In Print

Safeguards to Optimize Safety of Elective Surgical Care While Limiting the Spread of COVID-19: *Primum Non Nocere*

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This paper had received the Orthoregeneration Network (ON) Foundation Literature Grant

Abstract

COVID-19 has drastically altered our lives in an unprecedented manner, shuttering industries, and leaving most of the country in isolation as we adapt to the evolving crisis. Orthopedic surgery has not been spared from these effects, with the postponement of elective procedures in an attempt to mitigate disease transmission and preserve hospital resources as the pandemic continues to expand. During these turbulent times, it is crucial to understand that while patient and care-providers safety is paramount, canceling or postponing essential surgical care is not without consequences, and may be irreversibly detrimental to a patient's health and quality of life in some cases. The optimal solution of how to effectively balance the resumption of standard surgical care while doing everything possible to limit the spread of COVID-19 is undetermined, and could include strategies such as social distancing, screening forms and tests including temperature screening, segregation of inpatient and outpatient teams, proper use of protective gear, and the use of ambulatory surgery centers (ASCs) to provide elective, yet ultimately essential, surgical care while conserving resources and protecting the health of patients and health-care providers. Of importance, these recommendations do not and should not supersede evolving United States Centers for Disease Control and Prevention (CDC), and relevant federal, state and local public health guidelines.

Introduction

The first confirmed case in the United States was reported in Northern Washington on January 20th of this year. Since then, 2019 Novel Coronavirus (COVID-19) has upended our society and placed an unprecedented strain on health-care systems across the country.[1] Orthopedic surgery has not been spared from these drastic changes, particularly when considering the widespread cessation of elective clinical and surgical care. Most of these elective procedures have been postponed in the interest of patient and provider health, and to address anticipated shortages in staffing, beds, ventilators, and personal protective equipment (PPE) as the virus rapidly spreads through our communities.[2] This mandate effectively halted the traditional clinical structure of orthopedic practices, necessitating a new system for providing the highest quality of orthopedic care while practicing the principles of social distancing and preventative measures to prevent the transmission of COVID-19. While a shift to telemedicine has proven instrumental in providing care, questions about what is defined as an essential procedure have come to the forefront. A preeminent concern in this conversation is how delays in care, resulting in daily pain, functional disability, and unbearable financial damages will affect the long-term physical and mental health, employment capacity, and overall wellbeing of patients and our economy. Experiences in Hong Kong and Singapore have shown that mitigation strategies like social distancing, temperature screenings, inpatient/outpatient teams, and the use of ambulatory surgery centers (ASCs) have been effective for providing essential surgical care while conserving resources and protecting the health of patients and health-care providers.[3]

The purpose of this investigation will be to present and analyze the most up-to-date available evidence on how the COVID-19 pandemic has affected the orthopedic community. We will present relevant evidence-based literature from the 2002-2004 Severe Acute Respiratory Syndrome (SARS) outbreak. We will dive into the struggle between resuming state-of-the-art surgical care, while maintaining social distancing and using all precautions to limit the spread of COVID-19. We will explore pertinent terminology such as “elective”, “emergent”, “urgent”, and “essential/non-essential” surgery. Lastly, we will discuss and recommend guardrails to allow the continuation of best practices and high-quality patient care, while maintaining patient and staff safety. This will include reviewing the Center for Disease Control (CDC) recommendations, use of traditional protective gear, screening forms and tests, new-technological solutions, and more.

Methods

Due to the relatively recent onset of the COVID-19 outbreak, the lack of available evidence-based literature, and the timeliness required to present this information, a traditional systematic review and meta-analysis would have not served the purpose well.

We performed the following systematic searches as of April 17, 2020:

1. A systematic search of traditional databases, including:

a. Google Scholar
b. PubMed
c. Medline
d. Embase

2. A systematic search of online media, including:
    a. News websites
    b. Facebook
    c. Twitter
    d. Instagram
    e. Research Gate
    f. COVID-19 designated sites (John-Hopkins University Corona Virus resource center, Institute for Health Metrics and Evaluation, etc.)

Keywords included combinations of the following terms: "COVID-19", "Corona Virus", "Severe Acute Respiratory Syndrome", and "SARS" in conjunction with "Surgery", "Orthopedics", and "Elective/emergent/urgent procedures". Articles were screened by four independent reviewers and relevant key information was extracted with an emphasis of information regarding the 2002-2004 SARS outbreak, disease spread timeline, restrictions and orders affecting the orthopedic patient and care-provider communities, recommendations to proceed or halt different types of surgical care, and precautions that can be taken to mitigate the spread of COVID-19.

