A Protocol for Safe Head and Neck Reconstructive Surgery in the COVID-19 Pandemic

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INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) pandemic has swept across the globe and challenged healthcare systems worldwide. COVID-19 is the clinical disease manifested by infection with the single-strand RNA coronavirus SARS-CoV-2. The virus emerged in China in December 2019 and has circled the globe in the subsequent months, leaving a path of grim morbidity and mortality in its wake. As of July 2020, global SARS-CoV-2 cases have surpassed 17 million, with a case fatality rate of 3.9%. Total cases in the United States have surpassed 4.4 million with a case-fatality rate of 3.4%. These numbers reflect confirmed cases, which likely represent an underestimate of the total numbers of infected patients and deaths. Reverberations in global health systems are only now just beginning and will be felt for the foreseeable future.

The disease has a widely varied clinical spectrum from asymptomatic to severe infection, with ultimate acute respiratory distress syndrome and multi-organ system failure leading to death. In general, those with advancing age and comorbidities are disproportionately affected with the severe manifestations of the disease, but young, healthy individuals can be afflicted with a severe course as well, especially in the setting of obesity.

Transmission is largely via droplets and fomites, though aerosolization can occur especially with instrumentation of the aero-digestive tract. Droplets spreading 1–2 meters upon sneezing or coughing can transmit the virus upon inhalation, with ACE2-mediated cell entry. The virus can survive on inanimate surfaces up to 9 days and demonstrates tropism for mucosal surfaces such as the conjunctiva, oral, nasal, and pharyngeal mucosa. The incubation period ranges from 1 to 14 days, with a median of 3–7 days, and patients are infectious during this time even if asymptomatic. Testing for the novel coronavirus typically relies on reverse-transcription polymerase chain reaction (RT-PCR) assay; however, its true sensitivity is unknown, with 1 Chinese study demonstrating an approximately 70% sensitivity of the test in their cohort. Factors that may affect sensitivity include timing that the individual was infected, viral load and shedding, varying markers for detection, location of sample taken (nasopharynx, oropharynx, tracheal aspirate), and operator-dependent quality of sampling. Serologic antibody testing is being performed at some institutions, and it may indicate current or prior SARS-CoV-2 infection.

Intubation, extubation, and surgical intervention in the aero-digestive tract have been shown to be highly risky for COVID-positive patients due to aerosol generation. When aerosolization occurs from the pharyngeal region, the aero-digestive tract has been shown to be highly risky for COVID-positive patients due to aerosol generation.
a penumbra of high viral concentration is disseminated into the ambient air. Surgical interventions on this region, combined with mechanical ventilation, appear to create a supra-normal dose of viral transmission via aerosol that has caused what appears to be a more aggressive and dangerous variant of the disease, which has led to significant morbidity and even mortalities among surgeons. In fact, a report from China described an endonasal endoscopic procedure performed on an asymptomatic patient in which all 14 healthcare providers who entered the operating room contracted COVID-19, 3 of whom subsequently expired. The patient did not develop fever or symptoms until 3 days later. The lessons from this incident must be learned so as not to allow such occurrences to recur among surgeons in regions of the United States and in the rest of the world, who can have the benefit of an advance notice of this phenomenon.

Despite a moratorium on elective procedures, the plastic surgeon continues to play a critical role in urgent reconstruction. There is a significant risk to both head and neck surgeons and reconstructive surgeons involved in the care of patients requiring treatment for neoplastic, traumatic, or other pathologies. Until a vaccine is available, the virus is eradicated, or widespread accurate testing and contact tracing is achieved, extra precautions must be taken when operating on the aero-digestive tract. We aim to raise awareness of this safety issue and to arm surgeons with protective strategies when performing these high-risk surgeries. We present our conceptualization of these concerns and a framework for moving forward. We recognize that the situation is evolving, but these principles are likely to remain relevant for the foreseeable future, even after pandemic “peaks.”

CHALLENGE

As healthcare systems and hospitals are flooded with COVID patients to varying degrees, patients with unknown COVID status continue to present with traumatic and neoplastic reconstructive needs. They require conventional surgical care in a new and unconventional context. Much remains to be learned about the novel coronavirus and consequently, safety protocols are yet to be fully articulated and tested.

BALANCE

Balance must be struck in the effort to manage this situation for the reconstructive plastic surgeon. Local hospital and regional supply considerations must be considered when conducting any elective surgery in which personal protective equipment (PPE) is to be utilized. Allocation of these resources to front-line management of an influx of COVID patients must be carefully considered and regarded as a high priority in the larger public health context. These considerations must be weighed against the physician’s duty to provide care to trauma and cancer patients. Furthermore, balance must be reached between the safety of surgical teams and the care of our patients. Surgeons who fall ill and die are of no service to their future patients, and this factor must be considered in terms of the larger impact an individual surgeon can have on a population’s health over the course of many years.

