AO CMF International Task Force Recommendations on Best Practices for Maxillofacial Procedures during COVID-19 Pandemic

Executive Summary

1. Surgical procedures involving the nasal-oral mucosal regions are increased risk for infection of medical personnel due to aerosolization of SARS-CoV-2.
2. Asymptomatic patients may be infected with SARS-CoV-2.
3. Decisions should be locally based, as factors vary by locale; this includes incidence, prevalence, patient and staff risk factors, community needs, resource availability and personal protective equipment (PPE). It is imperative to accurately determine the disease burden and curve trajectory.
4. During times of potentially high incidence, elective procedures and routine ambulatory visits should be canceled, until guidance is provided by government or hospital officials, and professional organizations permitting re-opening for elective clinical services.
5. Appropriate PPE should be worn during surgical procedures and ambulatory visits, which may include FFP2/N95 and full-face shield or controlled air purifying respirators (CAPR) or powered air-purifying respirators (PAPR).
6. Intra-operative measures which limit the generation of aerosolized particles that may harbor virus are recommended.
7. Procedures (eg oncologic) in which a worse outcome is expected if surgery is delayed more than six weeks should be performed with appropriate PPE and testing, if available.

Background

The COVID-19 pandemic is a global problem that has adversely and significantly impacted the safe practice of maxillofacial surgery. It is important to compile information and experiences that have been gained by colleagues worldwide and define a set of best practice guidelines for staff performing and for patients undergoing maxillofacial operations. These recommendations should be treated as “expert opinion” and are based on personal communication, various national and international societies' guidelines, and peer-reviewed publications.

Operations involving the nasal-oral-endotracheal mucosal region are considered high risk due to aerosolization of the virus which is known to be in high concentration in these areas when compared to swabs from the lower respiratory tract[1]. Further it appears that if viral particles become aerosolized, they stay in the air for at least 3 hours, if not longer[2]. Based on experience

in Wuhan, China, and Northern Italy, FFP2/N95 masks were not enough to control this spread of the disease and it was not until powered air-purifying respirators (PAPR) were introduced that transmission of the virus was controlled among medical personnel. It has been reported that the entire staff (14 people) of an operating room in Wuhan were infected during an endoscopic trans-sphenoidal pituitary procedure, and there was a significant mortality of otolaryngologists and ophthalmologists in the Wuhan region, thought to be related to exposure to aerosolized virus from the nasal and oral airway mucosa. Of note, this is not the common experience of most surgeons.

General Comments/Observations

Pending government and local guidance in terms of reopening clinical practices, routine, elective procedures including dental should be cancelled and rescheduled when safe management strategies have been identified. Ambulatory visits should be limited to those patients requiring urgent intervention or follow-up. FFP2/N95 with eye protection or PAPR/CAPR should also be considered for urgent clinic procures. Non-urgent visits can be replaced by a telephone conversation, or videoconference if local regulations permit, and resources are available.

Procedures should be limited to those involving emergent airway management, epistaxis, surgical management of facial fractures which require ORIF, and oncologic procedures in which a delay in management could affect ultimate outcome.

Local disease burden and community spread will ultimately dictate testing protocol. Absent symptom and virus test status, all patients should be assumed to be infected and treated accordingly. Evidence of negative COVID-19 may be established by two negative COVID-19 tests separated by up to 48 hours due to the possibility of false negative results. Testing of asymptomatic patients may not be feasible and some trauma patients will not be able to provide a history to risk stratify the patient.

Consideration should be given to limiting patient contact for surgeons that are over 60 years of age, are immunosuppressed, have chronic pulmonary disorders, or multiple co-morbidities. The number of advanced practice providers and other medical personnel should be limited as much as possible. Proper PPE and training for all members of the team is required.

Personal Protective Equipment (PPE)

There are three categories of PPE: standard, special and enhanced:

- **Standard PPE** is a surgical cap and mask, gloves, gown, and eye protection
- **Special PPE** is minimum requirement FFP2/N95 mask plus face shield or goggles (or mask with attached shield over FFP2/N95), gloves, nonporous gown, disposable surgical cap.
- **Enhanced PPE** is minimum requirement FFP3 mask plus face shield, gloves, nonporous gown, disposable hat. Alternatively, PAPR/CAPR can be used.

