

Rehman, I., Ali, S., O'Brien, C. and Goodall, C. (2022) Assessing the impact of FFP3 masks to oxygen saturation and pulse rate in the Oral Surgery department at the Glasgow Dental Hospital during the COVID-19 pandemic: an observational study. *Oral Surgery*, 15(1), pp. 30-35.

(doi: [10.1111/ors.12648](https://doi.org/10.1111/ors.12648))

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Rehman, I., Ali, S., O'Brien, C. and Goodall, C. (2022) Assessing the impact of FFP3 masks to oxygen saturation and pulse rate in the Oral Surgery department at the Glasgow Dental Hospital during the COVID-19 pandemic: an observational study. *Oral Surgery*, 15(1), pp. 30-35, which has been published in final form at: [10.1111/ors.12648](https://doi.org/10.1111/ors.12648)

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Article type : Original Article

Assessing the impact of FFP3 masks to oxygen saturation and pulse rate in the Oral Surgery department at the Glasgow Dental Hospital during the COVID-19 pandemic: an observational study

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All data generated or analysed during this study are included in this published study (and its supplementary files).

All authors discussed the results and contributed to the final manuscript.

The authors declare no conflicts of interest.

This study does not contain any studies involving human participants performed by any of the authors.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/ORS.12648](https://doi.org/10.1111/ORS.12648)

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This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Clinical Relevance

Scientific Rationale for Study: The introduction of enhanced PPE since the inception of the COVID-19 pandemic has significantly reformed the delivery of surgical procedures. The physical effects of extensive FFP3 mask wear have been well documented in the media, however the physiological effects continue to draw speculation.

Principal Findings: SpO₂ and pulse rate readings remained largely unchanged following sessional use of FFP3 masks. Presence of previous COVID-19 symptoms did not impact these findings.

Practical Implications: Whilst there are no significant effects to these physiological parameters, FFP3 masks continue to contribute to physical discomfort which may impact staff wellbeing.

Abstract

Aim: The impact on physiological parameters and wellbeing from potential respiratory distress caused by FFP3 masks, particularly during extensive clinical sessions, has been widely speculated during the COVID-19 pandemic. This study aims to investigate the effect of FFP3 mask wear on clinicians' pulse rate and oxygen saturation.

Material & Methods: Clinical staff within the Oral Surgery department recorded their oxygen saturation (SpO₂) and pulse rate prior to donning an FFP3 mask, prior to doffing FFP3 mask and after doffing FFP3 mask using a finger pulse oximeter during a two-week period in May-June 2020. The duration of wear, the session (AM/PM), brand of mask and the presence of previous COVID-19 symptoms were also recorded.

Results: Twenty-eight data sets were collected from twelve participants (1M:11F). Of the FFP3 masks worn, nineteen (67.86%) were ARCO™, eight (28.57%) were 3M™ masks and one (3.57%) was 3M+™. At baseline, the mean SpO₂ was 98.39% and mean pulse rate was 72.11. Prior to mask removal, the mean SpO₂ was 97.82% and mean pulse rate was 70.04. The end of session mean SpO₂ was 98.14% and mean pulse rate was 69.54. The mean duration of wear was 150.34 minutes. Data sets were collected evenly across AM (14) and PM (14) sessions. Five participants (17.86%) reported previous COVID-19 symptoms.

Conclusion: The data demonstrated a mean reduction of 0.25% in oxygen saturation and 3.56% in pulse rate, following use of an FFP3 mask. These changes in physiological parameters are not clinically significant and sessional use appears to be safe.

Keywords: Aerosol Generating Procedures, COVID-19, FFP3, Pulse Rate, Oxygen Saturation.

