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The Mask Fitter, a Simple Method to Improve Medical Face Mask Adaptation Using a Customized 3D-Printed Frame during COVID-19: A Survey on Users' Acceptability in Clinical Dentistry

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Featured Application: The paper shows the procedure for producing a customized low-cost "Mask Fitter" made with a tablet-based 3D-face-scan and 3D-printing that could improve the sealing of FFP2 respirators.

Abstract: COVID-19 has deeply impacted clinical strategies in dentistry and the use of surgical masks and respirators has become critical. They should adapt to the person's facial anatomy, but this is not always easy to achieve. Bellus3D Company proposed to apply their face scan software, used with selected smartphones and tablets, to design and 3D-print a bespoke "Mask Fitter" to improve the sealing of surgical masks and respirators. Twenty dental staff participants were face scanned and a Mask Fitter for FFP2 respirators was designed and 3D-printed. Participants were asked to wear their Mask Fitter over one week and then completed a survey. Questions were asked about wearing comfort, sealing confidence, glasses or loupes fogging, both with and without the Mask Fitter. Dental staff gave positive feedback, with levels of comfort during daily use reported as similar with and without the Mask Fitter; and a higher confidence in achieving a proper seal, ranging from a 10% confidence rating of a proper seal without the Mask Fitter to 75% with the Mask Fitter. Moreover, fogging problems decreased considerably. The tested Mask Fitter device could represent an easy and low-cost procedure to improve the facial adaptation of the FFP2 respirator.

Keywords: 3D-face-scanning; 3D-printing; surgical mask; FFP2 respirator; mask fitter

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1. Introduction

After a report at the end of 2019 of unclear cases of pneumonia from China, in early 2020 the World Health Organization (WHO) declared the discovery of a new coronavirus, officially named SARS-CoV-2, with the resulting respiratory disease named COVID-19 (coronavirus disease) [1–4]. The disease continued to rapidly spread around the world, resulting in the declaration by the WHO of a pandemic [5,6]. Several countries have experienced a rapid dispersion of COVID-19, also related to the relatively easy transmission routes [7–9]. COVID-19 transmission is reported to occur through direct inhalation of droplets, coughing and sneezing or by contact with the mucous membranes of the oral cavity, the nasal cavity and the eye [10,11]. To et al. [12] reported a high concentration of SARS-CoV-2 in the saliva of people with COVID-19. Dental professionals are highly exposed to a risk of infection due to their exposure to saliva, blood and aerosol/droplet production during most dental procedures [13–16]. Therefore, the use of personal protective equipment (PPE), including gloves, masks, protective outerwear, protective surgical glass and shields, is strongly recommended to protect the eye, oral and nasal mucosa [13]. The

production of aerosols and droplets during routine dental procedures cannot be completely avoided, hence the generation of highly contaminated microbial aerosol [17,18]. PPE amongst the dental profession has become increasingly important, and use of facial masks, particularly, has also been recommended for most of the population during any kind of contact with other individuals. One of the fundamental pre-requisites of a surgical mask is its ability to properly adapt to the person's facial anatomy, creating a good seal to limit as much as possible the spread of bacteria and viruses. A good face mask seal is not always easy to achieve, especially since not all human faces allow an easy adaptation of the mask. To help address these surgical mask adaptation uncertainties, Bellus3D, a USA based company, (Bellus3D, Campbell, CA, USA) has developed a system for which a custom adapted low-cost Mask Fitter can be easily and rapidly produced. The Mask Fitter has already been reported to be potentially effective in an ophthalmology related study in which a quantitative fit test (QNFT) was performed [19]. More recently, another study still performed with a QNFT on dentists reported that the 3D printed frame fitted over a surgical mask offers advantages comparable to those offered by FFP2 respirators in terms of marginal fit. However, surgical masks do not offer the same protection in terms of filtering capacity, thus the use of surgical masks with mask fitter could be considered only as a replacement in case of a FFP2 shortage [20].

The aim of the present study was to evaluate several aspects of the use of the Mask Fitter produced and delivered to a cohort of dental staff, in general practice settings, particularly concerning low-, medium- and long-term (full day) wearability.

