

## A novel protective barrier for extremity surgeries during the COVID-19 pandemic

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### ABSTRACT

**Aim:** To present a novel protective barrier for COVID-19 transmission and investigate its effectiveness in protection against spreading aerosols and droplets during extremity surgery.

**Methods:** We enrolled 436 patients who underwent urgent and essential surgery on the upper and lower extremity using a novel protective barrier under wide-awake local anesthesia. All patients were investigated in detail for COVID-19 infection with anamnesis, symptom questionnaires, and the required tests before surgery. Patient satisfaction regarding comfort during the surgery behind the protective barrier was analyzed using a five-point Likert scale. The protective effect of the transparent barrier was quantitatively and experimentally analyzed using smoke and saline transmission tests in different clinic scenarios with and without the protective barrier.

**Results:** A total of 345 patients with no signs of COVID-19 infection underwent surgery. Ninety-one suspected patients who had positive COVID-19 symptoms or close contact with a COVID-19 infected patient underwent COVID-19 tests before surgery. All patients underwent urgent surgical treatment on the upper and lower extremities, and easily tolerated and were satisfied with the protective barrier. There was a statistically significant reduction in smoke and saline particles when using the protective barrier ( $p < 0.001$ ). The addition of negative suction and oxygen to the protective barrier potentiated the protective effect ( $p < 0.001$ ).

**Conclusions:** Extremity surgeries, especially hand surgeries, are one of the most common surgical procedures during the COVID-19 pandemic. Our protective barrier significantly reduced aerosol particles in our experimental model and was successfully used in clinical practice during extremity surgery.

**Key words:** Protective barrier, extremity surgery, COVID-19 transmission, pandemic.

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### Introduction

Coronavirus disease 2019 (COVID-19) has rapidly spread worldwide affecting millions of people, and has been declared a pandemic by The

World Health Organization [1]. COVID-19 is caused by a viral infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a highly virulent and easily transmissible pathogen [1-8]. It requires water and a mucous envelope to spread within an environment, and the viral load is at its highest concentration in airway particles, such as small aerosol and large respiratory droplets, that cause viral transmission [4-13]. Adequate safety measures such as physical social distancing and additional protection are required to mitigate

spreading particulates [4,10-16]. However, this is a challenge when performing invasive and surgical treatments.

During the pandemic, plastic surgeons, otolaryngologists, maxillofacial surgeons, and anesthesiologists have been performing emergency and time-sensitive invasive and surgical aerosol-generating procedures (AGPs) that are highly susceptible to the transmission of SARS-CoV-2 from the head and neck areas [5,6,12-20]. Therefore, various protective equipment and barriers have been introduced for head and neck surgeries and tracheal intubations [5,6,10-18,21-23]. Plastic, orthopedic and hand surgeons have also performed many emergency surgical interventions on the extremities, especially those of the hands, during the pandemic. Although the risk of potential transmission is lower in extremity surgeries compared to those of the head and neck, the total risk cannot be excluded due to the high number of these surgeries. There are also not enough studies regarding protective barriers during extremity surgery.

The aim of this study was to present an alternative protective barrier and investigate its effectiveness in the protection against the spread of aerosols and droplets during extremity surgery.

## Materials and methods

From April 2020 to July 2021, we gathered data on 436 patients who underwent urgent and essential surgeries on the upper and lower extremities using a novel protective barrier and under wide-awake local anesthesia. During this period, COVID-19 infection was spreading, the number of infected patients was increasing daily, we experienced intermittent closures of social activities, a stay-at-home instruction was applied, and elective surgeries were postponed in our

country. Surgeries requiring general anesthesia, *intraoperative* x-ray, surgical microscopy, and hospitalization were excluded.

This study was designed as a single-center, non-blind, prospective study. Before surgery, all enrolled patients provided written and verbal informed consent to participate in the study. The study was conducted in compliance with the principles of the Declaration of Helsinki and approved by the local committee (E-35700536 108.99-121129).

Before surgery, the patient medical records were reviewed to collect data on age, sex, previous treatments, comorbidities, and etiology, pathology, and localization of the trauma. All patients were investigated for COVID-19 infection through anamnesis and symptom questionnaires and, if necessary, blood, radiological, and polymerase chain reaction (PCR) tests were conducted. All surgical procedures were performed according to a previous report [19].

