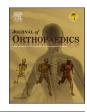


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Design, usage and review of a cost effective and innovative face shield in a tertiary care teaching hospital during COVID-19 pandemic



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ABSTRACT

Background: A major challenge of the coronavirus pandemic is personal protective equipment (PPE) shortage.
 The open source community mobilised solutions to combat this using 3D printing technology. One such solution was the face shield, which protects facial areas from droplet contamination when used by orthopaedic and other front line health care workers (HCWs).
 Objectives: To assess the efficacy of an in-house developed face shield based on feedback by HCWs and its usage in triaging zones and operation theatre in a tertiary care hospital.

Methods: A protective face shield was developed and distributed among the orthopaedic surgeons and front line HCWs involved in the ICU in our hospital and neighbouring facilities. Feedback was obtained using a questionnaire utilising a Likert scale.

Results: 227 face shields were distributed to the HCWs in our hospital (157) and neighbouring facilities (70). Design modifications were done as per the needs of the HCWs. 37 HCWs provided feedback giving the face shields an overall mean score of 7.92 out of 10. The poly vinyl chloride (PVC) film visors were better for airway management procedures as it can be tucked into PPE suit and visors with overhead projector (OHP) sheets were suitable for ICU and operative procedures.

Conclusion: A locally developed face shield design by an inter disciplinary team in synchrony with HCWs is found to increase its acceptability and efficacy. Face shields can be made more effective in different triaging and treatment situations by varying the device setup.

1. Introduction

Coronavirus disease or COVID-19 as labelled by the World Health Organization (WHO) has spread rapidly affecting more than 5,000,000 people in more than 210 countries.¹ The rapidity of its spread has placed an enormous burden on hospitals and other healthcare facilities. This accompanied with nation-wide lockdowns have hampered the availability and accessibility of required personal protective equipment (PPE).² The open source community emerged with cost effective solutions that could be developed locally like face shields, masks, etc. These solutions are being widely propagated in urban areas with large scale 3D printing facilities and Maker labs. However, the disbursement of said products to hospitals and clinics in smaller cities and towns is hindered due to the lockdown imposed and travel restriction within the country. In such cases, innovative design and in-house production becomes crucial to get the best functional outcomes in the production of PPE. The presence of a 3D printing facility at our institution enabled the immediate creation of protective face shields tailored to the needs of the Healthcare Workers (HCWs) at our hospital.

At first glance, compared with the field of infectious diseases and emergency medicine, the role of an orthopaedic surgeon in controlling this outbreak may, on the surface, appear to be limited. However, as part of the larger health-care ecosystem, orthopaedic surgeons play an important role in controlling the pandemic. In light of the COVID-19 outbreak, changes in clinal practice have been guided by three primary principles: 1. Clinical urgency 2. Patient and HCW protection and

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3. Conservation of health care resources.³ On these principles, changes to surgical and outpatient care have been made in hospitals especially with the stoppage of elective cases. Despite these changes in clinical practice, a large percentage of orthopaedic surgeons continue to perform unavoidable trauma surgeries.⁴ Orthopaedic surgeons and postgraduate residents are a part of emergency triage team in tertiary care teaching hospitals involved in frontline care of both COVID and non-COVID patients. In orthopaedic surgical procedures, power tools like bone saw, reamers, and drills are shown to produce aerosols.⁵ Thus, in the light of coronavirus pandemic which can propagate through aerosolized, droplet and contact contaminations⁶ the use of a face shield becomes imperative for orthopaedic surgeons in all these clinical settings.

A face shield is classified as a PPE that provides protection to the facial area and related mucous membranes (ear, nose and mouth) from splashes, sprays and splatter of bodily fluids.⁷ It is mostly used in conjunction with level D PPEs, which are commonly utilized by first receivers in hospitals and other facilities.⁸ In light of the coronavirus pandemic, which is spread primarily through aerosolized contaminants and droplet and contact infection,⁶ there are recommendations to use face shields as part of the PPE by the World Health Organization (WHO),⁹ and many other such organisations. Out of the four PPE for the facial region namely, Full face shield, Full face shield with N95 respirator; the Full-face shield with N95 respirator is the most effective.¹⁰

