Improving the fit of filtering facepiece respirators

Kamini Shah,*[1] Stefan Serban[2] and Gail V. A. Douglas[2]

Key points

A customised, 3D-printed face frame was effective in improving the qualitative fit test pass rates of two NHS-PPE-portal-available FFP3 masks in dental staff who had experienced fit test failures.

All participants were able to use smartphone technology for frame design, with just one participant reporting difficulty.

Provides a cost-effective solution for dental practices to improve fit test pass rates for members of their teams.

Abstract

Aims To assess the effectiveness and acceptability of smartphone customised frame technology to improve the fit of disposable filtering facepiece class 3 (FFP3) respirators for dental staff who previously failed fit testing.

Method In total, 20 volunteers who previously failed FFP3 fit testing were recruited to use smartphone technology (Bellus3D FaceApp) to have a 3D-printed bespoke face frame produced for them. They underwent qualitative fit testing with and without the frame with two freely available disposable FFP3 respirator designs (mask A: GVS F31000 Segre folded model; mask B: Valmy Spireor). The order of testing was random. Ease of use of the smartphone technology and the comfort of the frame were determined by questionnaire.

Results Fit test passes increased from 5% without the frame to 70% and 95%, respectively, for masks A and B with the frame ($p < 0.01$). Very few participants reported using the technology as difficult (n = 1/20) or the frame uncomfortable (n = 3/20) or difficult to wear (n = 0/20).

Conclusion Customised frames produced using smartphone technology improved qualitative fit test pass rates for two commonly available FFP3 respirators. Using smartphone technology for frame design, wearing a frame and frame comfort levels were all acceptable to the majority of participants.

Introduction

During the COVID-19 pandemic, respiratory protective equipment in the dental setting had become mandatory to protect healthcare professionals and their patients.[1] Dental healthcare workers (DHCWs) were required to wear a filtering facepiece class 3 (FFP3) respirator when undertaking aerosol generating procedures to protect the wearer against the inhalation of hazardous substances in the workplace environment.[2] This infection prevention and control guidance has now changed but still requires DHCWs treating patients on a respiratory pathway to wear FFP3 respirators.[3] To determine the adequacy and effectiveness of the respirator, individual fit testing is required, as inadequate fit can reduce the protection provided and lead to immediate or long-term ill health or can even put the wearer's life in danger.[1]

Factors that affect fit testing pass rates are reported to be: sex; ethnicity; age; weight; face length and width; lip length; nose length; and bridge width.[4] A recent audit undertaken in Yorkshire and the Humber with DHCWs reported that 1 in 5 people (19.4%) failed fit testing of disposable FFP3 respirators. Reasons for failure included lack of an adequate seal, especially for participants with small facial features.[5] This failure rate can have a significant impact on the ability of DHCWs to perform their clinical duties and often the only alternative is to purchase an expensive powered air-purifying respirator (PAPR). Stemen *et al.* have reported the use of a standardised frame to improve the fit of N95 masks using digital face scanning technology and 3D printing.[6] Cai *et al.* have reported the use of 3D laser scanning to design a customised frame for improving the wearing comfort and fit of N95.[7] Ahmed *et al.* have reported on the Bellus 3D smartphone application (app) to scan faces and produce a frame to improve the facial seal of medical face masks.[7] However, there is a paucity of studies using smartphone-technology-designed 3D frames to improve the facial seal with FFP3 masks.

This study aims to assess the effectiveness of a smartphone-customised 3D-printed frame to improve the facial seal and thus increase the rate of qualitative fit test passes with two commonly available FFP3 masks. Secondary aims are to determine the wearability and comfort of the frame and the ease of use of a smartphone app for customised frame production.[8]

[1]NHS England and NHS Improvement North East and Yorkshire, The Old Exchange Barnard Street, Darlington, DL3 7DR, UK; [2]School of Dentistry, University of Leeds, Clarendon Way, Leeds, LS2 9LU, UK.
*Correspondence to: Kamini Shah
Email address: kamini.shah@phe.gov.uk

Refereed Paper.
Submitted 27 January 2022
Revised 26 March 2022
Accepted 18 April 2022
https://doi.org/10.1038/s41415-022-4512-3

Methods

Ethical approval was given by the University of Leeds in April 2021. Participant recruitment started in May 2021 and field work was completed in November 2021 (DREC Ref. 130421/GD/325).

