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■ FOOT & ANKLE

The UK Foot and Ankle COVID-19 National (FAICoN) audit

RATE OF COVID-19 INFECTION AND 30-DAY MORTALITY IN FOOT AND ANKLE SURGERY IN THE UK DURING THE COVID-19 PANDEMIC



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Aims

The primary objective was to determine the incidence of COVID-19 infection and 30-day mortality in patients undergoing foot and ankle surgery during the global pandemic. Secondary objectives were to determine if there was a change in infection and complication profile with changes introduced in practice.

Methods

This UK-based multicentre retrospective national audit studied foot and ankle patients who underwent surgery between 13 January and 31 July 2020, examining time periods pre-UK national lockdown, during lockdown (23 March to 11 May 2020), and post-lockdown. All adult patients undergoing foot and ankle surgery in an operating theatre during the study period were included. A total of 43 centres in England, Scotland, Wales, and Northern Ireland participated. Variables recorded included demographic data, surgical data, comorbidity data, COVID-19 and mortality rates, complications, and infection rates.

Results

A total of 6,644 patients were included. Of the operated patients, 0.52% (n = 35) contracted COVID-19. The overall all-cause 30-day mortality rate was 0.41%, however in patients who contracted COVID-19, the mortality rate was 25.71% (n = 9); this was significantly higher for patients undergoing diabetic foot surgery (75%, n = 3 deaths). Matching for age, American Society of Anesthesiologists (ASA) grade, and comorbidities, the odds ratio of mortality with COVID-19 infection was 11.71 (95% confidence interval 1.55 to 88.74; p = 0.017). There were no differences in surgical complications or infection rates prior to or after lockdown, and among patients with and without COVID-19 infection. After lockdown the COVID-19 infection rate was 0.15% and no patient died of COVID-19.

Conclusion

COVID-19 infection was rare in foot and ankle patients even at the peak of lockdown. However, there was a significant mortality rate in those who contracted COVID-19. Overall surgical complications and postoperative infection rates remained unchanged during the period of this audit. Patients and treating medical personnel should be aware of the risks to enable informed decisions.

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Introduction

Since December 2019, the global COVID-19 pandemic has had a devastating effect on healthcare systems worldwide, with 38,002,699 confirmed cases and 1,083,234 deaths as of 14 October 2020.¹ In the UK, NHS England declared a Level-4 National incident

on 30 January 2020; as hospital resources became overwhelmed, NHS England requested that NHS hospitals reduce all elective activity to the point of postponing all nonurgent elective procedures for a period of at least three months from 15 April 2020. Globally, Phillips et al² found 11 reports of

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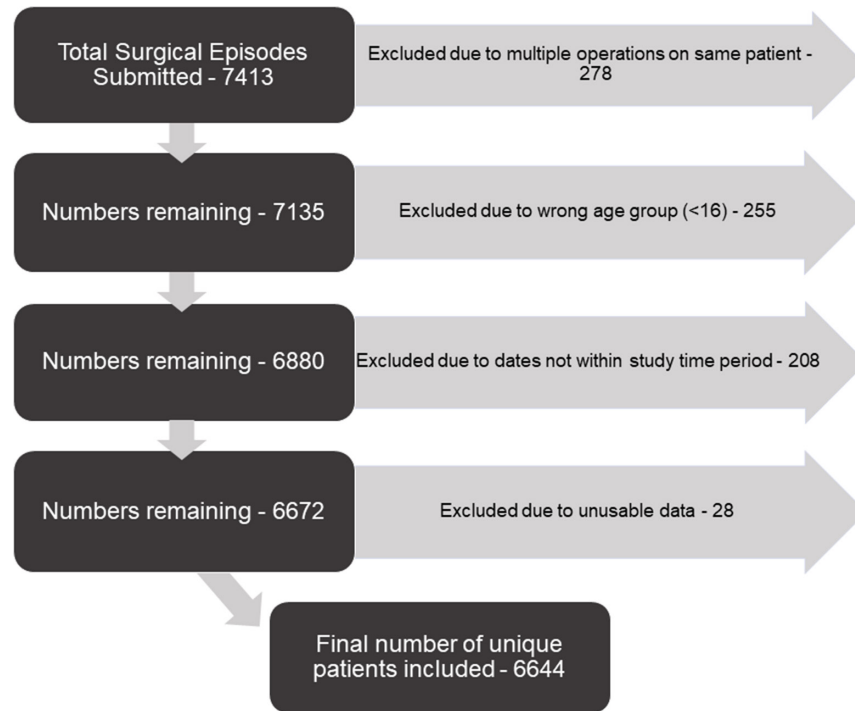


Fig. 1

Flow diagram displaying data cleansing of submitted data, with different levels of case exclusion.

either selective or complete postponement of elective activity issued by orthopaedic governing bodies. On 23 March 2020, the UK government announced a national lockdown with the publication of guidance on “Staying at home and away from others (social distancing)”.³ Surgical governing bodies also produced guidance on the rationing of services due to scarcity of hospital resources.⁴