Introduction

The Covid-19 pandemic has drastically changed the way in which healthcare services are delivered in the UK. The SARS-CoV-2 virus is predominantly transmitted via droplets (5-10 μ m)¹, and may remain stable and present on surfaces, such as plastic and stainless steel, for up to 72 hours. Aerosol Generating Procedures (AGPs) have the potential to aerosolise transmission for 3 hours² allowing the virus to spread in the vicinity of the procedure in a short period of time. Such procedures include intubation, extubation, tracheostomy, upper gastrointestinal tract surgery and dental procedures involving a drill or ultrasonic unit. Depending on the environment, there may also be potential for the aerosol to filter through ventilation systems and windows, thereby posing greater risk to inadequately protected staff³. Due to the highly transmissible nature of the SARS-CoV-2 virus, particularly the newer UK and South-African variants^{4,5}, healthcare workers (HCWs) need robust measures to physically protect themselves whilst providing essential care.

Terms such as Personal Protective Equipment (PPE) and Filtering Facepiece (FFP) have become common parlance, even among the general public. There are various forms of PPE which offer different degrees of respiratory protection. Type IIR fluid resistant surgical masks (FRSM), which are universally fitting, primarily block larger droplets and reduce transmission from the wearer to those in their close vicinity, but do not protect against aerosol. FFP masks are classified as FFP1, FFP2 and FFP3 according to the level of aerosol protection, with FFP3 masks offering 99% minimum filter efficiency⁶.

Guidance from the Public Health England⁷ outlines the requirement for HCW's to use FFP3 masks or hoods when undertaking AGPs, in addition to single use disposal gloves, gown and visor. Sessional use of FFP3 masks is approved for medium and high-risk pathways, where HCW's are providing continuous patient care. For low-risk pathways and non-AGP direct treatment within 2m of the patient, Type IIR FRSM are sufficient. The WHO also recommends the use of particulate respirators equivalent to at least FFP2/N95 when performing AGPs but deem FRSM adequate for routine care⁸. A significant proportion of activity within oral surgery involves AGPs without mitigation, such as surgical extractions of grossly carious teeth which may generate aerosol <5 μ m⁹. Clinical staff carrying out these procedures therefore require FFP3 masks, in line with guidance from the British Association of Oral and Maxillofacial Surgeons and the British Association of Oral Surgeons¹⁰.

As additional filtering layers are added to FFP masks to increase protection from aerosols, breathing resistance increases⁶. Greater resistance risks the possibility of leakage around the seal, hence additional sealing aids, such as foam seal, are utilized around the periphery of the

masks. Studies have shown that use of FFP2/N95 masks can cause significant discomfort due to breathing resistance, heat and tight fit^{11,12}. The discomfort and respiratory distress caused by extensive use of FFP3 masks may impact staff wellbeing. Mental health difficulties are the biggest cause of sickness absence in the UK¹³ and therefore assessing any physiological impact of sessional use of FFP3 masks may contribute to an understanding of clinicians' mental and physical fatigue.

The Oral Surgery department at the Glasgow Dental Hospital underwent a service transformation into an Urgent Dental Care Centre during the first wave of the COVID-19 pandemic. The department held responsibility for providing urgent surgical care for patients experiencing acute dental emergencies, including those with active SARS-CoV-2 infection. A significant proportion of clinical activity within the department involved AGPs, such as surgical extractions. Clinical staff within the department were therefore all face fitted for FFP3 masks and wore them routinely when carrying out surgical procedures.

This short-term observational study assessed the impact of FFP3 masks on the wearer's oxygen saturation and pulse rate. Despite the breathing resistance and subjective perception of discomfort, the null hypothesis suggests that wearing the FFP3 mask has no effect on the wearer's oxygen saturation levels or pulse rate.

Methods

This observational study was conducted over a two-week period in May-June 2020. The STROBE checklist was used to ensure the validity of the study was optimised¹⁴. Inclusion criteria for this study were; clinical staff members in the Oral Surgery department, including clinicians and nurses; had passed fit testing for an FFP3 mask; were involved in AGP while wearing the mask. Participation was voluntary.

