Case Study

Head & Neck Reconstruction During COVID-19 Pandemic: Our Experience & Protocols.

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Introduction

Initially originating and first confirmed cases being reported in early December of 2019 in the city of Wuhan, China, covid-19 infections have swept across the globe creating a major public health crisis **(**1**)**. WHO declared the Covid-19 outbreak to be a global pandemic on March 11, 2020 **(**2**)**. The speed and the mere intensity of the spread of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) have resulted in unprecedented pressures on health care services worldwide **(**3**)**. The need for hospitalization, High flow nasal oxygen, mechanical ventilation, extracorporeal membrane oxygenation (ECMO) and

support in an ICU setting for a considerable proportion of patients, in addition to staff shortages, have led to the severe curtailment of health care capacity & resources. Several constraints in the already overburdened health care system prevent the timely delivery of comprehensive care. It was obvious during the early stages of a pandemic that health care workers are affected in 29% of the cases, which is disproportionately high **(**4**)**. Fear of viral transmission and poor clinical outcomes among head & neck cancer patients developing covid-19 during the perioperative period have greatly influenced surgical practice and decision-making. Many clinical services have had to substantially reduce, or even cease their routine clinical activity. ENT surgeons, Facio-maxillary surgeons, ophthalmologists, Dentists, have to be aware that the risk of virus transmission between patients and medical staff and vice versa is very high and have to adopt new strategies for care delivery **(**5**)**.

In the setting of the covid-19 pandemic, adherence to previously established clinical protocols has proven difficult. Patient evaluation, disease surveillance, and achieving target wait time for surgery have all been affected **(**6**)**. In these difficult times of constrained resources, consideration should be given to the prioritization of surgical cases, within the subset of patients requiring surgery, microvascular reconstruction for head & neck squamous cell carcinoma needs more contemplation despite the ongoing pandemic **(**6,7**)**.

In this paper, we describe our experience and institutional approach in the perioperative management of patients undergoing surgery with microvascular reconstruction. These protocols and guidelines were developed through consensus among our Departments of surgical oncology, Plastic & facio-maxillary reconstructive surgery and are based on existing scientific literature and guidelines by Head & Neck cancer international group (HNCIG). **(**1,40**)**

During the COVID-19 pandemic, surgical care centers are restricted by their respective states to perform procedures only for life-sustaining measures. Cases that would fit under the guidelines would include (1) acute infection, (2) acute trauma that would significantly worsen without surgery, (3) potential malignancy, (4) uncontrollable pain that would otherwise require hospital admission, and (5) a condition or prognosis that would significantly worsen with a delay in treatment **(**8,9,10**)**.

In outpatient care at our institution for preoperative assessment, we encourage telemedicine video conferencing or a phone call. Although convenient, the limitation of telemedicine consultations is the inability to perform a comprehensive physical examination, vascular assessment of the donor site, although a CT angiogram is possible, cost remains a major concern. In-person assessment of patients is done in the preoperative holding area and proper CDC& OSHA guidelines are followed and encouraged

(11**)**. Post-operative visits have been conducted in person for wound care, flap assessment, tracheostomy care with full personal protective equipment, eye protection and N95 masks or respirators.

Preoperative Screening

As we aimed to restore non-urgent but essential surgical care to address the accumulating surgical needs of our population, we aimed to prioritize both patient and provider safety by developing an asymptomatic surgical patient testing guideline to identify subclinical Covid-19–infected patients. Surgeons have long been stalwart advocates for their patients and, now more than ever, we must navigate a path that carefully weighs benefits with new risks. Indeed, the consequences of performing operations on patients with subclinical Covid-19 infection can be dire, with a mortality rate as high as 20%, far higher than the adverse outcomes seen with other perioperative complications **(**13,14,15**)**.

Taking patients to the operating room with unrecognized Covid-19 infection is associated with an overlay of elevated risk both to the patient and all the health care workers in the operating room, clinic, on the floor, and/or in the intensive care unit **(**13**)**. Therefore, rightly so, perioperative providers have prioritized asymptomatic testing of all surgical patients as an essential stipulation for establishing a new norm for surgical care [Figure 1].

