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Improvising the surgical helmet system for aerosol-generating procedures in the OR: Surgeon designed 3D printed mould for augmented filtration system

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ABSTRACT

1. Background: The aim of this paper is to describe the process of designing and developing a mould for filter placement via 3D printing on top of the surgical helmet. This mould was designed to affix a filter material on top of the helmet system for use during the COVID - 19 pandemic.
2. Method: The authors performed 3D scanning of the Stryker Surgical helmet (Stryker T5, REF 400–610, US patents 6,973,677:7,753,682) and created a negative template of the top of the helmet. A mould for filter placement was printed and fitted onto the top of the surgical helmet. This construct was tested to evaluate the surgeon's comfort, aerosol filtration efficiency etc.
3. Result: The helmet provided adequate comfort, showed no evidence of staining on spill test and the filter passed the industry filtration efficiency standards.
4. Conclusion: The 3D printed mould is an inexpensive, efficient, and comfortable design to augment personal protection ability of the Stryker helmet system. This process can be extrapolated to 3D print templates for other surgical helmets.

1. Introduction

Orthopaedic procedures are traditionally considered aerosol-generating procedures (AGP).[1,2] Reaming, lavage, and use of saw (Fig. 1) have all shown to produce aerosols that vary in size from 0.7 to 5 μm[1,3] Surgical helmet systems are routinely used by arthroplasty surgeons to reduce the peri-operative infection rates and were also used as personal protective equipment.[2–4] However, their use during COVID 19 pandemic[5] is not recommended by the manufacturers and the orthopaedic community.[6,7] While Anesthesia Patient Safety Foundation recommended that healthcare workers wear an N 95 mask with a face shield while performing AGP,[8] there are no clear guidelines in orthopaedics on how to augment the protection while performing AGP. Many orthopaedic surgeons tend to rely on the use of powered air-purifying respirators (PAPR) to augment the standard personal protection attire.[9] These PAPR draw air through a HEPA (High Efficiency Particulate Air) or N95 grade equivalent filter and create a positive pressure environment inside the suit so that the air inside it is filtered and devoid of any virus-containing aerosol.[10] These PAPR systems are expensive and cumbersome to use.[11] Surgical Helmets, on the other hand, are readily available in the operating room and familiar to use for most orthopaedic surgeons. If improved and tested for efficacy, these may serve as a viable, easy to use, and inexpensive alternative to PAPR.

The process of 3D (Three dimensional) printing is pivotal for creating prototypes and newer designs for industrial use from aircraft to healthcare equipment in a short period. These 3D printed prototype designs can then be used for testing and subsequently improvised for end-use. Orthopaedic surgeons too have been routinely using rapid prototyping also known as 3D printing in a varied clinical setting.[12] These include creating bio-model for surgical planning and simulation, designing customised jigs and cutting blocks, and for designing implants. Over the years, engineers have collaborated with orthopaedic surgeons to enhance the patient outcome. This paper describes the process of designing and

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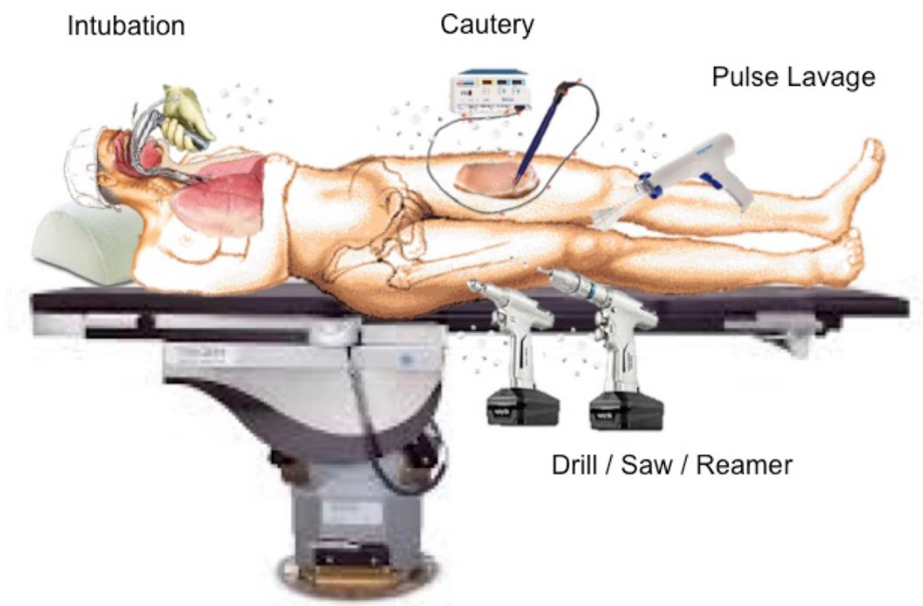