To allow compliance with social distancing, staff were briefed on the study and instructed on how and when to record their own readings for SpO₂ and pulse rate via a virtual meeting.

Staff were asked to record their oxygen saturation levels (SpO₂) and pulse rate at three intervals during a clinical session:

1. Before donning FFP3 mask (baseline)
2. Before doffing FFP3 mask (during)

3. After doffing FFP3 mask (end of session)

The readings were recorded using a single validated finger pulse oximeter while staff were seated upright, 30 seconds after applying the pulse oximeter to allow for standardisation. The index finger was designated for obtaining the readings and peer observation was implemented to ensure technique reproducibility. Supplementary data was also collected on the duration of mask wear, the session (AM/PM), brand of mask and history of COVID-19 symptoms. Staff were encouraged to repeat readings on different days, where appropriate.

The 10 specified data parameters were collected using the data collection form shown in Figure 1.

Participants were anonymised and assigned a number using a random number generator. The data was analysed by two independent assessors (IR, SA) to reduce bias and error. The data was then presented using descriptive analysis.

Results

Twenty-eight complete data sets were collected from twelve members of clinical staff in the Oral Surgery department (1M:11F). Data sets were collected evenly across AM (14) and PM (14) sessions. Participant ages ranged from 24-51, with a mean of 37.8 years. Nineteen (67.86%) staff wore ARCO™, eight (28.57%) 3M™ and one (3.57%) 3M+™ masks. Five staff (17.86%) reported a history of COVID-19 symptoms. The mean duration of wear was 150.36 minutes.

Raw data collected by each participant across the 10 specified parameters is shown in Table 1.

The relationship between the raw data collected for SpO₂ and pulse rate across the three intervals for each participant is demonstrated by Figure 2.

The SpO₂ and pulse rate measurements for each participant across the three intervals are statistically summarised in Tables 2 and 3.

The data demonstrates an overall mean reduction of 0.25% in oxygen saturation, and mean reduction of 3.56% in pulse, following use of an FFP3 mask.

Discussion

This study focused on the impact on the physiological parameters of SpO₂ and heart rate, of extended and sessional use of FFP3 masks within an Oral Surgery department.

Pulse oximetry is a simple, non-invasive method to simultaneously determine pulse rate and oxygen saturation. Manufacturers claim that pulse oximetry gives an SpO₂ value within 2-3% of the true arterial oxygen saturation, over the range of 70-100%¹⁵. Rory et al found that SpO₂ readings from finger pulse oximeters correlate well with arterial oxygen saturation (SaO₂) so for the purposes of this study this was deemed adequate¹⁶. In critical clinical circumstances, where a high degree of accuracy is required, measurement of arterial blood gases would be recommended¹⁷. An oxygen saturation of 94-100% in healthy individuals is deemed the normal range^{18,19}. There are several factors which may interfere with pulse oximetry to produce an inaccurate reading, including nail varnish, darker skin pigmentation, patient movement and poor peripheral perfusion¹⁸. In order to minimize the influence from preceding activity and to standardize data collection, readings were taken with staff seated upright 30 seconds after application of the finger pulse oximeter. Furthermore, the device was always placed on an index finger clear from nail varnish, and a process of peer observation, with social distancing, was adopted to ensure that the processes involved in data collection were consistent with the initial virtual training briefing. The pulse oximeter was decontaminated following each use, in accordance with local protocols. The accuracy of departmental finger pulse oximeters is ensured by annual calibration by the department of Medical Physics. A mean reduction in SpO₂ of 0.58% was observed from baseline to the reading prior to doffing. A mean increase of 0.33% was observed following doffing FFP3 masks, at the end of session reading. This represents an overall SpO₂ mean reduction of 0.25% across all 3 readings. Our data suggests that FFP3 masks had little influence over SpO₂ readings, and a 30 second acclimatization period following doffing saw a return to baseline SpO₂ concentration in 60.71% of participants, following a 150.36-minute mean duration of wear.