Our goal is to summarize existing recommendations and considerations to allow orthopedic care-providers to safely manage orthopedic patients during the COVID-19 pandemic.

What Can We Learn from the 2002-2004 SARS Outbreak?

When looking into the future, we can utilize lessons from the past. Perhaps the only real evidence-based literature available to date is from the SARS outbreak in 2002-2004, caused by SARS-CoV.[4] While there are many obvious significant differences between the two outbreaks, this is perhaps the most recent similar experience humanity had to endure, and we can definitely learn from it. Notably, the SARS outbreak in 2002-2004 was controlled (or subsided) in the absence of sophisticated diagnostic tests, effective therapies, or a vaccine.[5] The success of eliminating the outbreak was attributed to a multifaceted approach that included isolation of suspected cases, contact tracing, quarantine of potentially exposed individuals, provision of PPEs and training for health care workers, establishment of fever clinics, and enhanced communication efforts for health care professionals, policymakers, and the public.[5] Studies have shown that during the SARS outbreak, 22% of all persons affected in Hong-Kong and 43% of all affected persons in Toronto were health care workers.[6] Li et al. studied SARS infection among health care professionals in Beijing, China during the 2002-2004 SARS outbreak. They found that among the 770 health care workers who had contact with SARS patients, 2.43% (n=18) were

found to be infected with the virus. Importantly, no transmission was reported between hospital staff. They also reported that there was no use of negative pressure or N95 masks in their facilities and that simple protective measures and strictly enforced safety protocols are sufficient to control the in-hospital spread of SARS.[7] While Li et al. did not deem the use of N95 masks and negative-pressure isolation rooms necessary, the Canadian experience reported the following protective measures recommended: the use of negative-pressure isolation rooms where available; N95 or higher level of respiratory protection; gloves, gowns, and eye protection; and careful hand hygiene.[8] Simple PPEs were also found to be effective in a systematic review performed by Jefferson et al. and published in 2007.[9] Chu et al. investigated the impact of SARS on hospital performance in Taipei, Taiwan.[10] They reported the average monthly number of outpatient visits at base year was 52317 ± 4204. Outpatient visits for the year SARS emerged, 1-year, and 2-years later were 55%, 82%, and 84%, respectively. Orthopedic surgery was one of the outpatient departments that had not recovered by the 4th year following the SARS outbreak, with an estimated 84% of outpatient visits from baseline. Schull et al. reported that the rate of elective surgery in Toronto fell by 22% and 15% during the early and late restriction periods, respectively, and by 8% in the comparison regions (Ottawa and London, Ontario).[11]

COVID-19 shares 70%-80% of its genome with SARS-CoV, both have relatively similar aerosol and surface stability, are transmitted by droplets, contact with infected persons and surfaces, and both target the Angiotensin-converting enzyme (ACE)-2 receptor.[12, 13] While the COVID-19 transmission rate seems much higher, case fatality rate is estimated to be less than 2.3% and perhaps much lower. In comparison, SARS-CoV and Middle East respiratory syndrome (MERS)-CoV have a reported case fatality rate of 9.6% and 35%, respectively.[12, 14]

A higher transmission rate may be related to inherent viral properties, but also may in part be attributed to globalization, frequent air travel, and other changes in social habits occurring since 2004. While a lower case fatality rate may also be attributed to inherent viral characteristics, other contributing factors may include the improvement of health care services and protective equipment, and other significant protective measures taken worldwide.

In summary, the 2002-2004 SARS outbreak teaches us that health care workers are at high-risk and that PPEs and their proper utilization is essential. It is concerning that the current pandemic may reemerge next winter and that recovery of health care services may take several years or longer.