Regarding foot and ankle surgery in the UK, guidance was only issued specifically pertaining to the treatment of urgent orthopaedic conditions and trauma, aiming to maximize resource capacity, ensure patient and staff safety, and enable triage and contraction of services as physical and personnel resources diminished.⁴ Further guidance on the prioritization of cases in trauma and orthopaedics was issued by the Federation of Surgical Speciality Association, however only cases with removal of metal work across a joint and removal of intra-articular loose bodies were given elective ‘high priority’ status.⁵ The impact of COVID-19 and the risks it posed to healthcare personnel and patients who were to undergo surgery is still, at the time of writing, relatively unknown. The COVIDSurg collaborative published a multicentre observation study showing the significantly increased risks of mortality and morbidity in patients with COVID-19 infection at or around the time of surgical intervention. However, the risk of contracting the infection during or around the surgery was not assessed.⁶ Attempts have been made to estimate the risks of undergoing elective

Table 1. Summary of continuous variables of whole dataset.

Continuous variable	Mean	SD	Range
Age, yrs	51.90	17.96	16 to 99
Length of surgery, mins	84.50	55.52	0 to 620
Length of stay, days	3.79	8.91	0 to 165
Number of operations patient had	1.04	0.24	1 to 7
Time from listing/injury to surgery, days	56.81	97.34	0 to 983
Total number of comorbidities	0.95	1.16	0 to 10
Time from surgery to COVID diagnosis, days	10.38	8.99	-7 to 28

SD, standard deviation.

orthopaedic surgery for asymptomatic patients with a negative SARS-CoV-2 test, however this remains theoretical.⁷ A recent national cohort study on upper limb surgery in the UK found that in 1,093 surgically treated patients in April 2020, the risk of complication due to COVID-19 infection was 0.18%.⁸

The primary objectives of this study were to determine the percentage of patients receiving foot and ankle surgery in the UK during the audit period who were positive for COVID-19, and to audit their 30-day mortality rate. Secondary outcomes included comparing early complications of foot and ankle surgery in pre- and post-COVID-19 changes of practice.

Methods

Study design. This was a retrospective national audit of foot and ankle procedures, which had occurred in 43 UK centres (Supplementary Material) between 13 January

Table II. Summary of cross tabulation of COVID-19-positive and -negative cases by surgical type and time period.

COVID-19 status	Trauma, n				Diabetic, n				Elective, n			
	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total
Negative	1,413	687	1,481	3,581	92	27	84	203	2,476	30	319	2,825
Positive	12	13	3	28	1	3	0	4	3	0	0	3
Total	1,425	700	1,484	3,609	93	30	84	207	2,479	30	319	2,828
Percentage	0.84	1.86	0.20	0.78	1.08	10.00	0.00	1.93	0.12	0.00	0.00	0.11

Table III. Comparison of variables for propensity-matched data for COVID-19 diagnosis and mortality.

Variable	COVID-19 diagnosis			Variable	Mortality status		
	Negative	Positive	p-value		Alive	Dead	p-value
Number	105	35		Number	76	27	
Means (continuous)				Means (continuous)			
Number of operations	1.04	1.03	0.794	Number of operations	1.01	1.07	0.108
Age	64.7	64.46	0.949	Age	66.82	67.44	0.868
LOS	8.01	14.06	0.037	LOS	7.35	16.38	0.001
Operating time	78.89	107.08	0.025	Operating time	85.9	99.36	0.337
Comorbidities	2.23	2.2	0.941	Comorbidities	2.59	2.63	0.926
Categorical (significance)				Categorical (significance)			
Urgency	Higher COVID-19 rate in patients who had urgent surgery		0.001	COVID-19-positive	Higher COVID-19 rate in patients who died		< 0.001
Complications	Higher COVID-19 rate in patients who had non-surgical complications		< 0.001	NCEPOD	Higher mortality in those who had urgent surgery		0.022
Mortality	Higher mortality rate in patients with COVID-19		< 0.001	Complications	Higher non-surgical complications in patients who died		0.008
Trauma / Elective	High COVID-19 rates in trauma patients and diabetic patients		0.001	Trauma / Elective	Highest mortality in dementia; lowest mortality in elective		0.044
Time period (Pre-/post-lockdown)	Highest COVID-19 rates during lockdown		< 0.001				

LOS, length of stay; NCEPOD, National Confidentiality enquiry into postoperative deaths.

2020 and 31 July 2020. All patients who had undergone a foot and ankle surgical procedure were included in this study. Data was collected and anonymized by each participating NHS trust site and transferred securely to University Hospitals of Leicester NHS Trust (primary trust). Data collected were on comorbidities, physiological state, treatment/operation, and outcome. Data governance was dictated by European general data protection regulations. The study was approved and registered as a clinical audit at the lead centre (Ref No. 10795). To participate, each local project lead needed to confirm local audit approval.

