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Original Article

Safety of Otological Operating During the COVID-19 Pandemic: A National Prospective Audit of 1130 Cases from 79 Centers

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BACKGROUND: To assess compliance with guidance produced by the UK body representing all ENT Surgeons (ENT UK) and the British Society of Otology (BSO) on restarting otological surgery after the first wave of the COVID-19 pandemic. Safety was assessed by recording surgical complications and transmission of SARS-CoV-2 transmission during this period.

METHODS: A prospective multicenter audit of otological surgery was conducted over a 12-week period, from June 15, 2020, to September 6, 2020.

RESULTS: One thousand one hundred thirty cases from 79 hospital sites across Great Britain were involved in the study; 91.1% were tested for SARS-CoV-2 pre-operatively, none of whom tested positive; 70.4% were isolated for 7-14 days prior to surgery; 28.2% of surgeons wore full personal protective equipment, compared with 66.6% of anesthetists and 68.2% of scrub staff. The endoscope was used in 75 (6.7%) of all procedures, operations were changed to be performed under local rather than a general anesthetic in 3 cases (0.3%) and the "double drape" to protect against aerosol was used in 321 (27.4%) of cases. Trainees were present in 80.3% of cases. Complications occurred in 4% of cases. No patients or staff contracted SARS-CoV-2 during the audit.

CONCLUSION: ENT UK and BSO guidance was variably followed, with the highest compliance for the use of an FFP3 mask, a negative SARS-CoV-2 swab, and trainee presence in theater. Surgeons did not use full personal protective equipment as frequently as their anesthetic and scrub team colleagues. There were only minimal changes in surgical and anesthetic techniques. Otological operation after the first wave of the SARS-CoV-2 pandemic was performed safely with no reported COVID transmission or increase in major complications despite changes in operating practice.

KEYWORDS: SARS-CoV-2, otology, surgery, pandemic, operating

INTRODUCTION

The SARS CoV-2 pandemic resulted in many challenges for surgical teams across the UK. There were early concerns that otolaryngologists were at high risk. Otologists were concerned that coronaviruses had been shown to be present in the middle ear and mastoid during upper respiratory tract infection, and that powered instrumentation resulted in viral particle aerosolization.[1-3] On March 25, 2020, all elective ENT surgery was halted due to these concerns.

As the number of COVID-19 cases reduced across the UK, plans for the reintroduction of elective ENT surgery could be formulated. There was uncertainty about the safest way to do this and ENT UK (The UK body representing ENT Surgeons) and the BSO (British Society of Otology) produced guidance titled "A graduated return to the provision of elective ENT services during the COVID-19 pandemic" for surgeons with the following recommendations (referred to as "ENT UK-BSO guidance" forthwith) (Table 1).[4]

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Similar changes in operating practices occurred internationally.[6] A global survey of operative practices for otologists and neurotologists during the COVID-19 crisis found that 49.8% reported modifying their surgical technique.[7] Although there were slight differences globally, all techniques followed common themes of aiming to protect patients, and operating theatre staff from viral transmission. Certain countries around the world used the ENT-UK guidance to facilitate their own return to practice, while the American Academy of Otolaryngology–Head and Neck Surgery (AAOHNS) developed their own recommendations.[8,9] This is the first paper to assess the adherence to the recommendations regarding otology operating during the COVID-19 pandemic.

Objectives

The BSO and BSO Juniors devised a national prospective audit with the primary aim of identifying compliance of operating across Great Britain to the new guidance. Secondary aims were to identify whether changes in practice impacted safety, by reviewing changes in complication rates and any evidence of SARS CoV-2 transmission.

METHODS

This manuscript has been prepared with reference to the STROBE checklist.

Ethical Considerations

The Health Research Authority decision tool determined the study design to fall under the remit of audit and therefore ethical approval was not required.

Study Setting and Design

A prospective multicenter audit of otological surgery was conducted over a 12-week period, from June 15, 2020, to September 6, 2020. There were three 4-week data collection periods (audit periods 1, 2, and 3) with a final 3 weeks to collect follow-up data. A collaborative authorship model was used to recruit data contributors. The BSO council members recruited regional leads, who in turn recruited hospital site leads. Regional and site leads were ENT trainees or non-trainee middle-grades and were responsible for registering the audit with the local clinical governance department. In total, there were 151 possible sites across Great Britain identified. A standardized electronic data collection form was shared with contributors in microsoft word (Word Software, Microsoft Corporation) (appendix 1). Data were entered by the site lead or other members of the team (including consultants, middle grades, and more junior doctors and surgeons under the supervision of the site lead.

Participants

All emergency and elective otological procedures taking place in operating theatres across Great Britain were eligible to be included. We excluded any procedures that did not include operating on the ears (even when the indication was for an otological condition, for example, balloon eustachian tuboplasty and those performed in the outpatient department.

Categorical Variable Stratification

Operative procedures were classified into 4 categories (external, hearing, middle ear, and skull base). External included all cases in which did not enter the middle ear or mastoid space. Hearing surgery included ossiculoplasty, stapedectomy, and all implantable hearing aids. Middle ear surgery included any surgery which exposed the middle ear and mastoid respiratory epithelium including mastoidectomy and grommets, excluding those already included in hearing surgery. Skull-base surgeries included those which targeted the inner ear or intracranial contents such as vestibular schwannoma removal.

With regards to race and ethnicity, instruction was not given as to how this should be determined, and contributors may have asked participants, reviewed their electronic records, or made an observation. Race and ethnicity data were collected because of concerns about increased susceptibility to COVID-19 and subsequent adverse outcomes in Black, Asian, and minority ethnic patients.[10] We therefore categorized race and ethnicity into Caucasian and non-Caucasian to attempt to identify any differences.

