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# **Improving the fit of filtering facepiece respirators using smartphone customised frame technology for dental health care workers who previously failed fit testing**

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## **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**

Twenty volunteers who previously failed FFP3 fit testing were recruited to use smartphone technology (Bellus3D FaceApp) to have a three-dimensional (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.

## **Key points**

- A customised 3D printed face frame was effective in improving the qualitative fit test pass rates of two NHS personal protective equipment (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.
- Cost effective solution for dental practices to improve fit test pass rates for members of their teams.

## **Introduction**

During the COVID-19 pandemic, respiratory protective equipment (RPE) in the dental setting had become mandatory to protect healthcare professionals, and their patients.<sup>1</sup> Dental healthcare workers (DHCWs) were required to wear a FFP3 respirator when undertaking aerosol generating procedures (AGPs) to protect the wearer against the inhalation of hazardous substances in the workplace environment.<sup>2</sup> This infection prevention and control (IPC) guidance has now changed, but still requires DHCWs treating patients on a respiratory pathway to wear FFP3 respirators.<sup>3</sup> 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.<sup>1</sup>

Factors that affect fit testing pass rates are reported to be gender, ethnicity, age, weight, face length and width, lip length, nose length, and bridge width.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>7</sup> 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.<sup>8</sup>

## **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 twenty 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 twenty 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.<sup>9</sup> 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.<sup>10</sup> The authors of this study replicated this process, 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
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 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 (LDC) 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.<sup>11</sup> 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.

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 to 10.

1. How easy or difficult was it to complete the smartphone scan of your face? (scale from 'incredibly easy' to 'incredibly difficult')
2. How comfortable or not is wearing the frame? (scale from 'incredibly comfortable' to 'incredibly uncomfortable')
3. How easy or difficult do you find the frame to wear? i.e 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 (Stata Corp 4905 Lakeway Dr College Station, TX 77845 USA).

## Results

### Demographic data

20 participants meeting the inclusion criteria were recruited in this non-randomised intervention study. All participants were white Caucasian females 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

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

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

All twenty 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 1 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 2 Questionnaire data responses

Q1 How easy or difficult was it to complete the smart phone scan of your face? (N=20) (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 not is wearing the frame? (N=20)				

<b>(1 incredibly comfortable – 10 incredibly uncomfortable)</b>				
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
<b>Q3 How easy or difficult do you find the frame to wear? (N=20) (i.e. does it stay in place, interfere with your vision, etc) (1 incredibly easy – 10 incredibly difficult)</b>				
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% females. 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 ( $n = 1067$ ) and dental nurses-in-training ( $n = 179$ ) were female.<sup>12</sup> It might have been expected to have 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.<sup>13</sup>

### 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.<sup>6,14</sup> 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.<sup>15</sup> 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.<sup>15</sup> 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.<sup>5</sup>

### **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.<sup>7</sup> 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 i.e. 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 to £25, and the cost for a 1 metre roll of elastics with eyelets to secure the frame to the head of the individual was £2.99.<sup>16</sup>

Given the turnover of dental nurses, practices may be reluctant to spend large amounts of money to purchase a powered air purifying respirator (PAPR) which would be the only other

alternative for those unable to pass a fit test with any other FFP3 respirator.<sup>10</sup> 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.<sup>14</sup>

### **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 female and Caucasian, this limits the generalisability of the results to BAME communities, where fit testing failure rates have been reported to be significantly higher.<sup>17</sup> In addition, it is unclear whether the results can be generalised to males. However, given the frames were customised to individual faces, it might suggest that regardless of gender 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.<sup>16</sup> 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.<sup>1</sup>

- 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 useability of the smartphone technology and the comfort and wear of the frame were acceptable to the majority of participants.

### **Declaration of interests**

There is no declaration of interests

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Photographs taken by: David Bentley

### **Contributions**

KS led the project, collected the data, wrote the first draft of the paper, and agreed the final version. SS contributed to the drafts, performed data analysis, and agreed the final version. GVAD advised on the design of the project, completed the documentation to seek ethical approval, contributed to the drafts, and agreed the final version.

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