Fig. 1. Various ways in which an orthopaedic theatre may witness aerosols generation.

applying 3D printing technology to enhance the functionality of the surgical helmet system for use during the pandemic period.

2. Materials and methods

2.1. i. Design & deliberation process

When the reports and warnings on the use of the surgical helmet system were issued,[13] the authors embarked on a design process that would facilitate the optimal use of the helmet system. As users of these helmet systems for almost 2 decades, it was ascertained that modification of the system will be a valuable addition to the personal protection armamentarium. The designers thoroughly researched the mechanism of action of N95 masks and HEPA filters. This enabled better understanding about the process of aerosol generation, the filtration mechanism of the filters and how the same can be used for augmenting the helmet. The filters could act by blocking the aerosol thereby preventing their concentration under the surgical hood and toga.

Equipped with the information, cut sheets of N 95 were affixed on top of the helmet system with adhesive tape and their comfort evaluated while operating in a simulated environment. The comfort of the construct was ensured and a template for the mould was designed.

2.1.1. Initial design

The initial design was a plain rectangle sheet of Acrylonitrile Butadiene Styrene (ABS) plastic frame, 3D printed, to match the size of the fan grill located at the top of the helmet. However, the fit of this design was not adequate and demonstrated gaps and leakage at the periphery. To have a press-fit seal, this design was subsequently modified as follows (Fig. 2).

2.2. ii. Scanning the helmet system and getting a negative template

A 3D scanner, EinScan Pro 2*x* by Shining 3D (Hanghzou, China)

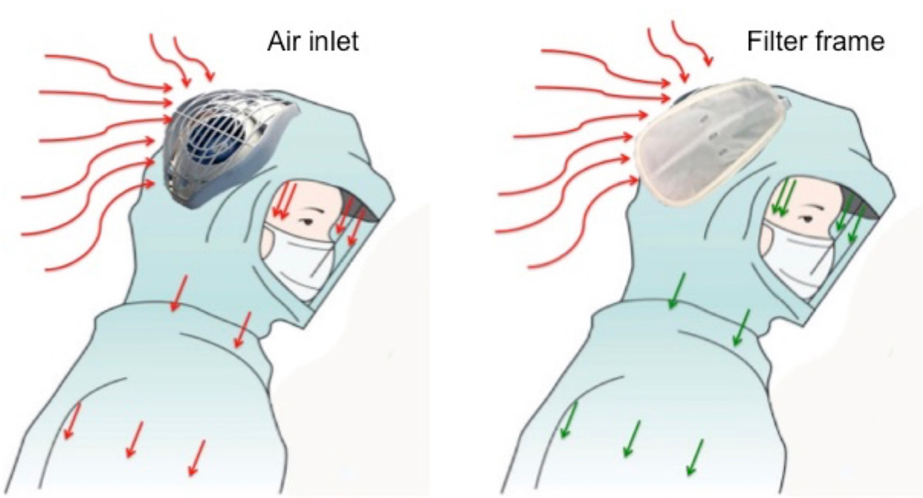

Fig. 2. Illustration demonstrating mechanism by which the augmented filtration system functions to block the aerosols generated in the operating room.

was used to scan the helmet and obtain a standard tessellation language (STL) file of the helmet. A negative template of this file was created using 3D Slicer software v 4.10.2.[14] An appropriately fitting and locking mould template was cartographically created on Blender 3D v 2.9 (Blender Institute, General public license).

