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Operation theatre protocol for COVID-19 cases requiring orthopaedic surgery: A workflow without altering the existing infrastructure

Anil K. Bhat [a], Sandeep Vijayan [b], Ashwath M. Acharya [a], Sourab Shetty [b, *], Nishanth Ampar [b], Madhava Pai Kanhangad [b], Nikhil Hegde [b]

[a] Unit of Hand and Microsurgery, Department of Orthopaedics, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, 576104, India
[b] Department of Orthopaedics, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, 576104, India

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ABSTRACT

Introduction: The surge in the number of trauma cases following relaxation of lockdowns in the backdrop of COVID-19 pandemic, has strained the existing infrastructure to cater to these patients and also prevent the spread of infection. Moreover, with the rise of newer strains, the period ahead has to be tread carefully to prevent resurgence of infections. There have been recommendations regarding the ideal setup to operate orthopaedic cases in this pandemic scenario. However, many of the hospitals in India with financial and logistic constraints are unable to implement these structural changes into their existing setup. We propose a model which can be used in an existing operation theatre which has a single entry and exit corridor, which is the layout in many hospitals.

Methodology: A protocol with the consultation of a panel of health care professionals was designed on the basis of WHO guidelines in a way so as to remain dynamic. Prior to its implementation, online classes were conducted and a dry run of the protocol was done with the whole team involved. The theatre layout is one with a single entry and exit and had predesignated rooms. The personnel were divided into 3 teams, each with a fixed set of people and preset workflow, to be followed during entry and exit. Five COVID positive cases have been operated since then using the protocol and has been used as a pilot study to further amend the protocol.

Conclusion: This model can be used as a guideline by hospitals having a limited infrastructure, to develop their own protocol to operate on COVID positive cases, in the present situation of increasing trauma cases post the relaxation of lockdown and also in any subsequent waves of infection with newer strains. Simulation and periodic stringent audits with the entire team would prove successful in rectifying errors and avoiding any possible contamination.

1. Introduction

The onslaught of the COVID-19 pandemic has brought a monumental change in healthcare systems in recent times with new information pouring in from various academic sources. One of the greatest challenges it brings is in the field of infrastructure and logistics. There is a constant and steady pressure on the stakeholders to balance between maintaining the utility of existing medical setup with those of innovative and creative designs to prevent the spread of disease among the medical fraternity and patients.

The spread of infection amongst the health workers can reduce workforce and handicap the system of healthcare which has already been observed and can be hazardous during the period of an impending resurgence.[1,2] In this regard, guidelines have been issued and advocated by the Indian Orthopaedic Association and Ministry of Health and Family Welfare on the management of orthopaedic diseases that need urgent or emergency surgical intervention.

Though there are many recommendations from various corners of the world regarding the ideal setup to undertake orthopaedic procedures during the current pandemic, the existing infrastructure and availability of resources in many standalone hospitals in

* Corresponding author.
E-mail addresses: anilbhatortho@gmail.com (A.K. Bhat), sandeep.vijayan18@gmail.com (S. Vijayan), anmacharya@gmail.com (A.M. Acharya), sourab.shetty.ss@gmail.com (S. Shetty), nishanth.a@manipal.edu (N. Ampar), madhava.pai@manipal.edu (M.P. Kanhangad), nikhil.hegde@manipal.edu (N. Hegde).

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India may not permit the implementation of these recommendations to its full.[3,4] Moreover, with the recent guidelines for sequential relaxation of lockdowns and return to occupation of people, the incidence of road traffic accidents and work place injuries has been on a rise.[5,6] Hence, the infrastructure available should be able to cater to these trauma cases and also the cases which were conservatively managed during lockdown, all of which are a major number along with the minor numbers of COVID positive patients who require emergency surgery.

In a recent review, Chabbra et al. stressed on the need for a satellite operation theatre with separate entry and exit platform for COVID positive patients requiring surgery, to prevent contamination of the entire theatre complex.[1] Such infrastructure may not be available in many hospitals and establishing such facilities may add huge constraints on finances and logistics. Moreover, the major operating room (OR) would now have to cater to the elective and COVID negative cases and having various ORs to manage COVID positive cases as suggested by various studies might not be possible. Therefore, each hospital may have to formulate a protocol suitable for them according to the resources available, giving prime importance to the safety of the patients as well as the healthcare providers. Hence, we propose a model which we believe would still be possible with an existing OR having a single and same entry and exit platform as observed in our hospital to operate on the COVID positive patients when required.

