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Primary Hip and Knee Arthroplasty

Preoperative Severe Acute Respiratory Syndrome Coronavirus 2 Polymerase Chain Reaction Test at Between 48 and 72 Hours Preoperatively is Safe for Patients Undergoing Primary and Revision Hip and Knee Arthroplasty: A Multicentre International Study

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ABSTRACT

Background: Patients undergoing lower limb arthroplasty who are severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) positive at the time of surgery have a high risk of mortality. The National Institute for Health and Clinical Care Excellence and the British Orthopaedic Association advise self-isolation for 14 days preoperatively in patients at a high risk of adverse outcomes due to COVID-19. The aim of the study is to assess whether preoperative polymerase chain reaction (PCR) for SARS-CoV-2 could be performed at between 48 and 72 hours preoperatively with specific advice about minimizing the risk of SARS-CoV-2 restricted to between PCR and admission.

Methods: A multicentre, international, observational cohort study of 1,000 lower limb arthroplasty cases was performed. The dual primary outcomes were 30-day conversion to SARS-CoV-2 positive and 30-day SARS-CoV-2 mortality. Secondary outcomes included 30-day SARS-CoV-2 morbidity.

Results: Of the 1,000 cases, 935 (94%) had a PCR between 48 and 72 hours preoperatively. All cases were admitted to and had surgery through a COVID-free pathway. Primary knee arthroplasty was performed in 41% of cases, primary hip arthroplasty in 40%, revision knee arthroplasty in 11%, and revision hip arthroplasty in 9%. Six percent of operations were emergency operations. No cases of SARS-CoV-2 were identified within the first 30 days.

Conclusion: Preoperative SARS-CoV-2 PCR test between 48 and 72 hours preoperatively with advice about minimizing the risk of SARS-CoV-2 restricted to between PCR and admission in conjunction with a COVID-free pathway is safe for patients undergoing primary and revision hip and knee arthroplasty. Preoperative SARS-CoV-2 PCR test alone may be safe but further adequately powered studies are required. This information is important for shared decision making with patients during the current pandemic.

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While the incidence of coronavirus disease 2019 (COVID-19) continues to fluctuate in many nations, attention must now be turned to how to maintain the safe provision of nonemergency, routine healthcare, including elective joint arthroplasty [1,2]. Over the last year, the number of patients waiting for joint arthroplasty has grown substantially and waiting lists have lengthened significantly [3]. Delaying arthroplasty is known to be associated with worse outcomes, and the number of patients waiting for joint

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arthroplasty with quality of life scores worse than death has nearly doubled during the current pandemic [4].

For patients and medical staff, the hospital presents a risk of nosocomial infection with, during the first wave (February to July 2020), across the United Kingdom between 20% and 25% of all infections estimated to be nosocomial in nature [5,6]. Improved knowledge about severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as well as improved hospital protocols, public health measures, and vaccination should all reduce this risk and the outcomes of patients with COVID-19 continue to improve. Despite this, for the foreseeable future, SARS-CoV-2 will be present within healthcare systems and we will have to manage the risk that it, and future variants, present.

In April 2020 in the United Kingdom, more than three-quarters of patients listed for joint arthroplasty did not want to proceed with surgery, and although that number has decreased, SARS-CoV-2 still presents a risk to this patient population [7]. It is now well established that surgery in patients who test positive for SARS-CoV-2, or who contract SARS-CoV-2 within 30 days, whether this is symptomatic or asymptomatic, is associated with a high risk of adverse outcomes including mortality [8,9]. In lower limb arthroplasty, prior to the introduction of vaccination, a mortality of between 20% and 40% was reported with the risk of mortality normalizing when surgery was performed 7 weeks following the SARS-CoV-2 diagnosis, provided any symptoms have resolved [8–12]. To reduce the risk that SARS-CoV-2 presents to patients undergoing lower limb joint arthroplasty, it is prudent to ensure that patients having surgery are not infected with SARS-CoV-2 at the time of surgery and they do get infected with SARS-CoV-2 during their recovery.