Participant recruitment and selection

Dental professionals working in Teesside were approached by email via the Tees Local Dental Committee with information about the study. Further snowballing of the email was used to ensure the invitation was disseminated more widely. Dental professionals who previously failed FFP3 fit testing and were interested in participating were asked to contact a named individual in the research team.

A sample size calculation required 20 participants based upon an assumption of a 35% difference between frame and no-frame, a power of 90% and confidence level of 95%. The first 20 self-selected volunteers were recruited to the study following screening for inclusion criteria. Inclusion criteria required previous failure of fit testing with disposable FFP3 respirators. Those eligible were invited to participate and their written informed consent recorded by trained members of the research team.

Mask selection

Two different types of FFP3 masks were chosen for testing: Valmy Spireor FFP3 and GVS F31000 Segre folded FFP3 models. Throughout the timeframe of this study, these masks were consistently available free of charge on the NHS personal protective equipment (PPE) portal.[9] All NHS dental practices have access to this portal: this ensured that the masks utilised had met a quality standard and would be freely and consistently available for further use.

Frame design and production

Shah and Bentley reported using the Bellus3D face-scanning app to design a frame using 3D scans of individual participants' facial features to improve the facial seal of respirators.[10] The authors of this study replicated this process, and the following instructions were sent to participants:

1. Download the app https://apps.apple.com/us/app/bellus3d-faceapp/id1352268131
2. Open the app and place your face in the red demarcated area

Fig. 1 Customised frame. Reproduced from K. Shah and D. Bentley, 'Fit testing troubles?', *British Dental Journal*, 2021, Springer Nature[10]

3. This produces a 3D scan of the face. Choose the 'Mask Fitter' option on the menu bar
4. Choose frame type
5. Choose Export (unless you have your own 3D printer)
6. Pay the export fee through the App Store (the basic frame is free)
7. Email the created standard triangle language (STL) files to the laboratory identified or any 3D printing centre
8. Purchase elastic roll with eyelets to fit the frame to the face.

Participants could choose where to send the STL files for 3D frame printing. However, for ease, a laboratory with 3D printing facilities had been identified that could be used at no cost to the practice. The frame fee of £25 was paid by Tees Local Dental Committee who agreed to fund the project.

The laboratory printing produced a customised frame (Fig. 1) which fitted over the FFP3 mask to produce a tight facial seal. The frame was held in place by attached elastic straps (Fig. 2).

Qualitative fit testing protocol

Qualitative fit testing was undertaken by two trained and accredited fit testers using Bitrex solution.[11] Each participant had to pass all seven exercises of the fit-testing protocol as set out by the Health and Safety Executive for an overall pass score, including: normal breathing; deep breathing; head turning side to side; head nodding up and down; talking; bending over; and normal breathing again.

Fig. 2 Frame held in place by attached elastic straps. Reproduced from K. Shah and D. Bentley, 'Fit testing troubles?', *British Dental Journal*, 2021, Springer Nature[10]

Firstly, each participant undertook a fit check of both mask models to ensure there was no obvious escape of air at the periphery of the mask. This procedure was undertaken with and without the frame in place. Secondly, each participant had a sensitivity test to ensure they could taste the Bitrex solution and finally the fit test procedure was completed. A pass score was achieved if the Bitrex solution could not be tasted by the participant throughout the seven exercises. If participants were in any doubt about tasting the solution, the test was recorded as a fail.

Each participant had four fit tests: two per mask type, both with and without the frame. The order of the fit tests was random. The frame was secured to the face by elastic straps attached to hooks on the frame (Fig. 2).

Questionnaire

On completion of the fit-testing process, each participant was invited to complete a questionnaire. Participants' responses to the following written questions were recorded on a scale of 1–10:

- How easy or difficult was it to complete the smartphone scan of your face? (Scale from 'incredibly easy' to 'incredibly difficult')
- How comfortable or not is wearing the frame? (Scale from 'incredibly comfortable' to 'incredibly uncomfortable')
- How easy or difficult do you find the frame to wear? ie does it stay in place, interfere with your vision, etc (scale from 'incredibly easy' to 'incredibly difficult').