If the COVID status of the patient is unknown, or unable to be determined, then *Special PPE* is strongly encouraged. It is generally accepted that *Enhanced PPE* with FFP3 or PAPR/CAPR

provide better protection and should be used in place of FFP2/N95 masks if available. We realize that PAPR/CAPR may not be widely available, and other systems or strategies can be used such as the helmet based personal protection product with an FFP3 mask, or an FFP2/N95 or FFP3 mask combined with goggles and a hood. Scrubs worn during the procedure should be changed immediately afterwards.

The life span of a FFP2/N95 mask, is designed as a single use device. When access is limited, it can be extended by at least two accepted sterilization processes:1) hydrogen peroxide vapor (Battelle) or 2) UV-C irradiation (Surficide). FFP2/N95 masks have been shown to tolerate 50 and 30 sterilization cycles respectively. These systems may be available in your hospital. Additionally, a standard surgical mask may be worn as single use on top of the FFP2/N95 or FFP3-mask to avoid contamination and to provide multiple use of the FFP2/N95 or FFP3-mask.

Specific Recommendations

Operating in the naso- or oro-pharynx put the provider at an increased risk for occupational exposure to SARS-CoV-2 as respiratory droplets or aerosolized particles are produced that may be contaminated with SARS-CoV-2. Specific tips and suggestions are provided to mitigate this risk as much as possible. Recall that standard surgical masks are not classified as respirators and are not tested for filtering. As such standard surgical mask does not provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered to be a respiratory protection. Only N95/FFP2, FFP3 and PAPR/CAPR are true respirators, and tested for filtering. Filtering effectiveness of a respirator is a determined value, not an estimate which is why that it is important to be fit tested for these devices.

If the surgeon wishes to alter PPE recommendations, the occupational risk for SARS-CoV-2 exposure should guide PPE recommendations. Estimates of occupation risk are summarized in appendix 1. If the estimated risk cannot be determined or it is higher than the surgeon is able to tolerate, then *Special PPE* is strongly encouraged, as *Standard PPE* would be in sufficient protection.

Airway Management

Intubation should be performed by the most experienced member of the team. This is not the time for multiple attempts, and letting everyone have a turn. Short term paralytic agents should be used to limit coughing. Limit the amount of mask/bag ventilation prior to intubation, and avoid jet ventilation, suctioning as little as necessary to mitigate aerosolization. Intubation is preferred over placement of LMA.

The OR team should be outside the door for 20 minutes following intubation before entering the OR. After this 20-minute delay, the team should enter with appropriate PPE (FFP2/N95 or PAPR/CAPR). The reason for this is after an aerosol generating procedure (AGP), the virus could be present. Based on the OR air exchange per hour, 99% of pathogens should be clear in 14 minutes, and 99.9% by 21 minutes[3]. All unnecessary personnel should be outside the room for

extubation and an oxygen mask should be placed over the face after the tube is removed to mitigate aerosolization with coughing.

Tracheotomy in COVID-19 patients is performed for similar indications to non-COVID-19 patients. Mortality in patients intubated for COVID-19 associated respiratory failure is greater than 50% and duration can be 3 - 6 weeks. The decision for percutaneous or open approach for the procedure is at the discretion of the surgeon. In general, in the hands of an experienced provider, an open approach may lead to less potential aerosolization, and therefore less risk. The patient should be paralyzed, preoxygenated, ventilation held before the trachea is incised to minimize aerosolization. Suctioning should be limited as much as possible, to avoid aerosolization. Bipolar cautery is preferred over monopolar. Advance the tube distally prior to incising the trachea, to avoid creating a hole in the ETT balloon. Closed suctioning systems are preferred for tracheotomy care.

Highlighted recommendations from the American Academy of Otolaryngology[4] include:

- Decision-making in tracheotomy should take into consideration the surgical and ICU team's discretion as well as institutional policy.
- Avoid tracheotomy in COVID-19 positive or suspected patients during periods of respiratory instability or heightened ventilator dependence.
- Tracheotomy can be considered in patients with stable pulmonary status but should not take place sooner than 2-3 weeks from intubation and, preferably, with negative COVID-19 testing.
- Adhere to strict donning and doffing procedures based on institutional protocol.
- Limit the number of providers participating in tracheotomy procedure and post-procedure management.
- Perform the entire tracheotomy procedure under complete paralysis.
- Rely on cold instrumentation and avoid monopolar electrocautery.
- Advance ETT and cuff safely below the intended tracheotomy site and hold respirations while incising trachea.
- Minimize tracheal suctioning during procedure to reduce aerosolization.
- Choose cuffed, non-fenestrated tracheotomy tube.
- Maintain cuff appropriately inflated post-operatively and attempt to avoid cuff leaks.
- Avoid circuit disconnections and suction via closed circuit.
- Place a heat moister exchanger (HME) with viral filter or a ventilator filter once the tracheotomy tube is disconnected from mechanical ventilation.
- Delay routine post-operative tracheotomy tube changes until COVID-19 testing is negative.