2. Methodology

Besides the main OR complex, we have two theatres which has a single entry and exit platform for the hospital consultants and patients. Change of layout in this system was not an option in view of logistics of time and space. Hence, a workflow protocol was designed keeping in mind the theatre layout and infrastructure presently available to the operating team, in consultation with a panel of operating Orthopaedic senior surgeons, anaesthesia consultants, infectious diseases department (IFD), senior nursing staff involved in care of COVID patients and the approval of the hospital administration based on the WHO guidelines for infection prevention and control of epidemics and pandemics in healthcare facilities.[7] Large clear signage boards to warn the general public and other healthcare workers were placed to indicate the COVID - OR. The protocol has been developed in a way that it remains dynamic and continually evolving.[8]

Prior to the implementation of the protocol, we conducted online classes and trained all our staffs in proper donning, doffing and disposal of personal protective equipment (PPE). Four classes of an hour each were conducted through the online platform by the department of Infectious diseases using pictures and videos. Short videos were circulated among all involved staff. The protocol was validated by the Institutional Infectious diseases control department based on WHO guidelines[7] and soft copies were circulated. Following this, a dry run of the protocol was done involving the surgical, nursing, technician and anaesthetic teams, to check for any missing critical steps in the protocol with the IFD auditing it. We have since operated five COVID positive cases who required surgery and used it as a pilot study to further incorporate amendments into the protocol.

The emergency services in our hospital received a total of 6552 cases during the non-lockdown period in 2019, of which 627 cases were orthopaedic related trauma and 3574 patients were received in 2020 of which 235 cases were orthopaedic related trauma. Hence, there was a reduction of 62.6% in the number of Orthopaedic related trauma cases in the lockdown period.[9] With the gradual relaxation of lockdown, the number of trauma cases have been surging, there by mandating the use of the major OR for managing COVID negative cases and the use of the single minor OR with single entry for the COVID positive cases requiring surgery. The protocol has thus been designed to handle this inflow of patients with the existing infrastructure keeping in mind the need to prevent the spread of infection.

2.1. The protocol

All known or suspected COVID positive patients requiring surgical intervention were treated as positive until proven otherwise. The theatre layout is given in Fig. 1. This is a common layout seen in hospitals in developing countries. Modifications to the setup shown is feasible in most theatre complexes with basic partitioning.

As soon as a suspected COVID-19 patient is posted for surgery, the concerned duty consultants and residents of orthopaedic and anaesthesia departments, nursing and other ancillary associated healthcare workers are informed about the time of surgery and the patient is kept ready for transfer at the concerned ward/ICU. Three teams are involved in such patient care, as shown in Table 1.

- Team 1 is involved in transfer of the patient and preparation of patient before surgery in the theatre.
- Team 2 is the surgical team. Scrub nurse (NS 1), Floor nurse (NS 2) and Orthopaedic theatre technician (ORT 2) make the necessary arrangements in Theatre A.
- Team 3 is the anaesthesia team. Apart from these teams, the housekeeping staff is kept standby.

A backup team of orthopaedic consultant, resident and vascular surgeons are kept informed in case support or replacement is required. Hence, for a patient 2 consultants and 3 residents (combining Orthopaedics and Anaesthesia), 2 nurses and 3 technicians (combining Orthopaedics and Anaesthesia) would be working in teams at different steps of the protocol with precautions to avoid cross infection. Besides them a security personnel and house keeping staff would be called for when required. Coordination among the teams is the key during the surgery. This includes the quick positioning and preparation of the patient, minimal movement in and out of the theatre once the procedure starts, the optimal use of instruments and implants, reducing the duration of surgery as much as possible with an aim towards damage control surgery and finally doffing of the PPE as per standard guidelines.

2.1.1. Step 1: Preliminary preparation in Theatre A (Team 2 and 3 at work)

Team 2 makes preliminary arrangements in Theatre A, supervised by an orthopaedic consultant, in coordination with Team 3 before the patient is shifted in.

1. NS 1 scrubs in and arranges the table in Theatre A with the help of NS 2. A mandatory checklist for surgery is made with confirmation from the orthopaedic consultant.
2. NS 2 also arranges preparation trolley/catheterization set (if needed) which is done by PGT 1. One sterile gown and long gloves is kept for PGT 1 for patient preparation.
3. ORT 2 and PGT 2 make arrangements for patient positioning like arranging fracture table, image intensifier, tourniquet, table attachments and drill attachments.
4. NS 2 coordinates with ORT 2 for draping image intensifier and arthroscopy related materials if required.
5. ORT 2 cling wraps all non-disposable multi-touch surfaces like monitors, keyboards and door handles.
6. NS 1 covers the prepared instrument table with sterile sheets and leaves the theatre. Orthopaedic consultant and PGT 2 proceed for surgical scrubbing.