Statistical Methods

Statistical analysis was performed using R version 3.6.3[11] with the use of additional software packages: Tidyverse,[12] compareGroup,[13] dplyr,[14] and ggplot2.[15] Non-parametric data were reported as the median with interquartile ranges, and the Kruskal–Wallis rank-sum test was used for analysis. Pearson's chi-squared test (X^2) or Fisher's exact test was used to assess the categorical data. Statistically significant differences were set at $\leq .05$. Missing responses were excluded from the analysis.

RESULTS

Patient Demographics

1130 procedures were captured during the audit period from 79 hospitals out of the 151 identified (52%). (Table 1). Sites did not contribute either because of lack of otology operating or lack of engagement with the audit. 93.9% (n = 1054) of patients in the study period had no or minimal co-morbidities (ASA 1 or 2). Hypertension was the most frequently encountered co-morbidity (8.69%, n = 97) followed by diabetes mellitus (3.49%, n = 39) (Table 1). In the population sampled, 83.2% (n = 929) were Caucasian, and 16.8% (n = 187) non-Caucasian which is reflective of the UK population and supports generalizability of these results (16). 1% (n = 8) of operations performed during the study were for malignant disease, external ear

MAIN POINTS

- Surgeons were less compliant with "full personal protective equipment" in comparison to their anesthetic and scrub team colleagues suggesting difficulty in using full PPE when operating.
- Recommended practices that deviated from usual operating or anesthetizing techniques were less well adhered to.
- The impact on training (through re-deploying junior staff to cover medical specialties) was seen with 19.7% of operations performed with no trainee present.
- Complications were reported in 4% of cases with surgical site infections being the most frequently reported. There was no increase in complication rates compared to the literature.
- There was no evidence of transmission of SARS-CoV-2 to patients or staff during the audit period.

Table 1. ENT UK- BSO Guidance

Pre-operative	a. Pre-operative negative COVID test b. Patients should self-isolate for 14 days prior to surgery
Theater environment	a. Surgery to be performed in a COVID-free area (COVID-free or a "zoned" site) b. Endoscopic ear surgery preferred to mastoid drilling (where surgeons suitably trained) c. Double draping techniques to help minimize aerosolization of tissues (5)
Personal protective equipment (PPE)	a. Full PPE for otological surgery including FFP3 mask or powered air-purifying respirators (PAPR) and goggles or a visor
Anesthetic changes	a. Local anesthetic preferred to general anesthetic
Surgical prioritization	a. Most elective ENT procedures were classified as priority level 4 (safely deferred for 3 months) except for cochlear implantation in pre-lingual children, posterior fossa/lateral skull base pathology if brainstem compression, acute worsening of existing conditions including facial nerve palsy and vertigo and acute mastoiditis not responding to conservative management. b. Mastoidectomies for cholesteatoma should be prioritized over tympanoplasty, myringoplasty, ossiculoplasty and stapedectomy.
Training	a. Trainees are no more at risk of COVID -19 than their consultant and so should be allowed to carry out sections of an operation under consultant supervision but timely completion of surgery should be a priority.

malignancies being the predominant subgroup. Fifty percent of the patients having surgery for a malignancy were ASA 3 or 4, compared to 6.1% (n = 69) for surgery overall. The proforma was fully completed in 80% of cases.

Primary aim: Audit Compliance with the ENT UK- BSO Guidance on Returning to Otological Operating During COVID-19 Pandemic

Pre-operative Measures

One thousand twenty-nine (91.1%) patients were known to have a negative COVID-19 status pre-operatively confirmed with a polymerase chain reaction test. COVID-19 status was not reported in 101 cases (8.9%), of which 84% (n = 85) were pediatric cases (Table 2).

70.4% (n = 786) of all patients isolated for 7-14 days preoperatively. By the third audit period there was a significant increase in those isolating for less than 7 days ($P < .05$).

Theater Environment

A total of 25.9% (n = 286) of patients were operated on at a COVID-free site, while 40.6% (n = 449) patients were operated on a zoned site where COVID and non-COVID patients were located in separate areas of the hospital (Table 2). There was a decrease in the number of cases being performed at a COVID-free site as the study progressed, with a statistically significant difference between audit periods ($P < .05$).

The microscope was used in 880 operations (83.1%), and the endoscope in 75 (6.7%) of all procedures. These rates were stable over the 3 audit periods. The drill was used in 562 (52.6%) of all operations.

The double drape method was used in 321 (28.4%) cases.[5] Other alternatives to prevent spread of aerosolized virus between patient and healthcare team included covering the patient's face with a surgical mask (n = 3).

Totally, 34.6% (n = 369) of cases lasted less than 60 minutes overall. The proportion of cases taking fewer than 60 minutes increased across the study periods, while operations lasting in excess of 3 hours showed a reciprocal decrease ($P < .05$).

Personal Protective Equipment

Full personal protective equipment (PPE) was defined as FFP3 mask or PAPR in conjunction with eye protection (visor, goggles, or PAPR hood) as advised in the ENT UK-BSO guidance. This was worn by 313 (28.2%) of surgeons (Table 3). There was a decrease in surgeons wearing full PPE across the audit periods ($P < .05$). A total of 66.6% (n = 703) of anesthetists and 68.2% (n = 754) of theater scrub team members wore full PPE for cases overall.

Surgical challenges included poor visualization (fogging of eyewear and the double microscope drape impeding visualization) (8.8%, 99/1130) and communication difficulties (0.3%, 3/1130).

Anesthetic Changes

Seven hundred sixty-three cases (67.5%) were performed in the surgeon's usual hospital setting. 965 cases (87.2%) were performed in a positive pressure environment. Local anesthetic was used in place of general anesthetic in 0.3% (n = 3) cases.

Changes in anesthetic practice compared to pre-pandemic were reported in 13.8% (n = 156) of procedures, including anaesthetizing patients in theater, longer turnaround times, and extubating the patients under a plastic cover.