The duration of surgery (between anesthesia and dressing), type of surgery (AGPs or not), and surgery related complications were recorded. Patient satisfaction about comfortability of the surgical period whilst using the protective barrier was recorded after the surgery using a five-point Likert scale: 1=very dissatisfied; 2=dissatisfied; 3=neutral; 4=satisfied; and 5=very satisfied.

All patients and surgical teams were followed closely for symptoms of COVID-19 infection for two weeks after surgery, during the incubation period of SARS-CoV-2. All patients were followed-up for 6-19 (average 13.6±4.1) months by telephone or polyclinic controls.

### *Protective barrier and surgical procedure*

We constructed a barrier room with floor space of 2.2x1 m and ceiling height of 2.4 m, including a patient stretcher, and covered by a transparent physical barrier of 3 mm thick polyvinyl chloride (PVC) sheets. This barrier

included two walls: the long wall had two 10 cm diameter windows to access the upper or lower extremities for surgery; and the short wall had a door for entry and exit. A negative suction and oxygen system were adapted inside the barrier to mimic laminar flow and decrease particle distribution; these were connected to the hospital vacuum (120 mmHg) and oxygen systems (6 ml/dk). During upper extremity surgery, the hole for the lower extremities was closed with transparent draping (Tegaderm™ film; 3M Health Care, MN, USA), to prevent particle spread, and vice versa.

All surgical procedures were performed by the same surgical team: a plastic surgeon; an experienced scrub nurse positioned opposite the surgeon; and auxiliary health personnel standing as far from the surgical field as possible in the standard day surgery room (approximately 90 sq. ft). During pre- and post-surgical periods, physical contact with patients was minimized. Surgical teams wore standard personal protective equipment (PPE) including a gown, gloves, N95 mask, and face shield.

Patients wore protective masks and were placed in the supine position on the stretcher, with the injured extremity on the surgeon side and their face turned to the opposite side within the protective barrier. The surgery was performed by taking the extremity and injured hand through the window (Figure 1).



**Figure 1.** Surgery was performed by taking the extremity or hand through the window.

An active suction catheter was used to reduce smoke and possible consequent hazard of infection during bipolar electrocautery. Aerosol-generating equipment, such as monopolar electrocautery and burrs, were not used during surgery.

Patients were discharged after surgery with oral medication and dressing. After each procedure, the PVC barrier was sterilized with disinfectants of 0.1% quaternary ammonium compound and 80% ethanol [24], the room air was exchanged, and the team waited a minimum of 45 minutes before the next surgery.

#### ***Evaluation of the protective barrier***

The protective effect of the transparent barrier was quantitatively analyzed using a smoke and saline transmission test for small aerosols (0.3-0.5  $\mu\text{m}$ ) and large droplets (0.5-5.0  $\mu\text{m}$ ), respectively. A particle meter (PCE-PQC 32EU particle counter, PCE Instruments, Southampton, UK) was used to quantify the number and size of particles in different clinical scenarios in standard day surgery rooms with hospital ventilation systems at 22.3°C and 62% humidity. The particle meter counts airborne particles within 0.3, 0.5, 1, 3, 5, and 10  $\mu\text{m}$ , and the counter flow rate was set to 2.83 l.min<sup>-1</sup>.

During the smoke and saline transmission tests, 20 puffs of ventilation smoke tube (MSA Smoke Tube Kit, Mine Safety Appliances Company, Pittsburgh, PA) and nebulized 10 ml saline solution at 6 l.min<sup>-1</sup> (Philips Respironics InnoSpire Essence, Philips Healthcare, West Sussex, UK) [13] were used to create smoke and saline particles. We waited for 2.5 minutes for the homogeneous distribution of particles and then began serial counting.

All preparatory experiments were performed on a 33-year-old healthy male volunteer lying in the patient position and wearing PPE. The particle meter was calibrated to 0.3-5.0  $\mu\text{m}$  and its air intake valve placed near the surgeon's

chest during surgery: approximately 70 cm outside the protective barrier and 110 cm above the floor.