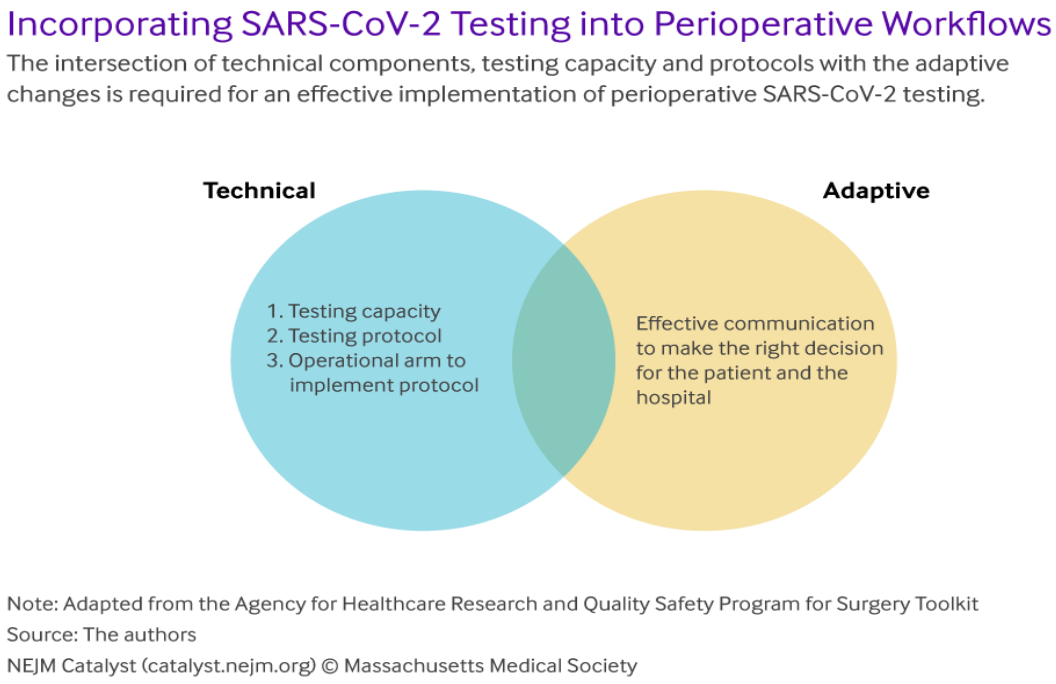

Figure 1

We used reverse transcriptase PCR (RT-PCR) testing to diagnose acute infection of Covid-19. This test detects RNA from the SARS-CoV-2 virus. Given the high analytic sensitivity of PCR testing (>98%) and the low estimated disease prevalence in the Bay Area, the negative predictive value for the test in an asymptomatic patient before surgery is very high. For example, if the prevalence in the Bay Area is assumed to be 1% and the sensitivity of a nasopharyngeal swab test is 75%, then the negative predictive value of the test is 99.3%. This high negative predictive value allowed us to depend on the test as an accurate determination of viral status in our asymptomatic surgical population [Figure 2].

