PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Injection Molded Autoclavable, Scalable, Conformable (iMASC) system for aerosol-based protection: a prospective single arm feasibility study
AUTHORS	Byrne, James; Wentworth, Adam; Chai, Peter; Huang, Hen-Wei; Babaee, Sahab; Li, Canchen; Becker, Sarah; Tov, Caitlynn; Min, Seokkee; Traverso, Giovanni

VERSION 1 – REVIEW

REVIEWER	Chun-Yip Hon School of Occupational and Public Health, Ryerson University Toronto, Ontario, Canada
REVIEW RETURNED	15-Apr-2020

GENERAL COMMENTS	This is a very important and timely project. The research team has developed a product that may be suitable in pandemic situations where supplies of personal protective equipment (respiratory protection in particular) for healthcare professionals might be limited. Essentially, the team has developed a product comparable to N95 filtering facepiece respirators (FFRs) which can be cleaned and disinfected multiple times for reuse. Overall, I believe that this novel product holds promise as the team has done a reasonable job in assessing the ability of the facepiece to create a suitable seal as well as the fact that it can be decontaminated without compromising its structural integrity. However, what is missing and what needs to be clearly indicated in the manuscript, is that this new product still needs to undergo certification testing as per NIOSH 42 CFR part 84 (or equivalent) in order for it to be legally used in the workplace (This statement applies to the United States and Canada only as I am not familiar with occupational health and safety legislation in other countries but I assume that many jurisdictions have similar requirements). Given the reports of counterfeit N95s, I strongly believe that it is in the best interest for readers, many of whom may not be intimately familiar with N95 FFR certification requirements, that a caveat statement be inserted into the manuscript (both in the abstract and in the Discussion). Specific comments are found below:

	Page 3, lines 31 to 33 - “The iMASC system as an alternative sustainable solution to the dwindling supply of disposable N95 masks”. Again, given the concerns above, this statement needs to be softened somewhat as the iMASC has not been NIOSH-certified. Perhaps the addition of the word ‘potential’ or ‘promising’ before the “alternative” Page 4, line 2 - the correct term should be “N95 filtering facepiece respirators (FFRs)”. Therefore, in all instances, please refrain from using the word ‘mask’ and substitute with “N95 FFRs” (this is also important to avoid any confusion with the term ‘surgical mask’ - which some people believe serve the same function as N95 FFR) Page 4, Methods - source/origin of materials is missing in this entire section. For instance, SolidWorks is manufactured where? Page 4, line 10 - I had no idea what SolidWords was as the team did not provide any detail. A simple explanation that this is a 3D software would suffice to inform the reader. Page 4, line 10 - what was the rationale of selecting the 3M 1860 model for the template of the new product? A sentence should suffice as many different N95 FFR make and models are commercially available. Did the research team also use the smaller size of this model i.e. the 3M 1860S? If so, this should be clearly indicated. If only 3M 1860 was used, then this is a limitation that needs to be mentioned in the Discussion as the 3M 1860 is a M/L size and not suitable for those with smaller faces. Page 4, line 22 - I am curious to know why the research team did not consider using material currently used to fabricate elastomeric half-facepiece respirators for the iMASC facepiece? This material is already in use, proven to create an adequate face seal and can be cleaned. Page 4, line 25 - include the full name/title of the ASTM method used. Page 4, lines 26 to 28 - It is not clear if the sterilization methods were mutually exclusive. This needs clarification as it is common in practice for a worker to clean their reusable respirator with a bleach- or alcohol-based wipe between uses and then a more thorough clean at the end of the day/week/as per policy. Page 4, subheading “Deformation studies” - This section was extremely technical and very difficult to follow. I am not sure if anyone in healthcare and/or occupational health and safety would have the knowledge to replicate this element (I am basing this statement on the assumption that these two disciplines are key target readers). Much appreciated if the research team could simplify this section for the uninitiated. Also, to clarify, was only one mould for the mask created for all 20 subjects? Page 4, lines 41 - spell out “FE” the first time that it is used

	Page 4, line 49 and 50 - Citation required for reference “Material characterization of the medical-grade silicone elastomer ” Page 5, subheading “Clinical studies” - This was a very lengthy and detailed section. Perhaps it would be simpler to reference qualitative fit-testing procedures such as OSHA 1910.134 App A (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA) and provide a quick summary? This will shorten the manuscript considerably and make it easier for the reader. Also, it should made clear that fit testing was performed on the iMASC (as opposed to the 3M 1860) Page 5, line 15 - the research team recruited subjects who had been previously fit tested successfully. Studies have demonstrated that a respirator user gains experience with subsequent donnings and this may result in improved fit-test pass rates and therefore, bias the findings. This bias needs to be mentioned in the Discussion. See below for references: Or, P., J., Chung, and T., Wong: A novel approach to fit testing the N95 respirator in real time in a clinical setting. Int. J. Nurs. Pract. 22(1):22–30 (2014). Lee, M.C., S., Takaya, R., Long, and A.M., Joffe: Respirator-fit testing: does it ensure the protection of healthcare workers against respirable particles carrying pathogens? Infect. Control Hosp. Epidemiol. 29(12):1149–1156 (2008). Hannum, D., K., Cycan, L., Jones, et al.: The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. Infect. Control Hosp. Epidemiol. 17(10):636–640 (1996). Page 5, line 20 - who performed the demonstration i.e. member of research team or job title? Was it the same individual for all subjects? If not, can the research team discuss any possible bias with using more than one demonstrator? Page 5, line 29 - 21 - Regarding the sentence that “Once the mask was deemed comfortable and of adequate fit, the subject performed a user seal check”, it should be made clear that this comfort and adequacy of fit was subjective. Page 5, line 23 - The authors indicate that the subjects selected a respirator from the two available sizes. It was not made known earlier in the Methods section that the iMASC came in two sizes. Page 5, lines 31 - 37. Did the user cover the filters when performing the positive and/or negative pressure seal test? Given that this is a novel product, clarity on how to conduct a seal check is appreciated. Page 5, line 38 - why was Saccharin chosen to conduct the qualitative fit test? A study has