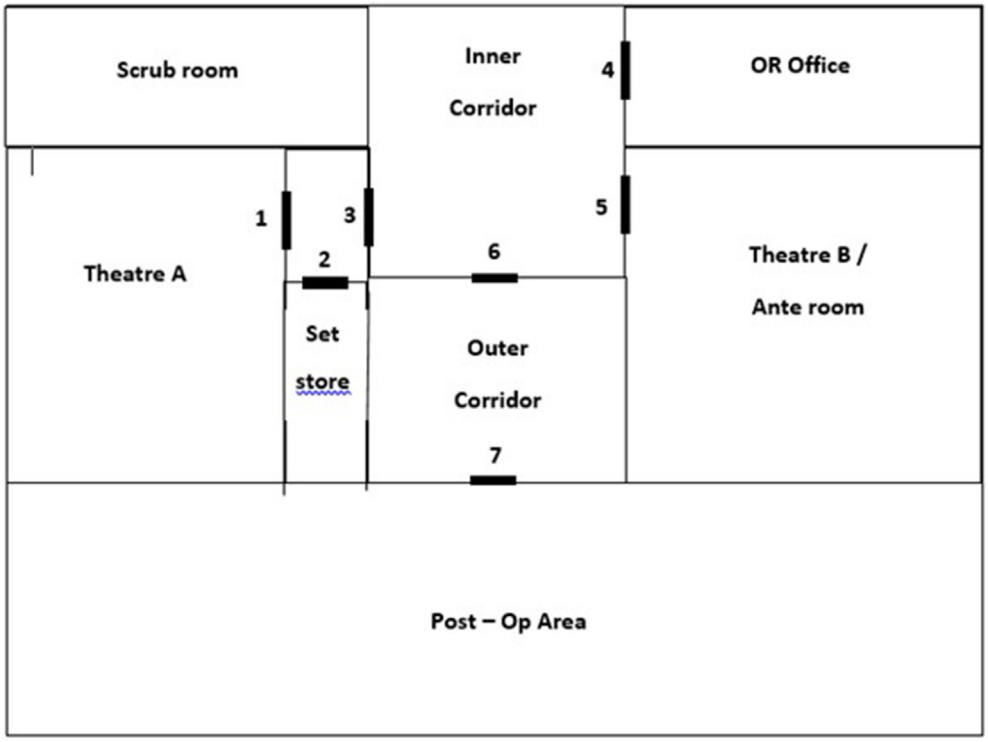

Fig. 1. OR complex layout; No. 1-7 represent the doors. OR – Operation Room; Set store – area where sterile instruments are kept.

Table 1
Division of teams involved in the management of COVID-19 patients for Orthopaedic Surgery.

Team 1	Team 2	Team 3
Orthopaedic resident 1 (PGT 1)	Orthopaedic consultant	Anaesthesia consultant
Orthopaedic technician 1 (ORT 1)	Orthopaedic resident 2 (PGT 2)	Anaesthesia resident
	NS 1 – scrub nurse	
	NS 2 – floor nurse	Anaesthesia technician
	Orthopaedic Technician 2 (ORT 2)	

An anaesthesia technician checks the monitors, drug tray, emergency crash tray and anaesthesia circuit in consultation with the anaesthesia consultant/PG, following the COVID recommendations.[10–12]

2.1.2. Step 2: Transport of patient from ward/ICU (Team 1 at work)

The patient is shifted to the OR from the concerned ward, without keeping him/her in the reception lobby or induction room, once Team 2 and 3 confirm. The consent is taken from the family members and the patient in the ward prior to shifting the patient. A predetermined shortest path with least exposure is designated, and the patient is transferred quickly by a trained personnel in PPE. The hospital security makes sure that the patient's pathway is cordoned off for the general public during transportation.[4,11–14]

1. Team 1 dons PPE in the anteroom (Fig. 1) and move out to bring the patient following the hospital protocol. The same trolley is used from the anteroom to shift patient from ward/ICU in order to reduce handling by multiple people. All non-intubated patients should wear a mask and a suitable gown to reduce any surface contamination.[4]
2. In case of patients on ventilator, Team 3 accompanies Team 1 to shift the patient. Transport ventilator/Mapleson B circuit with oxygen is used for transfer. Bacterial/viral filter is attached to the ET tube all the time.[15]
3. The resident, after handing over the patient to the anaesthesia consultant, removes the sterile gown and deposits it in the designated bin placed in the inner corridor and wears a new sterile gown over the PPE inside the theatre. If required, a lead apron is also worn under the sterile gown.