Review of the National and Regional Guidelines

By the time that the World Health Organization (WHO) declared COVID-19 a global pandemic on March 11th, it was apparent that the virus would place substantial strain on health care infrastructure and supplies throughout the country in the following days and weeks.[15] To meet these challenges, on March 13th the American College of Surgeons (ACS) put forth the first recommendations on elective care during this crisis. They recommended each surgeon to

"thoughtfully review all scheduled elective procedures with a plan to minimize, postpone, or cancel electively scheduled operations." They also stated this recommendation be in place until we have passed the anticipated inflection point of virus exposure and can reliably support a rapid uptick in patient critical care needs.[16] This statement was quickly supported by the US Surgeon General and followed-up by the Centers for Medicare & Medicaid Services (CMS), who provided a tiered framework when considering elective medical services.[17, 18] The three tiers, which are based upon acuity, guide which procedures are appropriate to be conducted at this time and which should be postponed. In general, they recommended surgeons to limit all non-essential planned surgeries until further notice.[17] Notably, initial recommendations were considered in the context of a global crisis and did not contemplate differences in local or regional disease burden.

Following these initial recommendations, most of the country's local hospital policies regarding elective surgical care have been guided by individual state recommendations. At the time of this writing, 35 states and the District of Columbia have issued individual statements or policies pertaining to elective care restrictions.[19] However, the recommendations have been dynamic and varied, with differing definitions of elective procedures and rare references to orthopedic practices in particular.[20] As such, individual institutions have been responsible in determining what orthopedic surgeries should be performed or postponed as they navigate the pandemic. Similarly, most discussions related to surgical policies initially pertained to the performance of surgery in a hospital or inpatient setting where the disease burden is greatest and resource availability is most challenged.

The many recommendations put forth raise some essential considerations as orthopedic surgeons adjust to the likely long-term impact that COVID-19 will have on surgical care. In this early period, with thousands of deaths occurring each day and health systems still under extreme stress, the decision to postpone elective procedures and allocate all resources towards the crisis has been clear. However, now that conditions have seemingly started to stabilize in certain regions, surgeons must weigh the relative risks of resuming their essential elective practice while taking all possible precautions to limit COVID-19 spread. This should only be performed following the White House and CDC "Opening Up America Again" guidelines, as well as relevant federal, state, and local public health guidance.[21] Currently, the resumption of elective procedures is planned to proceed during Phase I of the three-phase approach of the "Opening Up America Again" initiative.

Moving Forward

The Institute for Health Metrics and Evaluation at the University of Washington is supplying up to date projections on COVID-19 including deaths per day, total deaths, and hospital resource

use.[22] The projections take into account the "stay at home order", closure of educational facilities and non-essential services, and severe travel limitations, implemented on different dates in different states. While the projections change with time, it appears the outbreak has already peaked in many states and that many states will not sustain a deficit in hospital resources.

These projections support the motion to responsibly and gradually lift the ban on essential elective surgery worldwide. Lifting the constraints should not be done carelessly, and many factors should be taken into account, including the regional health-care resources available and the projection for a peak in transmissions and deaths in specific geographic regions. The resumption of shoulder, knee, and ankle arthroscopies (and other orthopedics procedures requiring ≤23 hours of hospital stay) in Singapore can be used as an example.[23]
Consistent with the need to provide additional essential services, the White House and CDC are currently supporting the reopening of elective surgery during Phase I. This also includes social distancing, return to work in stages, resumption of elective surgeries, opening of gyms, while schools and organized youth activities will remain closed.

This also proposes the formulation of region-specific plans how to operationally resume the practice of patient care, as well as how to financially survive during these turbulent times.[24-26] Private practices, hospitals, and health care systems (similar to other small and large businesses) are in jeopardy. With elective surgery constituting upwards of 47% of orthopedic care spending,[2] essential medical practices may default, resulting in irreparable long-term damage to public health.

Many new surgical management algorithms are circulating and while there are some differences, most algorithms agree with the following criteria for performing essential surgery without further delay: [21, 27, 28]

- Locations where the outbreak had most likely peaked
- Downward trajectory of ≥14 days in regional symptomatic and confirmed cases
- If there is no shortage of resources, including:
    - Staff
    - Beds
    - PPE
    - Ventilators
- Healthy asymptomatic patient
- ASA (American Society of Anesthesiologist) 1-2

The patient must understand the possibility of an additional risk that entails being operated on during the COVID-19 outbreak and provide written informed consent that speaks to the necessity and risks and benefits of receiving care at this time. In addition, the surgical management

algorithms should be considered in the context of hospital-based inpatient procedures on the one-hand and outpatient-based procedures commonly conducted in ambulatory surgical centers (ASCs).

Initially, ASCs are perhaps the best facilities to be used in this setting, as most do not include an emergency department or departments that typically admit elderly patients with infectious diseases and/or severe co-morbidities. Moreover, most are currently vacant and had not been transitioned to receive COVID-19 patients, as there was no need in most states to date.