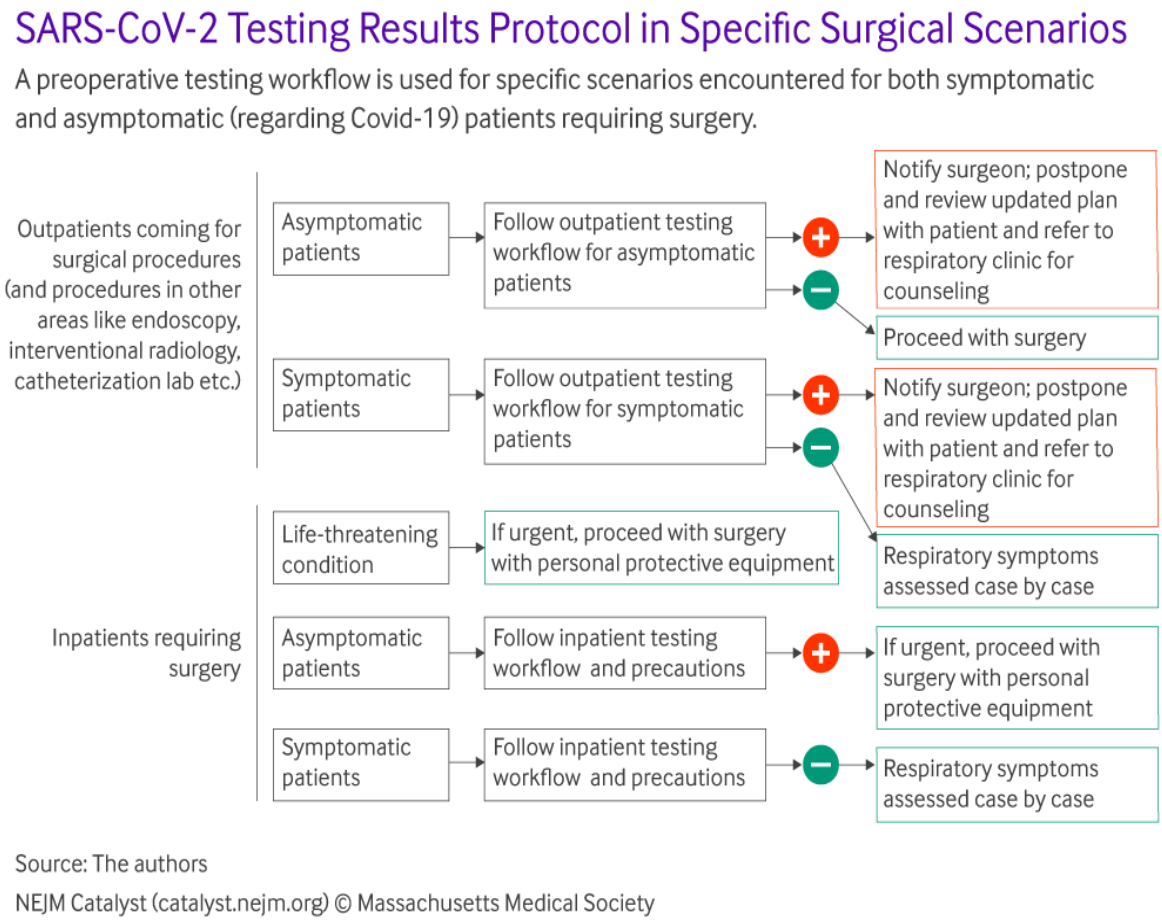

Figure 2

We also encourage rapid IgG/IgM antibody screening for surgical procedures performed in outpatient services. As a protocol, we tend to operate within 48 hrs after a negative RT-PCR test.

Case selection & reconstruction prioritization protocol

Patients with cancer may be at higher risk for COVID 19 disease. They are also more susceptible to infection because of systemic immune suppression caused by the malignancy and anticancer therapies, such as surgery, radiotherapy, chemotherapy, and immunotherapy. A retrospective review of oncology patients admitted to a hospital in Wuhan, China from December 30, 2019, to February 17, 2020, found that patients with cancer harbored a significantly higher risk of COVID 19 (OR, 2.31; 95% CI 1.89 3.02) compared with the community **(**12,16**)** Although current case numbers within our head and neck oncology patients remain low, ongoing community transmission and the vulnerability of our patient population suggests that this may not remain static. Not only are cancer patients more likely to become infected, but they are also more likely to have severe complications from COVID19. Early published reports from China on outcomes of oncology patients with the disease indicated a 3.5 times higher risk of requiring mechanical ventilation, ICU admission, or death compared to patients without cancer. **(**13,17**)** A review of over 72 000 COVID19 cases in Wuhan showed a case fatality rate of 5.6% for cancer patients compared to 2.3% for the overall population. **(**18,20**)**