2. Materials and Methods

The process for the fabrication of the Mask Fitter requires a face scan, followed by the design and 3D-printing of the Mask Fitter. For a face scan process, several options are available including photogrammetry, stereophotogrammetry, laser-beam scanning and structured light scanning [21]. An easy-to-use alternative is the "face ID" system implemented in the more recent generations of smartphones and tablets. The smartphones that at present can be used are any iPhone™ with a TrueDepth™ camera (iPhone X onwards), or an iPad Pro™ (all generations). For this survey, an iPad Pro 1st generation was used. The necessary software, Bellus3D Dental Pro, can be downloaded from the Apple store. Bellus3D Dental Pro is available as a free download for basic features offering in-app purchase for advanced functionalities. This face scan system has been reported to allow trueness and precision in a clinically acceptable range [21,22]. The design of the Mask Fitter has different options. The basic version of the Mask Fitter for a surgical mask can be generated and exported free of charge, whilst the generation of the Mask Fitter with holders' name or the FFP2 ("tall") version require payment of a USD 1.99 (USA currency) fee. After installing the software, the face scan acquisition procedure is straightforward. It consists of a voice guided procedure requiring a simple left, right, up, and down sequence of head movements (Figure 1).

Figure 1. Face scan acquisition procedure.

Of the three available scanning options (face, face + neck, full head) the second one is recommended by the authors of the present paper for the Mask Fitter purposes. Option one (face only) takes an insufficiently detailed scan of the chin area, while option three (full head) is redundant as the back of the head is not involved in the Mask Fitter design. At the end of an approximately 30 s scan process, followed by another approximately 20 s for data computing, the 3D-representation of the face is generated. After selection of the function "mask fitting" and subsequently the selection of the desired design ("standard" for surgical masks, "tall" for FFP2), a Mask Fitter consisting of an anatomic frame is automatically designed by the software with a 10 s processing time (Figure 2a).

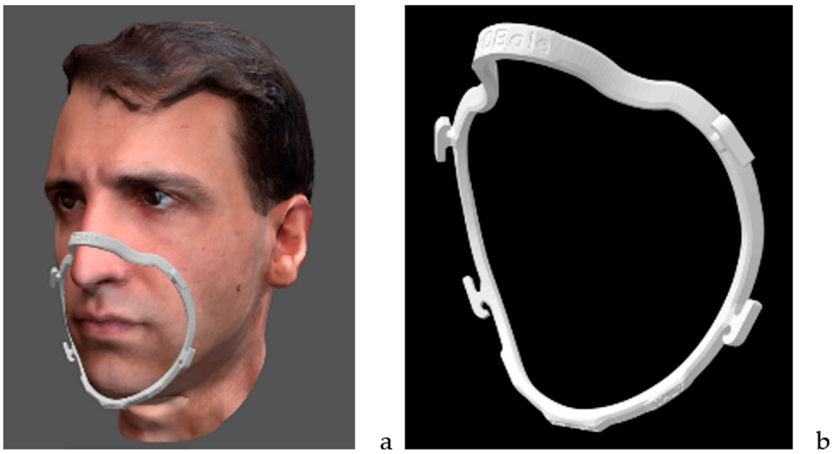

Figure 2. (**a**,**b**): The Mask Fitter design generated by the software.

The generated Mask Fitter design can then be exported as a .stl file (Figure 2b). The free version of the software does not allow the face-scanning to be saved, but it does allow the sending of the .stl file of the generated design of the Mask Fitter via email. Once the file is received by email it can be 3D-printed. Partner services are suggested from the Company itself, but any 3D-printing services, available online at different, but reasonable prices (e.g., GBP 10–15 UK currency), can be used. Alternatively, and more conveniently, the Mask Fitter can be printed by any Office, Department, University, Company, Dental Laboratory or even personal 3D-printer (Figures 3–5) as there are no special requirements for the printer and the material. A basic Stereolithography (SLA—Resin) 3D-printer or a basic Fused Deposition Modeling (FDM—filament) 3D-printer can efficiently 3D-print the Mask Fitter.