Statistical analysis

The outcomes of the qualitative fit testing (pass or fail) were classed as binary variables. The null-hypothesis stated no difference between pass rates of masks with and without a frame. McNemar's test was used to assess the significance between the pass and fail rates for each mask type with and without a frame. Percentage pass rates were calculated for each mask type before and after the use of the frame. Statistical analyses were completed using Stata 16.1 (StataCorp, College Station, TX, USA).

Results

Demographic data

In total, 20 participants meeting the inclusion criteria were recruited in this non-randomised intervention study. All participants were women who were white and under the age of 45. Most participants were dental nurses (n = 19) and one participant was a dentist (n = 1).

Qualitative fit test results

The pass rate for GVS F31000 Segre folded FFP3 masks increased from 5% without a frame to 70% with a frame and for the Valmy Spireor FFP3 masks, rates increased from 5% without a frame to 95% with a frame (Table 1). McNemar's test rejected the null hypothesis at the ($p < 0.01$) level for both mask types. There was a significant difference in fit test pass rates with and without a frame for both mask types.

Questionnaire data: ease of use of smartphone app and the wearability and comfort levels of the frame

All 20 participants completed all three questions in the questionnaire. Table 2 reports that 15 participants found it easy/incredibly easy to use the smartphone app and only one participant found it difficult. In terms of wearing the frame, most participants (n = 14) found it incredibly comfortable/comfortable. No participant reported difficulties in wearing the frame.

Table 1 Fit test pass rates of FFP3 masks, with and without frame

FFP3 mask type	Pass	Fail	Total
GVS F31000 Segre folded without frame	1 (5%)	19 (95%)	20
GVS F31000 Segre folded with frame	14 (70%)	6 (30%)	20
Valmy Spireor without frame	1 (5%)	19 (95%)	20
Valmy Spireor with frame	19 (95%)	1 (5%)	20

Table 2 Questionnaire data responses

Question	Response (N = 20)				
Q1: How easy or difficult was it to complete the smartphone scan of your face?	(1: incredibly easy – 10: incredibly difficult)				
	Incredibly easy (1–2)	Easy (3–4)	Not easy nor difficult (5–6)	Difficult (7–8)	Incredibly difficult (9–10)
	9	6	4	1	0
Q2: How comfortable or uncomfortable is wearing the frame?	(1: incredibly comfortable – 10: incredibly uncomfortable)				
	Incredibly comfortable (1–2)	Comfortable (3–4)	Not comfortable nor uncomfortable (5–6)	Uncomfortable (7–8)	Incredibly uncomfortable (9–10)
	8	6	3	2	1
Q3: How easy or difficult do you find the frame to wear? (N = 20) (ie does it stay in place, interfere with your vision etc)	(1: incredibly easy – 10: incredibly hard)				
	Incredibly easy (1–2)	Easy (3–4)	Not easy nor difficult (5–6)	Difficult (7–8)	Incredibly difficult (9–10)
	10	6	4	0	0

Discussion

Demographics of cohort

Given that our cohort consisted predominantly of dental nurses (n = 19), it is unsurprising we had 100% women, as this is consistent with the results of a dental workforce survey in the North East of England which reported 98% of both registered dental nurses (n = 1,067) and dental nurses-in-training (n = 179) were women.[12] It might have been expected to have seen more ethnic diversity in our self-selecting group as failure rates are reported to be significantly higher in staff from Black, Asian and Minority Ethnic (BAME) backgrounds.[13]

Use of the Bellus3D FaceApp

Use of face-scanning technology to produce both standardised (Stemen) and customised (McAvoy) face frames is widely reported in the literature.[6,14] Ahmed *et al.* have specifically reported on the use of the Bellus3D smartphone app to design a customised frame which improved the fit of medical face masks.[15] They reported a 80% quantitative fit testing pass rate, which is broadly comparable to this study's results of 70% or 95%, dependent on FFP3 mask design.[15] The use of a smartphone app brings face-scanning technology into the surgery, making it easy to replicate and readily available for practice frontline DHCWs to use. In addition, the reported ease of use of the app (only one participant found the app difficult to use) adds to its practical application.