The baseline particle level was determined by 10 measurements without aerosolization and the protective barrier. The time of maximum particle levels was determined by 10 serial counts during simultaneous aerosolization of saline and smoke without the protective barrier. Each count was performed at 30-second intervals, consecutively for 3 minutes, for 70 measurements in total. The maximum particle level was obtained eight times at 2.5 minutes, and twice times at 3 minutes. During the 3-minute maximum level, the second highest level was achieved at 2.5 minutes, with no statistically significant difference ( $p=0.01$ ). Homogeneous distribution and maximum particle levels were accepted at 2.5 minutes.

Using the protective barrier, particles were counted in three different scenarios: smoke particles only (s group); saline particles only (S group); smoke and saline particles together (s+S group). These scenarios were then combined with negative suction and oxygen to differentiate an s+SO group, S+SO group, and s+S+SO group, respectively. These six scenarios were tested serially ten times, at 2.5-minute aerosolization. After each count, the room doors were opened, and we waited 45 minutes to allow the baseline particle level to return to normal passively. This was confirmed by particle measurement.

**Statistical analysis:** Statistical analyses were performed using SPSS 22.0 (IBM Corp, Armonk, NY). To evaluate the effectiveness of the barrier, particle level differences between baseline, maximum, s, S, and s+S groups were compared with one-way ANOVA and post-hoc Tukey test. To evaluate the effectiveness of the combinations with suction and oxygen, we investigated particle levels of s, S, and s+S groups compared to s+SO, S+SO, and s+S+SO groups with *Student's t test*.  $p<0.05$  was considered statistically significant.

## Results

A total of 436 patients (105 females; 331 males; mean age  $38.7\pm 10.2$  years, range 15-88) were included. Seventeen patients had previously received COVID-19 treatment and healed without complication. Of the total number of patients, 134 had comorbidities that worsen COVID-19 (Table 1).

**Table 1.** Comorbidities of the patients.

Comorbidities	Number of the patients (N)
Elderly	23
Obesity	11
Smoking	52
Type II diabetes mellitus	18
Chronic renal failure	5
Chronic heart disease	5
Chronic obstructive pulmonary disease	7
Chronic asthma	13

A total of 308 patients had no clinical evidence of COVID-19, and 37 patients had negative clinic and PCR tests within two days of their surgery. Ninety-one patients were suspected of having contracted COVID-19; 67 had symptoms (fever, cough, weakness, sore throat, fatigue, chills, shortness and difficulty breathing, muscle and body aches, headache, loss of taste/smell, nausea vomiting, diarrhea); 24 of these patients had close contact with a COVID-19-infected patient in the two weeks prior. These suspected patients underwent COVID-19 tests (blood, radiological, or PCR test); 72 were negative and proceeded to surgery; 19 had positive COVID-19 tests with leukocytosis, typical x-ray or CT imaging of COVID-19 pneumonia, and a positive PCR test, so surgery was performed as per their comorbidity. Eleven COVID-19 confirmed patients without

comorbidities underwent surgery with maximum protective measures. The indications were reconsidered in eight other COVID-19 positive patients with comorbidities or poor CT findings, and their surgeries were performed after COVID-19 treatment. Nineteen patients with positive tests were followed-up and treated by the *Department of Infectious Diseases*. All patients underwent urgent surgical treatment on the upper (n=349) and lower (n=87) extremities (Table 2).

**Table 2.** Types of surgical procedures applied to the patients.

Types of surgeries	Number of patients (N)
Closing finger amputation stump with local flap	14
Repair digital neurovascular injury	23
Repair laceration of extensor tendon	31
Burn <i>debridement</i>	8
Finger fasciotomy due to injection injury	5
Drainage of abscess, paronychia and felon	72
Finger amputations of diabetic necrosis	33
Foreign body removal	41
Resection of pyogenic granuloma	8
Reduce dislocation of finger joint	5
Pin removal after union fractures	23
Malignant tumor resection	13
Skin laceration repair	20
Defect reconstruction with local flap	14
Necrotic wound debridement	37
Aching ingrown toe nail	33
Resection of infected and painful callus	5
Suturing dehiscence on flap margin	19

The average duration of surgery was  $36.8 \pm 8.7$  min (range, 23-61). Aerosol-generating surgery using bipolar electrocautery was performed in 261 patients. Wound dehiscence was observed in 15 patients; eight were re-sutured, and seven had secondary healing. Partial flap necrosis developed in eight patients, healed by debridement and secondary healing. Surgical site infection that responded to oral antibiotics was observed in 11 patients.