GENERAL PRINCIPLES

Plastic surgeons are familiar with operating in the aerodigestive tract for a multitude of reasons. Some of the principles for operating in these high risk locations where aerosolization is a major concern are concepts that must be adaptable to the changing nature of the COVID-19 environment, testing ability and quality, available treatments, vaccine development, and evolving community incidence. We believe that this requires a shift in the typical Westernized medicine paradigm where the full spectrum of techniques and broad indications for intervention are accepted. The crux of the issue is to approach surgery in this context with full safety procedures in place to address the situation of a patient clinically screened negative and double-tested negative who is in fact COVID-positive. Surgery involving the upper aero-digestive tract in this rare event can lead to widespread, severe infection amongst the surgical team. This is a low-frequency, high-consequence scenario and must be managed in a proactive manner. Louis Pasteur is credited with the famous aphorism (paraphrased): “fortune favors the well-prepared.”

1. Patient Selection: Patient selection and indication for surgeries must be carefully considered to safely balance risk and resources.

Non-operative measures that yield an acceptable functional result in facial trauma should be utilized as much as possible. Depending on local resources, difficult ethical considerations may be required. Operative intervention would be preferred in favorable oncologic cases over the geriatric patient with multiple comorbidities and recurrent or advanced cancer who has a poor prognosis.

2. Testing: The ability to test and the quality of those tests will be the keystone in providing essential care for these patients that optimizes both patient and operating team safety.

Reported sensitivity of currently available tests is between 70% and 80%. As a result, 2 negative tests are preferred before surgery. Two RT-PCR tests may be performed; the first test may be conducted 2–3 days before surgery and the second 24–48 hours pre-operative, with at least 24 hours between tests. An alternative option would be a single RT-PCR with a serologic antibody test, if readily available. Patients should be instructed to quarantine during this testing phase for at least a week before surgery; hospital admission and quarantine the day before surgery may be considered, dependent on hospital bed availability. Should the testing prove positive, surgery is to be delayed if not life-threatening until they have been asymptomatic for at least 10 days, as per our hospital protocol, and have a negative result on repeat testing. This may vary from institution to institution and incorporate CDC guidelines and local patient factors. Implicit in this approach is the understanding that COVID-positive patients requiring non-emergent but urgent operation for traumatic or neoplastic disease processes will be treated.
appropriately, but not during active viral infection to spare both risk and morbidity to the patient and the surgical team. Our proposed algorithms have been adapted from a foundation built on Stanford\textsuperscript{20} and Australian\textsuperscript{21} head and neck guidelines, and are depicted in Fig. 1 for facial trauma and in Fig. 2 for head and neck reconstruction.

3. **Operating room setting**: Despite negative testing, the procedure is approached as if the patient were COVID-positive.

   a. Procedure is performed in a negative pressure room or positive pressure with a HEPA filter.
   
   b. Limited operating team: Staff in the operating room should be minimized to those essential for safe completion of surgery.
   
   c. As intubation and extubation confer high risk for virus transmission, we recommend that all operating room staff that are not essential to the intubation process leave the room during intubation and extubation. The AO Foundation recommends waiting 20 minutes after intubation and extubation before surgical team entry.\textsuperscript{22}
   
   d. PPE: Full PPE that adequately protect at-risk surfaces for transmission of aerosolized virus must be worn even in patients who have tested negative (Table 1). Sealed eye protection is crucial because trans-conjunctival transmission with an aerosolized high viral load over a prolonged period of time is possible.\textsuperscript{23} Anti-fog solutions are useful adjuncts in this context. All personnel should be trained at safe donning and doffing of PPE.

### HEAD AND NECK CANCER RECONSTRUCTION

Our working group conceived 3 phases in facilitating safety in head and neck reconstructive surgery as the COVID-19 background evolves.

1. The first phase will vary from one setting to the next and consists of structural limitations on the ability to perform certain head and neck reconstructive operations to accommodate larger system needs, conserving resources to deal with an influx of COVID-19.

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**Fig. 1.** Algorithm proposed for facial trauma.
2. Phase 2 is a transition phase in which logistical stabilization permits selective performance of elective but urgent head and neck trauma and cancer operations with defined safety protocols in place. The capacity to test reliably for SARS-CoV-2 infection is critical to this process to move forward safely.

3. The third and final phase is one on the longer term horizon and is characterized by widespread testing, immunity determinations, and vaccination that will combine with improved understanding of viral behavior to allow for transition back to more normal reconstructive surgical protocols safely.

In addition to the general principles outlined above, considerations for conducting safe head and neck reconstruction are as follows:

1. Separate cancer resection and tracheotomy from reconstruction. The reconstructive team would not be present during the high-risk, major aerosolizing portion of the procedure.

A staged approach may be considered in cancer cases to separate the extirpation and tracheotomy portions from the reconstruction, providing a physical and temporal barrier to aspects of the procedure that

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**Fig. 2.** Algorithm proposed for head and neck reconstruction.
could potentially place the reconstructive team at risk. Although not uniformly preferred in a pre-COVID setting, delaying free tissue transfer reconstruction to the following day has safely been performed by packing of the defect and keeping the patient in the ICU overnight (or hospital ward if no tracheostomy required). This protocol may be strongly considered in the context of the current risk mitigation strategy.

