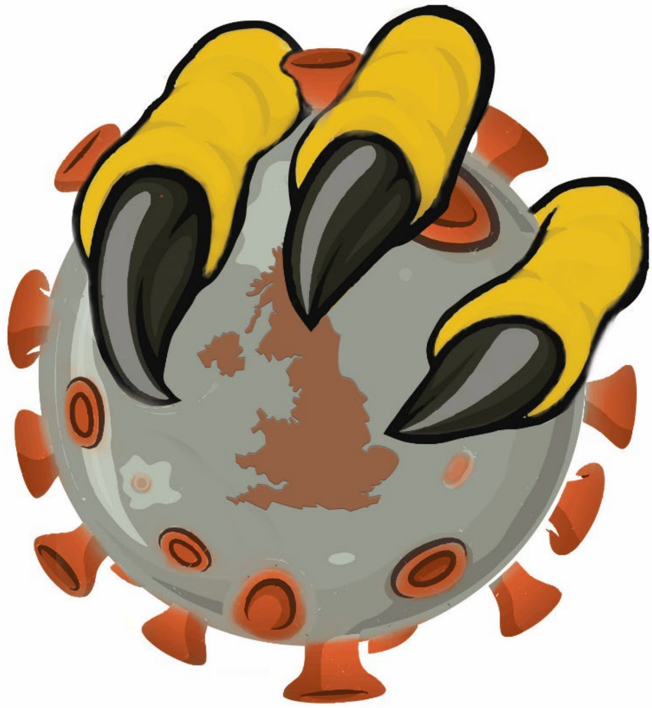
United Kingdom
Foot and Ankle COVID-19 National Audit

(UK-FALCON Audit)



Council Report for Phases 1 and 2

August 2021

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BOFAS Scientific Committee & Outcomes Committee

In Collaboration With

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1. Executive Summary

Introduction

COVID-19 has had a profound effect on healthcare systems worldwide and the UK is no exception. On 23rd March 2020, the UK announced a national lockdown and surgical governing bodies issued guidance to temporarily halt elective activity to enable staffing and resources to be redeployed to trauma and emergency care. However, the incidence of COVID-19 in the population undergoing surgery was not examined. There was therefore an urgent need to understand the incidence and impact of perioperative symptomatic COVID-19 in patients who had undergone foot and ankle surgery to estimate the possible risk going forward and to plan interventions to limit this risk. Such data could also be used to inform management and planning for subsequent waves of the disease.

Objectives

The primary objective of Phase 1 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. Further outcomes included examination of regional variations in activity and COVID-19 infection rate.

Phase 2 was carried out determine the incidence of COVID-19 after lockdown in the 'recovery phase' and also captured data on the second national lockdown. Phase 2 examines the differences between Phases 1 and 2 and reasons for the observed differences.

Design

Multicentre retrospective national audit.

Setting

This was a combined retrospective (Phase 1) and prospective (Phase 2) national audit of foot and ankle procedures in the UK in 2020. The audit period for Phase 1 was between 13th January 2020 and 31st July 2020. This phase encompassed the first UK national lockdown. Phase 2 was between 1st September 2020 and 30th November 2020 and captured the second UK national lockdown.

Participants

All patients aged 16 years and over undergoing foot and ankle surgery in an operating theatre during the audit period in the 43 participating centres in England, Scotland, Wales, and Northern Ireland. Patients were categorised as either a green pathway (designated COVID-19 free) or blue pathway. Main Outcome Measures

Variables recorded included demographics, surgical data, comorbidity data, COVID-19 and mortality rates, complications, and infection rates. Regional variation in COVID-19 rates and numbers of procedures undertaken.

Results

10,846 patients were included, 6,644 from phase 1 and 4,202 from phase 2.

COVID-19 related mortality

Of the 6644 patients were included in phase 1, a total of 0.53% of operated patients contracted COVID-19 (n=35). 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). The overall odds ratio for 30-day mortality with COVID-19 infection was 11.71 and statistically significant. The total 30-day mortality rate for the entire audit was 0.36% (39/10,846).

Incidence of COVID-19 Infection and impact of pathways

The rate of COVID-19 infection was highest during lockdown (2.11%, n=16) and lowest after lockdown (0.16%, n=3). Overall mean activity during lockdown was 24.44% of pre-lockdown activity with decreases in trauma, diabetic and elective foot and ankle surgery; the change in elective surgery was most marked with only 1.73% activity during lock down and 10.72% activity post lockdown as compared to pre-lockdown.

Over the 2 phases the infection rate on a blue pathway was 1.07% (69/6,470) and 0.21% on a green pathway (9/4,280). In Phase 1, there was no significant difference in the COVID-19 perioperative infection rate between the blue and green pathways in any element of the first phase (pre-lockdown (p=0.109), lockdown (p=0.923) or post-lockdown (p=.0577)). However, in Phase 2 there was a significant reduction in perioperative infection rate when using the green pathway in both the pre-lockdown (p<.001) and lockdown periods (Odd's Ratio 0.077, p<.001). There was no significant difference in COVID-19 related mortality between pathways.

Changes in Infection and Complication Rate

Matching for age, ASA and comorbidities, the OR of mortality with COVID-19 infection was 11.71 (95% CI 1.55 to 88.74, p=0.017). There were no differences in surgical complications or infection rates prior to or after lockdown, and amongst patients with and without COVID-19 infection. After lockdown COVID-19 infection rate was 0.15%. There were no deaths related to COVID-19 infection in the post-lockdown period.