2.3. iii. Generation of CAD model

The process of creating this CAD model was very similar to those used to create patient-specific jigs for knee arthroplasty. The surgeons and engineers worked on the Blender 3D, which is also used for creating the jigs for trauma cases. The only difference being that the input files were not generated from CT (Computed Tomography) scan or DICOM (Digital Imaging & Communications in Medicine) images but through the data obtained from scanning of the helmet. The process is described in Fig. 3.

2.4. iv. Printing process

Once the CAD file was virtually inspected and tested for fit, and locking mechanism - it was then made printer ready. The CAD model was converted into STL file format which was exported for printing. Two types of printers i.e. Fused deposition modelling (FDM) and Selective laser sintering (SLS) were tried. The quality and finish of the SLS printer was superior and subsequent prints were taken using this technology (Fig. 4).

2.4.1. Highlight of the design: the highlights of design include

1. Customized 3D printed design that accurately fits the Stryker helmet system (Michigan, USA).
2. The CAD process is standardized and can be used for any helmet systems.
3. Unique snap locking mechanism created by generating negative grooves that lock on the grid of the fan system eliminating the need for any additional locking mechanism.
4. A unique dual frame mechanism that allows change of the inner filters periodically.

2.4.2. Filter system

The key to the filtration system is the type of filter used. NIOSH Certified N95 material was procured from Magnum Health & Safety Pvt. Ltd. (Thane, India) and cut to the appropriate size. The unique dual frame mechanism ensures a complete fit. These filters are disposable and as per manufacturer's instruction was to be replaced after 40 h. As a matter of abundant precaution, it was recommended that they are changed after each positive or suspected positive COVID case.

2.4.3. Tests

To verify the appropriateness and efficacy of the system, the following tests were conducted:

2.4.3.1. i. Surgeon comfort. 10 surgeons were asked to wear the helmet for 2 surgeries each and ask to rate their comfort after wearing this modified helmet system. Their response to the use was registered as a) Felt no difference b) Felt that airflow is decreased c) Felt suffocated.

2.4.3.2. ii. Spill test. While not completely relevant here as the system would be mounted on the top of the helmet system where the blood products or spill was unlikely to reach, this test was conducted to complete the standard testing protocol for filtration devices. A coloured liquid was sprayed from distance 2, 3, and 5 feet and any spill as assessed by visualizing for any colour or wetting of the inner surface of the filter was assessed at 30 s and 3 min.

2.4.3.3. iii. Filtration efficacy for the filter. Standard tests were used for measuring the efficacy of the filter for 0.3-µm particle size. These particles were generated using the aerosol generator with sodium chloride aerosol. The lowest filter efficiency or highest penetration data point were recorded. The condensation particle counters (CPC) measured the particle concentration.