In each unit, patients were identified retrospectively if they had undergone foot and ankle surgery in an operating theatre. Patients were categorized into those who had COVID-19 at the time of surgery (identified as patients who had test-proven or clinically diagnosed COVID-19 infection up to seven days before surgery), patients who had developed COVID-19 after their surgery (identified as patients in whom COVID-19 was first suspected during their index admission or within the 30 days following surgery), or patients who did not contract COVID-19 or contracted COVID-19 outside of

the period described above. The thresholds for these different cohorts are in keeping with other COVID-19 surgical studies.⁶

The inclusion criteria for this audit were all patients undergoing any foot and ankle surgery in an operating theatre by an orthopaedic surgeon. Each theatre attendance was recorded as a separate event, and any multiple events required secondary analysis due to the theoretical increase in risk of COVID-19 infection. Diagnosis of COVID-19 was based on either a positive SARS-CoV-2 lab test or CT chest scan or a clinical diagnosis (no COVID-19 lab test or CT chest performed) as per study protocols of other COVID-19 surgical studies.⁶

Site investigators were provided with a range of written materials, including study protocols, data collection sheets, audit enrolment advice, and data protection agreements. In addition, investigators were invited to contact the national project leads for the purpose of troubleshooting site-specific recruitment issues and shared learning. These learning experiences were then shared across sites via electronic communication and displayed on the British Orthopaedic Foot and Ankle Society study specific website pages.

Data collection. Laboratory testing for COVID-19 infection was based on SARS-Cov-2 viral RNA detection by quantitative reverse transcription-polymerase chain reaction. Sampling, including nasal swabs or bronchoalveolar lavage, and analyses were done according to individual hospital protocols. All work was done in NHS hospitals in the UK, where the procedures for COVID-19 identification were standardized as per government guidelines. Due to the limited testing availability in the early part of the COVID-19 outbreak, patients were also included based on either clinical or radiological findings. Clinical diagnosis consistent with COVID-19 infection was made by a senior physician and based on clinical presentation of symptoms highly indicative of COVID-19 infection, including a new continuous cough, fever (37.8°C), or an inability to smell or taste.⁹ Radiological diagnosis was based on thorax CT, in keeping with locally implemented protocols. All patients included initially based on clinical or radiological criteria, who subsequently had laboratory testing for SARS-CoV-2 infection and returned a negative result, were excluded from the study.

Anonymized data were collected locally on encrypted spreadsheets before being uploaded to the Research Electronic Data Capture web application (REDCap, USA). Data were collected from 13 January 2020 to 31 July 2020, allowing final 30-day mortality data to be collected on 30 August 2020. Time periods were divided according to national guidance on the UK national lockdown (23 March 2020) and easing of the lockdown (11 May 2020).³

We collected patient demographic details such as sex, age, ethnicity,¹⁰ and American Society of Anesthesiologists (ASA)¹¹ physical status classification. The primary outcome for COVID-19 diagnosis was recorded with the timing of COVID-19 diagnosis as either preoperative or postoperative. The method of COVID-19 diagnosis was entered as categorical data based on clinical or laboratory-based diagnoses. Treatment of COVID-19 and any related complications were entered as categorical data.

Surgery-related variables were included. The foot and ankle diagnosis was recorded as categorical data. The diagnosis was classified based on limited variables based broadly on trauma, diabetic, and elective practice. This was further divided by anatomical region and procedure. Operative variables included urgency (elective or emergency surgery), primary procedure completed (classified into manipulation under anaesthetic/plaster, percutaneous surgery, external fixation, open surgery, injection, and arthroscopic procedure as categorical data), and anaesthesia used (local, regional, general, or combination). Other surgical data included length of stay (days, COVID-19-positive length of stay recorded to point of diagnosis), urgency of surgery, and length of operation (recorded in minutes, including anaesthetic time). Dates recorded included date of injury for trauma and date of listing for elective, date of admission, date of surgery,

and date of discharge. Emergency surgery was defined as procedures classified by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) as immediate, urgent, or expedited.¹² Comorbidities were entered as binary data into columns for current smoker, asthma/chronic obstructive pulmonary disease, cancer, chronic kidney disease, cardiac disease, dementia, diabetes mellitus, hypertension, peripheral vascular disease, and stroke. It was possible for other comorbidities to be entered by free text.

The secondary outcomes included surgery-related infection (recorded as either superficial or deep), complications as binary data (surgery-related and non-surgery-related), and the ability to free text. Mortality was entered as categorical data (alive, died on table, died on day 0 to 7, and died on day 8 to 30 with the day of surgery defined as day 0). Before locking of the dataset for analysis, the senior local principal investigator for each hospital was asked to confirm data completeness and that all eligible patients had been entered into the database.

Statistical analysis. The study was completed according to Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines for observational studies.¹³ Continuous variables were tested for normality distribution, and presented as means and 95% confidence intervals (95% CIs). Whereas categorical and qualitative variables are expressed as numbers and percentages. The independent-samples *t*-test and analysis of variance (ANOVA) were used for continuous variables if the criteria for normality and equality of variances were fulfilled. Alternatively, the Mann-Whitney U test was performed. Categorical variables were analyzed using the chi-squared test for sample sets greater than 5, otherwise the Fisher's exact test was used. Missing data were included in flowcharts and descriptive analyses, allowing denominators to remain consistent in calculations.

Normality tests were completed for all continuous variables as illustrated in Supplementary Material 1. The vast majority of continuous variables were normally distributed regardless of subset breakdown with the exception of age, length of stay, and duration of surgery for COVID-19-positive patients and for overall mortality. A summary of overall continuous variables is illustrated in Table 1.