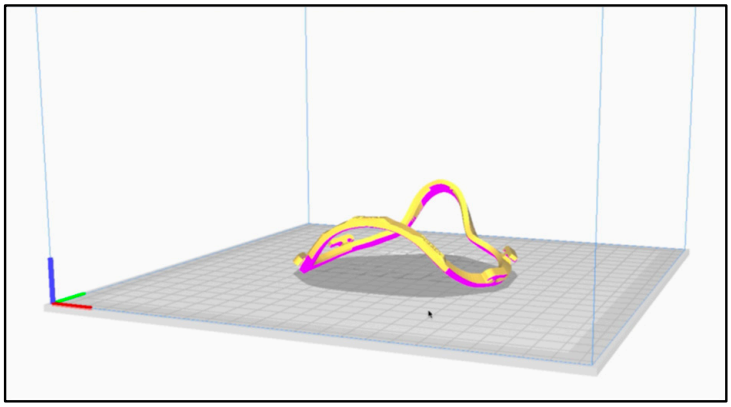

Figure 3. A GCode is generated by a 3D-printing slicing software (Ultimaker Cura).

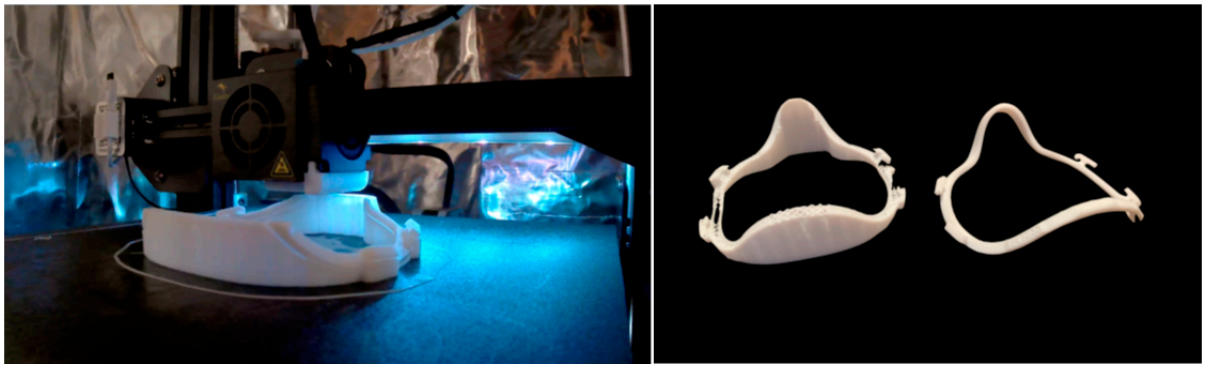

Figure 4. A 3D-printing process with a personal filament 3D-printer (left) and the Mask Fitter after printing and finishing.

Figure 5. The Mask Fitter adaptation to the scanned face anatomy.

For the present study, a total of 20 dental staff were recruited for this service evaluation selected following "convenience sample" selection criteria, and they voluntarily agreed to try the Mask Fitter. A written consent was obtained from each of the participants, by which they agreed to participate in the study and to have their data used as part of the research. They were face-scanned and then their Mask Fitters were 3D-printed as previously described. The emailed .stl files were processed for slicing with the software Ultimaker Cura 4.7.1 (Ultimaker BV, Utrecht, The Netherlands) and 3D-printed with the printer Anycubic Mega S (Anycubic, Shenzhen, Guangdong, China) set with Generic Polylactic Acid (PLA), Profiles 0.1 mm and Infill 100%. PLA and Acrylonitrile Butadiene Styrene (ABS) are the recommended filament, but there are no specific restrictions providing the printed surfaces are not porous. PLA and ABS can be disinfected by immersion in the disinfecting solution recommended for each material. The Mask Fitter is placed on the external side of the surgical mask, and thereby does not need any special biocompatibility or antiallergic properties. For the present survey, the filament 1.75 mm PLA 3D-Printer Filament (Anycubic, Shenzhen, Guangdong, China) in grey shade, was used. This is a biodegradable filament made from lactic acid, produced via starch fermentation during corn wet milling. The available information for this material is: Diameter 1.75 $\pm$ 0.02 mm, Tensile strength $\geq$55 MPa, Hardness HRC 105–110, Density 1.25 g $\pm$ cm^3. For the present study, it has been 3D-printed with the nozzle temperature at 210 °C and printing platform at 60°.