Surgical Prioritization

The number of otology procedures performed progressively increased across the three study periods (Table 1, Figure 1A). Middle ear procedures were the most frequently performed (69.1%, n = 781) while hearing procedures accounted for 15.3% (n = 173) of cases. Pre-lingual cochlear implantation rates increased initially, with adult cochlear implantation showing a subsequent greater rise in cases. The types of hearing implant and the demographic of recipients are shown in Figures 1B and 1C.

In the case of cholesteatoma, the disease was more advanced than expected in a total of 5.2% of cases (n = 59).

Impact on Training

Trainees were present for 80.3% (n = 907) of cases, the largest proportion of which were coded as supervisor-trainer scrubbed (a code

Table 2. Basic Demographics and Comorbidities

		[ALL]	External	Hearing	Middle Ear	Skull Base
Gender	Female	523 (46.3%)	71 (50.4%)	84 (48.6%)	355 (45.5%)	13 (37.1%)
	Male	607 (53.7%)	70 (49.6%)	89 (51.4%)	426 (54.5%)	22 (62.9%)
	Age	25.0 [8.00;50.0]	9.00 [4.00;42.0]	22.0 [4.00;55.0]	26.0 [10.0;49.2]	50.0 [41.5;63.0]
Age category	<18	474 (42.0%)	89 (63.1%)	76 (43.9%)	309 (39.6%)	0 (0.00%)
	18- 49	360 (31.9%)	22 (15.6%)	45 (26.0%)	276 (35.4%)	17 (48.7%)
	50- 59	110 (9.7%)	7 (5.0%)	13 (7.5%)	84 (10.8%)	6 (17.1%)
	60-69	89 (7.9%)	5 (3.5%)	15 (8.7%)	63 (8.1%)	6 (17.1%)
	>70	96 (8.5%)	18 (12.8%)	24 (13.9%)	48 (6.1%)	6 (17.1%)
Ethnicity	Caucasian	929 (83.2%)	113 (81.3%)	142 (83.5%)	646 (83.7%)	28 (80.0%)
	Non-Caucasian	187 (16.8%)	26 (18.7%)	28 (16.5%)	126 (16.3%)	7 (20.0%)
	Not reported	14				
Diabetes	No	1078 (96.5%)	129 (93.5%)	164 (94.8%)	754 (97.8%)	31 (88.6%)
	Yes	39 (3.5%)	9 (6.5%)	9 (5.2%)	17 (2.20%)	4 (11.4%)
	Not reported	13				
Hypertension	No	1019 (91.3%)	129 (93.5%)	156 (90.2%)	705 (91.6%)	29 (82.9%)
	Yes	97 (8.7%)	9 (6.5%)	17 (9.8%)	65 (8.4%)	6 (17.1%)
	Not reported	14				
Vascular disease	No	1068 (95.8%)	132 (95.7%)	159 (91.9%)	745 (96.9%)	32 (91.4%)
	Yes	47 (4.2%)	6 (4.3%)	14 (8.1%)	24 (3.1%)	3 (8.6%)
	Not reported	15				
Immuno-suppression	No	1098 (98.5%)	134 (97.1%)	171 (98.8%)	761 (99.0%)	32 (91.4%)
	Yes	17 (1.5%)	4 (2.9%)	2 (1.2%)	8 (1.0%)	3 (8.6%)
	Not reported	15				
ASA	1	742 (66.1%)	99 (71.2%)	97 (56.1%)	530 (68.2%)	16 (47.1%)
	2	312 (27.8%)	31 (22.3%)	57 (32.9%)	208 (26.8%)	16 (47.1%)
	3	65 (5.8%)	9 (6.5%)	17 (9.8%)	37 (4.7%)	2 (5.8%)
	4	4 (0.3%)	0 (0.00%)	2 (1.2%)	2 (0.3%)	0 (0.00%)
	Not reported	7				
Audit period	1	240 (21.2%)	28 (19.9%)	40 (23.1%)	159 (20.4%)	13 (37.1%)
	2	425 (37.6%)	47 (33.3%)	67 (38.7%)	296 (37.9%)	15 (42.9%)
	3	465 (41.2%)	66 (46.8%)	66 (38.2%)	326 (41.7%)	7 (20.0%)
Nation	England	969 (85.8%)	106 (75.2%)	160 (92.5%)	669 (85.7%)	34 (97.1%)
	Scotland	130 (11.5%)	16 (11.3%)	12 (6.9%)	101 (12.9%)	1 (2.9%)
	Wales	31 (2.7%)	19 (13.5%)	1 (0.6%)	11 (1.4%)	0 (0.00%)

used for the procedure that indicates that the trainee took a lead part in the majority of the surgery) (34.3%, n = 388). Trainee presence is shown according to region of Great Britain in Figure 2.

SECONDARY OUTCOME MEASURES

Complications

There was a total of 49 complications in 46 patients (4%) reported post-operatively (Figure 3). Two patients required a return to theater, 1 for washout of a temporal lobe abscess (after a combined approach tympanoplasty), and the other for repositioning of a cochlear implant electrode.

There were 2 intracranial infections, 1 detailed above, and a subdural empyema managed conservatively. Cranial nerve neuropraxia was reported in 8 cases; a sixth nerve palsy after translabyrinthine vestibular schwannoma (VS) resection, and seven seventh nerve palsies, 2 of which presented late. One of the reported facial nerve palsies had not resolved by the conclusion of the audit, although this was expected following VS surgery. A cerebrospinal fluid leak occurred in 2 cases, following a retrosigmoid approach to VS and after a mastoidectomy with blind sac closure. Post-operative vestibular dysfunction and bleeding each occurred in 4 patients and was managed conservatively. BIPP allergy and taste disturbance was reported in 3 patients each. There were 3 complications reported as "other," a