3. Results

3.1. i. Design fit

The 3D printed design was a perfect match to the top surface of

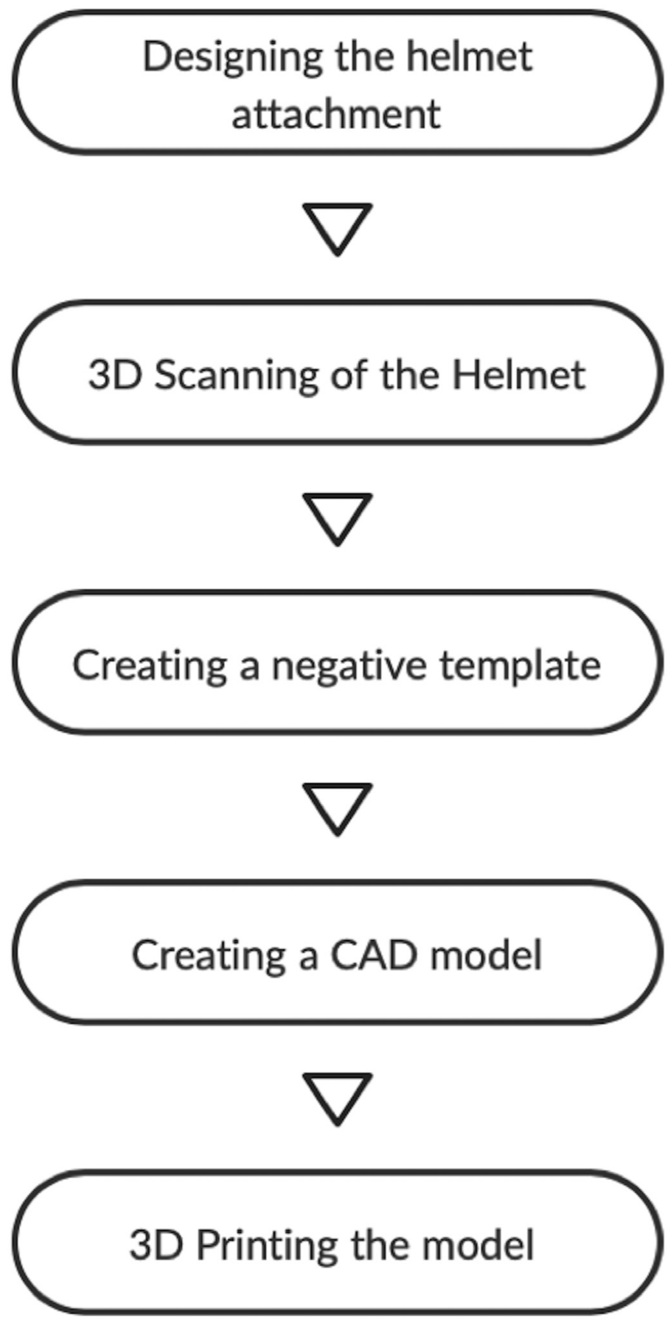

Fig. 3. Flowchart of the process of designing the mould for filter placement using 3D printing technology.

Fig. 4. CAD-CAM design of 3D printed template (A) and Helmet construct (B).

the surgical helmet system. There was no visual gap between the surfaces. The dual frame setup ensured that the intervening filter could be safely disposed and the rest of the fixture consisting of the two frames can be rapidly disinfected.

3.2. ii. Surgeon comfort

20 responses were recorded from 10 surgeons who used the system in the operating room. 19 responses were 'a' and one response was 'b'. 9 of 10 surgeons reported that they felt no difference, one surgeon felt that in one of the two surgeries the flow had decreased, however, he did not experience suffocation.

3.3. iii. Spill test

2 mL of blue ink was sprayed using a 20 cc syringe from a distance of 2 feet. The wettability of the inner surface was visually inspected and manually felt. There was no staining at 30 s and 3 min.

3.4. iv. Filtration efficacy

The filtration efficiency of the filter was tested on TSI 8130 filter tester using sodium chloride as an aerosol (0.3 μm particle size), passed at the rate of 85 L per minute (Fig. 5). The test was performed on three samples, all of which had a filtration efficiency consistently above the permissible limit of 95% with less than 24 mm of water breathing resistance (Table 1).

4. Discussion

There are several risks in performing surgeries that lead to the production of aerosols.[1,15] In orthopedics nearly, all procedures can be classified as aerosol-generating as most involve the use of the drill, saw, and use of pulse lavage system. Although unproven, it was speculated that the use of positive pressure theatres, space suits, and diathermy during these procedures increased the risks of the spread of infection to healthcare professionals.[13] While most emergency surgeries were performed, the elective surgeries were deferred. With pandemic showing signs of plateauing and abating, the surgeons have started to resume elective procedures.[16,17] Balancing patient care and ensuring healthcare personnel safety is of prime importance in the current scenario. The proposed solution of augmenting the surgical helmet system will be an added layer of safety for healthcare professionals including orthopaedic surgeons, scrub nurses, and anesthesia teams.