The National Institute for Health and Clinical Care Excellence (NICE) recommends that patients at a high risk of adverse outcomes due to COVID-19, and those at a high risk of developing the disease, may wish to self-isolate for 14 days with a SARS-CoV-2 polymerase chain reaction (PCR) test taken at 48 to 72 hours preoperatively [13]. This is mirrored by the British Orthopaedic Association who advises the use of COVID-free pathways with preoperative and postoperative 14-day self-isolation or shielding and PCR for SARS-CoV-2 at 72 hours preoperatively [1,2]. Using a 14-day preoperative isolation, preoperative SARS-CoV-2 PCR, and a COVID-free pathway, previous studies have reported that the rate of nosocomial SARS-CoV-2 infection in patients undergoing elective arthroplasty can be kept under 1% [7,14–17]. However, an independent analysis has found that more than 80% of patients cite a 14-day preoperative isolation period being a barrier to proceeding with surgery [7]. The aim of the study was to assess whether, in patients undergoing primary and revision hip and knee arthroplasty, preoperative PCR for SARS-CoV-2 could be performed at between 48 and 72 hours preoperatively with specific advice about minimizing the risk of SARS-CoV-2, including the duration of behavioral modification, reduced to between PCR and admission (<72 hours).

Methods

Between April 27, 2020 and November 10, 2020, a consecutive series of 1,000 patients who were undergoing primary or revision hip or knee arthroplasty on COVID-free pathways following negative PCR for SARS-CoV-2 was included. The study was conducted at 3 tertiary referral centers (Nuffield Orthopaedic Center, Oxford; Rothman Orthopaedic Institute, Philadelphia; and Copenhagen University Hospital Hvidovre, Copenhagen). Nasopharyngeal swabs were taken at two centers (Nuffield Orthopaedic Center and Rothman Orthopaedic Institute) and oropharyngeal swabs at one center (Copenhagen University Hospital Hvidovre). Patients were excluded from the study if they were identified as SARS-CoV-2 positive at the time of surgery. Both planned and emergency cases were included. Planned cases had a PCR performed between 48 and 72 hours prior to admission and following PCR were advised to modify their behavior to reduce the risk of SARS-CoV-2 infection. Emergency cases required a negative PCR for SARS-CoV-2 prior to admission to the orthopedic unit but due to the nature of their presentation, they did not complete a period of behavioral modification. The study start date varied between institutions due to the fact that it required the implementation of COVID-free pathways involving short duration behavioral modifications at each center. At the Nuffield Orthopaedic Center and Rothman Orthopaedic Institute following their PCR for SARS-CoV-2, patients were advised to isolate, or shield within their household until their admission, whereas at Copenhagen University Hospital Hvidovre, there was no request for patients to isolate but they were advised to follow the general restrictions (social distancing, washing of hands, and ventilation of rooms) set by the Danish Health Authority. The study continued for a consecutive series of 1,000 patients equally split across the three study sites. Both elective and emergency cases, who may not have a period of behavioral modification preoperatively, were included provided they have a negative SARS-CoV-2 result before surgery. Emergency arthroplasty cases were included as in all centers these cases were managed by the same surgical teams on the same pathways, as primary cases and as such presented a risk of secondary infection. Other nontrauma, nonlower limb arthroplasty, orthopedic patients were managed on the same unit on a COVID-free pathway but due to differences in surgical teams, presenting diagnosis and patient demographics were not included in the analysis.

The dual primary outcomes were 30-day conversion to SARS-CoV-2 positive and 30-day SARS-CoV-2 related mortality. Secondary outcomes included 30-day SARS-CoV-2 related morbidity including pneumonia, acute respiratory distress syndrome (ARDS), or unexpected postoperative ventilation. Where patients were diagnosed as COVID-19 positive within 30 days of surgery, we extended the period of follow-up to establish their final outcome. Postoperatively, patients were routinely tested by PCR for SARS-CoV-2 if they developed any symptoms of COVID-19 (high temperature, continuous cough, and from May 2020 loss of taste or smell), and if they were a contact of another patient or staff member who tested positive, on discharge to another hospital or care home. Data were retrieved from Electronic Medical Records (EMR) through a review of laboratory data and general health assessment performed at follow-up at the clinic 4 to 8 weeks postoperatively. The study was approved by the ethics and audit committee at each site with signed data sharing agreements in place prior to the commencement of the study.

