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Letter To The Editor

Safety concerns for facial topography customized 3D-printed N95 filtering face-piece respirator produced for the COVID-19 pandemic: initial step is respiratory fit testing

We commend the authors of the article ''Custom-made 3D-printed face masks in case of pandemic crisis situations with a lack of commercially available FFP2/3 masks''[1] for their determination in providing rapid solutions to personal protective equipment (PPE) shortages during times of crisis. However, we feel that it is misleading to provide a face mask solution without discussion of proper fit testing (quantitative or qualitative), which importantly may put individuals trying to replicate it at increased risk.

The authors aptly note in their discussion that filter efficiency and individual fit are essential components of mask performance in practical usage, however poor fit is responsible for greater particle penetration than poor filtration for commercially available solutions[2]. The authors subsequently provide an image of a sterilization nurse wearing the 3D mask prototype as evidence, stating ''Note the good clinical fit of the 3D-printed face mask''. Such statements are potentially misleading to the reader; poor fit may be imperceptible to both users and observers without quantitative metrics, and to rely on subjective measures of fit creates undue danger for the mask user[3]. The authors moreover imply that further testing of their solution is only ''ideally required'' rather than a necessary component of a mask solution implementation. Even commercially available masks are affected by poor fit; a single institution study in Japan noted that 30% of commercial N95 users experienced poor fit, which was reduced to only 4.5% with proper testing and user instruction[4]. Given the pervasive challenge of mask fit even in commercial masks, proper fit testing is imperative to the development of any mask solution.

Rapid publication of potential N95 solutions is important to provide work for others to improve upon in the time of the COVID-19 pandemic, and the authors' solution was, to the best of our literature search, the first published 3D-printed N95 alternative during the COVID-19 pandemic. However, limitations need to be clearly articulated. While physicians and healthcare professionals who have undergone proper fit testing for N95 filtering face-piece respirators may realize such limitations, those in the community at large may not. At writing, there are dozens of proposed N95 solutions on the National Institutes of Health 3D Print Exchange[5].

At our institution, 3D-printed N95 solutions, including those similarly based on facial topography, have not passed Occupational Safety and Health Administration-certified 7-minute quantitative fit testing; however, this directed letter is not the medium to fully present or discuss those data. Regulatory agencies such as the US Food and Drug Administration acknowledge the efforts of attempts at 3D-printed PPE[5], but state doubt regarding their effectiveness; ''For example, 3D-printed PPE may provide a physical barrier, but 3D-printed PPE are unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators''[6].

We would welcome the authors' clarifications on these points of additional testing, particularly if the 3D-printed N95 alternative successfully passed fit testing, and hope that their continued work will help provide effective real-time PPE solutions in times of further crisis.

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Competing interests

None.

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Reply to Scott et al., ''Safety concerns for facial topography customized 3D-printed N95 filtering face-piece respirator produced for the COVID-19 pandemic: initial step is respiratory fit testing''

The safety concerns raised in the letter of Scott et al. are correct and have obviously to be addressed.

Our paper merely describes a 'proof of principle', demonstrating that commercially available 3D photography apps allow data to be acquired that enable 3D printing with great precision, including for custom-made masks[1]. It is obvious that testing of these masks is necessary to provide assurances of safety, as is the case with all masks.

The current standard is that certified staff carry out standardized tests of the fitting of commercially available masks, to ensure that the masks are efficient and safe. Even then, the masks must be used correctly. This is a requirement in all oral and maxillofacial settings, as it is in specific hospital settings, dental surgeries, etc., especially when aerosol-generating procedures are performed. Once a certain type of mask is certified for a specific individual, it can be used by that person according to guidelines of precise use, including disinfection of the masks and durability of the filters used. This would evidently also apply to 3D-printed masks.

The paper is therefore not misleading, but demonstrates merely a proof of principle to make a custom-made mask that has to be submitted to the same standardized testing as any other type of commercially available mask.

The authors mention correctly that commercially available masks can be affected by poor fit. As the masks are based on 3D printing and are custom-made, they have a potentially higher probability of fitting well without either excessive compression of the skin or leaks.

In the first instance, the 3D-printed mask with its specific filter needs to be approved by the necessary regulatory authorities, and secondly these masks will have to pass the individual standardized fitting tests.

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