Table 3. Theater Environment and Pre-Operative Requirements

	[ALL]	Audit Period 1	Audit Period 2	Audit Period 3
COVID-free site				
Yes	286 (25.9%)	80 (33.3%)	101 (24.5%)	105 (23.1%)
"Zoned"/mixed	449 (40.6%)	89 (37.1%)	174 (42.2%)	186 (41.0%)
No	371 (33.5%)	71 (29.6%)	137 (33.3%)	163 (35.9%)
Not reported	24			
Setting:				
Usual location	763 (67.5%)	154 (64.2%)	289 (68.0%)	320 (68.8%)
Alternative within same hospital	232 (20.5%)	53 (22.0%)	92 (21.6%)	87 (18.7%)
Different hospital	135 (12.0%)	33 (13.8%)	44 (10.4%)	58 (12.5%)
COVID Status Preop				
Negative	1029 (91.1%)	220 (91.7%)	383 (90.1%)	426 (91.6%)
Not reported	101 (8.9%)	20 (8.3 %)	42 (9.9%)	39 (8.4%)
Pre-operative Self Isolation				
Did not self-isolate	171 (15.3%)	39 (16.2%)	66 (15.9%)	66 (14.3%)
<7 days	138 (12.4%)	0 (0.00%)	10 (2.4%)	128 (27.8%)
7-14 days	786 (70.4%)	190 (79.2%)	333 (80.0%)	263 (57.0%)
>14 days	22 (1.9%)	11 (4.6%)	7 (1.7%)	4 (0.9%)
Not reported	13			
Theater Environment				
Positive pressure	965 (87.2%)	205 (85.4%)	362 (86.6%)	398 (88.6%)
Negative pressure	142 (12.8%)	35 (14.6%)	56 (13.4%)	51 (11.4%)
Not reported	23			
Duration				
≤60 minutes	369 (34.6%)	68 (28.9%)	132 (31.7%)	169 (40.7%)
61-120 minutes	242 (22.7%)	38 (16.2%)	101 (24.3%)	103 (24.8%)
121-180 minutes	254 (23.8%)	66 (28.1%)	104 (25.0%)	84 (20.2%)
>180 minutes	201 (18.9%)	63 (26.8%)	79 (19.0%)	59 (14.3%)
Not reported	64			

pulmonary embolism (n = 1); failure to site a cochlear implant correctly (n = 1) and sigmoid sinus thrombosis requiring heparinisation (n = 1). There were no mortalities.

Transmission of SARS CoV-2 Between Patients or Staff

No staff or patients reported testing positive for SARS-CoV-2 during the audit.

DISCUSSION

Patient Demographics

The rates of co-morbidities including hypertension and diabetes were lower than identified in the UK population as a whole, reflective of a younger population in our audit.[12]

Pre-operative Measures

No known COVID-19-positive patients were operated on during the study period, therefore complying with the ENT UK-BSO audit standard. This may be explained by the low prevalence of COVID in the general population at the time of the study and the apparent small number of emergency cases included. We identified 12 emergency cases by reviewing all cases individually. These included 3 ear laceration repairs, 3 mastoidectomies for mastoiditis, and 6 drainages for an abscess or hematoma. We did not include foreign bodies in the ears as emergency operating (no cases of a button battery were identified). The majority of patients where the COVID-19 status was unknown were pediatric cases (84%), where pre-operative testing may not have been feasible. 70.4% of patients reported self-isolating for 7-14 days prior to surgery. The UK body representing ENT Surgeons and the British Society of Otology guidance was that patients should isolate for 14 days prior; however, NICE subsequently produced guidance in July 2020 that a 3-day isolation period was adequate before elective surgery. The publication of this new guidance CORRELATED with an increase in PATIENTS' isolating for 7 days or less by audit period 3.[13]

Theater Environment

Zoned sites or COVID-free sites were used for operating in 66.4% of cases. A higher compliance rate may have been difficult to achieve due to logistical restraints.

Endoscopic ear surgery was only reportedly used in 6.7% of cases. These rates are presumed to reflect the relative proportions of otological surgeons using endoscopes in their usual practice. It seems