The use of rapid prototyping technique by orthopaedic surgeons for pelvi-acetabular fractures, spinal deformities, and complex periarticular fixation is well known.[12] As familiarity with the technology grew, surgeons collaborated with the engineers to design patient-specific jigs for percutaneous fixation, osteotomies, and joint replacement.[18] Several companies today commercially offer these 3D printed jigs for knee replacement: Visionaire by Smith & Nephew (London, United Kingdom) and Signature by Biomet Zimmer (Indiana, United States) being the most commonly used ones. Most industrial design processes currently employ the 3D printing technology to rapidly produce prototypes of the product

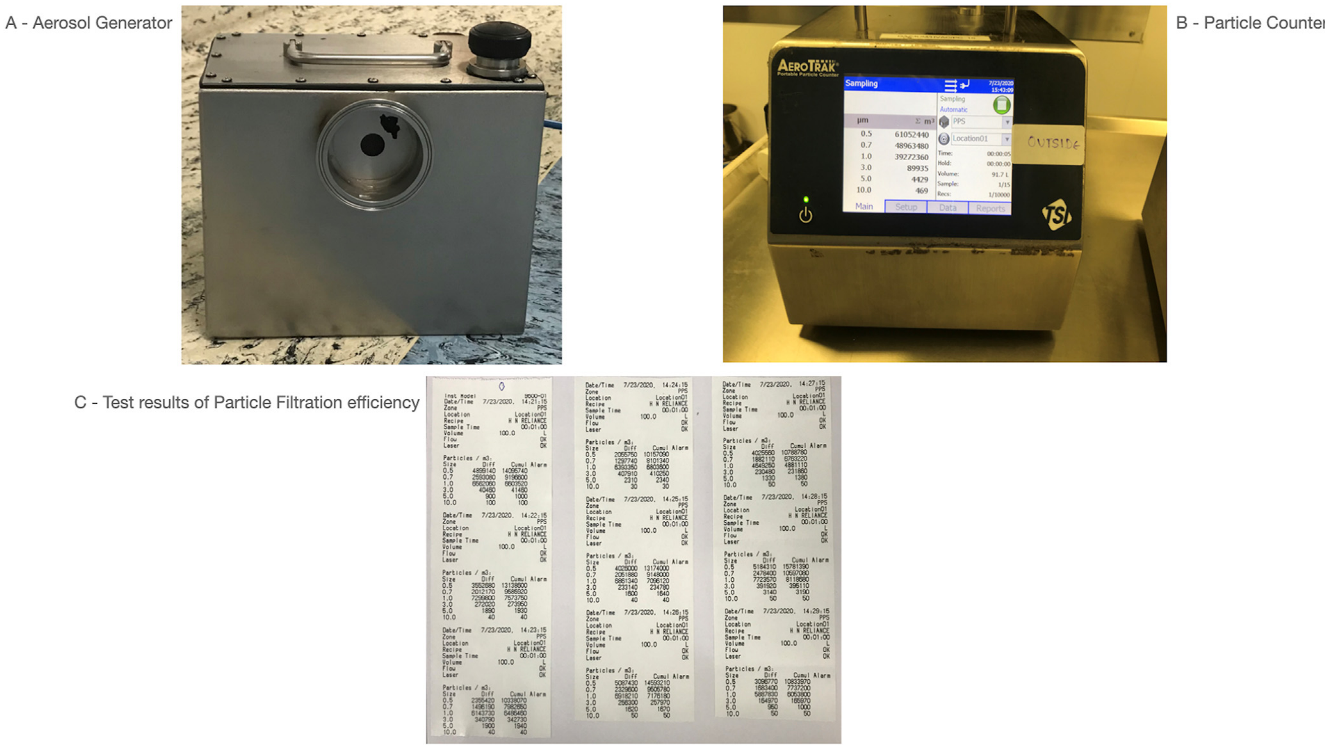

Fig. 5. Aerosol Generator (A), Particle counter (B), Test results of Filtration efficiency (C).

for evaluation and proof of concept demonstration. The use of 3D printing in this unprecedented crisis scenario of COVID 19 Pandemic has been a result of the collaborative effort of surgeons who defined the need and proposed a design and the engineers who worked on the design and 3D printed several versions to ultimately produce a model that matched the need and comfort of the surgeon.