	demonstrated that Bitrex should be the preferred choice for fit test solution as leak detection can be correctly identified with Bitrex, but not saccharin. See reference below. Use of saccharin needs to be mentioned as a limitation in the Discussion section. McKay RT, Davies E. Capability of respirator wearers to detect aerosolized qualitative fit test agents (sweetener and Bitrex) with known fixed leaks. Applied occupational and environmental hygiene. 2000 Jan 1;15(6):479-84. On a related note, the research team should comment about the possibility of conducting a quantitative fit test (QNFT) on the iMASC. A study found that the QNFT resulted in fewer false positives on the 3M 1860. See reference below. Hon CY, Danyluk Q, Bryce E, Janssen B, Neudorf M, Yassi A, Shen H, Astrakianakis G. Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector. Journal of occupational and environmental hygiene. 2017 Mar 4;14(3):175-9. Page 6, lines 22-25. Is there a reference for the following statement "The shape of the iMASC system was modeled from disposable regular N95 masks used in the hospital, which are amenable to many different face sizes and shapes"? In its current form, the statement is more anecdotal and not necessarily supported by science. Page 6, lines 34 - 36. Where is the evidence to support the following statement: "...based upon the material selection of a medical grade LSR, the iMASC system is reusable after sterilization by cleaning with hospital grade bleach/alcohol wipes, autoclave and heating methods"? Page 6, subheading "Characterization of mask material after sterilization" - were statistical tests done to confirm that there was no change to the integrity of the mask? If so, presenting the results of these statistical tests would strengthen the manuscript. As per an earlier comment, it is not clear if the sterilization methods were mutually exclusive. The authors need to address this matter in the Discussion and its possible limitations. Page 6, line 54, contrary to the authors' sentence, there is no "T" in figure S3. Page 6, lines 55 - 58. In my opinion, the different forces used to assess mask deformation should be in the Methods section. Page 7, line 18 - typo? "Duo" seems out of place. Page 7, lines 19 to 22. The use of the word "guarantee" is quite bold and may not be true considering that the research team did not assess a user wearing the iMASC for a long period of time. As such, I would suggest softening the language here.

	Page 7, line 47. The research team found 1 failure (out of 24 or 4.2%). Though a small proportion, it is worth mentioning in more detail why this person could not achieve a fit with the iMASC. Page 7, lines 49 to 51. What was used to assess that a subject was able to successfully replace the filter into the mask? This is important to clarify as several subjects indicated that they had some difficulty with filter replacement (lowest mean score of all subjective Likert scale questions) Page 7, lines 53 to 57. I see no value in presenting both the average and the median value (which are very similar to one another) of the different evaluations. Rather, I believe it is more important to present the max and min of every question that is rated on a Likert scale. By doing so, one has an idea of the range of responses for each of the subjective questions. Page 8, lines 1 to 4. It is unclear why the authors are asking if the subjects prefer to wear the iMASC vs. a surgical mask. A surgical mask does not require a faceseal to be established and also serves a different function i.e. does not filter the air. In my opinion, the iMASC should only be compared to N95 FFRs for which it is intended as an alternative. Page 8, line 7. What is a “standard issue mask”? Page 8, lines 17 to 19. The authors state “Our approach here was to develop a scalable, reusable face mask that can extend the amount of N95 material while providing the same droplet protection as standard N95 masks”. Technically, this is not correct as the iMASC has not been tested for droplet protection to the same level of certified N95 FFRs. Study limitations that authors must include in the existing Discussion on limitations: A. This new product has yet to undergo certification testing as per NIOSH 42 CFR part 84 (or equivalent) and, therefore, cannot legally be considered an alternative to N95 FFR in many jurisdictions B. Bias inherent in using participants that have successfully passed respirator fit-testing previously the research team recruited subjects who had been previously fit tested successfully C. Use of saccharin as the fit-testing agent may not be able to detect leakage as well as Bitrex Additional study limitations that authors should consider including to the existing Discussion on limitations: A. Presumably this study was conducted in North America and this means that the iMASC may not be suitable for workers outside of North America where face sizes may differ - further testing is required

	B. Further explanation regarding the one subject who failed to achieve a suitable fit on the iMASC - this may have implications when a larger cohort is asked to use the iMASC C. Responses to subjective Likert scale questions were based only on short term use and may not be reflective of users' perspectives after using iMASC for full-shift Practical issues that I believe should be discussed in the manuscript a) Where does one get these replaceable filters? b) The novel product still needs to be tested for comfort over an 8-hr or 12-hr shift (the latter is typical for healthcare workers). c) The novel product still needs to be tested to ensure that it is able to stay in position on a user's face for an 8-hr or 12-hr shift (the latter is typical for healthcare workers).