SARS CoV-2 is characterized by a rapid human to human transmission from droplet contamination arising from the upper aerodigestive tract. **(**19,21**)** Early reports also suggest the possibility of aerosol transmission in the setting of aerosol-generating procedures, such as an instrumentation of the upper aerodigestive tract. **(**22-28**)** Maxillofacial surgeons, ENT surgeons with frequent contact with the upper aerodigestive tract, are at particularly high risk for nosocomial transmission, as seen during the Wuhan outbreak. **(**29**)** Any transmucosal head and neck procedure, including flexible fiberoptic nasolaryngoscopy, should be considered high risk and appropriate PPE must be worn by all team members in the clinical examination room or operative suite. A discussion of what constitutes appropriate PPE for these procedures is out of the scope of this paper; however, in our opinion, PPE should include an N95 respirator, face shield, surgical gown, and gloves. There is debate regarding the viral load in the nasal cavity, pharynx and lower respiratory tract. A report with 17 patients suggested higher loads in the nasal cavity compared to the throat. **(**30,31**)** However, in a series with 82 patients, a close correlation was seen between viral load in throat swabs and sputum. **(**32**)** Further research will be required to determine the variable transmission risk of SARS CoV-2 across the head and neck surgical procedures. **(**33**)**

Our institution case priority criteria for head and neck surgery during the COVID 19 pandemic is shown in **Table I**. Cases have been classified into four major categories: urgent—proceed with surgery, less urgent—consider to postpone >30 days, less urgent and manageable —consider to postpone 30 to 90 days, and case by case basis decision.

TABLE I Prioritization of head and neck surgery cases

Level I: Less urgent & Manageable—Consider postponing between 30 to 90 days;

Thyroid

- Goiter without airway/respiratory compromise
- Routine benign thyroid nodules and thyroiditis
- Para-thyroidectomy with stable renal function

Benign salivary lesions, cysts & tumors

Skin cancer

- Melanoma ≤ 1 mm thickness
- Basal cell carcinoma where cosmetic impact/morbidity is likely low with further growth
- Low-risk squamous cell carcinoma

Level II: Less urgent—Consider postponing> 30 days

- Low-risk Papillary Thyroid Cancer without metastasis
- Low-grade salivary carcinoma

Level III: Urgent—Proceed with surgery

HNSCC (especially those with airway concerns)

HNSCC with significant disease burden or delay in diagnosis

HNSCC patients with complications of cancer treatment

Recurrent HNSCC

Thyroid

- Anaplastic thyroid carcinoma
- Medullary thyroid carcinoma
- Large (>4 cm) follicular lesions, neoplasms, or even indeterminate nodules
- Papillary Thyroid Cancer with suspicion or identified metastatic disease
- Locally aggressive Papillary Thyroid Cancer
- Revision Papillary Thyroid Cancer with the active progression of the disease

Para-thyroidectomy with renal function declining

Skull base malignancy

Salivary cancer

- Salivary duct carcinoma
- High-grade mucoepidermoid carcinoma

- Adenoid cystic carcinoma
- Carcinoma ex pleomorphic adenoma
- Acinic cell carcinoma
- Adenocarcinoma
- Other aggressive, high-grade salivary malignancy

Skin cancer

- Melanoma > 1 mm thickness
- Merkel cell carcinoma
- Advanced stage, high-risk squamous cell carcinoma
- Basal cell carcinoma in a critical area (orbit)

Case by case basis Rare histology with the uncertain rate of progression

Diagnostic procedures, such as direct laryngoscopy with biopsy Flap selection and planning, at our institution we have a multi-disciplinary team (MDT) & a tumor board. This was in place before the current pandemic. The week's cases are presented systematically and the reconstructive plan is discussed in detail. This board has transitioned to a virtual, video conference using the Zoom (Zoom Video Communications, Inc) platform **(**32**)**. Decision algorithms for our patients have changed. Given that these are highly aerosolizing mucosal cases, a major focus has been on simplifying reconstruction and reducing surgical duration when possible. This includes staging reconstruction when acceptable and substituting loco-regional flap reconstruction when feasible. We are limiting cases of microvascular reconstruction to those in which is it felt by consensus to be necessary. Often, these decisions are complex and controversial. Simplifying reconstructive techniques may have functional consequences and may increase the incidence of local wound complications. As such, these decisions much balance concerns regarding surgical expediency, creation of a safe wound, and functional restoration. To standardize this thought process, we have prioritized our maxillofacial and reconstructive cases in a leveled fashion similar to our oncology cases (**Table II**), (**Table III**) & (**Table IV**). The decision regarding performing composite soft tissue with bone reconstruction vs soft tissue reconstruction alone should be carefully considered. For most defects, the addition of bone reconstruction considerably increases operative time and complexity and in the current pandemic, may not be a good indication. Soft tissue reconstruction of small lateral mandibular defects has been shown in some studies to have comparable functional outcomes. **(**5-6**)**Our use of stereolithography models for surgical planning for complex oro-mandibular reconstructions has not changed. In the setting of delays, one might consider forgoing virtual surgical planning due to concerns regarding tumor progression and potential intra-operative plan changes.