In order to eliminate confounding demographic variables, propensity matching was performed with a 1:3 ratio for patients with COVID-19 infection and patients who died. The demographic variables to match with were chosen based on those which differed significantly between groups via ANOVA. The ratio of 1:3 was chosen so as to not discard usable data and matching was done with a random seed.

A binomial or multinomial logistic regression analysis was performed including all variables with *p*-values of < 0.15 from initial univariate analysis. For COVID-19 and mortality groups the regression was performed on

Table IV. Summary of 30-day mortality cross-tabulation by surgical type and time period.

Variable	Trauma				Diabetes				Elective				Total	Total
	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total		
COVID-19-negative														
Survived beyond 30 days	1,402	678	1,479	3,559	91	27	82	200	2,475	30	318	2,823	6,582	
Died within 30 days	7	6	0	13	1	0	2	3	1	0	1	2	18	
COVID-19-positive														
Survived beyond 30 days	8	12	3	23	0	1	0	1	2	0	0	2	26	
Died within 30 days	4	1	0	5	1	2	0	3	1	0	0	1	9	
Total	1,421	697	1,482	3,600	93	30	84	207	2,479	30	319	2,828	6,635	
Percentage mortality excluding COVID-19-negative cases	0.50	0.88	0.00	0.36	1.09	0.00	2.38	1.48	0.04	0.00	0.31	0.07	0.27	
Percentage mortality associated with COVID-19-positive cases	33.33	7.69	0.00	17.86	100	66.67	0.00	75	33.33	0.00	0.00	33.33	25.71	
Percentage mortality all-cause	0.77	1.00	0.00	0.50	2.15	6.67	2.38	2.90	0.08	0.00	0.31	0.11	0.41	

matched data. The results were reported as odds ratios (ORs) with 95% CIs. In general, a two-sided $p < 0.05$ was considered to be statistically significant. The primary adjusted model included preoperative variables to identify predictors of 30-day mortality. All data were assessed using SPSS v. 26.0 (IBM, USA).

Role of the funding source. This study was a collaborative effort of the Outcomes committee and Scientific committee of the British Orthopaedic Foot and Ankle Society who were involved in study design, data analysis, data interpretation, and writing of the report. The funders of the study had no role in the aforementioned aspects of the study. The corresponding author and analysis group had full access to all the data in the study and the corresponding author and the writing committee had final responsibility for the decision to submit for publication.

Results

A total of 43 UK centres participated in the audit and submitted cases as per the audit protocol. The total number of submitted episodes of surgically treated foot and ankle pathology was 7,413. As per the flow diagram in Figure 1, following exclusion of cases as per audit protocol, 6,644 cases were left for further analysis. There was a 92.14% completion rate of all continuous and categorical data, with length of surgery being the most common missing continuous variable and ethnicity being the most common categorical missing variable. The breakdown of variable completion is documented in Supplementary Material 2. All COVID-19-specific cases had 97% completion of continuous data and 100% completion rate of categorical data.

Cases positive for symptomatic COVID-19. A total of 35 patients were confirmed positive for symptomatic COVID-19. All but one case was diagnosed subsequent to the surgical procedure. The one patient who developed

COVID-19 preoperatively was a 32-year-old trauma patient with ASA grade 2 (hypertension and asthma). They sustained their injury after their COVID-19 diagnosis and underwent urgent open fixation of an ankle fracture under regional anaesthesia. They suffered only minor respiratory complications, requiring ward-based oxygen during their admission. They recovered uneventfully and were discharged five days postoperatively.

The categorization of cases into both surgical type (trauma surgery, diabetic surgery, and elective surgery) and time period is illustrated in Table II. More COVID-19-positive cases were seen in trauma and diabetic patients ($p < 0.001$, ANOVA) with the highest percentage being in diabetic patients during lockdown (10%, 3/30). Variables which correlated significantly with being positive for COVID-19 included an increase in age (COVID-19-negative mean 51.83 years (SD 17.92) vs COVID-19-positive mean 64.46 years (SD 20.38); $p < 0.001$), length of stay (COVID-19-negative mean 3.74 days (SD 8.86) vs COVID-19-positive mean 14.06 (SD 13.18) $p < 0.001$), increase in urgency on NCEPOD ($p < 0.001$), higher ASA grade ($p < 0.001$), and presence of comorbidities ($p < 0.001$, all independent-samples t-test). Using propensity matching controlling for age, comorbidities, and ASA grade there was a significantly lower risk of COVID-19 in the elective group and in the post-lockdown time period. These data are summarized in Table III. There were 237 patients who underwent multiple surgical procedures. Having multiple surgical procedures did not increase the incidence of COVID-19 in this cohort.