REVIEWER	Linh Phan Stanford University
REVIEW RETURNED	11-May-2020

GENERAL COMMENTS	The manuscript presented a new method to design a respirator based on the current 3M 1860 N95 respirator to address the shortage of N95 respirator amid of the coronavirus pandemic and to prevent COVID-19 transmission in healthcare settings. Specific comments. 1. Please use the term "N95 respirator" consistently in the manuscript. "N95 respirator" should be used instead of "N95 face mask" or "N95 mask" as it needs to be distinguished from the "surgical face mask" which does not provide adequate protection for aerosol-transmissible diseases. • Page 3, line 10: change mask to respirator 2. Method 2.1 iMASC fabrication • Please provide further information about the filters. Are they self-designed? If so, did the authors validate the filter efficiency? 2.2 Material selection and testing • Indicate autoclaving temperature and duration. • Indicate isopropanol concentration. 2.3 Clinical studies • Page 4, line 9: write the full name of OSHA because this is the first time it is mentioned in the text. • Page 4, line 12: written or verbal consent? • The authors should add the baseline assessment questionnaires as a supplemental material of this manuscript. • Can the authors clarify whether the fit testing history of participants is related to the participant's enrollment? Did you collect the fit testing method and the types of respirator model that the participants were tested as part of the hospital policy? Are they the same with the 3M 1860 N95 respirator that the authors used to design the iMASC fabrication? Typically, the following respirator models are used in healthcare settings: 3M 1860 N95, 3M 1860S N95, 3M 1870+ N95, and Kimberly Clark N95 pouch style. • Page 4, line 18: Gerson Respirator Fit Test Kit (Manufacturer, City, State)

	• Page 4, line 17. Indicate who performed the qualitative fit tests and the fit test method was Saccharin Solution Aerosol Protocol per OSHA §1910.134. • Please confirm in the method section that the qualitative fit test would not proceed if there is any hair growth between the skin and facepiece sealing surface. 3. Results Characterization of mask material after sterilization: • Page 5, line 42: Change to “10 minutes in 1:10 bleach solution”. • The authors concluded that there was no significant difference in the sterilized respirators compared to the non-sterilized respirators. I think this conclusion is very qualitative. The authors can validate this conclusion by using a quantitative fit testing method for future study. This should be one of the study limitations that the authors should discuss in the discussion. Clinical trial evaluating and mask fitting: • Page 6, line 31: Don’t need to state OSHA full name here. • Page 6, line 32-29: The fit testing protocol was described in the method section so the authors should not repeat them in the results. Discussion: • Page 7 line 16: higher disease transmission risk? • In figure 1, it looks like the IMASC respirators use a similar elastic strap design with the 3M 1860 N95 respirator. If the iMASC are effectively decontaminated, how often the elastic straps should be replaced? Some studies found that after 5 uses, the strap may be loosened and may decrease the respirator fit. • The authors should also discuss the iMASC respirator decontamination effectiveness against SARS-CoV-2. This study has some limitations that I recommend the authors should acknowledge at the end of the discussion and maybe propose ideas for future studies. • Lack of filter efficiency testing data. If the authors plan to test the filter efficiency data, I suggest using the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. • The authors need to discuss the limitations of the qualitative fit testing method. I strongly suggest the authors should explore the options of using quantitative fit testing for future studies. One of the limitations of the qualitative method is that it cannot verify the respirator protection factor. Per Cal/OSHA CCR 5199, a fit factor of 100 must be obtained during the quantitative fit testing for healthcare workers to use for protection against the aerosol-transmissible pathogens.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. This is a very important and timely project. The research team has developed a product that may be suitable in pandemic situations where supplies of personal protective equipment (respiratory protection in particular) for healthcare professionals might be limited. Essentially, the team has developed a product comparable to N95 filtering facepiece respirators (FFRs) which can be cleaned and disinfected multiple times for reuse. Overall, I believe that this novel product holds promise as the team has done a reasonable job in assessing the ability of the facepiece to create a suitable seal as well as the fact that it can be decontaminated without compromising its structural integrity. However, what is missing and what needs to be clearly indicated in the manuscript, is that this new product still needs to undergo certification testing

as per NIOSH 42 CFR part 84 (or equivalent) in order for it to be legally used in the workplace (This statement applies to the United States and Canada only as I am not familiar with occupational health and safety legislation in other countries but I assume that many jurisdictions have similar requirements). Given the reports of counterfeit N95s, I strongly believe that it is in the best interest for readers, many of whom may not be intimately familiar with N95 FFR certification requirements, that a caveat statement be inserted into the manuscript (both in the abstract and in the Discussion). We thank the reviewer for their kind remarks. To address the additional certification requirements, we have updated the abstract and discussion to include these details. Please see *page 2, paragraph 1* and *page 7, paragraph 2* of the clean version of the revised manuscript.