The fitter is designed with hooks and is secured to the FFP2 mask elastic band by means of these hooks (Figure 6).

Figure 6. The Mask Fitter positioning.

After a preliminary phase designed to achieve a comfortable fit of the Mask Fitter, the subjects involved in the study were asked to wear the FFP2 for: (i) 1 h (short-term use, simulating a single patient treatment time); (ii) 4 h (mid-term use, simulating half-day work); and (iii) 8 h (simulating full-day work), with and without the Mask Fitter. A Google form survey was designed with 27 questions. The 20 dental staff were invited to complete the survey in order to provide a preliminary report on some aspects of PPE use, and on the acceptance and first impressions of its daily use.

3. Results

The survey and its results are reported in Table 1 (Demographic data); Table 2 (Prior to COVID-19); Table 3 (After COVID-19); Table 4 (The Mask Fitter); Table 5 (Fogging). Numbers refer to the relative question of the survey. Responses were received from all the participants (20).

Table 1. Section 1: Demographic data.

Demographic Data				
1. Age	20–29	30–39	40–49	50+
	0 (0%)	6 (30%)	5 (25%)	9 (45%)
2. Gender	Male	Female	Non-binary	Prefer not to say
	5 (25%)	15 (75%)	0 (0%)	0 (0%)
3. Qualification	Dentist	Dental Nurse	Dental Hygienist	Other
	7 (35%)	11 (55%)	2 (10%)	0 (0%)

Table 2. Section 2: Prior to COVID-19.

Prior to COVID-19				
4. Prior to COVID-19 did you routinely wear a face mask?				
Yes	No			
19 (95%)	1 (5%)			
5. If you wore a mask was it:				
All the time	Only for contact with patients	Only for treating patients	Only for aerosol generating procedures	
5 (25%)	4 (20%)	7 (35%)	4 (20%)	
6. What type of mask was it? (more than one choice allowed)				
Simple face mask (e.g., acrylic screen)	Surgical face mask	FFP2	FFP3	other
9 (45%)	20 (100%)	0 (0%)	0 (0%)	1 (5%)
7. For how many years have you been wearing a mask of any type?				
0–5	6–10	11–20	20+	
3 (15%)	2 (10%)	7 (35%)	8 (40%)	

Table 3. Section 3: After COVID-19.

After COVID-19				
8. What type of face mask do you currently use? (more than one choice allowed)				
Simple Face Mask (e.g., Acrylic Screen)	Surgical Face Mask	FFP2	FFP3	Other
17 (85%)	10 (50%)	20 (100%)	1 (5%)	2 (10%)
9. How easy is it to achieve a comfortable fit of your mask on your face?				
Very easy	Easy	Medium	Difficult	Very difficult
0 (0%)	0 (0%)	4 (20%)	5 (25%)	11 (55%)
10. Over short-term use (up to one hour) how comfortable is your mask?				
Very low	Low	Medium	High	Very high
0 (0%)	0 (0%)	9 (45%)	6 (30%)	0 (0%)
11. Over mid-term use (up to four hours) how comfortable is your mask?				
Very low	Low	Medium	High	Very high
0 (0%)	3 (15%)	11 (55%)	6 (30%)	5 (25%)
12. Over long-term use (full working day) how comfortable is your mask?				
Very low	Low	Medium	High	Very high
3 (15%)	9 (45%)	6 (30%)	2 (10%)	0 (0%)
13. How confident are you that you have achieved an effective seal?				
Very low	Low	Medium	High	Very high
0 (0%)	3 (15%)	8 (40%)	7 (35%)	2 (10%)
14. Do you think that a customized face mask adapted to you face anatomy would be beneficial?				
Yes	No	Do not know		
15 (75%)	1 (5%)	4 (20%)		

Table 4. Section 4: The Mask Fitter.