CMF Trauma

Procedures should be performed by an experienced surgeon, with a minimal number of assistants possible. In general, closed procedures, if internal fixation is not required for stability of the reduction are favored. Specific recommendations follow based on the anatomical region.

Lower face/mandible fractures:

1. Consider closed reduction with self-drilling MMF screws
2. Scalpel over monopolar cautery for mucosal incisions
3. Bipolar cautery for hemostasis on lowest power setting
4. Self-drilling screws for monocortical screw fixation
5. When drilling is required, limit or eliminate irrigation
6. If drilling is required, consider a battery powered low speed drill
7. If a fracture requires ORIF, consider placement of MMF screws intra-orally, then place a bio-occlusive dressing over the mouth, and use a trans cutaneous approach rather than an extended intraoral approach
8. If osteotomy is required, consider osteotome instead of power saw

Midface fractures

1. Consider closed reduction alone if fracture is stable following reduction
2. Consider using Carroll-Girard screw for reduction, and avoid intra-oral incision, if two-point fixation (rim and ZF) is sufficient for stabilization
3. Scalpel over monopolar cautery for mucosal incisions
4. Avoid repeated suctioning/irrigation
5. Bipolar cautery for hemostasis on lowest power setting
6. Self-drilling screws preferred
7. If osteotomy is required, consider osteotome instead of power saw or high-speed drill

Upper face fractures/frontal sinus procedures

1. Consider delay of non-functional frontal bone/sinus fractures
2. Endoscopic endonasal procedure, and the associated instrumentation (power micro debriders) carry a very high risk of aerosol generation and should be avoided if possible
3. When stripping of the mucosa is necessary, minimize the use of high-speed burr or power equipment
4. Avoid repeated suctioning/irrigation
5. Bipolar cautery for hemostasis on lowest power setting
6. Self-drilling screws preferred
7. If osteotomy is required, consider osteotome instead of power saw

Oncologic Care (adapted from Kaiser Permanente Northern California; see "Other Resources")

If non-surgical therapy is equivalent to surgery + radiation, non-surgical therapy is recommended.

1. Cases in which a worse outcome is expected if surgery is delayed more than 6 weeks, eg squamos cell carcinoma of the oral cavity, oropharynx, larynx, hypopharynx
2. Cancers with impending airway compromise
3. Papillary thyroid cancer with impending airway compromise, rapidly growing, bulky disease
4. High grade or progressive salivary cancer
5. T3/T4 melanoma (see new recommendations for treatment of melanoma)

6. Rapidly progressing cutaneous SCC with regional disease
7. Salvage surgery for recurrent/persistent disease
8. High grade sino-nasal malignancy without equally efficacious non-surgical options

Advisement Concerning Dental Procedures (adapted from AAOMS 3/17/2020)

1. Emergency and urgent care should be provided in an environment appropriate to the patient's condition, and with appropriate PPE. Recall that any procedure involving the oral cavity is considered high risk.
2. Asymptomatic patients requesting removal of disease-free teeth with no risk of impairment of the patient's condition or pending treatment should defer treatment to a later date.
3. Asymptomatic patients, patients under investigation (PUI), and patients tested positive for COVID-19, who have acute oral and maxillofacial infections, active oral and maxillofacial disease, should be treated in facilities where all appropriate PPE, including FFP2/N95 masks, are available.
4. Patients with conditions in which a delay in surgical treatment could result in impairment of their condition or impairment of pending treatment (e.g., impairment of the restoration of diseased tooth when another tooth that is indicated for removal prevents access to the diseased tooth) should be treated in a timely manner if possible.

This is an evolving dynamic situation, and these recommendations are based on the best currently available information. Please remember, these are recommendations, not mandates. The decision of the treatment of patients still rests with the individual practitioner. Our primary goal is to provide safe and effective treatments for our patients, while minimizing the risk to the practitioner and staff as much as possible.