We should remember that while removing these constraints, it will be critical to track any suspicion for a local surge in infections and immediately contain the local outbreak with all means, including immediate reporting to all relevant authorities.

Definition of Types of Surgery

One key consideration is the distinction between "essential" and "non-essential". Initial recommendations in mid-March in the United States were primarily focused on managing disease burden, such that the hospital system in general would not be overwhelmed in terms of available resources including PPE, ventilators, and manpower. In addition, the benefits of mitigation and social distancing were emphasized to meet that same goal. Thus, "elective surgery" was determined to be "non-essential". Subsequently, discussions ensued that related to activities that are essential with "emergent" procedures being the most clearly defined. Interchangeably, the terms including "urgent" were utilized often referring to conditions that if left untreated over some subsequent period of time (i.e, 4-6 weeks), the outcome of neglecting that condition would have a negative impact on the patient's condition. Urgent conditions would implicitly include those that are also considered emergent conditions, but arguably, there is latitude depending upon tangible and intangible considerations to discuss what other conditions would fall into the urgent category. The 4-6 week time line was essentially based upon expectations for a greater clarity related to changes in disease burden and the effects of mitigation and social distancing with some additional insights into the timing and duration of "stay at home" orders. Notably, these same discussions have evolved to consider local demands of the disease burden on the hospital system rather than the global impact of the disease state on the entire hospital or medical system.

Some states have provided additional guidance. The Illinois Department of Public Health, for example, defined elective procedures as those that are pre-planned by both the patient and the physician, are advantageous to the patient, but are not urgent or emergent. As such, sports medicine and orthopedic procedures in many institutions during this crisis have been limited to those thought to be urgent or emergent, such as acute tendon injury, ligamentous tears, bucket

handle meniscus tear with a locked knee, intra-articular loose bodies causing acute symptoms, acute fracture management, dislocated joints that cannot be closed reduced, infected joints among several others. Expanding on these definitions which are relatively easy to define as emergent conditions requiring relatively immediate treatment (as a class of essential services), has included discussions related to conditions that are urgent (short of being emergent) whereby surgical intervention is required to otherwise avoid worsening the condition should surgery be delayed. Related to this is the further consideration that pain, dysfunction, and loss of occupation can relate to the concept of urgency for an individual patient and thus, essential provision of timely care may be indicated.

Other states have provided guidance on what to consider as essential or non-essential at the discretion of licensed providers. In Ohio, for example, non-essential surgery is defined as a procedure that can be delayed without undue risk to the current or future health of a patient. However, in areas where resources are available and health systems are adequately equipped to handle an uptick in COVID-19 cases, it may be appropriate to broaden the definitions of essential procedures. As an example, outpatient hip, knee, and shoulder arthroscopies produce little burden on hospital resources and can be reliably performed at outpatient ambulatory surgery centers.[23] In these cases, postponing care may needlessly prolong patient pain, disability, and loss of occupation.

While most would agree on what is an urgent or emergent orthopedic condition requiring surgical intervention, broadening the definition of essential surgery may be more difficult and subjective. Furthermore, practice patterns today will likely be in place for the foreseeable future and "living with COVID" will continue to guide our policies and procedures.
Our institution (Midwest Orthopaedics at Rush University Medical Center) has implemented the following definitions for urgent surgery to be performed in a limited capacity in the ASC system that are not necessarily considered emergent, but rather urgent and, thus essential based upon relevant clinical parameters. Ultimately, decisions may be multifactorial and made with board oversight, comprehensive documentation and depend upon local resource demands, downward changes in the disease burden and federal and local policies.[29] These factors might include:

1. Conditions that without treatment could result in compromised outcomes
2. A condition that has failed to respond to non-surgical care
3. Neurologic deficits and/or progressive neurologic deterioration
4. Conditions with intolerable pain especially when narcotics are required
5. Functional losses precluding return to activities including activities of daily living
6. Conditions resulting in significant financial hardship

Protective Measures

In contemplating "living with COVID-19" we must assume that the protective measures we implement today may remain with us for years to come. Jefferson et al. demonstrated that routine long-term implementation of PPEs to interrupt or reduce the spread of respiratory viruses is effective and many simple and low cost interventions could be useful in reducing the spread.[9]

The following is a list of precautions and actions that may limit transmission, protect patients and health care providers, and allow the resumption of essential surgical services.[30-32]