2. Keep high-risk anatomic regions covered when possible during the procedure.

Cover the airway or tracheotomy with an occlusive dressing during the operation, and only expose the oral cavity during flap inset. Once the inset is complete, cover the oral cavity and nose with an occlusive dressing.

3. Microsurgery is to be performed with sealed goggles.

Use of full-sealed eye protection at all times, to include with utilization of the operative microscope, should be considered and has been proved feasible in our hands (Fig. 3). Depending on the resolution, consider performing microsurgery by utilizing the microscope screen, rather than viewing through the eye pieces with sealed goggles. Future innovations may include the production of high magnification goggle loupes to perform microsurgery without the microscope, development of virtual microscope goggles that transmit the magnified images, or use of the surgical robot for microsurgery while sitting in another room.24

4. Microsurgical aspects of the procedure should be performed by the most experienced and efficient members of the microsurgical team.

5. Consider using an anastomotic coupler for both venous and arterial anastomoses (if feasible), based on vessel compliance to reduce operative time.25

6. Post-operatively, these patients require frequent tracheostomy and oral care, which may aerosolize the virus. Proper PPE should be donned when performing postoperative care. Rounding should be conducted with the minimal number of providers necessary to conserve resources and limit exposure.

7. There is increasing evidence of thrombotic-related complications associated with COVID-19, including disseminated intravascular coagulation, acute coronary syndromes, and venous thromboembolism.26–28 Microsurgical reconstruction in the setting of COVID-19 may confer a greater risk of flap failure, and delay of the case should be considered when possible.29

MAXILLOFACIAL TRAUMA

The AO Foundation developed recommendations for craniomaxillofacial trauma, which recognizes the added risk with these procedures and provides several suggestions on ways to mitigate risk.22 Just as operating in the aerodigestive tract confers increased risk, many of these injuries occur in individuals that may be considered high risk, as they may not be performing social distancing. We have incorporated these guidelines in our pre- and peri-operative approach and technique. Their specific guidelines are listed in Table 2.22 Additionally, we have developed a process for management of these patients, which optimizes patient care while minimizing risk and conserving resources. There may be concerns about potential medico-legal consequences, as these recommendations deviate from current standard of practice; however, they are supported by international guidelines such as the AO Foundation, providing some medico-legal protection. The following recommendations may be

Table 1. Recommended PPE in the Setting of Head and Neck Treatment

| Recommended PPE                                      |
|------------------------------------------------------|
| Boot covers                                          |
| Impermeable gown                                     |
| Hair cover                                           |
| Sealed goggles or powered, air-purifying respirator (PAPR), if available |
| N95 mask (with additional surgical mask on top to protect the N95) |
| Double gloves                                        |

Fig. 3. Simulation of operating microscope use, with surgeons donned with N95 masks and fully sealed goggles.
3. Expedite surgery to limit community transmission between time of injury and surgery.

Although many facial fractures can be delayed up to 2 weeks, we attempt to perform repairs within 2–3 days, which allows time for COVID testing on 2 occasions separated by 24 hours followed by surgery. Patients are given instructions to self-isolate.

4. Consider external or closed approaches where feasible
   a. Orbital: Consider a mid-lid or subciliary over trans-conjunctival incision
   b. Zygoma, zygomatic arch: Prefer a Gilles approach over Keen, although many of these may not fall under medically necessary as, except for trismus, these are largely performed to restore form and secondary correction can be performed.
   c. Mandible, Le Fort: Utilize maxillo-mandibular fixation over open reduction internal fixation if possible.

5. Avoid aerosolizing techniques
   a. Limit monopolar cautery. Use scalpel for mucosal incisions, and utilize bipolar cautery on a low setting for hemostasis. When monopolar cautery is necessary, smoke evacuators may be employed.
   b. Avoid high power drilling, and use self-drilling screws when possible. If drilling is required, use a low-power, battery-operated drill and restrict irrigation/suctioning.
   c. Avoid powered saws, and use osteotomes if osteotomies are required.

FUTURE DIRECTIONS AND ULTIMATE RESOLUTION

There are specific challenges that the plastic surgeon will face in providing continued and high-quality care in a COVID-19 environment while maintaining patient, surgeon, and team safety. It is in the DNA of plastic surgeons to adapt and innovate, and thus, we are uniquely prepared to face these challenges successfully. We recognize that our protocol is specific to the context of COVID in our community and hospital as well as our institutional resources; however, these factors provide a framework for plastic surgeons to consider when managing these patients in high-risk surgery.

Further understanding of viral kinetics and viral load (as they pertain to operating room aerosolization and transmission) will be critical to further understanding this issue. Deeper insights into the extent to which immunity is protective from high viral-load transmission as in the case of aerodigestive tract surgery will be critical information to further facilitate a safe return to more normal protocols. Widespread vaccination, serologic immunity assays, and feasibility of contact tracing will be critical in further adaptation of protocols back toward conventional approaches in the future. These developments will likely take many months. In the meantime, it is our group’s sincere hope that the information provided in this discussion is helpful in establishing safe protocols for plastic surgeons and our patients in the context of the COVID-19 pandemic.
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