The British Heart Foundation defines a normal resting heart rate as 60-100bpm²⁰. Factors such as age, underlying medical problems, smoking and medications such as beta-blockers may influence this²¹. At heart rates below 155bpm, pulse oximeters significantly correlate with ECG readings²². Our data showed a 2.87% mean reduction in pulse rate from baseline to the reading prior to doffing FFP3 mask. A further mean reduction of 0.71% was observed following doffing, at the end of session reading. This represents an overall mean reduction in pulse rate of 3.56% across all readings. These data suggest that FFP3 mask wear has only a minimal impact on heart rate.

There was no identifiable relationship between presence of previous COVID-19 symptoms and SpO2 and pulse rate.

Studies have shown that clinical staff find FFP3 masks uncomfortable due to the increased warmth and tight fit, find communication with patients more challenging and subjectively believe them to cause breathing difficulties^{11,12}. The latter point was not borne out by observational measurement of physiological parameters during this study. Despite this it is still conceivable that extensive use of FFP3 masks may contribute to decreased physical and mental wellbeing. This may be because of the discomfort they cause and the situations in which they are worn, which may involve treating COVID positive patients, thereby increase the perception of personal risk. The impact on mental health of the COVID-19 pandemic has been well reported in the literature^{23,24,25,26}. Public Health England's guidance for the public on mental health and wellbeing during COVID-19 outlines the importance of seeking help, physical exercise and looking after sleeping patterns²⁷. Several bodies, including the NHS and the Public Health Agency, extrapolate this advice to employers and outline how they can support staff during the pandemic^{28,29}. *Wellbeing Support for the Dental Team* is a profession-specific initiative set up to provide mental health and wellbeing assistance to all members of the dental team, including non-clinical staff and students³⁰.

Conclusion

The results of this study demonstrate that the impact of FFP3 mask wear on pulse rate and oxygen saturation is not clinically significant and sessional use appears to be safe. Although the masks may cause physical discomfort during extensive use, the benefit of aerosol protection against a highly transmissible and insidious virus takes precedence.

Limitations of Study

The sample size in this study was small but was reflective of the staff profile in the Oral Surgery department. FFP3 masks were worn for varying lengths of time due to variation in clinical activity.

There are several confounding variables which may affect SpO₂ and pulse rate, including underlying medical problems, smoking status, fitness, anxiety and age. However, none of the staff fell outside the recognised normal range for SpO₂ and variations in pulse rate could be accounted for by fitness level at the lower end of the range while the upper range showed only a minimal deviation from normal.

The results of this study can be broadly extrapolated to a population of oral surgeons involved in AGPs, whilst wearing FFP3 masks. However, further study is required with strict inclusion and exclusion criteria to minimise the potential confounding characteristics of study participants, including medical history and smokers' status. Recruitment of study participants from different clinical specialties may also minimise differences in physical exertion and duration of wear amongst HCWs, thus representing the wider workforce using FFP3 masks over the COVID-19 pandemic.

Declaration of Interests

The authors declare no conflicts of interest.