The Mask Fitter				
15. How easy is it to achieve a comfortable fit of the Mask Fitter on your face?				
Very low	Low	Medium	High	Very high
2 (10%)	1 (5%)	5 (25%)	7 (35%)	5 (25%)
16. Over short-term use (up to one hour) how comfortable is your Mask Fitter?				
Very low	Low	Medium	High	Very high
2 (10%)	2 (10%)	6 (30%)	6 (30%)	4 (20%)
17. Over mid-term use (up to four hours) how comfortable is your Mask Fitter?				
Very low	Low	Medium	High	Very high
2 (10%)	5 (25%)	8 (40%)	6 (30%)	2 (10%)
18. Over long-term use (up to eight hours) how comfortable is your Mask Fitter?				
Very low	Low	Medium	High	Very high
5 (25%)	8 (40%)	5 (25%)	2 (10%)	0 (0%)
19. How confident are you that you have achieved an effective seal with the Mask Fitter?				
Very low	Low	Medium	High	Very high
0 (0%)	1 (5%)	1 (5%)	3 (15%)	15 (75%)
20. How would you rate the cleaning procedure for the Mask Fitter?				
Very difficult	Difficult	Medium	Easy	Very easy
0 (0%)	0 (0%)	1 (5%)	4 (20%)	15 (75%)
21. Would you routinely use the Mask Fitter to improve the FFP2 seal?				
Yes	Only for selected patients	Only for selected procedures (aerosol-generating)	For both selected patients and procedures	No
5 (25%)	0 (0%)	3 (15%)	10 (50%)	2 (10%)

Table 5. Section 5: Fogging.

Fogging				
23. Do you wear loupes?				
Yes	No			
3 (15%)	17 (85%)			
24. Do you wear glasses?				
Yes	No			
13 (65%)	7 (35%)			
25. Is loupes or glasses fogging a problem when wearing FFP2 without Mask Fitter? (only for those answering yes to either question 22 or 23)				
Very low	Low	Medium	High	Very high
1 (6.7%)	3 (20%)	4 (26.7%)	5 (33.3%)	2 (13.3%)
26. Is loupes or glasses fogging a problem when wearing FFP2 with the Mask Fitter? (only for those answering yes to either question 22 or 23)				
Very low	Low	Medium	High	Very high
6 (40%)	5 (33.3%)	3 (20%)	0 (0%)	1 (6.7%)

22. Can you please give the reason (for your answer to question 21)?

18 responses received.

The comments broadly followed the response to question 21, "for both selected patients and procedures" and "positive comments".

For both selected patients and procedures

Wearing all the time is heavy but for selected procedures and patients it is fine.

Breathing is anyway more difficult and without it, thus I would say that selected patients and procedures would be better.

Positive comments

Better seal and no fogging on screen even when used for a long time.

I have a thin face and all the masks (with the only exception of 3 M Aura which is a FFP3) have sealing problems.

Better seal thus better protection.

A final overall comment was posed to the participants

27. Any other comments that you have regarding face masks or Mask Fitter

12 responses which centred on pressure on the nose.

Nose is a little compressed.

Easier to fit than the other protections. Nose is a problem because my glasses and my screen go on the nose, thus the position of the filter (on the nose) is not "free" and gives some pain after hours of use.

The fitting is never perfect. Without elastic bands it creates problems for the ears. With the elastic bands it creates problems to the nose and chin.

4. Discussion

It is known that FFP2 masks can provide an efficient filter against droplets responsible for the transmission of the COVID-19 infection. The more the FFP2 is securely adapted to the face, the better the seal, thereby preventing the spread of infection. Fit testing is mandatory in some countries e.g., in the United Kingdom and has been employed to ensure masks (FFP2 and FFP3) fit adequately to ensure a good seal for people working in public health systems.

In dentistry, great attention has been directed towards Aerosol Generating Procedures (AGP) such as ultrasonic scaling and use of a high-speed air turbine handpiece with water. During these procedures, aerosols are generated, and the possibility to be infected is high. The "Mask Fitter" is an attempt to help dental professionals wearing masks in clinical environments to improve the seal of the mask.