TABLE II Prioritization of reconstructive head and neck surgery

Level I: Stage reconstruction with wound care, skin grafting, or local flap.

Small oral cavity defects without neck communication.

Small oro-antral communications or fistula after maxillectomy.

External skin defects without exposed critical structures.

Facial nerve reanimation (functional muscle transfer) Traumatic maxillofacial injuries requiring free tissue transfer.

Level II: Consider free flap reconstruction, substitute loco-regional flaps if feasible.

Small Maxillectomy defects (Also consider prosthetic obturator).

Segmental mandibular defects.

Tongue, the floor of mouth defects <50% without large neck communication.

Patch or overlay reconstruction after laryngectomy

Radical neck dissection with exposed great vessels

Large external skin defects with exposed vital structures/bone.

Level III: Free flap reconstruction required

Anterior oromandibular defects.

Lateral mandibular defects.

Large maxillectomy defects.

Hemi-mandibulectomy defects.

Hemi-glossectomy or sub-total glossectomy.

Tongue, the floor of mouth defects >50% with neck communication.

Total laryngopharyngectomy defects requiring tubed reconstruction.

Skull base defects with exposed intracranial structures/CSF leak.

Table III Prioritization of Oral and maxillofacial surgery

The team involved in procedures generating aerosols and at risk of contamination from bodily fluids must be equipped with full barrier precautions. The covid-19 virus is transmitted in nasal, lacrimal and salivary secretions as well as blood. Consideration should be given to treatment under LA if possible to reduce the risk of aerosol-generating procedures under GA.

Level I: Low Risk

- Routine dental extraction.
- Surgical extractions of impacted teeth (Level II when a lot of bone-cutting involved)
- Bridle wire, arch bars, Leonard buttons/ eyelet wiring/bonded brackets, or IMF Screws as an alternative to ORIF
- TMJ arthroscopy.

There is evidence that 0.04% of chlorohexidine mouth-rinse reduces viral load in saliva.

Level II: High Risk

- Spreading fascial space infections, surgical management of oral cavity infection not responding to antibiotics, Incision & Drainage.
- Cleft lip & palate management.
- Closed reduction of fractures (e.g. elevation zygoma).
- Open reduction & internal fixation under local anaesthesia.
- Intraoral soft tissue trauma management.
- Laser soft tissue excisions.
- Intra oral incisional or excisional biopsy.

Level III: High Risk

- Soft and hard tissue trauma, exploration of wound/arrest of hemorrhage.
- Exploration and repair of nerve.
- Facial bone fractures: Craniofacial/pan facial injuries, midface, zygoma, mandible/condylar fractures, Zygomatic complex fractures, Orbital floor fractures: Exploration and repair with an orbital implant as indicated clinically
- TMJ surgeries.
- Orthognathic procedures & access osteotomies
- Local/Distant/Free Flap reconstructions.
- Benign head & neck tumors, cyst management.
- Head and neck cancer.
- Dental and maxillofacial implant procedures
- Placement of extra oral and intra oral distractors.
- Tracheostomies & care.

Table IV Case statistics during Pandemic lock down (March to August 2020)

CATEGORY	CASES
TRUAMA	
Pan facial fracture	03
Zygomatic complex fracture	07
Mandibular fracture	06
NOE fracture	03
Orthognathic Surgery	
Bilateral sagital split	01
Pathology	
Pleomorphic adenoma	01
Ameloblastoma	02
Odontogenic keratocyst	01
Oncology	
CA Buccal mucosa	19
CA Tongue	10
Mucoepidermoid CA of Maxilla	03
CA maxilla	04
CA Alveolus	13
CA Parotid	03
Micro-vascular reconstruction	20

Intra operative protocol

A key focus at this point is ensuring staff safety and the efficient use of resources. **(**14-15**)** this relates to both the provision of theatre space and the use of full personal protective equipment (PPE). The number of staff in the theatre has reduced due to the increased time required to intubate, extubate the patient and both interventions are aerosol-generating and, therefore important to reduce cross-contamination.