Mortality. In the entire cohort there was a total of 27 deaths, including nine deaths of COVID-19-positive patients. Therefore, the all-cause mortality rate in foot and ankle surgery in this cohort was 0.41%. Excluding the COVID-19 cases from analysis, the all-cause mortality reduces to 0.27%. The further breakdown of numbers

Mortality Rate in Patients Diagnosed with COVID-19

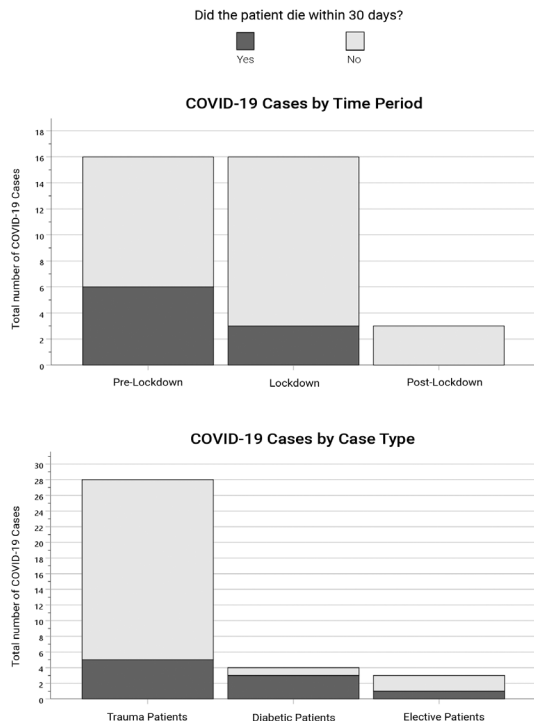


Fig. 2

Graphical representation of mortality rates for patients diagnosed with COVID-19, categorized into time periods and by case type.

Table V. Logistic regression results of significant predictors for propensity matched data for patients with COVID-19 diagnosis (35 positive patients vs 105 negative patients). Propensity matching was performed for age, American Society of Anesthesiologists grade, and comorbidities. The only significant variables predicted by COVID-19-positive status were morbidity and presence of non-surgical complications (e.g. respiratory/renal complications).

Variables included

Mortality	
NCEOPD	
Type of anaesthetic	
Pathway type	
Infection	
Complications	
Type of case	
Model significance	p < 0.001*
Pseudo R-Squared	0.426
Predictor of COVID-19-negative status	98.1%
Predictor of COVID-19-positive status	37.5%
Overall COVID-19 model prediction	83.3%

Variables with significant correlation	p-value	OR	95% CI
Mortality	0.005*	39.85	2.97 to 534.22
Complications (overall)	0.065	N/A	N/A
Non-surgical complications vs No complications	0.028*	14.86	1.34 to 164.23

CI, confidence interval; N/A, not applicable; NCEOPD, National Confidentiality enquiry into postoperative deaths; OR, odds ratio.

Table VI. Logistic regression results of significant predictors for propensity matched data for patients who died within 30 days of surgery (27 mortality patients vs 76 non-mortality patients). Propensity matching was performed for age, American Society of Anesthesiologists grade, and comorbidities. The only significant variables predicting mortality were presence of COVID-19 infection and NCEOPD ‘Urgent’ cases.

Variables included

COVID-19 status	
NCEOPD	
Type of anaesthetic	
Pathway type	
Infection	
Complications	
Type of case	
Model significance	p < 0.001*
Pseudo R-Squared	0.481
Predictor of ‘Alive’ status	94.7%
Predictor of mortality status	50.0%
Overall Mortality Model Prediction	83.2%

Variables with significant correlation	p-value	OR	95% CI
COVID-19-positive	0.017*	11.71	1.55 to 88.74
NCEPOD (overall)	0.098	N/A	N/A
NCEPOD ‘Urgent’ vs NCEPOD ‘Elective’	0.034*	39.31	1.32 to 1,175.24

CI, confidence interval; N/A, not applicable; NCEPOD, National Confidentiality enquiry into postoperative deaths; OR, odds ratio.

depending on surgical type and time period is illustrated in Table IV. The highest rate of 30-day all-cause mortality, excluding COVID-19 cases, was witnessed in diabetic surgery post-lockdown (2.38%). The highest rate of both 30-day all-cause mortality was witnessed in diabetic foot and ankle surgery during lockdown (6.67%) and the highest rate of mortality associated with COVID-19 was witnessed in diabetic foot and ankle surgery group pre-lockdown; there was only one patient in this subgroup, and this patient died.

On analysis of only the COVID-19-positive cases, the overall mortality rate was 25.71%. The factors that correlated with COVID-19 cases on regression analysis were also found to correlate with mortality. There were significant differences between COVID-19-negative-related and COVID-19-positive-related mortality rates pre-lockdown (p < 0.001) and during lockdown (p = 0.001), however post-lockdown there was no difference. There has not been a COVID-19-related death in the post-lockdown time period (Figure 2).

On propensity matched regression analysis (1:3 matching), the strongest independent risk for mortality was a positive diagnosis of COVID-19 (OR 11.7, 95% CI 1.55 to 88.74; p = 0.017). Urgency of surgery was the next major factor in increasing all-cause 30-day mortality, with immediate surgery having an OR of 39.31 (95% CI 1.31 to 1,175.23) compared to elective surgery, however urgency was not significant overall. There was a reduced risk of death in elective surgery and an increased risk

Table VII. Summary of complication cross-tabulation by surgical type and time period.