2.1.3. Step 3: Donning of Team 2

1. Once the preliminary arrangement is made and before the patient goes into Theatre A, the relevant members of Team 2 will scrub for the case and assemble in anteroom (Fig. 1) and help each other to don the PPE (Fig. 2). As the OR entry and exit is single, it is ensured that Team 2 is already in the anteroom in their PPE so that they are not exposed to the patient's entry path.

Lead apron and plastic apron is worn over the PPE. A face shield with visor is preferred. Fogging is a major issue when surgical teams cannot wear the PPE with an exhaust system. Options are to wear a face shield with visor along with N95 mask and eye goggles following the standard guidelines.[3,4,8,12,16] Although power air-purifying respirators (PAPR) offer better protection than N95 respirators and are reusable, they have been discouraged due to difficulty in wearing, doffing and sterilization after each case which often may be inadequate.[17] We preferred using the face shields with

headbands as it protects the N95 mask from getting contaminated and less fogging of the plastic sheet during surgery. All personnel inside the OR wear an additional disposable sterile surgical gown and double pair of gloves over the PPE to maintain sterility.

2. Team 2 waits in the anteroom till they are alerted by Team 1 to move into Theatre A after anaesthesia.

2.1.4. Step 4: Anaesthesia and patient positioning (Team 1 and 3 at work)

1. The patient is shifted into Theatre A by Team 1. Team 3 takes over for anaesthesia.
2. Team 3 decides on the type of anaesthesia after evaluating the patient and usually tries for regional anaesthesia to reduce aerosol generation, but general anaesthesia (GA) with all the standard precautions is used if necessary.[4,12,16]
3. If GA is decided, Team 1 informs the central air conditioning (AC) unit to keep the AC at maximum cycles (25/min), and then wait in OR office till the procedure is complete. We maintain a positive pressure inside the OR along with a high air exchange cycle rate of 25 cycles per hour and use high-efficiency particulate air (HEPA) filters to reduce viral load and other airborne pathogens.[3,4]
4. The housekeeping staff waiting in the OR office is called if any need arises such as cleaning soiled floor or table before the start of the case.
5. Once anaesthesia is complete, Team 1 enters Theatre A for positioning and preparing the patient. Special drapes with bilateral pouch can be used to avoid spillage.
6. Once preparation is done, they leave the theatre after doffing the sterile gown and long gloves and wait in OR office. Team 2 is alerted to enter.

2.1.5. Step 5: Surgery and exit of Team 2

1. Team 2 enters Theatre A. Door 1 and 3 are shut. Patient is draped with disposable drapes.
2. NS 2 stays near the set store after draping is done (Fig. 1). ORT 2 inflates the tourniquet, oversees the lighting arrangements, operates the image intensifier and coordinates with NS 2 for providing instruments to NS 1. This minimises theatre personnel inside Theatre A.
3. Once the plaster slab/dressing has been completed following the surgery, all the members of Team 2 remove and discard the outer sterile gown and outer gloves into bins placed inside the theatre and leave the theatre, before the patient is extubated.
4. If regional anaesthesia was used, Team 2 informs Team 1 to help Team 3 in shifting the patient.
5. Team 2 proceeds to the inner corridor between Theatre A and B and dispose their PPE completely along with long gloves and foot cover in a large closed bin with foot control. Lead apron is left on the stand. Face shield is discarded in the hypochlorite solution basin kept, before exiting door 6 (Fig. 1).
6. In the outer corridor the inner glove is removed and alcohol rub is used for the exposed hands and new gloves are worn. Surgical mask worn on top of N95 is then discarded in a bin before exiting door 7 (Fig. 1). The team still wearing their surgical cap, N95 mask, OR scrubs, gloves and footwear, now discard them inside the surgeons room and take a shower.

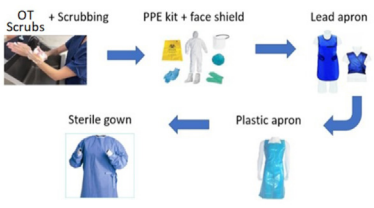

Fig. 2. Demonstrating the sequence of wearing the protective equipment and sterile surgical gown; OT – operation theatre, PPE – Personal Protective Equipment.