At any stage that an aerosol-generating procedure (AGP) is undertaken, full PPE is worn by staff members required to be in theatre at the time in line with national guidelines. **(**16-17**)** Working in full PPE for long periods is challenging.

Intubation is carried out by a minimum number of the anaesthetic team (typically two anaesthetists and one operating room assistant). After successful intubation, the theatre is cleaned and a rest period of 15 minutes minimum is allowed before any other members of the team enter the theatre.

Our intraoperative procedures have been adjusted to adapt to the COVID-19 pandemic. Changes have been made with the primary goals to decrease exposure risk for the operating room team and to conserve PPE. Given the potentially high viral titers on aerodigestive tract mucosal surfaces, all head and neck

free flap cases involving mucosal surfaces are performed with N95 masks or respirators. We have reduced the size of the operative team to conserve PPE. These major cases are performed with two surgeons. Thus, the reconstructive component of the procedure is performed entirely by the attending surgeon and senior resident. We have worked to optimize case flow to decrease the total amount of PPE used during a case. All flap harvest is done concurrently with flap ablation in a two-team approach so that there is no delay in flap transfer to the defect site after the ablation is completed. Diathermy should be set to the lowest effective settings to minimize aerosolization, and plume extractors should be utilized with monopolar diathermy. High air exchange cycle rates (>25cycles/hr) should be maintained in the theatre during the entire procedure.

The surgical team has decreased the number of times scrubbing in and out during a case to conserve PPE, to remain scrubbed in until their portion of the case is completed. Importantly, this also decreases the number of times that team members are donning and doffing PPE, with PPE removal specifically being a high risk for self-contamination. **(**3,34**)**

Strategies used during tracheostomy to decrease aerosolization are similar to those published after the SARS outbreak and include using full muscle relaxant to prevent coughing, holding ventilation before airway entry, and only resuming ventilation once the tracheostomy tube has been placed with the cuff inflated. **(**8**)** The number of individuals present during the performance of the tracheostomy is limited to two surgeons. We try to utilize tracheostomy judiciously and avoid it in cases in which the indication is marginal. We have noticed subjectively some challenges with prolonged use of the N95 respirators with some surgeons preferring to wear full-face respirators, but these respirators make it difficult to wear loupes. There is some evidence that the prolonged use of N95 respirators alters pulmonary gas exchange and promotes hypercarbia. **(**10,35**)** This can present as a headache or lightheadedness. Headache symptoms are present in 81% of N95 users in one recent study. **(**11**)** Several of our staff members have noted these symptoms during these cases. This has the potential to impact surgical efficiency, performance, and alter decision-making capacity. We recommend strategic team breaks during these prolonged cases for recovery. All free flaps have an arterial and double venous anastomosis. We do not use venous coupler & implantable Doppler due to cost concerns.

Postoperative protocol

The entire head and neck surgery team has been restructured to decrease the risk of exposure to the entire team from a single patient or a single team member with COVID19. Each team has at least one ablative and one reconstructive consultant, one head and neck fellow, one senior resident, and one

intern. Interactions between teams have been minimized including separate times to ward/ICU rounds and elimination of shared workspaces. As mentioned previously, discussions are now on a virtual video conferencing platform, which also eliminates physical interaction between teams. The frequency of rounds has been reduced from twice daily to once a day **(**35,36**)**.