2. Page 3, lines 31 to 33 - "The iMASC system as an alternative sustainable solution to the dwindling supply of disposable N95 masks". Again, given the concerns above, this statement needs to be softened somewhat as the iMASC has not been NIOSH-certified. Perhaps the addition of the word 'potential' or 'promising' before the "alternative". We appreciate this clarification and have added the word "promising". Please see *page 2, bullet 5* of the clean version of the revised manuscript.

3. Page 4, line 2 - the correct term should be "N95 filtering facepiece respirators (FFRs)". Therefore, in all instances, please refrain from using the word 'mask' and substitute with "N95 FFRs" (this is also important to avoid any confusion with the term 'surgical mask' - which some people believe serve the same function as N95 FFR). We have updated the term to N95 FFRs.

4. Page 4, Methods - source/origin of materials is missing in this entire section. For instance, SolidWorks is manufactured where? We apologize for missing this section and have included this. Please see *page 3, paragraph 2* of the clean version of the revised manuscript.

5. Page 4, line 10 - I had no idea what SolidWords was as the team did not provide any detail. A simple explanation that this is a 3D software would suffice to inform the reader. We have added more detail describing SolidWorks. Please see *page 3, paragraph 3* of the clean version of the revised manuscript.

6. Page 4, line 10 - what was the rationale of selecting the 3M 1860 model for the template of the new product? A sentence should suffice as many different N95 FFR make and models are commercially available. Did the research team also use the smaller size of this model i.e. the 3M 1860S? If so, this should be clearly indicated. If only 3M 1860 was used, then this is a limitation that needs to be mentioned in the Discussion as the 3M 1860 is a M/L size and not suitable for those with smaller faces. These are excellent points. We used the 3M 1860 model, which is the current model used at the hospitals in the Partners Healthcare network. In addition, we have added this limitation in the discussion. Please see *page 3, paragraph 3* and *page 7, paragraph 2* of the clean version of the revised manuscript.

7. Page 4, line 22 - I am curious to know why the research team did not consider using material currently used to fabricate elastomeric half-facepiece respirators for the iMASC facepiece? This material is already in use, proven to create an adequate face seal and can be cleaned. The elastomeric half-facepiece respirator and the iMASC facepiece are made from the same general class of silicone rubbers, albeit slightly different polymers. For the specific polymer for elastomeric half-facepiece respirators, the mask is stiffer, and the recommended sterilization technique is the bleach wipe. The material selection for the iMASC system was largely based upon flexibility and the wide variety of sterilization methods.

8. Page 4, line 25 - include the full name/title of the ASTM method used. The full name/title has been included. Please see *page 3, paragraph 4* of the clean version of the revised manuscript.

9. Page 4, lines 26 to 28 - It is not clear if the sterilization methods were mutually exclusive. This needs clarification as it is common in practice for a worker to clean their reusable respirator with a bleach- or alcohol-based wipe between uses and then a more thorough clean at the end of the day/week/as per policy. Thank you for this point of clarification. The sterilization methods were mutually exclusive. We have updated the text to reflect this. Please see *page 3, paragraph 4* of the clean version of the revised manuscript.

10. Page 4, subheading "Deformation studies" - This section was extremely technical and very difficult to follow. I am not sure if anyone in healthcare and/or occupational health and safety would have the knowledge to replicate this element (I am basing this statement on the assumption that these two disciplines are key target readers). Much appreciated if the research team could simplify this section for the uninitiated. Also, to clarify, was only one mould for the mask created for all 20 subjects? We completely understand and have attempted to simplify this section. The single mask used for all 20 subjects in the deformation studies came directly from the CAD software that was used to generate the injection molded mask. Please see *page 4, paragraph 2* of the clean version of the revised manuscript.

11. Page 4, lines 41 - spell out "FE" the first time that it is used. We have spelled out "FE". Please see *page 4, paragraph 1* of the clean version of the revised manuscript.

12. Page 4, line 49 and 50 - Citation required for reference "Material characterization of the medical-grade silicone elastomer ". We have deleted this reference, as it was included in error. Please see *page 4, paragraph 2* of the clean version of the revised manuscript.

13. Page 5, subheading "Clinical studies" - This was a very lengthy and detailed section. Perhaps it would be simpler to reference qualitative fit-testing procedures such as OSHA 1910.134 App A (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA) and provide a quick summary? This will shorten the manuscript considerably and make it easier for the reader. Also, it should made clear that fit testing was performed on the iMASC (as opposed to the 3M 1860).
We have shortened this text by referencing and summarizing the qualitative fit-testing procedure. Also, we clarified that the fit testing was performed on the iMASC. Please *page 4, paragraph 3* of the clean version of the revised manuscript.