Concerning the Survey, Section 1, questions 1, 2 and 3 reported demographic data. Of the 20 dental staff participants, 30% were aged 30–39 years, 45% were aged 40–49 years and 55% were 50+ years old; and 75% were female. The dental staff comprised Dentists 35%, Hygienists 10%, and Dental Nurses 55%. The dental staff who participated in the study came from 4 different general dental practices.

Section 2 concerned the use of PPE prior to the COVID-19 pandemic. In question 4, 95% of the dental staff declared that they already routinely used a protection system with only one exception. All of the dental staff used the surgical face mask, 45% a shield with or without the surgical mask. In question 5, before COVID-19, 20% wore a mask all the time, another 20% only when having clinical contact with patients, 35% when treating patients and only 25% wore a mask all the time. As expected, the situation changed substantially after the COVID-19 health emergency (Section 3).

Dental staff declared the use of a wide range of protection, with FFP2 adopted by 100% of the participants. Face shields were also widely used in combination with FFP2 masks. Surgical masks were still used but mostly overlaying the FFP2 as an additional layer of protection, with a view to replacing the surgical mask between patients, retaining the FFP2 mask which has a higher cost and at least early in the pandemic were much harder to source. Only one operator reported using a FFP3 mask (with valve and surgical mask overlying) and 2 reported using alternative systems such as an open helmet and special glasses resembling a scuba diver mask, both used with FFP2.

Fitting and ease of use of the FFP2 (question 9) was reported to be medium to very high for all the staff members involved, showing that this PPE is now routinely used in daily practice. However, the wearing of FFP2 masks is considered to be tiring. In questions 10, 11 and 12 dental staff reported that wearing the mask is comfortable for up to 1 h (rating 3, 4 or 5 out of 5), reducing between 1 to 4 h (rating 2, 3 and 4 out of 5), and further reduced comfort over a full day of use (rating 1 to 4 out of 5 with 45% rating 2).

Confidence in obtaining a proper seal (question 13) was widely reported, with 15% rating 2 out of 5, 40% rating 3, 35% rating 4 and only 2% rating 5 out of 5. This means that dental staff were wearing the FFP2, but they still had some concerns regarding its efficacy. Interest in a system designed to improve this efficacy (question 14) was 75% with only 1 staff member answering no (Figure 7).

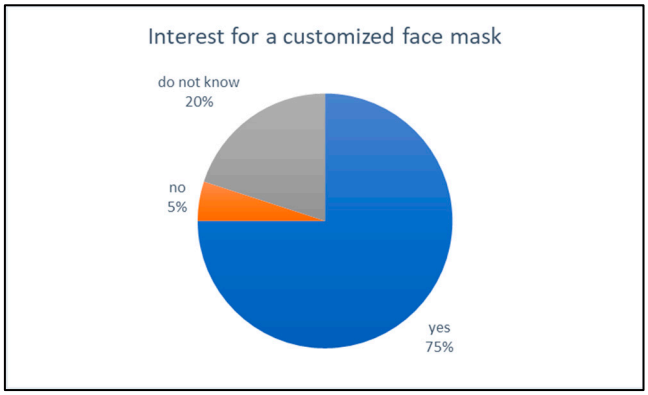

Figure 7. Interest for a customized device.

Section 4 evaluated the Mask Fitter.

Concerning the ease of wearing the Mask Fitter (question 15), the outcome was widespread, with 10% of dental staff rating 1 out of 5, 5% rating 2, 25% rating 3, 35% rating 4 and 25% rating 5. In total 85% rated the ease of wearing from medium to very high.

Wearing (questions 16, 17 and 18) was reported to be comfortable over time, within one hour (3 out of 5 for 30%, 4 for 30%, 5 for 20%). The percentage decreased when worn 1 to 4 h, as well as all day long, with only 10% still rating 4 and no one rating 5 at the end of the working day.

Interestingly, even if slightly differently distributed, the percentage from medium to very high levels of comfort at the end of the day were globally very similar both without and with the Mask Fitter (respectively 40% and 35%), showing a good acceptance of this extra item (Figure 8).