The unique design of this design is the anatomical fit over the grid of the existing helmet system and the ease with which filter can be changed. Modifications of helmet system exist,[21] however, the simplicity of our design and cost - effectiveness will enable mass production of the augmented system which can be easily modified to fit helmet systems of other companies. Moreover, since only the N 95 filter needs to be changed periodically, the modification is financially sustainable. We were able to 3D print this augmented system for INR 2500 with the N 95 filter costing an additional INR 400. The total cost with the filter comes up to approximately INR 2900 or USD 40. Average cost of 3D printing a pelvis is approximately 220 USD.[22] This economical price was possible as the surgeons' were primarily responsible for designing the augmented filtration system. This enabled the development of an extremely cost - effective augmented filtration system. No mechanical removal of parts or procuring of tubes etc. as demonstrated in other studies[21] is required in our system. There is no need to sterilise our system, whereas the modification done by Erickson et al. may require sterilisation of the tubes as they can easily contaminate surgical gowns of fellow assistant/nurse. As per our knowledge, no similar fixture has been described in the literature. Using a negative mould to generate an exact mirror print is a standard prototyping technique and has been harnessed for producing this design. A two-frame snap-fit design makes the changing of filter an easy task for the operator. This may be especially relevant when operating on suspected or proven COVID positive patients. In such a scenario, the filter can be discarded and the rest of the unit may be disinfected along with the mould template in a standard fashion. While this particular design process was for the Stryker Helmet system, the design and prototyping process has been standardized and can be extended to all kinds of commercially available helmet systems.

Evaluating the efficiency and safety of any new product design is paramount to ensure its widespread intended usage. There has been a lot of debate about the particle filtration efficiency standards for these devices. Several studies have shown that this is not the same as bacterial filtration efficiency (BFE) or Virus Filtration Efficiency (VFE). A virus is submicron in size averaging 0.025 μm and thus much smaller than bacteria which are around 3 μm. While intuitively it may seem that to be effective the filter must prevent sub microns from entering the hood system but this is not the case. The virus cannot survive on their own and for them to be transmitted they need to be suspended in the aerosolized droplet.[19,20]

Table 1
Particle Filtration efficiency test results.

Sample Number	Filtration Efficiency (NaCl Test)	Breathing Resistance (mm of Water)	Result
1	95.14%	23	Pass
2	95.26%	22.9	Pass
3	95.32%	22.8	Pass
Permissible Limit	**95%**	**24**	

Studies have shown that most aerosols are less than 5 μm in size.[1] The particle efficiency studies done on this construct have revealed a 95.24% reduction in the particle count. The tests conducted on the filter were as per norms laid down by the CDC (Center of Disease Control).[23] Most surgeons were initially apprehensive to use this system fearing it would compromise their comfort. Most healthcare workers have reported discomfort and excessive sweating with the use of the recommended PPE and the surgeons felt the same apprehension. However, the study conducted to evaluate surgeon comfort found that in 19 of 20 instances, the operator did not find any discomfort or difference from their usual practice. Only in one instance did the surgeon experience mild discomfort not amounting to the need for its removal while performing the procedure. Moreover, after submission of this manuscript, the augmented filtration system has been distributed amongst five tertiary care hospitals in the city. Over 200 surgeries have been performed by approximately 50 surgeons, using this system. No surgeon had a negative feedback with respect to the breathing discomfort/excessive sweating etc, thereby adding strength to our test result findings.

This modified helmet system has the potential of being used not only by the orthopaedic surgeons while performing AGP but also by any frontline healthcare professionals. These include anesthetists, scrub nurses, and intensivists. As a part of the comfort test, anesthetists and scrub nurses used it and reported in favour. While not explicitly tested in other subgroups, it will likely be adapted for its comfort and enhanced safety.

Despite its unique design, interdisciplinary collaboration, and successful efficiency and safety testing, the modified system does have its limitations. The efficiency of the system is dependent on the type of filter used and the end-user must ensure that this is sourced from a certified agency. Furthermore, the parameters used to measure 'Surgeon comfort' were subjective in nature and was difficult to quantify. Given the nature of the epidemic and the urgent need for adaption of this safety measure, a lengthier multicentric study with multiple operators would have been difficult. However, for long term use, a larger study with a variety of healthcare professionals is recommended.

5. Conclusion

The 3D printed mould for filter placement is an inexpensive, efficient, and comfortable design to augment the personal protection of the Stryker helmet system. Interdisciplinary collaboration for innovation seems to be the way forward in solving some common problems during these uncommon pandemic times.

Declaration of competing interest

The authors confirm they have no conflicts of interest.

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