Results

A total of 1,000 patients were studied across the three sites. At all centers for planned cases, patients were seen prior to their procedure and the risks of COVID-19 and surgery were discussed as a part of the informed consent process with a SARS-CoV-2 swab taken 48 to 72 hours prior to admission. Swabs were taken a minimum of 48 hours before admission to ensure that the swab could be processed prior to admission because at times the laboratories were under extreme pressure processing emergency samples. For planned cases, admission (935 patients) was on the day of, or in isolated cases day prior to, surgery via a COVID-free pathway with symptomatic screening for COVID-19 on admission. At one site, Oxford, admission was to a stand-alone, COVID-free, hospital. At the two other sites admission was to a COVID-free, dedicated orthopedic unit within the general hospital which was also treating patients with COVID-19. In addition to planned

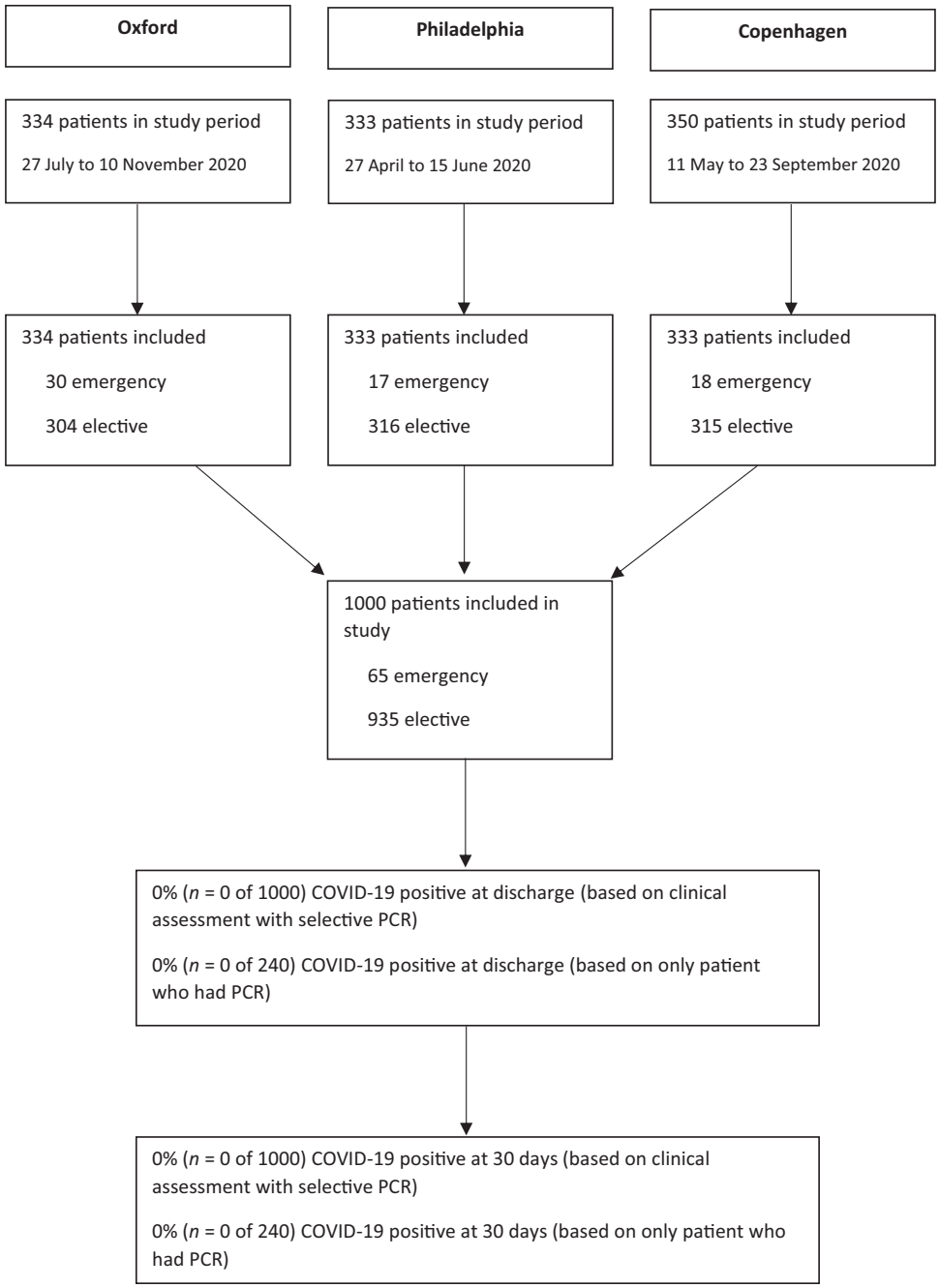

Fig. 1. Study flow.

elective cases in all centers, emergency arthroplasty (65 patients) cases were operated on during the study period and were also included. Fifteen of the 65 emergency cases had PCR between 24 and 72 hours prior to admission (typically when transferred from another hospital), when this had not been performed PCR was performed on admission. In addition, on admission all emergency cases were screened for symptoms with a negative result of clinical and laboratory assessments required for admission to the orthopedic unit. A flow chart of study participants is outlined in Figure 1. The disease burden of SARS-CoV-2 in each country during the study period is outlined in Figure 2.