2.1.6. Step 6: Transport of patient to ward/ICU (Team 1 and 3 at work)

1. In case of GA, Team 3 extubates the patient and calls Team 1.
2. Members from both the teams shift the patient to COVID-ICU. Anaesthesia consultant and technician follow the above doffing protocol in Step 5 and exit theatre.
3. The security team aids in the transfer and also coordinate the sterilization of the pathway.
4. Team members shifting the patient doff their PPE in the room provided at ICU.
5. The housekeeping staff bring the trolley and the lead aprons back to the trauma theatre for disinfection.
6. The remaining members leave the theatre after doffing their PPE, as shown in step 5 and start the fumigation process.
7. Theatre A is shut with no attempt to be made to touch any of the instruments for an hour.
8. Nursing consultant and housekeeping staff dispose off the used instruments under sterile precautions. Thorough cleaning of the OR is undertaken and surfaces of all the equipments are wiped down with either Virkon™ or 1% sodium hypochlorite solution.[3,4,12,18]
9. The breathing circuit, mask, endotracheal tube, HME filters, gas sampling lines, soda lime and water trap are discarded after each case. All metallic instruments are kept immersed in 1% sodium hypochlorite for half an hour, washed and sent for autoclaving. All contaminated disposable materials and PPEs are put in closed lid containers and sealed.[3]
10. Histopathology or culture specimens, if any, are kept in tight fit plastic boxes, wiped clean and placed in a biohazard bag inside the OR and subsequently placed in another biohazard bag in the containment room before being sent to the lab after being labelled.[19] Currently there is no data on the COVID-19 viral load in tissue samples.[4]

2.2. Pilot study

A simulation of the protocol was done in the designated OR, including all the departments involved, with inputs to rectify any errors to its functionality.

Five patients were operated following the dry run which included 4 males and 1 female with a mean age of 36.6 years (Range: 26-64 years). Four of these patients presented post road traffic accidents and one patient post slip and fall at home as depicted in Table 2. 4/5 patients were proven RT-PCR positive for COVID and 1/5 patient was suspected to be positive and was taken up for surgery prior to the report, in view of deteriorating haemodynamic status because of the multiple open fractures and open book pelvic injury. One patient was operated within 6 hours post admission, 3 patients were operated within 48 hours of admission and 1 patient of neck of femur fracture was sent home in view of positive COVID report and non urgency of the surgery but was operated at 3 weeks using the same protocol. The mean surgical time was 60 mins (Range: 45-105 mins). Patients were started on

low molecular weight heparin postoperatively considering the high risk of thromboembolic complications.[20]

2.3. Observation

A thorough follow up was kept on all the personnel involved in the execution of the protocol amongst the cases operated to look for any symptoms. On presentation of symptoms, they underwent RT-PCR testing for COVID and quarantine as per guidelines by the Ministry of Health and family welfare. An audit of the cases was also done to look for any errors and to incorporate any changes in the protocol as and when required. A follow up on the outcome of surgery and the clinical and rehabilitation status of the patient post surgery was also done using teleconsultations.

Being a pilot study, there was no validation done but observations made during the study were used to make the following changes in the protocol:

- During patient positioning and preparation in Step 4, it was noted that there was a lack of manpower in cases where both upper and lower limbs were involved. In such cases it was decided that ORT 2 can step in till the patient is draped.
- It was observed that patient trolley was kept in the inner corridor after shifting the patient on to the table. Moreover, the personnel had to doff partly in the inner corridor before exiting door 6. Hence, the inner corridor could be a potential breach in the protocol as a source of infection. Therefore, surface cleaning with Virkon™ solution[17] of the inner corridor and trolley was done by the house keeping staff once Team 2 enters theatre A after patient preparation in Step 4.

Furthermore, for all the cases operated using the model a close follow up of all the personnel involved shall be kept to check for infections for a period of fourteen days.[17] An audit interview of the steps followed shall also be done to check for any unseen leeways in case of infections. A follow up on the surgical outcome of the patients operated shall also be done. All the cases operated by this model shall be kept a log on to evaluate the success of the workflow.

3. Discussion

With the advent of vaccine and return to normal practice, we are bound to continue working with the backdrop of an ever persisting risk of resurgence and learning the long term effects of SARS-CoV-2, which may demand further changes to our practice. It is crucial that while emergency policies and protocols are rapidly made, they should be dynamic enough to be collaboratively improved and be able to incorporate new knowledge. This protocol should also serve as a template to be tailored to the unique setup of each health care facility which is very important in a country like India where every standalone hospital cannot alter the existing infrastructure due to the population it has to cater to and also due to financial logistics.