14. Page 5, line 15 - the research team recruited subjects who had been previously fit tested successfully. Studies have demonstrated that a respirator user gains experience with subsequent donnings and this may result in improved fit-test pass rates and therefore, bias the findings. This bias needs to be mentioned in the Discussion. See below for references:
Or, P., J., Chung, and T., Wong: A novel approach to fit testing the N95 respirator in real time in a clinical setting. Int. J. Nurs. Pract. 22(1):22–30 (2014).
Lee, M.C., S., Takaya, R., Long, and A.M., Joffe: Respirator-fit testing: does it ensure the protection of healthcare workers against respirable particles carrying pathogens? Infect. Control Hosp. Epidemiol. 29(12):1149–1156 (2008).
Hannum, D., K., Cycan, L., Jones, et al.: The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. Infect. Control Hosp. Epidemiol. 17(10):636–640 (1996).
Thank you for this insight. We have addressed this in the discussion section and added these references. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

15. Page 5, line 20 - who performed the demonstration i.e. member of research team or job title? Was it the same individual for all subjects? If not, can the research team discuss any possible bias with using more than one demonstrator? The demonstration was performed by the same individual for all subjects. We have updated the text on *page 4, paragraph 2* of the clean version of the revised manuscript.

16. Page 5, line 29 - 21 - Regarding the sentence that "Once the mask was deemed comfortable and of adequate fit, the subject performed a user seal check", it should be made clear that this comfort and adequacy of fit was subjective. Thank you, we deleted this sentence to condense the section. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

17. Page 5, line 23 - The authors indicate that the subjects selected a respirator from the two available sizes. It was not made known earlier in the Methods section that the iMASC came in two sizes. We apologize for this error and have deleted this sentence. There was only one size available for testing. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

18. Page 5, lines 31 - 37. Did the user cover the filters when performing the positive and/or negative pressure seal test? Given that this is a novel product, clarity on how to conduct a seal

check is appreciated. We did have the subject cover the filters with their hands when performing the positive pressure seal test. In an effort to condense this section, we removed this statement from the methods.

19. Page 5, line 38 - why was Saccharin chosen to conduct the qualitative fit test? A study has demonstrated that Bitrex should be the preferred choice for fit test solution as leak detection can be correctly identified with Bitrex, but not saccharin. See reference below. Use of saccharin needs to be mentioned as a limitation in the Discussion section.
McKay RT, Davies E. Capability of respirator wearers to detect aerosolized qualitative fit test agents (sweetener and Bitrex) with known fixed leaks. Applied occupational and environmental hygiene. 2000 Jan 1;15(6):479-84.
Saccharin was chosen due to the availability during the pandemic. We have mentioned the use of saccharin as a limitation in the discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

20. On a related note, the research team should comment about the possibility of conducting a quantitative fit test (QNFT) on the iMASC. A study found that the QNFT resulted in fewer false positives on the 3M 1860. See reference below.
Hon CY, Danyluk Q, Bryce E, Janssen B, Neudorf M, Yassi A, Shen H, Astrakianakis G. Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector. Journal of occupational and environmental hygiene. 2017 Mar 4;14(3):175-9.
We added a comment about conducting quantitative fit test. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

21. Page 6, lines 22-25. Is there a reference for the following statement "The shape of the iMASC system was modeled from disposable regular N95 masks used in the hospital, which are amenable to many different face sizes and shapes"? In its current form, the statement is more anecdotal and not necessarily supported by science. We have modified this statement to, "The shape of the iMASC system was modeled from disposable regular N95 FFRs used in the hospital." Please see *page 5, paragraph 2* of the clean version of the revised manuscript.

22. Page 6, lines 34 - 36. Where is the evidence to support the following statement: "...based upon the material selection of a medical grade LSR, the iMASC system is reusable after sterilization by cleaning with hospital grade bleach/alcohol wipes, autoclave and heating methods"? We completely agree and have deleted this statement. Please see *page 5, paragraph 2* of the clean version of the revised manuscript.

23. Page 6, subheading "Characterization of mask material after sterilization" - were statistical tests done to confirm that there was no change to the integrity of the mask? If so, presenting the results of these statistical tests would strengthen the manuscript. We were remiss in not including this and have added statistical analyses of the mechanical testing of the iMASC. Please see *page 5, paragraph 3* of the clean version of the revised manuscript.

As per an earlier comment, it is not clear if the sterilization methods were mutually exclusive. The authors need to address this matter in the Discussion and its possible limitations. We concur and have added a sentence describing this in the discussion. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

24. Page 6, line 54, contrary to the authors' sentence, there is no "T" in figure S3. We apologize for the error, as the text should say figure S1. We have updated the text. Please see *page 5, paragraph 4* of the clean version of the revised manuscript.

25. Page 6, lines 55 - 58. In my opinion, the different forces used to assess mask deformation should be in the Methods section. We have added this to the Methods section. Please see *page 4, paragraph 2* of the clean version of the revised manuscript.

26. Page 7, line 18 - typo? "Duo" seems out of place. We apologize and have updated this. Please see *page 6, paragraph 2* of the clean version of the revised manuscript.

27. Page 7, lines 19 to 22. The use of the word "guarantee" is quite bold and may not be true considering that the research team did not assess a user wearing the iMASC for a long period of time. As such, I would suggest softening the language here. We have removed guarantee and updated the text. Please see *page 6, paragraph 2* of the clean version of the revised manuscript.

28. Page 7, line 47. The research team found 1 failure (out of 24 or 4.2%). Though a small proportion, it is worth mentioning in more detail why this person could not achieve a fit with the iMASC. We have updated the text to reflect the exact case, where the participant was unable to get the mask over her hair to place it on her face. This was an issue with the elastic straps rather than the fit of the mask. She did not end up performing the fit test. Please see *page 6, paragraph 3* of the clean version of the revised manuscript.