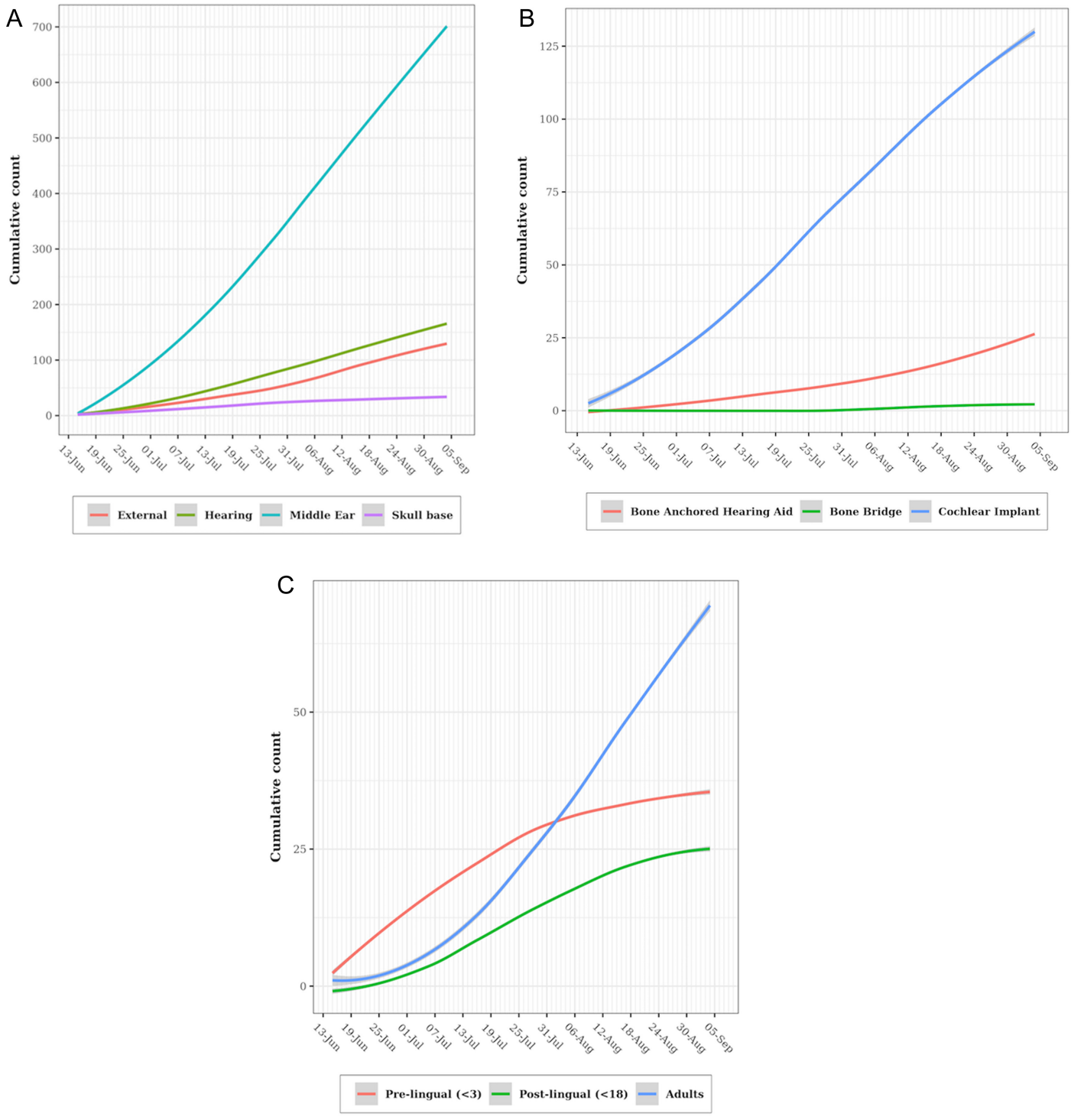

Figure 1. a-c. (a) Operations by category, changes in operating capacity over time. (b) Hearing implant operations, changes in operating capacity over time. (c) Cochlear implantation, changes in population receiving implant over time.

likely that surgeons would not CHOOSE to trial new, unfamiliar techniques in an already challenging surgical environment. The reasons for this include the challenges of learning a new technique when visualisation and comfort are reduced in PPE and pressure to complete the cases in a timely fashion in order to reduce the exposure of operating room staff to aerosolised viral particles.

Across the audit, the "double drape" method was used in 28.4% of all cases.[5] The drape was usually only used for cases requiring drilling as surgeons and scrub staff found it difficult to pass instruments and there was a perceived lack of additional benefit of double draping, if full PPE is also being worn.

There was a statistically significant difference in the duration of operations across the audit periods, with the average operation time reducing. As the audit progressed, the surgeon and theater team's familiarity with COVID safety precautions may have increased resulting in shorter operations over time.

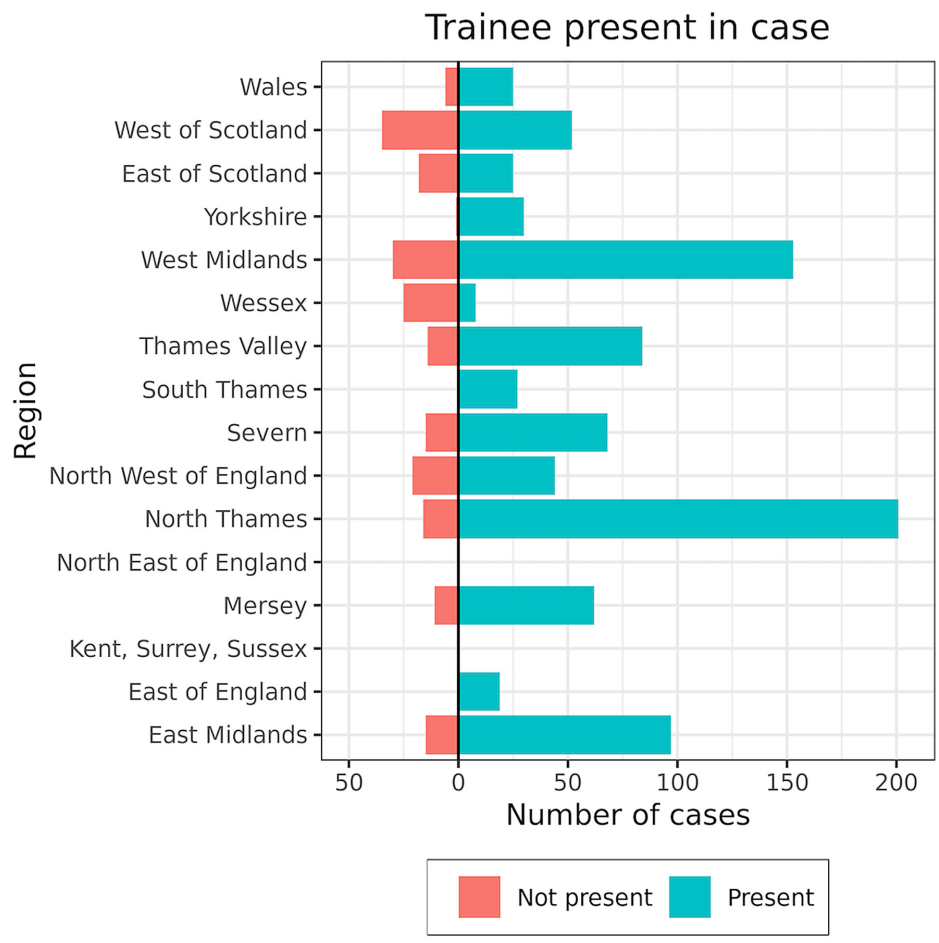

Figure 2. Trainee presence in theater by region.