There have been a lot of studies published setting out guidelines for the requirements of a OR to operate on a trauma case who is COVID positive. Ti KL et al. recommended a OR at the corner of the theatre complex with separate access.[10] Rodrigues-Pinto et al. have set out a detailed surgical team flow for orthopaedic surgeries in a COVID-19 dedicated operating theatre dividing the complex into five zones.[21] Other studies have also recommended an OR closest to the complex entrance.[4] All these protocols served as guidelines when the majority of the infrastructure in the hospital was dedicated to COVID care. With the relaxation of lockdown and increase in the number of cases, the main OR complex in most of the hospitals has now been involved in the management of COVID negative and elective cases which have been on a rise due to the backlog in lockdown period. Hence, the limited infrastructure now available for operating COVID positive cases is usually a single entry OR in most of the hospitals for which our protocol can be used as a template. Modifications to the protocol may be needed based on the unique setup of individual hospitals, the demographics of the patient population they cater to and the expertise and resources available.

Our experience also highlighted the need to keep a new protocol dynamic, which can be audited and improvised through the conduct of training and simulation exercises with the staff involved. By performing drills and simulating their roles in an imaginary scenario, we gained new insights and modifications were done that helped in refining the protocol. Dieckmann et al. highlighted that simulation has played an important role in managing the current global crisis and will further help in battling future pandemics.[22]

Even in the present situation there should be no relaxation in the way we deal with a COVID positive case and all the measures should be taken to avoid contamination and prevent infection of the staff involved. A decision-making algorithm for risk-stratification of elective procedures based on the indication of surgical care and predicted resource consumption should still be followed as suggested by Stahel.[23] Conservative management as and when required and minimally invasive shorter surgical procedures should be preferred over longer and complex surgeries producing more aerosols.[24] In the follow up of the personnel involved in our pilot study, there were no staff who turned symptomatic or tested positive. However, a larger study would be required to validate and justify the same.

Morbidity, mortality and physiological responses in patients undergoing surgeries during the pandemic are still being reported in literature. Lei et al. studied 34 patients who underwent surgeries during the incubation period of COVID at 3 hospitals of which five were orthopaedic cases. It was noted that all of them developed pneumonia, 44.1% of patients needed intensive care and the mortality rate was 20.5%. This is attributed to the probable lowering of cell-mediated immunity after surgery which plays an important role in defending against viral infections.[25]

The limitation of the study is that this is a protocol which has

Table 2
Demographics of patients who were operated using the protocol.

Patient	Age	Sex	Injury	Associated injuries	COVID report	Procedure	Surgical time
P1	26	M	Open femur and tibia fracture, Open book pelvic injury	Head injury, 3rd,4th,5th rib fractures	Suspected	Debridement and external fixator	1.5 h
P2	28	M	Open femur fracture	Head injury	Positive	Debridement and Interlocking nailing	1 h
P3	32	M	Subtrochanteric femur fracture	Head injury, Haemothorax	Positive	Interlocking nailing	45 min
P4	33	M	Subtrochanteric femur fracture	Chest injury	Positive	Interlocking nailing	45 min
P5	64	F	Neck of femur fracture	None	Positive	Hemireplacement arthroplasty	1 h

been run only in a single institution and has undergone only a pilot study. A feedback from multiple institutions and follow up of a larger population of patients would be required to validate the efficacy of the protocol.

4. Conclusion

Every hospital must develop their own protocols integrating various departments based on their infrastructure and logistics to tide over the present scenario for which a broad guideline has been presented here. A dry run and periodic stringent audits of the protocol with the entire team would prove successful in avoiding any possible contamination and also serve the purpose of keeping the entire team safe thereby avoiding a loss in manpower again. Though this protocol highlights the current pandemic, it serves as a template for surgical readiness for the next infectious disease catastrophe that will inevitably unfold.

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Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and evaluation were performed by Anil K Bhat, Ashwath M Acharya, Sourab Shetty, Nishanth Ampar and Madhava Pai Kanhangad. The first draft of the manuscript was written by Sandeep Vijayan and Nikhil Hegde and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Declaration of competing interest

Anil K Bhat, Sandeep Vijayan, Ashwath M Acharya, Sourab Shetty, Nishanth Ampar, Madhava Pai Kanhangad and Nikhil hedge declare that they have no **conflict of interest**.

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