Patient demographics are recorded in Table 1 with a mean age of 70 years, 45% being male, and a mean body mass index (BMI) of 30 kg/m^2. Patients were older in the Copenhagen cohort (69.0 years) as compared to the Oxford (66.6 years; $P = .02$) and Philadelphia cohorts (65.0 years, $P < .01$). There was no difference in the proportion of male or female patients ($P = .05$), nor BMI ($P = .19$), nor a proportion of patients classified as American Society of Anesthesiologists (ASA) grade 1 or 2 versus 3 or 4 between sites. Overall 6% of operations were classified as emergency operations, by Royal College of Surgeons (RCS) 1a or 1b with 73% conducted under spinal anesthesia [18] (Table 2). Primary knee arthroplasty was performed in 41% of cases, primary hip arthroplasty in 40%, revision knee arthroplasty in 11%, and revision hip arthroplasty in 9% (Table 2). There was no difference between the proportion of emergency (RCS 1a/1b) versus nonemergency (RCS 2/3/4) cases between centers.

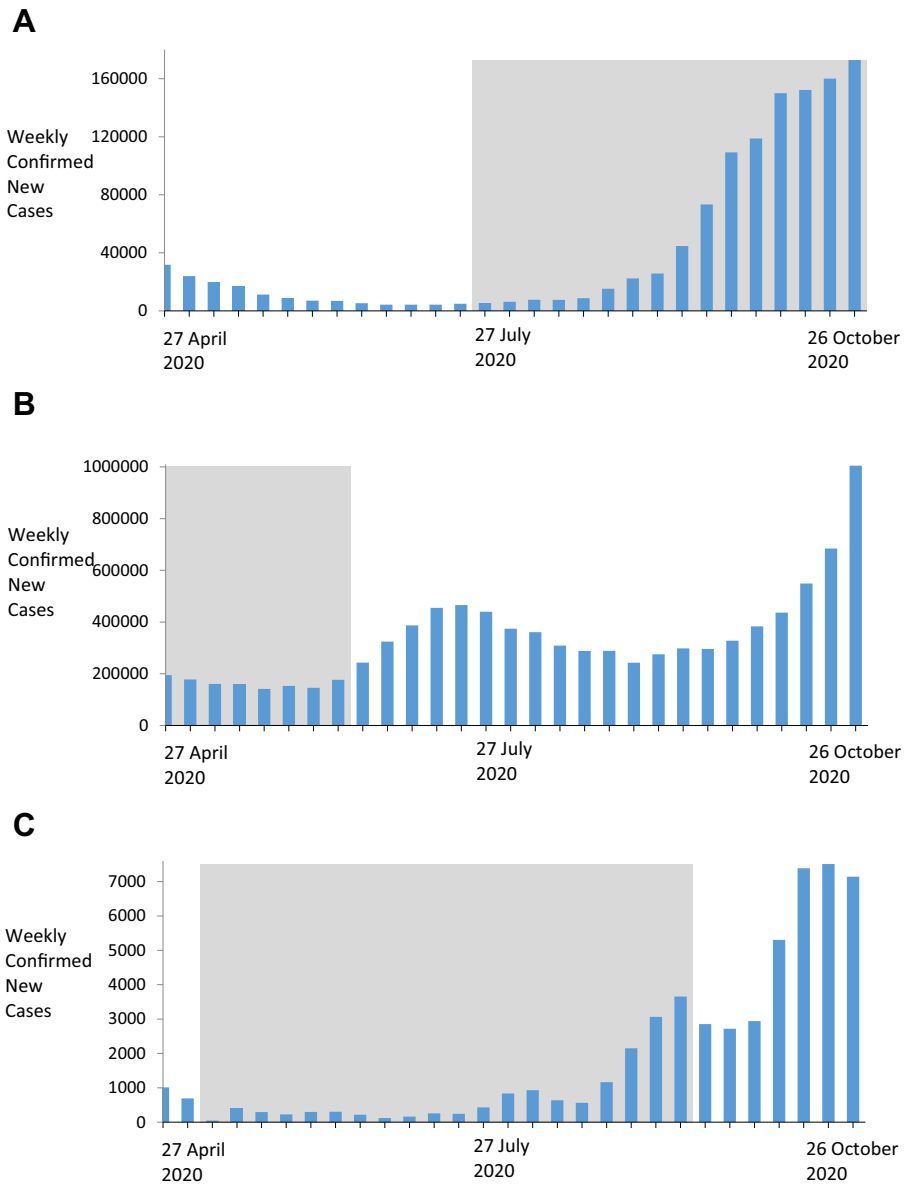

Fig. 2. Weekly confirmed SARS-CoV-2 cases by country A: UK; B: USA; and C: Denmark. Gray area represents study period at each center [27].

Fewer cases in the Oxford cohort were performed under regional anesthesia (43%, $P < .01$) as compared to the Philadelphia (89%) or Copenhagen cohorts (86%). A higher proportion of revision cases were performed in the Oxford cohort (27%, $P < .01$) as compared to Philadelphia (15%) or Copenhagen (86%) cohorts.

Across the three centers no patients swabbed positive for SARS-CoV-2. Across the whole cohort 2 patients died within 30 days postoperatively, both after undergoing primary elective hip arthroplasty. One patient died as an inpatient on the third postoperative day due to cardiac arrest. They did not have any clinical symptoms or signs of COVID-19 and did not have a postoperative PCR SARS-CoV-2 test. One further patient died on the 28th postoperative day due to pneumonia. They had 3 negative oropharyngeal SARS-CoV-2 PCR tests and negative bronchoalveolar sampling and their death was not attributed to COVID-19. Overall, 24% of patients received a postoperative SARS-CoV-2 test within 30 days of surgery (Oxford: 22%, Philadelphia: 11%, and Copenhagen: 40%).