With technical experts mobilizing to help front line HCWs, face shields are being produced in large numbers as they can be made by readily available materials. Methods of manufacture range from easy Do It Yourself (DIY) options to 3D printed options. Face shields are used as alternatives to goggles as they extend protection to other facial areas apart from the eyes and protect from splashes, sprays and aerosolized contaminants. Lindsley et al.¹¹ experimented to gauge the efficacy of face shields against coughs using a coughing patient simulator and a breathing worker simulator. They found that, for an influenza laden aerosol with a volume mean diameter (VMD) of 8.5 μ m, face shields reduced inhalation exposure by 96% and surface contamination of a respirator by 97% immediately after a cough at a distance of 45.7 cm. With smaller cough aerosols of VMD 3.4 µm, the face shield blocked 68% of the inhalation exposure and 78% surface contamination. If the aerosol is allowed to disperse in a room, the effectiveness of the face shield reduces and it blocks inhalation by 23%. Suboptimal adherence to wearing face shields during aerosol generating procedures was identified by Tak Ching et al.¹² as an independent risk factor associated with the acquisition of an influenza like illness by health care workers. Shmuel Shoham et al.¹⁰ performed a comparative test on the protection of ocular contamination with different disposable eyewear products. They sprayed a fluorescent dye onto a mannequin wearing the safety apparatus from a distance of 127 cm and assessed mucosal contamination visually at ambient and UV light and found the Face Shield with N95 respirator produced the best results. Thus, there is substantial evidence of the effectiveness of face shields against aerosolized or droplet infection for HCWs.

This article explores the in-house design, manufacture and usage of protective face shields in various clinical settings of triage, ICU and operation theatre by orthopaedic surgeons and frontline emergency care workers during COVID 19 pandemic in a tertiary care teaching hospital.

2. Methodology

2.1. Development of face shield

A face shield is simple in its construction consisting of three parts: the frame, an elastic band for fastening and a clear plastic visor. The face shield presented in this article was created at the 3D printing centre at our institution. It needed to fulfil the following parameters: fast production, easy disinfection, and end user comfort. Multiple face shield

designs were printed and utilized by the HCWs and based on their response, the final model was established.

The process began by 3D printing and testing available open source face shield models like the Prusa Protective Face shield. Models like these were assessed by the HCWs and based on their feedback, we began the design process for the face shield presented in this article. The comparison and the design modification between open source and our design is shown in Fig. 1. The frame was designed using Autodesk Fusion 360 (Fig. 1). It has an inner and an outer band. The inner band rests on the forehead of the user and the outer band is meant to house the plastic visor. This design allows an offset to be maintained between the visor and the face of the user. The offset was further extended when required by using clip on extensions with a U-shaped frame perpendicular to the face shield (Fig. 1). The U-shaped frame provides structure to the lower part of the visor. The extended offset is vital when surgeons need to use a hood over the PPE jumpsuit and wear eye protection goggles and N95 masks inside the hood. The necessary offset to accommodate the goggles and N95 mask increases user comfort and provides an opportunity to create an exhaust at the top of the hood to prevent fogging during surgery. We used a one-inch thick nylon elastic bands attached to the frame to provide more comfort which was anchored to the protrusions at the ends of the frame.

The plastic visor can be any clear plastic sheet. The sheets used in this study were soft 0.125 mm Polyvinyl Chloride (PVC) film and stiff A4/A3 Overhead Projector (OHP) sheets. The PVC film was chosen because of its soft and malleable form, allowing it to be inserted into the PPE gown which can provide a greater degree of protection during procedures such as wound care, dressings, traction and those involving the airway at triage area and ICU. The stiff OHP sheet was also an alternative because it can be cleaned easily and can be used by HCWs not utilising the level D PPE gown as it maintains its shape and provides good visibility. This was used in wards and operation theatre predominantly. These are attached to the frame using either paper or binder clips. The use of binder clips is essential to the design as it reduces the manufacturing effort in negating the need for punching holes into the plastic visors. It also allows for quick disassembly and can be disposed off and replaced if contaminated. The steps in the assembly process can be seen in Fig. 2.

2.2. Manufacture

Additive manufacturing (3D printing) was used for the face shield designed above. The material used was polylactic acid (PLA). The print settings were optimized to achieve the lowest time possible on the given printer: 0.25 mm layer height, 20% infill, and 2 shells. The model takes 1 h and 59 min to print and uses 20.2 g of PLA material. The settings can be adjusted on different 3D printers to yield faster prints. The model can also be stacked one on top of the other to maximize overnight printing efficiency. The total cost of production amounts to INR 75/- making this an economical device considering the capacity for reuse.

2.3. Disinfection of the face shields

The face shields can be reused and it is important that each healthcare professional using the face shields must be assigned one dedicated device for use, disinfection and reuse.¹³

Prior to disinfection, the face shield set-up must be disassembled. Face shields with the PVC film visor need to discard the visor after use and replace it for the next cycle of use. Face shields with the OHP sheet as the visor can have the OHP sheet changed if it is excessively scratched, damaged and it impairs user vision. The disinfection procedures to be followed are as per the recommendations by the CDC with standard disinfection solutions like isopropyl alcohol or sodium hypochlorite and perform proper hand hygiene later^{13.} It is advised to discard the paper or binder clips after a cycle of use, however in situations requiring reuse they can be disinfected using an EPA registered hospital disinfectant solution.