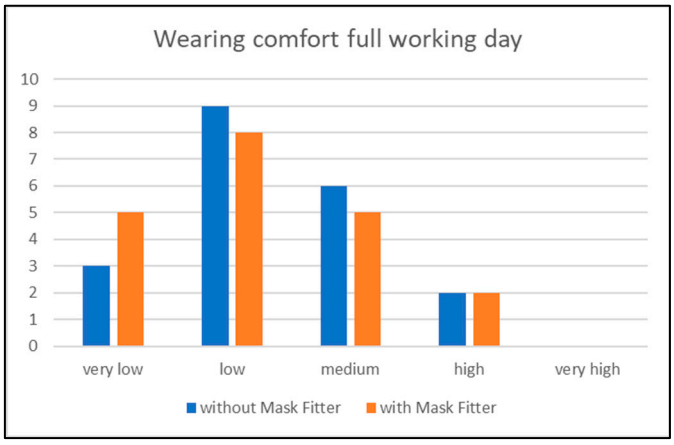

Figure 8. Wearing comfort over full working day, without and with Mask Fitter.

A remarkable outcome from this service evaluation was question 19 where dental staff declared, when wearing the Mask Fitter, to have reached a higher confidence on obtaining a proper seal with 75% rating 5 out of 5. The difference with the same data without the Mask Fitter (only 10% rating 5 out of 5) was impressive (Figure 9).

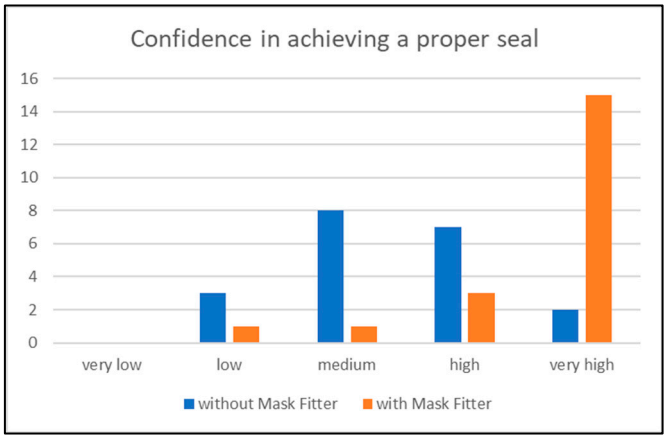

Figure 9. Confidence in achieving an appropriate seal with and without Mask Fitter.

In question 20, 75% of the dental staff rated 5 out of 5 the ease of cleaning the face mask (performed by immersion in disinfectant). When asked (question 21) if they would introduce the Mask Fitter routinely, 25% of the staff stated that they would use it all the time, while 65 % declared that they would use it for selected patients, or procedures, or both. Only 10% reported that they would not use the Mask Fitter (Figure 10).

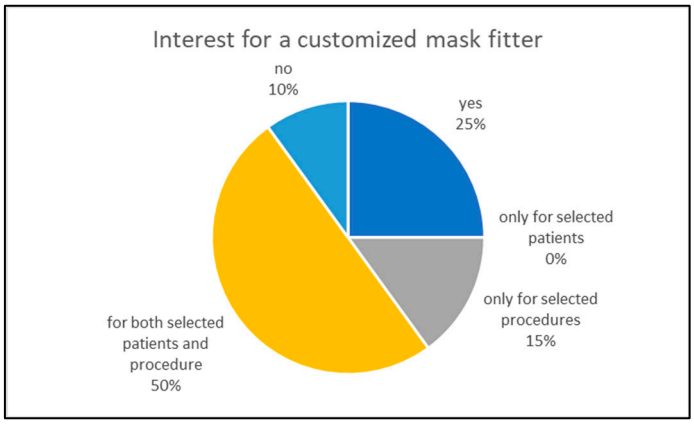

Figure 10. Interest in wearing the Mask Fitter routinely.

Question (22) invited free text feedback from the participants on the reasons for their responses to question 21. The reasons for not adopting the routine use of the Mask Fitter were that people feel sufficiently safe with the FFP2 alone. The most frequent reason for not adopting the Mask Fitter for continuous use, but more likely for patients and/or selected procedures, was that wearing the Mask Fitter all the time was tiring. Therefore, its use for limited situations such as aerosol generating procedures or for those occasions when patients declare no symptoms at the COVID-19 triage stage, with the absence of a fever, but there may be some uncertainty due to a sporadic cough and/or the need to occasionally blow their nose, might be the appropriate indication for the Mask Fitter.