Personal Protective Equipment

Full PPE (FFP3 and appropriate eye protection) was worn by only 28.2% of surgeons overall, and there was a decrease in the number of surgeons wearing full PPE across the audit periods ($P < .05$), perhaps because surgeons could not find a full PPE solution compatible with microscope use. A higher proportion of both anesthetists (66.6%) and theater staff (68.2%) wore full PPE, which supports this conclusion as unlike surgeons, they did not need to use the microscope (Table 4).[19] This may also be reflective of differing attitudes to risk across these professional groups. For surgeons, the relative risk of causing morbidity to the patient from poor visualization may have outweighed the perceived minimal safety risk from operating on a patient who had tested COVID negative.

There were no reports of PPE shortages, and no staff or patients tested positive for SARS-CoV-2 post-operatively. This suggests that the existing guidance with regard to testing, isolation, and PPE use was adequate to protect staff and patients having otological procedures.[4]

Anesthetic Changes

Although the ENT UK-BSO guidance stated that local anesthetic should be used in preference to general anesthetic, this was only achieved in 0.3% of cases, with the majority of surgeons choosing not to deviate from their usual practice.

Surgical Prioritization

Middle ear surgery (69.1%) was the most frequent operation performed throughout the audit, reflective of usual otological practice. Across the audit period, the number of cases of middle ear surgery increased, demonstrating an increase in surgical capacity and as hospital sites re-started operating and theater teams became more familiar with COVID safety measures increasing theater throughput (Table 1). Cochlear implantation for pre-lingual children was prioritized over post-lingual children and adults initially (Figure 1C).

The disease was thought to be more advanced than expected in 5.2% of cases which may have been a result of otology operations being delayed at the start of the pandemic.

Training

Trainees were present in 80.3% of all cases submitted, which is similar to proportions found in the British Rhinology Society COVID-19 audit.[20] However, in many departments across Great Britain, surgical trainees were redeployed to support additional bed capacity in medical wards or the intensive care unit, missing much valuable operating experience, and when they were present in the theater, only 23.2% of cases had a trainee in a leading role in the case (defined as cases coded as supervised trainer unscrubbed (cases where the trainer is present in theatre but not scrubbed for the

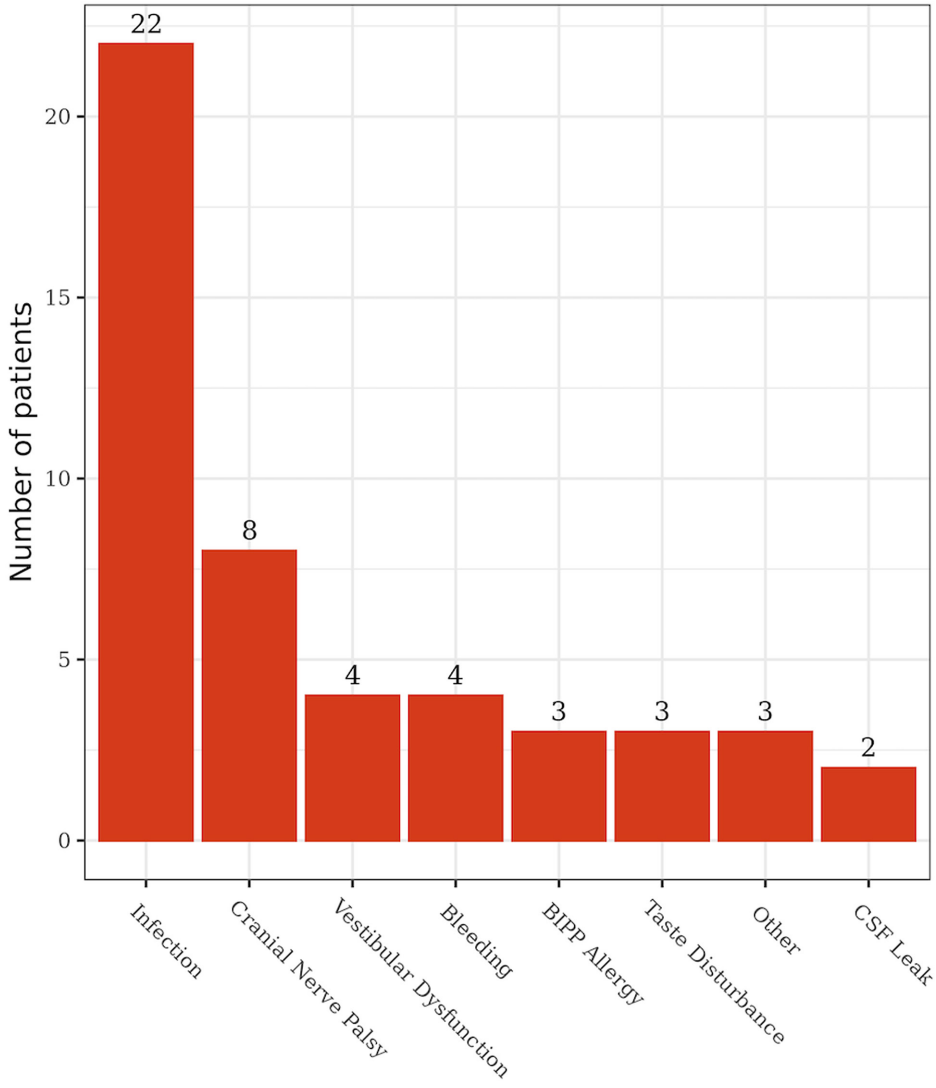

Figure 3. Operative complications.

case as trainee performing it independently) or performed (no consultant trainer present).

A Joint Committee on Surgical Training study evaluating the comparative numbers of surgical logbook cases showed that ENT trainees case throughput was 32% compared with the same period the previous year.[21] The involvement of trainees at a time when overall caseloads were low shows enthusiasm for training from trainers and trainees despite the prevailing situation.

