filter function is compromised by respirator wear. However, as the fit and filter function are not markedly affected by 60 mins of steam autoclave reaching temperatures of over 120°C it unlikely that a short period of wear would cause significant damage, (2) In this study the respirators are not washed prior to autoclaving (which would likely damage the woven fabric) in contrast to the standard process for surgical equipment sterilisation in which debris is removed by washing prior to autoclaving. However, respirators are very unlikely to be in contact with macroscopic patient debris and if they are soiled during usage, reuse would not be considered (3) This study examined filter function using a particle count method, rather than aerosol photometry which is specified in EN149;2001 requirements.[19] However our aim was to ascertain respirator filter function for a range of flow rates and particle sizes (including ultrafine particles which approximate viruses and other pathogens[20]) rather than to achieve certification (4) We performed filter testing with non-neutralised aerosolised salt, which may reduce the ability to test the residual electrostatic charge function of the fibres. N95 respirator testing in the United States requires the use of neutralised salt, but EN149 standards do not, (5) Qualitative fit testing was used, which provides a subjective measure of seal integrity, rather than quantitative fit testing which provides an objective measure, which could introduce bias as participants were not blind to the autoclave status of their respirator. (6) We tested the currently widely used 3M generation 1 1863 respirator, but the generation 2 1863+ respirator is likely to be increasingly widely used, and although it would be expected to perform similarly after autoclave, it would need to be formally tested.

We have demonstrated that the fit of the widely used 3M model 1863 FFP3 respirator was not affected by one cycle of 121°C autoclave and the filter function did not appear to be affected by multiple cycles. Further research is required to address the separation of the nose foam from the mask fabric, which likely underlies the failure of the seal. Because autoclaves are widely available in healthcare settings, overcoming such barriers may enable an accessible and affordable method for reusing respirator masks.

Acknowledgements

We would like to acknowledge:

Eschmann Technologies Limited, Lancing, UK for the provision of autoclaves and sterilisation expertise

Filter Integrity Limited, Durham, UK for testing the respirator filters and filter expertise.

Funding

This research study has been supported by a grant awarded by the Applied Research Collaboration Kent, Surrey and Sussex (ARC KSS).

References

1. Liu Y, Ning Z, Chen Y, et al. Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals. Nature 2020.
2. Ran L, Chen X, Wang Y, Wu W, Zhang L, Tan X. Risk Factors of Healthcare Workers with Corona Virus Disease 2019: A Retrospective Cohort Study in a Designated Hospital of Wuhan in China. Clin Infect Dis 2020.
3. Polkinghorne A, Branley J. Evidence for decontamination of single-use filtering facepiece respirators. J Hosp Infect 2020.
4. Rengasamy S, Eimer BC, Shaffer RE. Comparison of nanoparticle filtration performance of NIOSH-approved and CE-marked particulate filtering facepiece respirators. Ann Occup Hyg 2009;53:117-28.
5. Lee SA, Hwang DC, Li HY, Tsai CF, Chen CW, Chen JK. Particle Size-Selective Assessment of Protection of European Standard FFP Respirators and Surgical Masks against Particles-Tested with Human Subjects. J Healthc Eng 2016;2016.
6. Lin TH, Chen CC, Huang SH, Kuo CW, Lai CY, Lin WY. Filter quality of electret masks in filtering 14.6-594 nm aerosol particles: Effects of five decontamination methods. PLoS One 2017;12:e0186217.
7. Viscusi DJ, Bergman MS, Eimer BC, Shaffer RE. Evaluation of five decontamination methods for filtering facepiece respirators. Ann Occup Hyg 2009;53:815-27.

8. Viscusi DJ, Bergman MS, Novak DA, et al. Impact of three biological decontamination methods on filtering facepiece respirator fit, odor, comfort, and donning ease. J Occup Environ Hyg 2011;8:426-36.
9. Lore MB, Heimbuch BK, Brown TL, Wander JD, Hinrichs SH. Effectiveness of three decontamination treatments against influenza virus applied to filtering facepiece respirators. Ann Occup Hyg 2012;56:92-101.
10. European Standards. BS EN 13060:2014+A1:2018. Small steam sterilizers2018:88.
11. United States Department of Labour. Occupational Safety & Health Administration (OSHA). Fit testing procedures (mandatory). Washington: Government Publishing Office; 2020.
12. UCL Plastic Waste Innovation Hub. The environmental dangers of employing single-useface masks as part ofa COVID-19 exit strategy2020.
13. Maier HJ, Bickerton E, Britton P. Preface. Coronaviruses. Methods Mol Biol 2015;1282:v.
14. The Dutch National Institute for Public Health and Environment. Reuse of FFP2 masks. Bilthoven: Ministerie van Volksgezondheid, Welzijn en Sport; 2020.
15. de Man P, van Straten B, van den Dobbelsteen J, van der Eijk A, Horeman T, Koeleman H. Sterilization of disposable face masks by means of standardized dry and steam sterilization processes; an alternative in the fight against mask shortages due to COVID-19. J Hosp Infect 2020;105:356-7.
16. Kumar AK, B. Leung, A. Cutts, T. Strong, J.E. Hills, K. Vazquez-Grande, G. Rush, B. Lother, S. Zarychanski, R. Krishnan, J. N95 Mask Decontamination using Standard Hospital Sterilization Technologies. medRxiv2020.
17. Zhang H, Liu J, Zhang X, C. H, Jin X. Design of electret polypropylene melt blown air filtration material containing nucleating agent for effective PM2.5 capture. RSC Advances 2018;8:7932-41.
18. Darnell ME, Subbarao K, Feinstone SM, Taylor DR. Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV. J Virol Methods 2004;121:85-91.
19. Morgridge R, Baxter N. Market surveillance of FFP3 disposable respirators: Health and Safety Executive; 2015.
20. Eninger RM, Honda T, Reponen T, McKay R, Grinshpun SA. What does respirator certification tell us about filtration of ultrafine particles? J Occup Environ Hyg 2008;5:286-95.