Complications	Trauma				Diabetes				Elective				Total
	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total	Pre-lockdown	Lockdown	Post-lockdown	Total	
None	1,286	641	1,359	3,286	71	17	58	146	2,340	27	301	2,668	6,100
Surgical	101	43	96	240	13	7	11	31	116	2	14	132	403
Non-surgical	34	13	27	74	9	6	15	30	23	1	3	27	131
Total	1,421	697	1,482	3,600	93	30	84	207	2,479	30	318	2,827	6,634
Percentage surgical	7.11	6.17	6.48	6.67	13.98	23.33	13.10	14.98	4.68	6.67	4.40	4.67	6.07
Percentage non-surgical	2.39	1.87	1.82	2.06	9.68	20.00	17.86	14.49	0.93	3.33	0.94	0.96	1.97

Table VIII. Regression analysis on the overall risk of surgical related complications.

Surgical complications	Significance	OR	95% CI
Factor			
Length of stay	0.18	1.014	1.002 to 1.026
Dementia	0.023	2.828	1.152 to 6.94
NCEPOD	0.001	7.473	2.376 to 23.505
Superficial infections			
Time from injury to surgery	0.006	1.002	1.001 to 1.004
Length of procedure	0.022	1.003	1 to 1.006
Smoker	0.004	1.809	1.202 to 2.72
Diabetes	0.035	1.853	1.045 to 3.288
Deep infections			
Length of stay	0.004	1.021	1.007 to 1.036
Non-surgical complications			
COVID-19-positive	0.009	5.218	1.523 to 17.876
Mortality	0.013	5.193	1.409 to 19.178
Length of stay	< 0.001	1.029	1.018 to 1.041
Infection	< 0.001	0.068	0.028 to 0.162

Appendix 1 - Normality tests of continuous variables.

CI, confidence interval; NCEPOD, National Confidentiality enquiry into postoperative deaths; OR, odds ratio.

of death in patients with non-surgical complications, but this was not statistically significant. The analysis for mortality can be seen in Tables IV to VI.

Complications. Complications were recorded initially as surgical and non-surgical related. Across all surgical procedures there was a 6.07% incidence (n = 403) of surgical and 2.05% incidence (n = 136) of non-surgical complications. The highest incidence of both surgical and non-surgical related complications occurred in the diabetic foot and ankle surgery group (n = 31, 14.98% and n = 30, 14.49% respectively). The breakdown of complications by surgical type is illustrated in Table VII.

Regression analysis (Table VIII) on the overall risk of surgical related complications showed the highest independent risk factor was the urgency of surgery, with immediate surgery having an OR of 7.47 (95% CI 2.37 to 23.51; p = 0.001) increased risk of complications compared to elective surgery. No other measured surgery related factors showed a significant increase in risk of overall non-surgical complications. Of the comorbidities

recorded, dementia had a small increase in risk of developing surgical complications.

Specifically regarding surgical related infections, small increases in risk for superficial infections were seen in longer operations, smokers, diagnosis of diabetes, longer surgery procedure time, and increased time from injury to surgery. For deep infections there was an increased risk with length of stay, however this could be an effect rather than a cause.

Relating to COVID-19-positive cases, respiratory complications were reported in 51.43% of the 35 cases, with minor respiratory complications in 17.14% (n = 6) and major respiratory complications in 34.29% (n = 12). Diabetic surgery had a higher rate of respiratory complications. Renal complications were reported in 17.14% of COVID-19-positive cases (n = 6), again more commonly in diabetic surgery compared to trauma or elective surgery (25.00%, 17.86%, and 0% respectively), as summarized in Figure 3.

Discussion

The primary objective of this national audit was to determine the percentage of patients receiving foot and ankle surgery in the UK during the audit period who were positive for COVID-19, and to audit their 30-day mortality rate. Although the audit did not include all centres in the country, the percentage of patients receiving foot and ankle surgery who had a positive diagnosis for COVID-19 in the perioperative period was determined to be 0.52% (35 COVID-19-positive cases in 6,644 patients). A number of authors have discussed the concept of establishing non-COVID-19 Care zones including standalone hospitals, separate units on site, or specialized wards to facilitate patient admission and discharge.¹⁴ Before lockdown there were three COVID-19-positive patients in elective foot and ankle surgery, one of whom died (Table II).

The total all-cause 30-day mortality rate in our study was found to be 0.41%, decreasing to 0.27% if COVID-19 positive patients were excluded. In patients positive for COVID-19, there was a 25.71% chance of mortality (Table IV). This rate is not dissimilar to rates reported in hip fracture patients who underwent surgery for