Complications and Comparison to Other Studies

Complication rates (4%) are comparable to previous literature, suggesting that otological surgery was being performed safely in Great Britain, despite the pressure of operating within the restrictions necessitated by a pandemic. We compared our mastoidectomy cases (n = 342) with a Royal College of Surgeons (RCS) audit of 536 mastoidectomies in 1995 and found no increase in major complications. There was 1 (0.2%) permanent facial palsy compared to their 0.6%, and no (0%) dead ears compared to 1.3% in the RCS audit.[22] Surgical site infection for mastoidectomy in our study (n = 8) was less than that detected in a recent study looking at surgical site infections following mastoid surgery (2.3% vs. 3.9%).[23]

Clinical Applicability and Generalizability

This is the first paper to describe adherence to any guidance for otology operating and the findings are generalizable as many of the recommendations were similar to those used internationally.[6,10] The British Rhinological Society Juniors team performed an almost identical audit of rhinology operating which also found no increase in complication rates or COVID-19 transmission.[20]

Limitations

A limitation of this study was that there were no reports of COVID transmission, therefore comparison of practices that have a significant impact on transmission is not possible. Although there are very large data sets, there are some gaps. First, out of the 151 hospitals we hoped to include in the audit, 79 (52%) did contribute. Second, only a small proportion of emergency cases were captured (n = 12) which may have been due to the challenges of collecting data from emergency cases out of hours. Third, as trainees and middle grades collected the majority of the data, there may have been additional cases not captured (by consultants operating in the private sector) in their absence. Finally, 20% of datasets were not completely filled in. We did not provide any training to complete the form and so some

Table 4. Personal Protective Equipment and Instruments Used

		[ALL]	Audit Period 1	Audit Period 2	Audit Period 3
Surgeon mask	FFP3	924 (83.2%)	217 (90.4%)	351 (84.2%)	356 (78.4%)
	FFP2	54 (4.8%)	13 (5.4%)	26 (6.2%)	15 (3.3%)
	Surgical Mask	133 (12.0%)	10 (4.2%)	40 (9.6%)	83 (18.3%)
	Not reported	19			
Surgeon eye protection	Airtight goggles	86 (7.7%)	25 (10.4%)	29 (7.0%)	32 (7.0%)
	Goggles	69 (6.1%)	13 (5.5%)	26 (6.3%)	30 (6.5%)
	All in 1 hood	22 (2.0%)	8 (3.3%)	11 (2.6%)	3 (0.7%)
	Visor	154 (13.8%)	51 (21.2%)	61 (14.6%)	42 (9.1%)
	None	786 (70.4%)	143 (59.6%)	290 (69.5%)	353 (76.7%)
	Not reported	13			
Surgeon full PPE	Yes	313 (28.2%)	95 (39.6%)	118 (28.4%)	100 (22.0%)
	No	796 (71.8%)	145 (60.4%)	297 (71.6%)	354 (78.0%)
	Not reported	21			
Anesthetist mask	FFP3	898 (83.3%)	200 (85.8%)	341 (83.0%)	357 (82.3%)
	FFP2	44 (4.1%)	13 (5.6%)	21 (5.1%)	10 (2.3%)
	Surgical Mask	136 (12.6%)	20 (8.6%)	49 (11.9%)	67 (15.4%)
	Not reported	52			
Anesthetist eye protection	Yes	744 (70.2%)	174 (75.3%)	279 (69.8%)	291 (67.8%)
	No	316 (29.8%)	57 (24.7%)	121 (30.2%)	138 (32.2%)
	Not reported	70			
Anesthetist full PPE	Yes	703 (66.6%)	166 (71.9%)	264 (66.3%)	273 (64.1%)
	No	352 (33.4%)	65 (28.1%)	134 (33.7%)	153 (35.9%)
	Not reported	75			
Scrub mask	FFP3	885 (79.9%)	209 (88.2%)	334 (81.1%)	342 (74.5%)
	FFP2	58 (5.2%)	14 (5.9%)	26 (6.3%)	18 (3.9%)
	Surgical Mask	165 (14.9%)	14 (5.9%)	52 (12.6%)	99 (21.6%)
	Not reported	22			
Scrub eye protection	Yes	836 (75.2%)	185 (78.1%)	320 (76.9%)	331 (72.1%)
	No	276 (24.8%)	52 (21.9%)	96 (23.1%)	128 (27.9%)
	Not reported	18			
Scrub full PPE	Yes	754 (68.2%)	170 (72.0%)	288 (69.9%)	296 (64.6%)
	No	352 (31.8%)	66 (28.0%)	124 (30.1%)	162 (35.4%)
	Not reported	24			
Drill use	Yes	562 (52.6%)	144 (62.6%)	223 (55.3%)	195 (44.8%)
	No	506 (47.4%)	86 (37.4%)	180 (44.7%)	240 (55.2%)
	Not reported	62			
Visual aids	Microscope	880 (77.8%)	188 (78.3%)	335 (78.8%)	357 (76.8%)
	Microscope and Endoscope	104 (9.2%)	25 (10.4%)	39 (9.2%)	40 (8.6%)
	Endoscope	75 (6.7%)	16 (6.7%)	29 (6.8%)	30 (6.5%)
	None	71 (6.3%)	11 (4.6%)	22 (5.2%)	38 (8.1%)

data fields were interpreted differently. For example, free-text data capture for complications gave autonomy to site leads about the threshold of complication data to include. This may have led to the under-reporting of minor complications such as taste disturbance. Despite a 3 week follow-up period, it would have been challenging to assess COVID rates given the rates of asymptomatic cases and the logistical difficulties of following up of staff and patients. The study period in which the data collection was performed was immediately following the end of the first wave of SARS-CoV-2, where the community prevalence of SARS-CoV-2 was low, and before more

transmissible variants emerged. The risk of significant complications for the majority of routine otological procedures is minimal and therefore even a large study such as this may be underpowered. This study is unable to address concerns regarding cholesteatoma recurrence rates secondary to visualization challenges while operating.