29. Page 7, lines 49 to 51. What was used to assess that a subject was able to successfully replace the filter into the mask? This is important to clarify as several subjects indicated that they had some difficulty with filter replacement (lowest mean score of all subjective Likert scale questions). We wanted to ensure that the subject understood and could replicate the demonstration by a member of the research team. We have updated the text in the methods section. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

30. Page 7, lines 53 to 57. I see no value in presenting both the average and the median value (which are very similar to one another) of the different evaluations. Rather, I believe it is more important to present the max and min of every question that is rated on a Likert scale. By doing so, one has an idea of the range of responses for each of the subjective questions. We appreciate this and have provided the range of responses. Please see *page 6, paragraph 3* of the clean version of the revised manuscript.

31. Page 8, lines 1 to 4. It is unclear why the authors are asking if the subjects prefer to wear the iMASC vs. a surgical mask. A surgical mask does not require a faceseal to be established and also serves a different function i.e. does not filter the air. In my opinion, the iMASC should only be compared to N95 FFRs for which it is intended as an alternative. We wanted to understand the subjects overall experience, including comfort and breathability, compared to N95 FFRs and surgical masks.

32. Page 8, line 7. What is a "standard issue mask"? We have updated the text to say N95 FFR. Please see *page 6, paragraph 4* of the clean version of the revised manuscript.

33. Page 8, lines 17 to 19. The authors state "Our approach here was to develop a scalable, reusable face mask that can extend the amount of N95 material while providing the same droplet protection as standard N95 masks". Technically, this is not correct as the iMASC has not been tested for droplet protection to the same level of certified N95 FFRs. Thank you, we have removed the statement on droplet protection. Please see *page 7, paragraph 1* of the clean version of the revised manuscript.

Study limitations that authors must include in the existing Discussion on limitations:
A. This new product has yet to undergo certification testing as per NIOSH 42 CFR part 84 (or equivalent) and, therefore, cannot legally be considered an alternative to N95 FFR in many jurisdictions. We have updated this. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.
B. Bias inherent in using participants that have successfully passed respirator fit-testing previously the research team recruited subjects who had been previously fit tested successfully. We have updated the discussion to state this bias. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.
C. Use of saccharin as the fit-testing agent may not be able to detect leakage as well as Bitrex. We have updated the discussion to state this. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

Additional study limitations that authors should consider including to the existing Discussion on limitations:
A. Presumably this study was conducted in North America and this means that the iMASC may not be suitable for workers outside of North America where face sizes may differ - further testing

is required. We have updated the discussion to state this. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

B. Further explanation regarding the one subject who failed to achieve a suitable fit on the iMASC - this may have implications when a larger cohort is asked to use the iMASC. We apologize for the lack of clarity regarding this one subject. She did not undergo the OSHA fit testing as the elastic straps continued to break due to the size of her hair. We completely agree that modification will be necessary for future iterations and have added this into the discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

C. Responses to subjective Likert scale questions were based only on short term use and may not be reflective of users' perspectives after using iMASC for full-shift Practical issues that I believe should be discussed in the manuscript. We completely agree and have added this into the Discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

a) Where does one get these replaceable filters? We would need to manufacture the replaceable filters and large-scale production would need to be outsourced. We are currently working on scaling up such a service.

b) The novel product still needs to be tested for comfort over an 8-hr or 12-hr shift (the latter is typical for healthcare workers). We completely agree and have added this into the Discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

c) The novel product still needs to be tested to ensure that it is able to stay in position on a user's face for an 8-hr or 12-hr shift (the latter is typical for healthcare workers). We completely agree and have added this into the Discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

Reviewer: 2

1. Please use the term "N95 respirator" consistently in the manuscript. "N95 respirator" should be used instead of "N95 face mask" or "N95 mask" as it needs to be distinguished from the "surgical face mask" which does not provide adequate protection for aerosol-transmissible diseases. Thank you for this clarification. We have updated the manuscript to say, "N95 FFR".

2. Page 3, line 10: change mask to respirator. We have updated this text and removed mask. Please see *page 2, paragraph 2* of the clean version of the revised manuscript.

3. Please provide further information about the filters. Are they self-designed? If so, did the authors validate the filter efficiency? We laser cut filters from unused N95 FFRs, which have undergone filter efficiency testing. Please see *page 3, paragraph 3* of the clean version of the revised manuscript.

4. Indicate autoclaving temperature and duration. We have updated this information. Please see *page 3, paragraph 4* of the clean version of the revised manuscript.

5. Indicate isopropanol concentration. We have updated this information. Please see *page 3, paragraph 4* of the clean version of the revised manuscript.

6. Page 4, line 9: write the full name of OSHA because this is the first time it is mentioned in the text. We added the full name. Please see *page 4, paragraph 3* of the clean version of the revised manuscript.

7. Page 4, line 12: written or verbal consent? Verbal consent. Please see *page 4, paragraph 3* of the clean version of the revised manuscript.

8. The authors should add the baseline assessment questionnaires as a supplemental material of this manuscript. Absolutely. We have added these to the supplemental material.