Patients easily tolerated the protective barrier and were satisfied with the surgical period (mean satisfaction score,  $4.78 \pm 0.3$ ). COVID-19 infection was detected in 17 patients within two weeks after surgery, all of which healed uneventfully, and there was no sign of contamination to the surgical team within two weeks after the surgeries.

#### **Transmission test**

In total, 140 experimental particle measurements were performed and averaged (Table 3). The average baseline level of particles was  $554.1 \pm 59.6$  particles/L in the day surgery room. The average maximum level of particles was  $16322.9 \pm 1069$  particles/L and the particle level returned to baseline at a mean of 45 minutes after measurement. Average particle levels of s, S, and s+S groups were  $3150 \pm 390.8$ ,  $2207.7 \pm 228.8$ , and  $4637.3 \pm 402.2$ , respectively. When compared to maximum particle levels, there was a statistically significant reduction in the three groups ( $p < 0.001$ ). Additionally, with concomitant use of negative suction and oxygen, the average particle levels of the s+SO, S+SO, and s+S+SO groups reduced by  $802.8 \pm 62.4$ ,  $605.7 \pm 47$ , and  $907.5 \pm 77.4$ , respectively. These decreasing levels were statistically significant for each group ( $p < 0.001$ ).

#### **Discussion**

Health care workers (HCWs) fight at the forefront of the COVID-19 pandemic and have

**Table 3.** The measurement results of airborne particles.

	Baseline particles	Maximum particles	Smoke particles (s group)	Saline particles (S group)	Smoke and saline particles (s+S group)	Smoke particles with suction and oxygen (s+SO group)	Saline particles with suction and oxygen (S+SO group)	Smoke and saline particles with suction and oxygen (s+S+SO group)
1 test	495	18346	3236	1955	4843	843	620	972
2 test	551	15448	2751	2129	3966	790	533	865
3 test	533	16167	3872	2585	5277	875	569	1058
4 test	678	17342	3462	1882	4664	909	616	868
5 test	559	14760	2705	2217	4431	758	591	888
6 test	520	16459	3359	2546	5125	831	655	974
7 test	607	15932	2760	2153	4751	741	608	792
8 test	594	15236	3045	2231	4348	707	554	841
9 test	531	16478	3459	2320	4230	802	692	885
10 test	473	17061	2851	2059	4738	772	619	932

increased risk of hazard infection [4,14,25]. COVID-19 affecting HCWs causes unprecedented challenges on healthcare systems [2,4-6,10-14,19,22,25,26]. Thus, it is very important to protect HCWs to maintain the smooth running of healthcare services [2,4,5,8,10,25] and the use of PPE to reduce aerosol contamination is recommended [4-7,10-15,22,25-27]. However, PPE does not offer full protection, creating a need to identify and treat all SARS-CoV-2 infected patients, and develop new protective equipment [5,10,11,17,18,21]. The reliability of diagnostic tests for identification of infected patients is not sufficient. Lung tomography causes radiation exposure and is useless in the absence of lung involvement. PCR test availability may be limited, and these fail to identify all COVID-19 infected patients due to high false negative rates [8,22]. Thus, creating a safe environment during physical examination, endotracheal intubation, and surgical management is essential, and an effective barrier system needs to be developed [21].

Various protective equipment, such as aerosol boxes, plastic drapes, wraps, and sheets have been proposed to prevent viral transmission

[2,10-18,21-26]. Plocienniczak et al. [21] used a protective hood in different clinic simulations of sneezing during nasolaryngoscopy, and aerosols exposure was significantly decreased. Simpson et al. [13] tested different aerosol containment devices during in situ simulation of tracheal intubation, and showed that vertical or horizontal barriers are insufficient to reduce particle transposition; but a sealed aerosol containment box with active suction presents a significant decrease in airborne particles. Cubillos et al. [11] introduced a protective barrier to the head and neck area, including a rigid PVC frame chamber made using CAD software and 3D printers. This included suction, oxygen, and nebulizer ports, and was covered by a transparent plastic bag. The effectiveness of this barrier was evaluated by preliminary and qualitative simulation of a leaked fluorescein solution to the surrounding environment and visualization under ultraviolet light. Similarly, Blood et al. [2] developed the COVID-19 Airway Management Isolation Chamber (CAMIC), a physical barrier with suction and oxygen ports which covered the head, neck, and shoulders to isolate the patient airway. They used a clinical simulation model of smoke and saline nebulization and prevented