One of the biggest changes made in response to COVID19 from a free flap perspective is the postoperative flap monitoring protocol for intraoral/extraoral flaps by decreasing the frequency of flap checks. The goals were to limit the use of PPE needed for flap checks and to limit surgical team and nursing staff exposure risk. Our previous nursing flap monitoring protocol had been flap checks every 1 hour for the first 24 hours (postoperative day 1), every 2 hours for the next 48 hours (POD 2 to 3), every 4 hours for the next 72 hours (POD 4 to 6), then every 8 hours until discharge. Resident flap checks were performed 6 hours immediately postoperatively, then every 12 hours for the first 72 hours, then once daily. Flap checks previously included external handheld Doppler sonography and clinical examination of the skin paddle for color, temperature, turgor and capillary refill. **(**12,37**)**.

In our new flap monitoring protocol, nursing checks are performed at the prior timing interval but only include checking external skin paddle for any color changes. Importantly, the intraoral skin paddle is only checked every 6 hours and requires the use of proper PPE for the examination. Resident intraoral skin paddle assessment is now performed once at 6 hours postoperatively and then once daily on morning rounds.

We have introduced infrared imaging for non-contact monitoring of free flaps. Infrared imaging is a concept introduced in 1800 by Sir William Herschel while measuring the temperature of light this is when the discovery of infrared radiation was made. Based on the concept that all objects emit a “heat signal” in the form of infrared radiation, a thermographic camera detects the radiation in the same way that a normal camera detects light and generates visible heat maps. The flow in vessels & good perfusion in flaps emits a detectable heat signal, which can be identified & localized with thermo-graphic imaging. These changes in flap monitoring decrease the frequency of skin paddle examinations and force a greater emphasis on thermographic camera imaging for sudden temperature changes. we are now able to monitor free flaps continuously and efficiently with the virtually non-contact protocol. Before this change, our protocol called for continuous monitoring for all free flaps with handheld Dopplers and clinical assessment of perfusion in flaps with a skin paddle amenable to clinical examination.

Ultimately, our new protocol reduces the dependence on the postoperative physical examination & prolonged exposure in an ICU setting. It is reasonable to assume that such a change in free flap monitoring could potentially lead to slightly higher flap failure rates, during this time of pandemic we

have not experienced any difference in flap survival rate and the fact we have successfully been able to salvage free flaps with early detection of venous and arterial thrombosis. As a reconstructive unit, this is a risk we have accepted with the hope of reducing potential viral exposures to our team. The effect of resident postoperative flap monitoring frequency on flap survival rates, however, is unclear and controversial. One recent multi-institutional study showed no difference in flap survival rates with reduced resident monitoring frequency. **(**38-39**)**

Conclusion

The recent surge in COVID-19 cases across the globe has caused an extraordinary demand for its health care system. Many institutions have cancelled all elective and non-urgent procedures to conserve PPE, free up inpatient beds, and limit exposure of patients and staff. While operational definitions of elective and urgent categories of surgery exist, there is a degree of surgeon judgment in these designations. To ensure that our identification of a surgical patient as "urgent" is both consistent and evidence-based, we have established a framework to prioritize patients for the operating room, risk categories for transmission, and clinical pathways for preoperative evaluation and transmission alleviation. This current global health crisis will continue to present new challenges for providing high quality and efficient head and neck reconstructive care. In providing care to patients with cancer whose treatment often cannot be postponed, we need to adopt new approaches and thinking to optimize patient outcomes and ensure provider safety.

Our experience with the COVID 19 pandemic has stimulated a fair amount of change in our clinical and administrative practice. It is forcing us to reexamine the urgency of our interventions. At our institution, we have adopted a leveled multidisciplinary approach to our reconstructive decision-making. As surgeons, we bear the responsibility of our decisions and must at all times avoid placing the entire operating room team at risk. When a surgeon schedules an urgent case, the justification for adding it has to be genuine and should not be hypothetical. The surgeon must always consider each patient's oncologic situation, comorbid conditions, social circumstances, and needs. Given the high risk of SARS-CoV-2 nosocomial transmission in a majority of head and neck procedures, as head and neck surgeons we have a unique obligation to employ a conservative operational definition of "urgent." At times it is difficult to determine where we are on the "curve" of the pandemic. We need to be relatively stringent in our current operational approach, but we hope that these criteria will gradually liberalize over some time. Some of the current drastic changes made will call for introspections but we also believe that these changes may lead to lasting quality control and improvement.

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