Improved fit of FFP3 respirators using a customised face frame

This study had self-selected participants that has previously failed fit tests with other makes and models of mask. Therefore, the initial very low fit test rates of 5% with both models selected for this study were to be expected in this cohort. Both respirator models produced significantly improved fit test results with a frame: pass rates improved from 5% (without a frame) to 95% (with a frame) ($p < 0.01$) for the Spireor by Valmy FFP3 masks and from 5% (without a frame) to 70% (with a frame) for the GVS F31000 Segre folded FFP3 model ($p < 0.01$). The null-hypothesis stating no difference between pass rates of masks with or without the frame was rejected.

Fit testers reported the different mask designs affected how the frame was positioned on the face. Frame placement was not an issue with the Spireor Valmy mask; however, the metal incorporated nose piece often interfered with frame placement with the GVS F31000 Segre folded FFP3 model. This may explain the differences between the fit testing results between the two mask designs with the frame. Stemen *et al.* also reported differences in improved fit testing rates using frames dependent on filtering face mask respirators make and models.[5]

Participant-reported acceptability of the frame

Very few studies have asked participants to report on comfort levels wearing a frame. Cai *et al.* reported on improved contact pressure of frames thereby improving fit of the respirators by reporting on a force sensing system, but unlike this study, it did not ask participants their perceived levels of comfort.[7] In this study, participants were asked to report by a questionnaire: how comfortable they found the frame to wear and how easy it was to use that is, did it stay in place or did it interfere with their vision. No participant found the frame difficult to wear but (n = 3/20) found the frame uncomfortable. This perceived lack of comfort of the frame may limit its practical application. Pressure on the nose was identified by participants as leading to discomfort; however, more qualitative research is needed to understand what factors contribute to comfort levels when wearing the customised frame.

Costs of replicating the technique

The total cost of this smartphone technology solution, including purchasing the app, downloading STL files, laboratory fees and elastics, was around £25 per participant. The download of the app, the accompanying STL files and fit testing were all free. Laboratory fees for frame production ranged from £15–25 and the cost for a one metre roll of elastics with eyelets to secure the frame to the head of the individual was £2.99.[16]

Given the turnover of dental nurses, practices may be reluctant to spend large amounts of money to purchase a PAPR which would be the only other alternative for those unable to pass a fit test with any other FFP3 respirator.[10] As of March 2022, the PAPR hoods costs vary from a few hundred pounds up to £1,500 at various online retailers. Thus, this frame technique could present practices with a cost-effective alternative.[14]

Limitations of the study

The following limitations are identified with this study:

- Small sample size and lack of diversity of the cohort. All the participants recruited to the study were women and white, which limits the generalisability of the results to BAME communities, where fit testing failure rates have been reported to be significantly higher.[17] In addition, it is unclear whether the results can be generalised to men. However, given the frames were customised to individual faces, it might suggest that regardless of sex or ethnicity, the customisation of the frame is the factor in improving the fit of standardised respirators but further research would be required to test this hypothesis
- The study only assessed improved fit of respirators using a frame on two FFP3 mask models. More research needs to be undertaken to assess whether a customised frame can replicate improved fit with other mask designs
- It was not possible to blind either the fit testers or the participants. However, as participants' taste perception judgement resulted in a failed test, this obviated the need for fit testers to be blinded. All participants had experience of previously failed tests and in cases where they were uncertain of their taste perception, the test was classed as failed
- A qualitative fit test was used in this study which relied on taste perception of a Bitrex aerosol by the test person, where a perceived taste indicated a leak in the seal around mouth and nose. Some studies report the gold standard for fit testing should be quantitative fit tests, as these provide an objective fit factor score measured by a Portacount machine.[16] However, the equipment required to undertake quantitative fit testing is expensive and not freely available to dental practices; therefore, as HSE standards for fit testing are met using the qualitative test, this technique was considered most appropriate[1]
- The perceived wearability and comfort of the frame were only assessed after short-term use on a single occasion. User comfort after prolonged use on multiple occasions is required to assess the practical application of the frame.

Conclusion

Customised frames produced using smartphone technology improved qualitative fit test pass rates for two commonly available FFP3 respirators. Both the usability of the smartphone technology and the comfort and wear of the frame were acceptable to the majority of participants.