more than 99% spread of particles into the surrounding environment. These experimental simulation models showed that using closed system protective barriers to isolate the patient airway from the surgical environment reduces the dispersion of particles, and the effectiveness thereof increases when combined with negative suction and oxygen. Similar barriers have been used in clinical treatment. Tolisano et al. [22] modified a CAMIC and successfully used it for surgical treatment of urgent otologic pathology. Leow et al. [28] used a disposable waterproof protective barrier including a transparent window to see and communicate with the patient during treatment of biliary obstruction by endoscopic retrograde cholangiopancreatography. However, no protective barrier has been used and reported for extremity surgeries. We performed smoke and saline aerosolization without any protection, and particle levels increased approximately 30 times in the day surgery room. This shows that our aerosol generation model is useful for aerosol and droplet spread. With use of our protective barrier, the number of spreading particles significantly decreased, and it was an effective barrier in the prevention of the spread of aerosols and droplets.

The concomitant use of negative suction and oxygen increased the effectiveness of the protective barrier by mimicking laminar flow to reduce particle distribution to the environment. Patients who underwent urgent surgical treatment on the upper and lower extremities easily tolerated the protective barrier and were satisfied with the surgical duration. There was a statistically significant reduction in smoke and saline particles with use of the protective barrier, and the further addition of negative suction and oxygen potentiated the protective effect.

Extremity surgery, especially of the hand, was one of the most common surgical procedures during the pandemic. During the stay-at-home

period, simple home-type injuries that can be treated with outpatient procedures increased. Proximity and direct contact with a patient's respiratory system, the main reason for virus transmission, is unnecessary during treatment of these injuries. We clinically used this barrier during wide-awake local anesthesia surgeries of extremities. In this way, some pre-surgical preparation, blood and radiological tests, and timely inpatient services can be skipped; and the duration of the patient's hospitalization, workload of HCWs, and risk of viral transmission can be reduced. COVID-19 infection was confirmed in 3.9% of our patients within two weeks after surgery, but no signs and symptoms of COVID-19 were observed in the surgical team.

During wide-awake local anesthesia, and just before and after general anesthesia, patient comfort and the patient-physician relationship are especially important. Protective barriers should not negatively affect this relationship and the practice of the physician. Querney et al. [10] tested the satisfaction of anesthesiologists during airway management with two different protective barriers. They showed high acceptance rate of barriers without negative effects on communication, visualization, or maneuverability, which will be effective with high user uptake. However, the physical and psychological conditions of patients in clinical practice limits the use of these protectors. Also, similar satisfactory results cannot be obtained with different anesthetic equipment such as direct laryngoscopy or a supraglottic device; some barriers that isolate the head and neck may be uncomfortable and provoke claustrophobia, anxiety, and combativeness [16]. Our barrier was larger than simply a head and neck isolation barrier, so may ease patient comfort and tolerance, and improve the patient-physician relationship.

Our protective barrier is universal, readily available, simply constructed, low cost, reusable, and easy to disinfect. It allows proper isolation of the patient during procedures, increases patient and HCW safety, does not affect communication, allows observation of the patient, permits versatile manipulation of its transparent structures, and allows for a comfortable procedure with high patient satisfaction. However, our study has some limitations. We did not perform an antibody test for SARS-CoV-2 on the members of the surgical team interacting with the patients. This may have allowed asymptomatic contamination to be overlooked in follow-ups. We also did not include the study of our barrier in high-risk AGPs; however, these procedures can be performed with our protective barrier by taking extra precautions. The baseline particle level could not be reached in our study. This shows that protective barriers alone are not sufficient to entirely protect from aerosolization but provide the significant reduction of spread of particles into the surgical environment. Protective barriers still need further development and maximum precautions should be taken during the COVID-19 pandemic.

## Conclusions

Emergency surgery is a challenging procedure during a pandemic. The surgical team is at increased risk during the COVID-19 pandemic, so an additional barrier is required for protection against viral transmission. It is well known that mechanical barriers reduce the risk of environmental contamination. Our novel transparent protective barrier including continuous negative suction and oxygen in the operative field helps to reduce occupational transmission of SARS-CoV-2 and patient airborne particles to HCWs during extremity surgeries.

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