Treatment and Complications of COVID-19 Patients

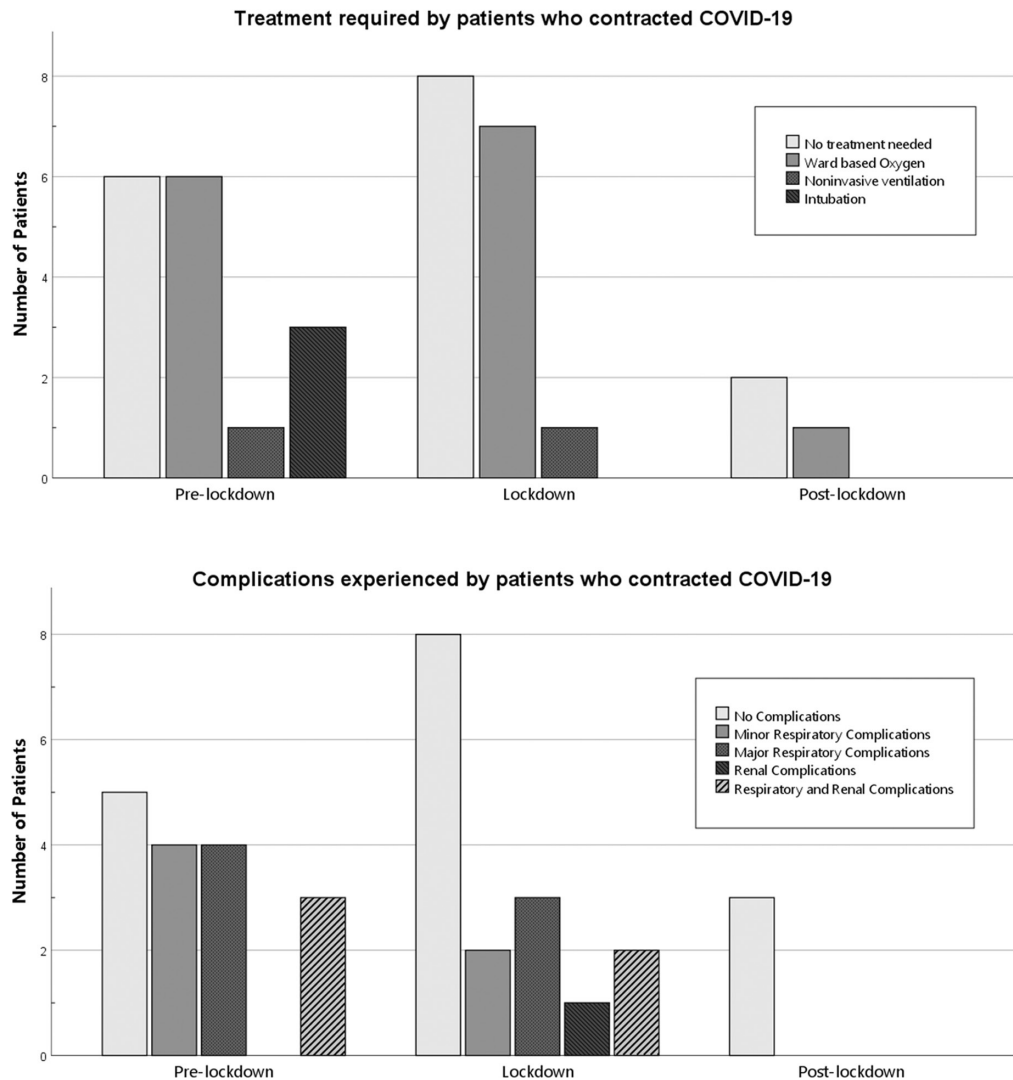


Fig. 3

Graphical representation of type of treatment received by patients with COVID-19 and the related complications they experienced.

proximal femoral fractures, with a Spanish multicentre observational study on 136 proximal femoral fractures reporting a mortality rate for 23 COVID-19-positive patients to be 30.4% (7/23) at a mean follow-up of 14 days.¹⁵ A large multicentre review in the UK, comparing 340 COVID-19-negative patients with 82 COVID-19-positive patients undergoing surgery for hip fractures, also reported a substantial increase in mortality rates (30.5% (25/82) vs 10.3% (35/340)).¹⁶ A national cohort study on upper limb surgery in the UK in April 2020 found the overall 30-day mortality was 0.09% (one pre-existing COVID-19 pneumonia) and the mortality of day case surgery was zero.⁸ They also report that there were 19 confirmed cases of COVID-19 in their cohort (1.7%), but when only including the confirmed

cases the percentage of mortality in COVID-19-positive patients was 5.25%. The COVIDSurg collaborative reported a 30-day mortality of 23.8% in 1,128 COVID-19-positive patients undergoing surgery of any kind.⁶ Therefore, the current study highlights the importance to counsel patients of the increased risk of mortality when undergoing foot and ankle surgery during the COVID-19 pandemic.

Our audit may not be comparable to the previous studies in other surgical specialties, due to the larger numbers in our cohort and the longer period of time it analyzed. For example, the upper limb study by Dean et al⁸ only analyzed the reported UK COVID-19 peak in April, however 45.71% (16/35) of our positive cases and 66.67% (6/9) of our COVID-19-related deaths occurred

prior to their date of analysis. The mortality rate across the three time periods has significantly reduced, with no cases of deaths related to COVID-19 reported after lockdown. Similarly, the studies relating to hip fractures and all surgery reported on the early stages of the pandemic.^{6,15,16} There are many factors contributing to the relative reduction over time of the mortality rate in our study, such as reducing prevalence in the population, triaging of surgical practice,⁴ and an improvement in the care of the respiratory sequelae of the COVID-19 infection.¹⁷ In our cohort, all but one patient developed COVID-19 post-surgery. The COVIDSurg collaborative recently published evidence that waiting longer than four weeks post-positive test for COVID-19 was protective of both pulmonary complications and mortality.¹⁸ In our series, there was only one patient who underwent surgery following a positive COVID-19 diagnosis. This was classed as urgent ankle trauma surgery under regional anaesthesia and did not develop any major pulmonary or renal complications.