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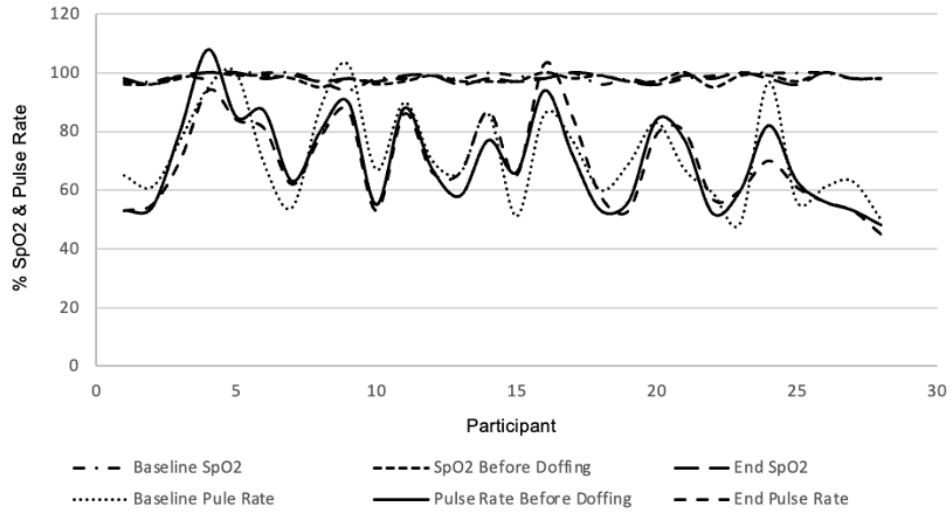
Participant	Baseline SpO2 (%)	During SpO2 (%)	End SpO2 (%)	Baseline Pulse Rate	During Pulse Rate	End Pulse Rate	Duration of Wear (mins)	Session (AM/PM)	Brand of Mask	Previous COVID Symptoms
1	97	96	98	65	53	53	125	AM	Arco	No
2	97	96	96	61	54	55	240	PM	Arco	No
3	99	98	99	77	80	70	90	AM	3M	No
4	98	100	100	95	108	94	155	AM	Arco	No
5	100	99	100	100	85	84	164	AM	3M	No
6	100	99	98	69	87	81	40	AM	Arco	No
7	100	98	99	54	63	62	240	PM	Arco	Yes
8	97	95	97	88	80	78	190	PM	Arco	No
9	94	98	98	103	90	87	170	PM	Arco	No
10	98	96	97	67	55	53	134	AM	Arco	No
11	98	97	99	90	88	86	75	AM	Arco	No
12	99	99	99	70	67	66	140	AM	Arco	Yes
13	98	97	96	66	58	66	100	AM	Arco	No
14	100	97	98	86	77	87	50	PM	Arco	No
15	99	97	97	51	66	65	180	AM	Arco	No
16	98	100	98	86	94	103	170	PM	3M	No
17	100	98	100	77	72	85	167	AM	3M	No
18	96	99	99	60	53	58	185	PM	Arco	Yes
19	98	97	97	69	56	53	155	PM	Arco	No
20	96	97	96	83	84	79	90	AM	3M	No
21	98	100	99	67	77	80	170	PM	Arco	No
22	99	95	98	59	52	57	135	PM	Arco	No
23	100	99	100	49	60	60	150	AM	Arco	Yes
24	100	99	98	97	82	70	190	PM	3M	No
25	100	97	96	56	63	61	180	AM	Arco	No
26	100	100	100	61	56	56	180	PM	3M+	Yes
27	98	98	98	63	53	53	185	PM	3M	No
28	98	98	98	50	48	45	160	PM	3M	No

Parameter	Mean	Upper Limit	Lower Limit	Standard Deviation
SpO2 Before Donning (%)	98.39	100	94	1.52
SpO2 Before Doffing (%)	97.82	100	95	1.47
SpO2 After Doffing (%)	98.14	100	96	1.30

<i>Parameter</i>	<i>Mean</i>	<i>Upper Limit</i>	<i>Lower Limit</i>	<i>Standard Deviation</i>
Pulse Rate before Donning	72.11	103	49	15.95
Pulse Rate Before Doffing	70.04	108	48	15.89
Pulse Rate After Doffing	69.54	103	45	15.02

FFP3 wearer initials:		Previous Covid-19 symptoms (circle):			Yes	No	
Session (circle):		AM	PM	Mask brand (circle):	Arco	3M	3M+
	1. Baseline - before mask is worn	2. Before mask is removed	3. End of session - after mask is removed				
SPO2							
Pulse							
Duration of mask wearing session: ____ hours ____ minutes							

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