9. Can the authors clarify whether the fit testing history of participants is related to the participant's enrollment? Did you collect the fit testing method and the types of respirator

model that the participants were tested as part of the hospital policy? Are they the same with the 3M 1860 N95 respirator that the authors used to design the iMASC fabrication? Typically, the following respirator models are used in healthcare settings: 3M 1860 N95, 3M 1860S N95, 3M 1870+ N95, and Kimberly Clark N95 pouch style. This is an excellent point. The study team ensured that the participants had performed fit testing over the past year for 3M 1860 model, which used the same fit testing system used in the study. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

10. Page 4, line 18: Gerson Respirator Fit Test Kit (Manufacturer, City, State). Thank you. We have added these details. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

11. Page 4, line 17. Indicate who performed the qualitative fit tests and the fit test method was Saccharin Solution Aerosol Protocol per OSHA §1910.134. We have added these details. Please see *page 4, paragraph 4* of the clean version of the revised manuscript.

12. Please confirm in the method section that the qualitative fit test would not proceed if there is any hair growth between the skin and facepiece sealing surface. We have added these details. Please see *page 4, paragraph 3* of the clean version of the revised manuscript.

13. Page 5, line 42: Change to "10 minutes in 1:10 bleach solution". We have made this change. Please see *page 3 paragraph 4* of the clean version of the revised manuscript.

14. The authors concluded that there was no significant difference in the sterilized respirators compared to the non-sterilized respirators. I think this conclusion is very qualitative. The authors can validate this conclusion by using a quantitative fit testing method for future study. This should be one of the study limitations that the authors should discuss in the discussion. We absolutely agree and have added this into the study limitations. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

15. Page 6, line 31: Don't need to state OSHA full name here. We have made this change. Please see *page 6, paragraph 3* of the clean version of the revised manuscript.

16. Page 6, line 32-29: The fit testing protocol was described in the method section so the authors should not repeat them in the results. We have removed this text from the results section. Please see *page 6, paragraph 3* of the clean version of the revised manuscript.

17. Page 7 line 16: higher disease transmission risk? We have removed this statement. Please see *page 7, paragraph 1* of the clean version of the revised manuscript.

18. In figure 1, it looks like the IMASC respirators use a similar elastic strap design with the 3M 1860 N95 respirator. If the iMASC are effectively decontaminated, how often the elastic straps should be replaced? Some studies found that after 5 uses, the strap may be loosened and may decrease the respirator fit. We absolutely agree. In future studies, we will replace the elastic strap with a silicone strap for reusability. We have added these details in the discussion section. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

19. The authors should also discuss the iMASC respirator decontamination effectiveness against SARS-CoV-2. The iMASC is able to be sterilized through three methods currently approved as successful decontamination techniques against SARS-CoV-2, including autoclaving and sterilization in either a 1:10 bleach or 70% isopropyl alcohol solution. Please see *page 7, paragraph 1* of the clean version of the revised manuscript.

20. This study has some limitations that I recommend the authors should acknowledge at the end of the discussion and maybe propose ideas for future studies. Lack of filter efficiency testing data. If the authors plan to test the filter efficiency data, I suggest using the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059.
We have added these limitations and future studies in the discussion. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

21. The authors need to discuss the limitations of the qualitative fit testing method. I strongly suggest the authors should explore the options of using quantitative fit testing for future studies. One of the limitations of the qualitative method is that it cannot verify the respirator protection factor. Per Cal/OSHA CCR 5199, a fit factor of 100 must be obtained during the quantitative fit testing for healthcare workers to use for protection against the aerosol-transmissible pathogens.
We appreciate the reviewer's insight and have added this to the limitations section of the discussion. We plan to explore the quantitative fit testing for future studies. In addition, we have added text in the discussion addressing the limitations of the qualitative fit testing methods. Please see *page 7, paragraph 2* of the clean version of the revised manuscript.

22. Required amendments will be listed here; please include these changes in your revised version:
- Supplementary File. Please re-upload your supplementary file in PDF format. We have added our questionnaires into the supplementary file section and have re-uploaded in PDF format.

VERSION 2 – REVIEW

REVIEWER	Chun-Yip Hon Ryerson University, Canada
REVIEW RETURNED	27-May-2020

GENERAL COMMENTS	The authors have done an admirable job of responding to the concerns that were brought forward in the previous review. There are, however, some minor issues that remain outstanding which need to be addressed. Abstract Objective: please change to "N95 FFR comparable mask" Results: lines 8-9 reads awkwardly Results: lines 10-11 the meaning is unclear Conclusion: the authors mention OSHA fit testing but it was not specifically mentioned previously in the Methods section of the abstract Article summary: Fourth bullet: The authors listed the departments of the participants here which is not mentioned in the body of the manuscript. Perhaps change to the types of job categories that were assessed as this would be more meaningful (and would be consistent with the information in the body of the manuscript). . Methods "Materials" and "iMASC fabrication" have some overlap/duplication of presented information. Page 4, lines 39 - 41 is repetitive with information found in earlier sub-sections in the Methods Page 4, lines 43 to 45: in its current form, it is not clear if three different sterilization methods were tested. Consider "...sterilization methods including a) 10 cycles of autoclaving, b) 10 minute soak in 1:10 bleach solution and c) 10 minute soak in 100% IPA". Also, were these sterilization methods mutually exclusive or performed sequentially? Page 4, Lines 50-51 - where are the results of the unpaired t-tests? There is no figure or table of results - just descriptive.