Section 5 focused on the effect of wearing the Mask Fitter on the fogging of glasses or loupes. From questions 23 and 24 it was reported that only 15% of the participants used loupes, while 65% wore glasses. A total of 25% of the participants wore neither loupes nor glasses, thus they did not answer the following two questions (25 and 26). Even if the distribution of the fifteen answers related to fogging was quite widespread, the effect of

the Mask Fitter looked beneficial. Without the Mask Fitter (question 25), the participants reported a total of 73% medium (3 out of 5) to very high (5 of 5) fogging problems, that decreased to a total of 27% (question 26) when wearing the Mask Fitter, thus showing a high capability to reduce fogging problems (Figure 11).

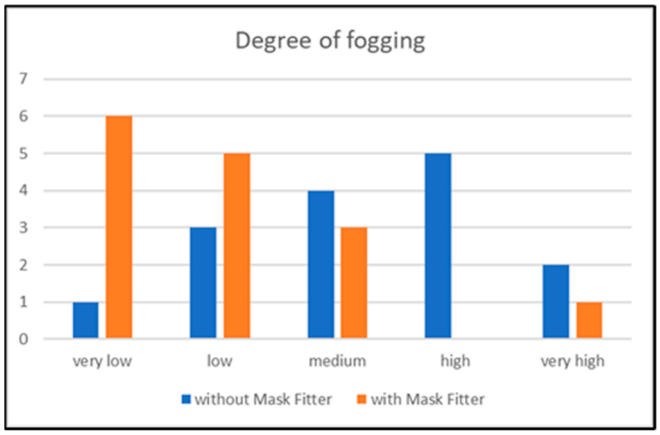

Figure 11. Effects of Mask Fitter on fogging of loupes and glasses.

The last question of the survey (question 27) invited free text answers on the use of the Mask Fitter. There were some reported problems in obtaining the proper adaptation using a trial-and-error procedure for obtaining an appropriate tightening with or without the use of an additional rubber band on the back of the head. Staff reported that once a good adaptation was obtained, it was easy to be reproduced when worn again. They commented on a sense of constriction on the nose and consequent oral breathing. Some participants reported that due to the position of the nasal arch, even light pressure immediately made it difficult to breathe through the nose. This might be due to a possible slight deformation on the face scan in the nasal area, as reported by Alisha et al. [23]. Participants generally agreed that this is the main aspect requiring improvement, even if none of the participants reported any sores and/or scars. The authors of the present paper consider proposing to the Company an optional function to be implemented in the software that could allow to "lift" the nose arch by a small amount, e.g., 0.5, 1.0, 1.5, 2.0 mm, both in the vertical and lateral dimension, to improve the wearability of the Mask Fitter, reducing the pressure on the nose. Alternatively, the application of a patch on the nose before face-scanning is another possible option to investigate. Another alternative that can be explored is the 3D-printing of polymers less rigid than the PLA used in the present study, like Polyethylene Terephthalate Glycol-modified (PETG), Thermoplastic Polyurethane (TPU) or Thermoplastic Elastomer (TPE). Further research is also required to categorize the variations in facial anatomy, which may explain the differences in comfort reported. A further study is in progress aimed at evaluating whether dental staff tested for mask sealing efficacy, and not passing the test, could have a beneficial effect from the use of the Mask Fitter. In the future, the use of different three-dimensional digitation technologies, or virtualization, reverse engineering and development of numerical methods could also be evaluated.

5. Conclusions

Dental staff using the bespoke Mask Fitter reported positively, with levels of comfort during daily use comparable with and without the Mask Fitter. Moreover, a much higher confidence in achieving a proper seal was reported. Moreover, fogging problems decreased considerably. Based on this preliminary survey, it can be concluded that the Mask Fitter device designed by Bellus3D received a good acceptance by Dental staff and therefore could represent an easy, low-cost procedure to improve the adaptation of the FFP2 mask.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to the university policy on access.

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