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Identifying FFP Mask Seal Leakage using Fluorescein Aerosols

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Description

Healthcare workers involved with Aerosol Generating Procedures (AGPs) require well-fitting FFP masks to reduce transmission of pathogenic particles such as coronavirus. The commonest way to check a facemask's seal is a qualitative fit-test that relies on the participant tasting a bitter aerosol. This subjective 'taste-test' is biased by placebo [1]. In the study reviewed in this communication, we proposed a cost-effective adaptation to the 'taste-test' using fluorescein-stained aerosols to visualise and quantify the leakiness of FFP masks. A bitter-tasting solution containing fluorescein was aerosolised around participants' FFP masks during the fit-test. Filter paper was placed on the inner surface of masks. Participants reported whether they could taste the solution to determine their 'taste-test' result. The filter papers were photographed in a bespoke environment and digital image analysis used to quantify the amount of fluorescein staining (total fluorescence, 'TF'). 56 healthcare professionals underwent the FFP fit-test with fluorescein modification. Based on taste alone, 32 (57%) were classified as 'pass'. There was significantly different TF between the 'pass' and 'fail' groups ($p<0.001$). A TF cut-off of 5.0 × 106 units was determined by balancing precision (78%) and recall (84%). Applying this cut-off to the original fit-test outcomes resulted in 12 reclassifications; 5/56 (9%) from 'pass' to 'fail' and 7/56 (12%) from 'fail' to 'pass'. Fluorescein can be detected around mask-wearers' faces after a fit-test [2]. The fluorescein fit-test is a cheap adaptation to the taste-test that is sensitive at identifying FFP mask leaks. Using TF rather than relying on subjective perception of taste mitigates placebo bias in the taste-test and enables reclassification of mask-wearers into 'pass' and 'fail' groups based on quantified aerosol leakage.

The global COVID-19 pandemic has refocussed the attentions of the international healthcare community on the safety of healthcare workers. In our study entitled 'Aerosolised fluorescein can quantify FFP mask seal leakage: a cost-effective adaptation to the existing point of care fit test' we proposed an innovative adaptation to the existing qualitative mask 'fit-test' that can quantify the amount of aerosol leaking around the mask-wearer's face.

Well-fitting Filtering Face-Piece (FFP) masks are a central tenet of effective Personal Protective Equipment (PPE) for healthcare workers involved in high-transmission activities such as Aerosol Generating Procedures (AGPs). For this reason their use is mandated in published guidelines by public health bodies. For an FFP mask to be effective at reducing transmission of infectious pathogens via droplets and aerosols, they must provide a secure seal around the wearer's face and minimize leakage [3]. At the point of care, healthcare professionals are required to undergo a mask 'fit-test' to check that the mask they're about to use provides a sufficiently secure seal. The commonest method of fit-testing is to spray bitter tasting (e.g. sodium benzoate) aerosols around the mask-wearer's face whilst they perform a protocolised set of actions designed to replicate typical movements in clinical practice, In this 'taste-test' if they can't taste the bitter aerosols the mask is deemed to be well-fitted ('pass'), but if they can taste bitterness this is regarded to be due to a leak in the seal and they are deemed to 'fail' the taste-test. The main problem with this approach is that it relies inherently on the subjective perception of taste. Previous work from our centre has shown that nearly a quarter of participants perceive tasting even a neutral solution as bitter when it is aerosolised around their face during an FFP fit-test.

Why would the taste-test be biased by placebo in this way? First, there are intrinsic variations in human perception of taste. Second, the impact of COVID-19 itself on taste and smell is well established [4]. Third, it may reflect anxieties about the outcome of the fit-test within healthcare workers. The risk of using such methods is that workers may be exposed or excluded based on the qualitative perception of taste rather than the actual degree of mask leakage. We believe such tests should not place the onus on the wearer to self-report the outcome, but instead should be quantitative and reproducible. We used aerosolised fluorescein a visible and measurable surrogate of leakage to create a low-cost, quantitative adaptation to the existing fit-test.

Although fluorescein is well established in a number of medical domains ranging from ophthalmology to pulmonary diagnostics, our study sheds light on a previously uninvestigated application of medical fluorescein [5]. 56 healthcare workers underwent the 'fluorescein fit-test' - a modified version of the 'taste-test' in which the sodium benzoate solution was stained with fluorescein and participants had a scientific filter paper placed behind their mask during the test. We hypothesized that if aerosols were able to bypass the mask due to an insufficient faceseal, they would settle on the 'active' filter paper and be detectable after the test. Participants were still asked whether they could taste the bitter aerosols to establish their status according to the current taste-test.

How could we be sure that the fluorescein staining the filter paper was truly due to aerosols bypassing the FFP mask, and not just because there was generally more fluorescence in the test-environment? To control for this important confounder, a second piece of filter paper (the control) was placed on a flat surface next to the participant and exposed to the test environment for the duration of the test. Later, any fluorescence observed on the control was used to adjust the fluorescence reading obtained from the 'active' filter paper. Only fluorescence on the active paper above the background fluorescence level contributed to the participants' results.

Since one of the main aims of this study was to quantify mask-seal leakage, we developed a parameter called Total Fluorescence (TF) based on digital fluorescence pixel counts. In the published paper we present a step-by-step recipe to do this. In summary the process involved re-humidification of the active filter papers, photography under a short pass filtered light (475 nm) through a yellow long pass filtered lens (500 nm) to create fluorescein excitation, digital separation of the 'green' channel and fluorescence quantification using a technique.

Based on the taste-test, 32 (57%) participants 'passed' and 24 (43%) 'failed'. There was an associated significant difference in the corresponding fluorescein-test: median TF in the 'pass' (2.6 × 106 units) and 'fail' (9.0 × 106) groups (p<0.001). We interrogated the precision and recall of the taste test to determine a cut-off of TF=5.0 × 106 units at a precision of 78% and recall of 84%. Applying this cut-off to the taste-test resulted in 12 (21%) participants'' results being overturned. 5/56 (9%) changed from 'pass' to 'fail' and 7/56 (12%) from 'fail' to 'pass'.

Our study has a number of important findings. First, fluorescein is detectable in this setting and can be used to quantify degree of FFP mask-seal leakage. Second, the fluorescein test is capable of classifying participants into 'pass' and 'fail' groups similarly to the taste-test. Third, a TF cut-off can be applied by users depending on the acceptable false positive rate for that scenario [6]. Fourth, the cut-off results in some result changes for individuals compared to the taste-test. For the people whose results were changed from 'pass' to 'fail' (9%) they could be protected from ill-fitting FFP masks by finding out that even though they didn't taste the bitterness, there was substantial fluorescent aerosol leak around their mask. For those whose results changed from 'fail' to 'pass' (12%) they could be reassured that even though they thought they tasted the bitterness, there was hardly any leak. This would be a positive impact on workforce productivity and human resource management. These benefits can be achieved by adaptations that are less than one tenth of the cost of commercial particle counting quantitative mask fit testing kits.

We advocate using fluorescein in point of care mask fit testing. We invite healthcare workers to use our methods in their clinical practice to validate our results and adopt the recommendations.

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