Our audit also established that there was no difference between surgical and non-surgical complications of foot and ankle surgery between the time periods of pre-lockdown, lockdown, and post-lockdown (Table VII). There was, however, a significant difference in rate of complications between surgical types, with diabetic foot and ankle surgery carrying the highest risk, followed by trauma surgery, and with elective surgery carrying the lowest risk. Therefore, any system changes that have occurred during or post-lockdown do not appear to have increased the risk of complications in patients. Smeeing et al¹⁹ reported an increased risk of wound complications in ankle fractures with increasing age, ASA grade, and smoking. Our audit has shown these risk factors to be ubiquitous across all foot and ankle surgery regardless of relation to COVID-19 infection. The main overall factor for the development of complications across the audit, however, was the urgency of surgery.

Diabetic surgery had the highest risk of respiratory and renal complications related to COVID-19, although diabetes as a comorbidity did not carry an increased risk across the entire audit population. This may represent the difference of 'complicated' diabetes or decompensated diabetic disease, as termed by Gougoulias et al,²⁰ where the act of undergoing diabetic surgery (i.e. surgery to the foot and ankle due to pathology manifested by decompensated diabetes) is evidence of the presence of chronic poor glycaemic control. A number of studies have reported changing practices globally in an effort to reduce the exposure of diabetic patients with related foot pathology to COVID-19.^{21,22} However, our audit has shown the significant COVID-19-related risk (i.e. respiratory complications and death) diabetic surgery incurs in the time of the COVID-19 pandemic

and therefore all effort needs to be made in prevention of foot and ankle complications that may result in the need for surgery.

Our study has limitations. Firstly, this was a retrospective audit of observational data. Although it is the largest audit of its kind in foot and ankle surgery, it does not fully represent the UK practice. This study included all patients undergoing foot and ankle surgery in an operating theatre, however during the lockdown period a number of patients may have had interventions outside of an operating theatre or may have been treated nonoperatively; this may include patients who had sedation in the emergency department or patients who may have had COVID-19. These patients would not be captured by this audit. We included patients who had COVID-19 between seven days prior to and 30 days after their procedure; it is not currently known whether one week is sufficient to reduce the perioperative risk. It may be that we have therefore not captured complications in patients who had COVID preoperatively, but longer than seven days prior to surgery. However, our protocol is in line with other large published studies such as COVIDSurg.⁶ In the early phase of our study COVID-19 swab testing was not widespread and patients were considered to have COVID-19 based on symptoms – therefore it is possible that the incidence of COVID-19 was higher than reported for this time period. Similarly, identification of COVID-19 status post-discharge was based on local/regional databases and data from readmissions. Patients who had asymptomatic COVID-19 or who travelled to another region postoperatively and developed COVID-19 there may not have been captured. As such, the number of COVID-19-positive patients may be an underestimate. As a retrospective series, some datasets were incomplete and there is a higher chance of errors in dates recorded. However, with a large cohort size of over 6,000 patients we feel that the data presented is representative. Our primary outcome measures looked at rates of COVID-19 infection and mortality, however the numbers of cases of COVID-19 and mortality were small. Therefore, even small increases in numbers could change significance and some of the percentages presented may provide a misleading picture. It is therefore important that absolute numbers be considered when using this data to plan future interventions or counselling patients. Finally, there were significant differences in age, ASA grade, and comorbidity profile between patients who died and contracted COVID-19 versus those who did not. These factors are to be expected, but to mitigate these we performed propensity matching with a 1:3 ratio. This allowed us to better compare groups, but it is possible that other factors played a role that we did not capture in this audit.

In conclusion, the national audit in foot and ankle surgery across the UK before, during, and after the UK national lockdown showed that the percentage of patients receiving foot and ankle surgery who had a positive diagnosis for COVID-19 in the perioperative period was 0.52%. The 30-day mortality rate in our audit was found to be 0.41%, decreasing to 0.27% if COVID-19-positive patients were excluded. In COVID-19-positive patients, there was a 25.71% chance of mortality. Patients and treating medical personnel need to be aware of the risks to enable informed decisions.

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Supplementary material



Tables showing the normality tests of continuous variables and variable completion of full dataset, and STROBE checklist of items that should be included in reports of cross-sectional studies.

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Data sharing statement:

- Data was collected by each participating NHS trust site and transferred securely to University Hospitals of Leicester NHS Trust (primary trust). The data collected locally on encrypted dated sheets was then uploaded to the Research Electronic Data Capture web application. All data was anonymised. Only anonymised data was transferred to the primary trust. All data complied with the requirements of the current legal framework in relation to data processing and with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) as set out in the data processing agreement (uploaded separately). The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.

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Ethical review statement:

- This study was a national audit governed under the auspices of audit practice. The audit was approved and registered as a clinical audit at the lead centre (Ref No. 10795).

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