Please send your input, comments and questions to: erich.roethlisberger@aocmf.org

7 June 2020

The members of the AO CMF COVID-19 International Task Force

Michael Grant, MD, PhD, FACS	Baltimore, Maryland USA
Daniel Buchbinder DDS MD	New York, New York, USA
Thomas B. Dodson DMD MPH FACS	Seattle, USA
Stefano Fusetti MD DMD FIBCSOMS	Padova, Italy
Mike YY Leung BDS MDS PhD	Hong Kong
Alexander Schramm DDS MD	Ulm, Germany
Brad Strong MD	Sacramento, California, USA
Eppo Wolvius DDS MD	Rotterdam, Netherlands
Gregorio Sánchez Aniceto DDS MD	Madrid, Spain

References

1. Zou L, Ruan F, Huang M, et al. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. N Engl J Med. 2020 Mar 19;382(12):1177-1179. doi: 0.1056/NEJMc2001737. Epub 2020 Feb 19.
2. van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. N Engl J Med. 2020 Mar 17. doi: 10.1056/NEJMc2004973. [Epub ahead of print]
3. Website of the Centers for Disease Control and Prevention: Infection Control > Environmental Infection Control Guidelines > Part IV. Appendices > Appendix B. Air > Airborne Contaminant Removal > Table B. 1. ACH and time required for airborne-containment removal by efficiency https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html
4. Tracheotomy Recommendations During the COVID-19 Pandemic; American Academy of Otolaryngology – Head and Neck Surgery https://www.entnet.org/content/tracheotomy-recommendations-during-covid-19-pandemic

Other Resources

- HN Cancer Care Guidelines during COVID-19 Epidemic, Kaiser Permanente Northern California
- University of Stanford Commentary on Nasal Procedures in the COVID-19 Era (Stanford University SOM, Depts. of Oto-HNS & Neurosurgery, March 2020)
- Integrated infection control strategy to minimize nosocomial infection of coronavirus disease 2019 among ENT healthcare workers (Journal of Hospital Infection, February 22, 2020)
- Guidance for Surgical Tracheostomy and Tracheostomy Tube Change during the COVID-19 Pandemic (ENT UK, March 19, 2020)
- British Association of Head & Neck Oncologists – Statement on COVID-19 (BAHNO, March 17, 2020)
- Guidance for ENT surgeons during the COVID-19 pandemic (Australian Society of Oto HNS, March 20, 2020)
- Managing Cancer Care During the COVID-19 Pandemic: Agility and Collaboration Toward a Common Goal (Journal of the National Comprehensive Cancer Network, March 15, 2020)

Appendix I

The occupational risk for SARS-CoV-2 exposure operating on a single SARS-CoV-2 negative patient is a function of three parameters:

- SARS-CoV-2 prevalence in the community (x)
- Filtering effectiveness of the surgical mask (y)
- False negative rate of the test (z).

To estimate the occupational risk, multiply the three parameters together, i.e. x * y * z. For example, if the prevalence of SARS-CoV-2 in symptomatic patients is 10%, the filtering effectiveness of the surgical mask is >95%, and the false negative rate is 5%, the estimated risk for occupational exposure is 2.5 SARS-CoV-2 exposures per 10,000 patient contacts (0.1 * <0.05 (1 minus filtering effectiveness) * <0.05). The surgeon would need to determine specific values for these three variables in order to provide situation-appropriate estimates for the risk of occupational exposure to SARS-CoV-2 in their communities. The accuracy of the estimate of the exposure risk is dependent on the quality of the measurements of SARS-CoV-2 prevalence, false negative rates, and filtering effectiveness of the mask. Over time, through improved volume of testing and accuracy of tests, we should obtain good values for SARS-CoV-2 prevalence and false negative rates. Recall that standard surgical masks are not classified as respirators and are not tested for filtering. This would be the analysis required for a single patient encounter. However, we do not treat single patients, we treat many patients over time, and therefore the surgeon would incur a cumulative risk over time. The Bernoulli chain for binominal probability is the simplest model to estimate cumulative risk. For example, if the exposure risk for 1 patient is calculated to be 0.0001, then for every 1% of patients may be SARS-CoV-2 positive.For 1000 patients, it may be as high as 9%.Surgeons must assess their comfort with the cumulative risk and employ appropriate *Standard* or *Special PPE*.