Discussion

This study has confirmed that a SARS-CoV-2 PCR test between 48 and 72 hours preoperatively with specific advice about minimizing the risk of SARS-CoV-2 restricted to between PCR and admission (<72 hours) in conjunction with a COVID-free pathway is safe for patients undergoing primary and revision hip and knee arthroplasty. There were no symptomatic or PCR-confirmed cases of SARS-CoV-2 within 30 days across the cohort of 1,000 patients with 239 patients having postoperative PCR for a range of indications. These results are consistent with the results seen previously with a 14-day preoperative isolation period which demonstrate that elective lower limb arthroplasty can be safely delivered during the COVID-19 pandemic [14–17].

The key to the COVID-free pathway is to ensure that patients who are infected with SARS-CoV-2 are not admitted to ring fenced wards, do not undergo surgery, and in addition it is important that patients undergoing arthroplasty do not contact COVID-19 patients

Table 1
Patient Demographics.

	Overall $n = 1,000$	Oxford $n = 334$	Philadelphia $n = 333$	Copenhagen $n = 333$
Mean Age (SD)	66.9 (11.8)	66.6 (13.9)	65.0 (10.5)	69.0 (10.4)
% Male	44.7 (447)	42.2 (140)	50.2 (167)	42.0 (140)
Mean BMI (SD)	29.7 (5.9)	29.6 (6.4)	30.2 (5.2)	29.4 (6.0)
ASA				
I % (*n*)	8% (84)	17% (55)	1% (2)	8% (27)
II % (*n*)	61% (690)	55% (184)	64% (212)	64% (213)
III % (*n*)	29% (294)	26% (88)	34% (114)	28% (92)
IV % (*n*)	1% (13)	2% (7)	2% (5)	0.3% (1)
CDC BOA Risk Factors				
Age >65 *n* (%)	61% (605)	58% (195)	56% (187)	67% (223)
BMI >40 *n* (%)	5% (48)	6% (19)	4% (14)	5% (15)
Asthma (moderate/severe) *n* (%)	7% (70)	4% (14)	8% (25)	9% (31)
Chronic Lung Disease *n* (%)	4% (36)	5% (16)	0.3% (1)	6% (19)
Diabetes *n* (%)	11% (107)	10% (34)	9% (29)	13% (44)
Serious Cardiac Disease *n* (%)	6% (62)	8% (28)	6% (19)	5% (15)
Dialysis *n* (%)	1% (7)	1% (2)	1% (2)	1% (3)
Immunocompromised *n* (%)	3% (34)	6% (20)	4% (14)	0% (0)
Liver disease *n* (%)	1% (9)	1% (2)	2% (6)	0% (1)