	Results Page 6, line 17 - please change to “N95 FFR comparable mask” Page 6, Line 26 - there is a “(5)” but not sure what this relates to. Page 6, Line 26 - replace “N95 mask” with “N95 FFR” Discussion Page 8, line 8 - please provide example(s) of certification testing Table S1 Are prices indicated in US dollars? Please specify for the sake of the reader. Please indicate the source of the listed prices

REVIEWER	Linh Phan Stanford University, United States
REVIEW RETURNED	05-Jun-2020

GENERAL COMMENTS	I would like to thank the authors for addressing my comments. Good work!

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

1. The authors have done an admirable job of responding to the concerns that were brought forward in the previous review. There are, however, some minor issues that remain outstanding which need to be addressed. Thank you for your excellent edits and comments. We have addressed these issues to the best of our abilities. Please see below.

2. Objective: please change to “N95 FFR comparable mask”. We have updated this to stay “N95 filtering facepiece respirator (FFR)-comparable face mask”. Please see *page 1, paragraph 1*.

3. Results: lines 8-9 reads awkwardly. We apologize and have updated the text to read more clearly. Please see *page 2, paragraph 2*.

4. Results: lines 10-11 the meaning is unclear. We apologize and have updated the text to read more clearly. Please see *page 2, paragraph 2*.

5. Conclusion: the authors mention OSHA fit testing but it was not specifically mentioned previously in the Methods section of the abstract. We have updated the methods to include OSHA-approved fit testing method. Please see *page 2, paragraph 1*.

6. Fourth bullet: The authors listed the departments of the participants here which is not mentioned in the body of the manuscript. Perhaps change to the types of job categories that were assessed as this would be more meaningful (and would be consistent with the information in the body of the manuscript). Thank you. We have updated this section to list the job categories instead of departments. Please see *page 2, bullet 4*.

7. “Materials” and “iMASC fabrication” have some overlap/duplication of presented information. We have deleted the duplicated information. Please see *page 3, paragraph 3*.

8. Page 4, lines 39 - 41 is repetitive with information found in earlier sub-sections in the Methods. Thank you, we have deleted the repetitive information. Please see *page 3, paragraph 4*.

9. Page 4, lines 43 to 45: in its current form, it is not clear if three different sterilization methods were tested. Consider “...sterilization methods including a) 10 cycles of autoclaving, b) 10 minute soak in 1:10 bleach solution and c) 10 minute soak in 100% IPA”. Also, were these sterilization methods mutually exclusive or performed sequentially? Thank you for edits. These

help to clarify the sterilization techniques. We have adjusted to the text to state that these methods were performed mutually exclusively. Please see *page 3, paragraph 4*.

10. Page 4, Lines 50-51 - where are the results of the unpaired t-tests? There is no figure or table of results - just descriptive. We apologize and have added the p values onto figure S2. Please see *supplemental information, figure S2*.

11. Page 6, line 17 - please change to "N95 FFR comparable mask". We have updated the text to reflect this change. Please see *page 5, paragraph 2*.

12. Page 6, Line 26 - there is a "(5)" but not sure what this relates to. We apologize for this error and have changed this to a superscript. Please see *page 5, paragraph 2*.

13. Page 6, Line 26 - replace "N95 mask" with "N95 FFR". We have updated the text to reflect this change. Please see *page 5, paragraph 2*.

14. Page 8, line 8 - please provide example(s) of certification testing. Thank you. We added examples of certification testing. Please see *page 7, paragraph 1*.

15. Are prices indicated in US dollars? Please specify for the sake of the reader. Please indicate the source of the listed prices. *We have updated the US dollars onto the table and included sources on the table. Please see supplemental information, table S1.*

Reviewer: 2

I would like to thank the authors for addressing my comments. Good work!
Thank you very much for all of your wonderful comments, edits, and recommendations.

VERSION 3 – REVIEW

REVIEWER	Chun-Yip Hon Ryerson University, Toronto, Ontario, Canada
REVIEW RETURNED	10-Jun-2020

GENERAL COMMENTS	The authors have addressed all of my previous concerns. The lone concern of mine is that I am not certain why the following sentence was removed in the Methods section, under the "Deformation" subsection. "Multiple levels of the reaction forces were exerted from the mask to the face, including F= 0 (undeformed), 4.5 (initial contact), and 10 (full contact) N". I personally believe that it should remain to allow another team to replicate the study as it is not mentioned elsewhere. Will leave this to the discretion of the editor whether the statement should be included.

VERSION 3 – AUTHOR RESPONSE

Reviewer: 1

1. The authors have addressed all of my previous concerns. The lone concern of mine is that I am not certain why the following sentence was removed in the Methods section, under the "Deformation" subsection. "Multiple levels of the reaction forces were exerted from the mask to the face, including F= 0 (undeformed), 4.5 (initial contact), and 10 (full contact) N". I personally

believe that it should remain to allow another team to replicate the study as it is not mentioned elsewhere. Will leave this to the discretion of the editor whether the statement should be included. Thank you again for all of your excellent reviews. We have added this back into the methods section. Please see page *4, paragraph 1*.