Ethics declaration

The authors declare no conflicts of interest.

Written consent to publish was obtained for Figure 2.

Acknowledgements

With thanks to the Tees Local Dental Committee for funding the laboratory costs of the project and assisting in the recruitment of participants. The authors would also like to thank fit tester (Susan Cook) and participants who generously gave their time to support this project. Photographs were taken by David Bentley.

Author contributions

Kamini Shah led the project, collected the data, wrote the first draft of the paper, and agreed the final version. Stefan Serban contributed to the drafts, performed data analysis, and agreed the final version. Gail V. A. Douglas advised on the design of the project, completed the documentation to seek ethical approval, contributed to the drafts, and agreed the final version.

References

1. Health and Safety Executive. Guidance on respiratory protective equipment (RPE) fit testing. 2019. Available at https://www.hse.gov.uk/pubns/indg479.htm (accessed December 2021).
2. Office of the Chief Dental Officer England. Standard operating procedure: Transition to recovery. 2021. Available at https://dentistry.co.uk/wp-content/uploads/2021/07/C1287-Standard-Operating-Procedure_Transition-to-Recovery-A-phased-transition-for-dental-practices-towards-the.pdf (accessed December 2021).
3. UK Government. COVID-19: infection prevention and control dental appendix. 2022. Available at https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-infection-prevention-and-control-dental-appendix (accessed March 2022).
4. Regli A, Sommerfield A, von Ungern-Sternberg B S. The role of fit testing N95/FFP2/FFP3 masks: a narrative review. *Anaesthesia* 2021; **76:** 91–100.
5. Robertson S, Ramsdale M P. Audit of qualitative fit testing for FFP3 respirators. *Br Dent J* 2021; DOI: 10.1038/s41415-021-2716-6.
6. Stemen D, Ge M, Hwang D *et al.* Frame to Improve the Fit of N95 Filtering Face Mask Respirators. *J Occup Environ Med* 2021; DOI: 10.1097/JOM.0000000000002223.
7. Cai M, Li H, Shen S, Wang Y, Yang Q. Customized design and 3D printing of face seal for an N95 filtering facepiece respirator. *J Occup Environ Hyg* 2018; **15:** 226–234.
8. Bellus3D. Bellus 3D FaceApp. Available at https://www.bellus3d.com/ (accessed December 2021).

9. NHS England. Accessing supplies of Personal Protective Equipment (PPE). Available at https://www.england.nhs.uk/coronavirus/primary-care/infection-control/ppe/ (accessed December 2021).
10. Shah K, Bentley D. Fit testing troubles? *Br Dent J* 2021; **230:** 184.
11. Fit2Fit. Fit2Fit Accreditation. Available at https://www.fit2fit.org/ (accessed December 2021).
12. Holmes R D, Burford B, Vance G. Development and retention of the dental workforce: findings from a regional workforce survey and symposium in England. *BMC Health Serv Res* 2020; **20:** 255.
13. Green S, Gani A, Bailey M, Brown O, Hing C B. Fit-testing of respiratory protective equipment in the UK during the initial response to the COVID-19 pandemic. *J Hosp Infect* 2021; **113:** 180–186.
14. McAvoy M, Bui A-T N, Hansen C *et al.* 3D Printed frames to enable reuse and improve the fit of N95 and KN95 respirators. *BMC Biomed Eng* 2021; **3:** 10.
15. Ahmed A, Zhong Z, Suprono M *et al.* Enhancement of peripheral seal of medical face masks using a 3-dimensional-printed custom frame. *J Am Dent Assoc* 2021; **152:** 542–550.
16. Amazon UK. Black & White Elastic Bands with Buttonhole for Trouser Waistbands, Maternity Clothes, Sewing, Knitting, Crafting (16mm, 19mm, 25mm) (Black, 25mm – 1 Metres). Available at https://www.amazon.co.uk/Buttonhole-Waistbands-Maternity-Knitting-Crafting/dp/B091D9DZK6?th=1 (accessed January 2022).
17. Hon C-Y, Danyluk Q, Bryce E *et al.* Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector. *J Occup Environ Hyg* 2017; **14:** 175–179.