ASA, American Society of Anesthesiologists; CDC, Centers for Disease Control and Prevention; BOA, British Orthopaedic Association.

during their recovery period. Previous reports have demonstrated that up to 18% of orthopedic trauma patients may be infected with SARS-CoV-2 at the initial presentation, particularly those from institutional living accommodation [19–22]. Early in the COVID-19 pandemic, there was reliance on symptomatic assessments to determine SARS-CoV-2 status; however, it has since been established that a substantial proportion of patients may be asymptomatic and as such testing for COVID-19 prior to arthroplasty is now recommended by all major societies [1,2,13,23]. Mathematical modeling of the performance of COVID-19 testing to assess for SARS-CoV-2 status prior to surgery has suggested a 1 in 1,400 risks of a false negative preoperative swab result assuming a PCR sensitivity of 71%, specificity of 95%, and disease prevalence of 0.24%. The modeling results match those of our study which identified no cases of SARS-CoV-2 of 1,000 patients admitted following a negative PCR result [24].

Another key component to ensuring the success of a COVID-free pathway is making sure that patients do not acquire COVID-19 as an inpatient. The use of COVID-free sites has been reported to be associated with a lower risk of nosocomial SARS-CoV-2 infection. In our study, one site was COVID-free with the two other sites using dedicated wards to minimize the risk. Both methodologies were associated with a very low risk of COVID-19 transmission and the results of this study suggest either method would be appropriate to reduce nosocomial transmission. Although we did not evaluate the influence of length of stay (LOS) on a risk of nosocomial infection, previous work has identified that LOS, particularly more than 3 days, is a key modifiable risk factor, and it must be noted that all centers in this study minimize LOS through evidence-based protocols covering anesthetic, surgical, and rehabilitation [25].

The natural extension to this work is to question whether there firstly is any requirement for isolation prior to elective lower limb arthroplasty, and secondly whether PCR for SARS-CoV-2 could instead be performed on admission. The benefit of a short, <72-hour period of absolute isolation remains uncertain. At Copenhagen University Hospital Hvidovre, where none of the elective patients isolated, but instead followed general restrictions (social distancing, washing of hands, and ventilation of rooms), no positive SARS-CoV-2 cases were recorded in elective patients. Likewise, in the 65 emergency cases, who had a negative PCR swab, but who had not undergone preoperative isolation, there were no positive SARS-CoV-2 cases. This indicates that a preoperative SARS-CoV-2 PCR test alone may be safe but further adequately powered studies are required to guide the practice as it may be that isolation is not required, or is only required in high risk patient groups such as those in institutional living or at the time of high community prevalence. Until definitive evidence is available about whether patients should isolate or not, it would be prudent to follow a cautious approach that takes into account not only the safety of the patient but also that of the medical staff and other inpatients who would be potentially put at a risk of nosocomial transmission.

Admission PCR is another option to reduce hospital contacts and the burden on patients. At present, the turnaround time for PCR is

Table 2
Operation Characteristics.

	Overall $n = 1,000$	Oxford $n = 334$	Philadelphia $n = 333$	Copenhagen $n = 333$
RCS Classification				
Ia % (*n*)	1% (7)	0.3% (1)	2% (6)	0% (0)
Ib % (*n*)	6% (55)	8% (26)	3% (11)	5% (18)
2% (*n*)	5% (49)	9% (29)	3% (10)	3% (10)
3% (*n*)	7% (68)	13% (43)	0% (0)	8% (25)
4% (*n*)	82% (821)	70% (235)	92% (306)	84% (280)
Anesthetic Strategy				
General % (*n*)	27% (274)	57% (191)	11% (35)	14% (48)
Regional % (*n*)	72% (726)	43% (143)	89% (298)	86% (285)
Primary TKA	41% (407)	42% (140)	37% (122)	44% (145)
Primary THA	40% (396)	31% (103)	48% (161)	40% (132)
Revision TKA	11% (106)	15% (50)	9% (30)	8% (26)
Revision THA	9% (91)	12% (41)	6% (20)	9% (30)