Open Source Face Shield Models:

Fig. 1. Top: Open Source Face Shield Frames; Bottom: Face Shield Frame designed as per HCW Feedback.

elastic band

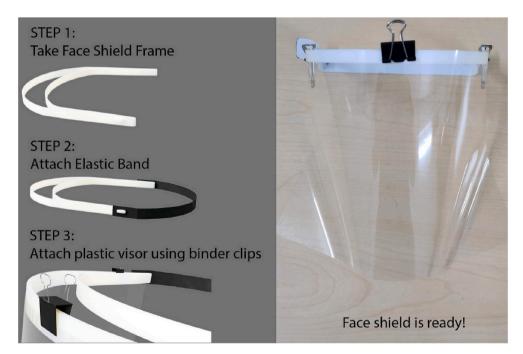


Fig. 2. Face shield assembly.

2.4. Usage in a tertiary care centre

options:

The face shields were distributed to the HCWs in our hospital to a cohort of orthopaedic surgeons, emergency medicine physicians, and nurses. The institutional triage guidelines for COVID-19 patients/suspects based on Indian Council of Medical Research (ICMR)¹⁴ guidelines led to the setup of different zones in the hospital: Hot zones: areas of treatment for COVID patients/suspects, Warm zones: areas of possible contact with COVID patients such as help/registration desks, and Cold zones: the other areas of the hospital that are not directly involved with COVID patient care. The face shields were provided with three setup

Outer Band

1. In Intensive Care Units in Hot zones: PVC film or A3/A4 size OHP sheets was used for the visor in conjunction with an N95 respirator and/or goggles according to the WHO guidelines.⁷

Extensions with U Frame

- 2. In NON-COVID triage: A3/A4 size OHP sheets was used as the visor of the face shield to provide basic splash and droplet protection.
- 3. In Orthopaedic Operation Theatre (OT): When using the PPE hood for Covid or Covid suspect patients, the face shield frame was used in conjunction with the hood to provide an offset between the face and

the hood visor to accommodate the eye goggles and the N95 mask for greater comfort.

A questionnaire (Table 1) was designed to gain feedback on the devices. The questionnaire uses a Likert scale to record the responses, with the range: 0–3 indicating a negative response, 3–6 indicating a neutral response, and 6–10 indicating a positive response. Following the use of the face shields after a duration of two weeks, the questionnaire was filled by the end users.

3. Results

A total of 227 face shields were printed of which 157 were distributed to the HCWs in our hospital with the options for using PVC film or the OHP sheet. An additional 70 shields were distributed to other local clinics and hospitals. We obtained a feedback from 37 healthcare professionals of our institute during the design and manufacturing phase of these protective face shields. The results of the feedback can be seen in Table 2. Thus, the feedback makes it evident that the protective face shield was well received by the end users and hence we could finalise the design and release it for larger use to become an essential part of the PPE.

The orthopaedic surgeons found the face shields with stiff OHP sheets useful during the triage duties where patient interaction involved wound care, splinting and traction application. In the wards and ICU, all groups of health care workers found the face shields with the soft PVC film to be effective during airway management and other aerosol generating procedures as they could insert the PVC film visor into the level D PPE gown to provide a complete closure of the facial region albeit with an opening at the top for ventilation. The feedback also shows positive reception to the face shield setup compared to existing devices like the conventional PPE hood setup (Question 8 of the feedback questionnaire). The HCWs found the face shield with the stiff OHP sheets to be better suited for patient care not requiring the donning of the level D PPE gown as it provided better visibility. The Orthopaedic Surgeons in OTs found the use of the face shield frame with an offset inside the PPE hood increased their comfort during surgery. The images for the different setups (face shield with PVC film, face shield with OHP sheet, and face shield with PPE hood) can be seen in Fig. 3.

4. Discussion

Shortage and ineffective implementation of PPE were the primary reasons behind the high number of infected healthcare workers during

Table 1

Questionnaire for feedback on 3D printed Protective Face Shield.

Answer on a scale of 0–10: 0 1 2 3 4 5 6 7 8 9 10	
0-3: negative response,	
3-6: neutral response.	
6-10: positive response.	
Questions:	Score
1. Ease of use (wearing and removing)	
2. Visibility during the procedures	
3. Comfort during the procedures	
4. Ease of Assembly	
5. Ease of disassembly	
6. Ease of cleaning	
7. Confidence to reuse	
8. How strongly do you prefer to use the face shield setup provided vs	
alternative devices (conventional PPE hood set up)?	
9. How strongly do you prefer to use the face shield vs no face shield?	
10. Acceptability in wearing the face shield along with spectacles/goggles?	
11. Comfort during the procedure wearing the face shield along with spectacles/goggles?	
12. Ease of use (wear and remove) the face shield along with spectacles/ goggles?	