The Patient

- **Age < 65 years old, may consider healthy older patients (ASA 1) on a case-by-case basis**
- **ASA 1-2, may consider ASA 3 if necessary and approved by anesthesiologist or medical director**
- **No Influenza Like Symptoms (ILI):**
  - **Fever 100.4° or greater**
  - **Cough**
  - **Shortness of breath**
  - **Malaise**
- **No other risk factors, such as recent travel, sick family member, or COVID-19 exposure**
- **Signed a specific COVID-19 consent form**
- **Tested for fever on admission**
- **Must wear PPE including surgical mask, gown, and gloves**
- **Test all patients for COVID-19 within 72 hours prior to surgery (once tests are readily available).[26] Preferably tests should be conducted 24 hours or less prior to surgery.**
  Current tests include:
  - **Detection test – Reverse Transcriptase PCR**
  - **Antibody test – Enzyme-linked Immunosorbent assay (ELISA)**
- **One or preferably no accompanying family member**
- **Wrist band to verify screening completion**

The Staff

- **Hand hygiene is key**
- **Staff should keep social distancing (minimum 6 feet distance when possible) and use PPE (gloves, gown, surgical mask, and goggles)**
- **Intubation should be performed with only the necessary staff in the operating room, wearing N95 masks and eye protection**
- **Delays between room re-entrance by necessary staff and in between cases**
- **Minimize staffing as possible**
- **Test all staff for COVID-19 on arrival or prior (once tests are readily available)**
- **Wrist band to verify screening completion**
- **Staff should be trained at protecting themselves and patients**
- **Supporting measures to address staff fatigue and emotional distress**

Facility and Region

Each geographic region and facilities within must assess the availability of the following and proceed accordingly if a shortage occurs or is expected[32]:

- **PPE supply**
- **Staffing**
- **Beds (specifically intensive care unit beds)**
- **Ventilators**
- **Medications, anesthetics, and all surgical supplies**

Facilities should implement the following:

- **One exit and one entrance**
- **Elevator management to minimize crowding of patients and staff**
- **Operating/procedural rooms must meet engineering and Facility Guideline Institute standards for air exchanges**
- **Protocols to managing and isolating patients and staff suspected or confirmed of COVID-19 infection**
- **Case prioritization strategy set in place**
- **Data should be collection as proposed by the ACS in order to reassess policies and procedures frequently**

Other regional considerations include:[26]

- **A sustained reduction in COVID-19 cases for ≥14 days**
- **Access for COVID-19 testing**
- **Availability of active monitoring of confirmed or suspected cases and their contacts**

Surgery

- **Same day preoperative admissions are preferred (rather than a day before)**
- **Updated preoperative checklists with questions pertaining to COVID-19**
- **Surgical times should be kept short**
- **Limited number of operations per operation room block**
- **Limit operating room traffic**
- **Disinfect the operating room strictly**
- **Additional room turn-over delay as necessary**
- **Expedited postoperative recovery and discharge procedures**

Postoperative Management
Should include the use of the following if possible: - **Minimize face-to-face consultation** - **Telemedicine and telerehabilitation[32]** - **Wearable sensors[33, 34]** - **Technology-assisted rehabilitation[32, 35, 36]** - **Patient guidance regarding adequate nutrition, hydration, and electrolyte balance**

Limitations:

A significant limitation of all studies investigating aspects of the COVID-19 pandemic is the lack of evidence-based trustworthy resources. While this study is unique by its attempt to analyze studies performed following the 2002-2004 SARS outbreak, recent literature on the COVID-19 pandemic is mostly level V evidence. Moreover, due to the rapidly unfolding reality we are facing, this manuscript, like many others pertaining to the COVID-19 pandemic, may not be relevant within a few weeks or even a few days.

Summary:

"First, do no harm" is embedded in our core as health care providers in addition to the privilege to help those in need. We must limit all unnecessary activities to mitigate the harmful effects of this pandemic. At the same time, we must remember that in our profession, failure to act and provide essential care can be irreversibly detrimental to the patient's health and quality of life. Whether the COVID-19 outbreak is close to an end, if the outbreak will reemerge next winter, or if another contagious pathogen will appear, is unknown. However, it is clear that we must adapt and find the way to resume our lives, providing high-quality medical and surgical care while utilizing the best protective measures available to protect our patients and staff.

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