Summary

This audit has demonstrated variable compliance with the ENT UK-BSO guidance produced to guide the restarting of otology operating practice in Great Britain. Pre-operative SARS CoV-2 testing, wearing FFP3 masks (but not full PPE) by all staff groups, and trainee presence in the theater was satisfactory. Surgeons did not use full PPE as much as their anesthetic and scrub team colleagues. Where surgeons were encouraged to deviate from their usual surgical practice (use of the endoscope or local anesthetic encouraged) the compliance was much lower, suggesting surgeons did not feel the benefits of these interventions to reduce SARS CoV-2 aerosolization justified the risks of using less familiar operating practices. We also found that the resumption of otological surgery following the first UK wave of the SARS-CoV-2 pandemic has been conducted safely, with no major increases in complications, and without transmission of SARS-CoV-2 to patients or to theater staff.

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Peer-review: Externally peer-reviewed.

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BSO/ BSO Juniors. Elective Otological Surgery during COVID-19 Audit Questionnaire

Thank you for participating in this audit. Please select all that apply for each question.

Name of NHS Hospital _____

Name of person entering information: _____

Patient Demographics

Age (years): _____

Gender: ▢ Male ▢ Female

Ethnicity:
- ▢ White
- ▢ Black
- ▢ South Asian (Indian, Pakistani, Bangladeshi)
- ▢ South-East Asian (Chinese, Korean)
- ▢ Mixed Please state _____
- ▢ Other Please state _____

Comorbidities:
- ▢ None
- ▢ Diabetes
- ▢ Hypertension
- ▢ Vascular disease (IHD, stroke or PVD)
- ▢ Immunosuppression

Anaesthetic performance status (I-V): _____

Pre-operative management

For how long did patient self-isolate prior to surgery?
- ▢ Did not self-isolate
- ▢ 7 days
- ▢ 14 days
- ▢ Other. Please state _____

COVID status?
- ▢ Positive
- ▢ Negative
- ▢ Previous COVID
- ▢ Unknown

Surgery

Diagnosis _____

Name of procedure _____

Date of procedure _____

Setting of surgery:
- ▢ Usual location
- ▢ Alternative within same hospital
- ▢ Different hospital to usual

Is this a “COVID-free” site? ▢ Yes ▢ No ▢ “Zoned/mixed site”

Anaesthetic used: ▢ General ▢ Local

Is this a change from the type of Anaesthetic that would have been used pre COVID
▢ Yes ▢ No

Type of theatre environment: ▢ Positive pressure ▢ Negative pressure

Were any of the following visual aids used?
▢ Endoscope ▢ Microscope
▢ Loupes ▢ None
▢ Other: Please state _____

Is the visualisation method different from what you would use “pre COVID”?

▢ Yes ▢ No

Please comment:
_____
_____

<u>Team</u>

Trainee Involvement:
▢ No trainee present ▢ Supervised scrubbed
▢ Observed ▢ Supervised unscrubbed
▢ Assisted ▢ Performed

PPE Used by Surgical Team:
▢ FFP3 mask
▢ FFP2 mask ▢ Double gloves
▢ PAPR Hood ▢ Single gloves
▢ Oxygen tent
▢ Other: Please state _____

Please state manufacturer of mask: _____

Eye protection Used by Surgical Team
▢ None ▢ Glasses
▢ Visor ▢ Airtight goggles
▢ All in one hood ▢ Other: Please state
_____

Please state manufacturer of eye protection equipment: _____

Did Eye protection change throughout the course of the procedure?

▢ Yes ▢ No

Please comment:
_____
_____

Was it possible to see adequately? ▢ Yes ▢ No

PPE Used by Anaesthetic Team:

- ▢ FFP3 mask
- ▢ FFP2 mask
- ▢ PAPR Hood
- ▢ Disposable hood
- ▢ Visor/ eye protection
- ▢ Double gloves
- ▢ Single gloves
- ▢ Other: Please state

_____

PPE Used by other Theatre Staff:

- ▢ FFP3 mask
- ▢ FFP2 mask
- ▢ PAPR Hood
- ▢ Disposable hood
- ▢ Visor/ eye protection
- ▢ Double gloves
- ▢ Single gloves
- ▢ Other: Please state

_____

Were any other protective measures used?

- ▢ Double draping of microscope over patient
- ▢ Drape
- ▢ Other: Please state _____

Procedure

Instruments used:

- ▢ Cold Steel
- ▢ Drill
- ▢ Laser
- ▢ Electrocautery
- ▢ Other: Please state _____

Duration of general anaesthesia:

- ▢ ≦60minutes
- ▢ 61-120 minutes
- ▢ 121 - 180 minutes
- ▢ >180 minutes

Was the patient recovered in theatre? ▢ Yes ▢ No

Any changes in anaesthetic/surgical technique/practice?

▢ Yes ▢ No

Please comment:

_____

_____

Any challenges in performing surgery? ▢ Yes ▢ No

Please comment:

_____

_____

Intra-operative complications? ▢ Yes ▢ No

Please comment:

_____

_____

Was the disease more advanced than expected? ▢ Yes ▢ No

Please comment:

_____
_____

Return to theatre? ▢ Yes ▢ No

If yes, please state reason:

_____
_____

Follow-up (3 weeks)

Patient complications? ▢ Yes ▢ No

If yes, please state:

_____
_____

Was patient subsequently found to be COVID +ve?

- ▢ No
- ▢ Confirmed COVID
- ▢ Suspected COVID symptoms

Patient mortality? ▢ Yes ▢ No

If yes, please state cause of death:

_____

In the three weeks following surgery are you aware of?

a. Staff morbidity/COVID Cases in theatre team?
   - ▢ None
   - ▢ Surgical team
   - ▢ Anaesthetic team
   - ▢ Theatre staff

   Please state number of people affected and details: _____
   _____

b. Did the operating surgeon or assistant develop COVID symptoms or test positive?
   - ▢ No
   - ▢ Yes. Please give details _____
   _____

Thank you for completing this questionnaire. Please feel free to state any further comments:

_____
_____
_____
_____