RCS, Royal College of Surgeons; TKA, total knee arthroplasty; THA, total hip arthroplasty.

variable and institution specific and therefore the logistics of performing PCR on admission for all patients may limit its application. The original rationale for PCR at between 48 and 72 hours prior to admission was to permit adequate time for processing of samples, but performing PCR early has several other potential advantages. First, although the majority of patients with infection will be identified through preoperative PCR, some may not. One group is of those who are very early in their disease course, where PCR may have a false negative result, which may become positive on serial testing due to a temporally increasing viral load. In this group, serial assessment at both between 48 and 72 hours prior, and then again on admission, provides a further opportunity to assess for signs and symptoms of disease. Although in our center, prior to the start of this study, we piloted PCR on admission (in addition to between 48 and 72 hours prior), we found that the results of the admission PCR were not available on time to change the clinical pathway and therefore we moved to assess all patients on admission to the orthopedic unit by a way of clinical screening questions. Another advantage of performing PCR early is that patients positive for SARS-CoV-2, and who cannot go ahead with their planned surgical procedure, are identified early which is helpful in ensuring that a replacement surgical case can be identified and screened for SARS-CoV-2 in adequate time. An alternative approach to PCR is to use point-of-care test devices such as lateral flow tests which produce results much quicker than laboratory assessments, typically within 30 minutes. Lateral flow tests however have a lower sensitivity and as such, at a low prevalence of disease between one-half and three-quarters of positive results would be false positives, which would lead to a high level of potentially unnecessary cancellations and unnecessary anxiety for all concerned [26]. The outcomes of the day of surgery testing have not been reported in elective orthopedics; however, the IMPACT-Scot 2 report found the false-negative rate of admission nasopharyngeal PCR swab to be 0% in asymptomatic hip fracture patients as compared to 2.9% in symptomatic patients indicating that admission testing may be a valid approach [22]. While further work is required to confirm these findings, there should be caution about extrapolating these results into the current practice, as external factors such as the behavioral change invoked by scheduled preoperative testing may also influence the risk of infection with SARS-CoV-2 in this population and in addition admission testing may not detect SARS-CoV-2 detected in the days immediately preceding admission.

The limitations of this study include that the cohort of patients presented represents the experience of 3 tertiary referral centers operating between the first and second peaks of the COVID-19 pandemic. Although a lot had been learnt during the first peak, our policies and procedures have continued to evolve to reflect global and local knowledge about the disease. At the time of this report, outside of clinical trials, no patients were vaccinated against COVID-19, but equally the prevalence of new, potentially more infectious, variants was low. During the study period, the mean national weekly confirmed new COVID-19 cases was 50/100,000, but this ranged from 1/100,000 to 254/100,000 weekly new cases varying between study sites (Fig. 2), and the prevalence of disease within the population of patients waiting for lower limb arthroplasty was uncertain [27]. Finally, not all patients underwent screening for SARS-CoV-2 postoperatively, some patients may have been asymptomatic and some patients' infection was not captured by our EMR or follow-up general health assessment and as such the prevalence of infection may be higher than we identified. Although asymptomatic infection does not likely present a risk to the individual patient, the risk of spread is uncertain.

Overall, this study offers important information to patients, surgeons, and healthcare providers about the potential level of risk associated with orthopedic surgery in patients undergoing lower limb joint arthroplasty. Based on the data presented, we believe that a SARS-CoV-2 PCR test between 48 and 72 hours preoperatively with specific advice about minimizing the risk of SARS-CoV-2 restricted to between PCR and admission (<72 hours) in conjunction with a COVID-free pathway which minimizes the risk to patients and that elective lower limb joint arthroplasty can be safely conducted at the present time. As the number of patients, and their relatives, vaccinated against COVID-19 increases, we expect the risk presented by this disease to decrease; nonetheless, we must be mindful of the local situation with regards to the prevalence of disease and the presence of new variants, from which current vaccination may offer less protection.

Conclusion

In summary, a preoperative SARS-CoV-2 PCR test between 48 and 72 hours preoperatively with specific advice about minimizing the risk of SARS-CoV-2 restricted to between PCR and admission (<72 hours) in conjunction with a COVID-free pathway is safe for patients undergoing primary and revision hip and knee arthroplasty. A preoperative SARS-CoV-2 PCR test alone may be safe but further adequately powered studies are required.

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