Table 2

Feedback obtained from the end users.

Question	Mean	Standard Deviation (SD)
1. Ease of use (wearing and removing)	8.43	1.59
Visibility during the procedures	7.34	2.27
3. Comfort during the procedures	7.98	2.38
4. Ease of Assembly	7.98	1.79
5. Ease of disassembly	8.76	1.99
6. Ease of cleaning	7.78	2.66
7. Confidence to reuse	7.68	2.23
 How strongly do you prefer to use the face shield setup provided vs alternative devices (conventional PPE hood set up)? 	7.58	1.98
 How strongly do you prefer to use the face shield v/ s no face shield? 	8.76	1.79
 Comfort during the procedure wearing the face shield along with spectacles/goggles? 	7.67	2.23
12. Ease of use (wear and remove) the face shield along with spectacles/goggles?	7.25	2.48
Overall:	7.92	2.13

the beginning of the pandemic.¹⁵ As per the literature, face shields, while not providing absolute protection from contamination, do significantly mitigate the chances of contracting the virus.^{10–12} Face shields have seen a major upsurge in production by individuals with access to 3D printers and by large companies.¹⁶ Most of the mass produced face shields utilize open source designs. The face shield presented in this article underwent multiple iterations utilising feedback from the end users at each step until the final model was arrived at. Designing it in accordance with the suggestions and needs of the end users helps provide a device better suited to their needs. This can be seen in the positive feedback given for the face shield.

The feedback for ease of use, visibility during procedures and comfort during procedures showed very positive reviews from the end users. This influences the likelihood of continued device usage in the future and discourages device abandonment. Ease of assembly, ease of disassembly, ease of cleaning, and confidence to reuse also showed positive reviews. Thus, the end users were compliant and comfortable with following the procedures for reuse and showed their willingness in using the face shield as part of the PPE. The final questions assessing the use of the face shield along with spectacle/goggle users had positive, though relatively lower scores. This indicates that future iterations are required for the face shields to eliminate fogging and increase the comfort especially in operating surgeons.

Considering the feedback, a method for effective utilization of face shields in a tertiary care centre can be formulated. In hot zones, and departments with droplet and aerosol generating procedures, using a face shield with the 0.125 mm 20in by 20in PCV film, inserted into the PPE gown will help minimize chances of infection. Having the face shield visor inserted into the gown leaves fewer areas in the facial region exposed, providing better protection from droplet and aerosol infections. In warm and cold zones transmission of the virus occurs primarily through contact or droplet infection, there also exists a risk of infection via asymptomatic carriers,¹⁷ Spread of the infection through contact can be mitigated by practicing good hand hygiene. Considering the HCWs do not don the level D PPE gown, the face shield with an A3/A4 sized OHP sheet used in conjunction with an N95 respirator can provide sufficient protection from droplet infection. In OTs, the use of the face shields with the PPE hood to augment user comfort is shown to work and can be implemented in not just Orthopaedic OTs but other areas as well where the PPE hood has to be used.

One of the major issues with face shields and the PPE hood is the fogging of the visor which impairs the end users' ability during procedures and surgery. The discomfort of the end user due to lack of adequate ventilation is also a major area of concern. Although majority of these problems of PPE discomfort can be evaded by using a level C PPE with a Powered Air-Purifying Respirator (PAPR), these devices are



For Use in Hot Zone ICUs

For Use in NON COVID Triage

Fig. 3. Different face shield setup.

For Use in Othopaedic Opertation Theatre

expensive and not easily available in Low and Middle Income Countries such as India. We circumvented this problem by making a small opening at the top of the PPE which is not a part of sterile area and has given reasonably good results. However, this is not a permanent solution to the issue. Thus, a major area for innovation in the future would be the development of low cost devices that reduces fogging, improves venti-

5. Conclusion

lation and user comfort.

The face shield in light of the coronavirus pandemic has become an integral part of the PPE used by HCWs. The collaboration between technical experts and HCWs will play a pivotal role in the success of such endeavours. Through this article, we can summarise that it is an achievable task to design, manufacture and use locally developed 3D printed face shields. The cost effectiveness, ergonomics, reusability and acceptance were assessed among orthopaedic surgeons and emergency medicine personnel and revealed positive feedback on all variables considered. The acceptability of the 3D printed face shield was high and it held preference over the regular hood setup that are donned as part of the level D PPE. Face shields can also be made more effective in different triaging and clinical settings by varying the device setup. Thus, we suggest that economic and innovative local solutions like these may help tide over the current PPE crisis which is unmasked by the COVID-19 pandemic.

The present initiative addresses the basic principles of health care delivery in terms of availability, accessibility, acceptability and affordability with an interdisciplinary approach which makes it eligible to upscale for a mass production level.

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Declaration of competing interest

Nil.

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