Regional Variations

There was marked regional variation in numbers of cases performed, but the proportion of decrease in cases during and after lockdown was comparable between all regions. There was a significant difference in both rates of COVID-19 and cumulative COVID-19 infections between regions with the highest rate noted in South East England (3.21%). The overall national peak infection rate was 1.37%, occurring during the final week of lockdown; however, the peaks of infection varied between regions.

Summary

COVID-19 infection was uncommon in foot and ankle patients even at the peak of lockdown (roughly 1 in 200). However, there was a significant mortality rate in those who contracted COVID-19 (roughly 12 times greater than patients who did not contract COVID-19). Overall surgical complications and post-operative infection rates remained unchanged during the period of this audit. National surgical activity reduced significantly for all cases across the country during lockdown with only a slow subsequent increase in elective activity. The COVID-19 infection rate and peaks differed significantly across the country. There was a five-fold reduction in the perioperative COVID-19 infection rate when using designated COVID-19 green pathways over the whole study period; however, the success of the pathways only became significant in Phase 2 of the study, where there was a 13-fold reduction in infection rate. The study shows a developing success in to using green pathways in reducing the risk to patients undergoing foot and ankle surgery. Patients and treating medical personnel should be aware of the risks to enable informed decisions.

Key Messages

- A marked decrease was seen in elective activity leading up to Phase 2 followed by a slow recovery.
- There was significant regional variation in COVID-19 rates across the country, nevertheless cumulative rates of infection suggest that in some regions the risk of contracting COVID-19 in patients undergoing foot and ankle surgery is not insignificant.
- For patients undergoing foot and ankle surgery who contracted COVID-19, the mortality rate was high in Phase 1, but reduced significantly in Phase 2 – likely reflecting the improvement in care.
- There was a thirteen-fold reduction in the perioperative COVID-19 infection rate when using designated COVID-19 green pathways once established (in Phase 2).
- Patients should therefore be appropriately counselled and national and local guidelines for prevention should be strictly adhered to, to minimise the risk of peri-operative COVID-19 infection.

Phase 1 Report

2. Introduction

Since December 2019, a global pandemic has had a devastating effect on healthcare systems worldwide with 38,002,699 confirmed cases of COVID-19 and 1,083,234 deaths as of 14th October 2020.[1] In the UK, NHS England declared a Level-4 National incident on the 30th January 2020, due to the COVID-19 global pandemic. As the hospital resources became overwhelmed, further announcements by NHS England asked NHS hospitals to reduce all elective activity, to the point of postponing all non-urgent elective procedures by the 15th April 2020, for a period of at least three months.

Globally, Phillips et al found 11 reports of either selective or complete postponement of elective activity issued by orthopaedic governing bodies.[2] On 23rd March 2020, the UK Government announced a national "lockdown" with the publication of guidance "Staying at home and away from others (social distancing)".[3] Guidance was produced by surgical governing bodies on rationing of services due to scarcity of hospital resources as the COVID-19 pandemic besieged the services.[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 maximise resource capacity, ensure patient and staff safety and enable triage and contraction of services as physical and personnel resources diminished.[4] Further guidance to the prioritisation of cases in trauma and orthopaedics was issued by the Federation of Surgical Specialty Association, however only cases with removal of metal work across a joint and removal of intra-articular loose bodies were given an elective 'high priority'.[5] The impact of the COVID-19 and the risks it posed to health care personnel and patients who were to undergo surgery is still 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 to patients undergoing elective orthopaedic surgery, in 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 1093 surgically treated patients in April 2020, the risk of complication due to COVID-19 infection was 0.18%.[8]

1. WHO. WHO Coronavirus Disease (COVID-19) Dashboard. 2020. https://covid19.who.int (accessed 15th October 2020 2020).

2. Phillips MR, Chang Y, Zura RD, et al. Impact of COVID-19 on orthopaedic care: a call for nonoperative management. *Ther Adv Musculoskelet Dis* 2020; **12**: 1759720X20934276.

3. Government U. Staying at home and away from others (social distancing). 23rd March 2020. https://www.gov.uk/government/publications/full-guidance-on-staying-at-home-and-away-from-others/full-guidance-on-staying-at-home-and-away-from-others (accessed 15th October 2020 2020).

4. BOAST. Management of patients with urgent orthopaedic conditions and trauma during the coronavirus pandemic. In: Association BO, editor.; 2020.

5. FSSA. Clinical Guide to Surgical Prioritisation During the Coronavirus Pandemic. In: Associations FoSS, editor. UK; 2020.

6. Collaborative C. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. *Lancet* 2020; **396**(10243): 27-38.

7. Kader N, Clement ND, Patel VR, Caplan N, Banaszkiewicz P, Kader D. The theoretical mortality risk of an asymptomatic patient with a negative SARS-CoV-2 test developing COVID-19 following elective orthopaedic surgery. *Bone Joint J* 2020; **102-B**(9): 1256-60.

8. Dean BJF. Mortality and pulmonary complications in patients undergoing upper extremity surgery at the peak of the SARS-CoV-2 pandemic in the UK: a national cohort study. *BMJ Quality & Safety* 2020: bmjqs-2020-0121.

2.1. Scope

The UK-FALCON Audit was approved by the BOFAS Outcomes and Scientific Committees in August 2020, as the UK emerged out of the first wave of COVID-19. There was an urgent need to understand the incidence of perioperative symptomatic COVID-19 in patients who have undergone foot and ankle surgery to estimate the possible risk going forward and to plan interventions to limit this risk. This data will look to inform management and planning for subsequent waves of the disease/ national lockdowns.

The **primary aim** 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.

Secondary aims were to look at regional variation in COVID-19 incidence and to determine if there was a change in infection and complication profile with changes introduced in practice.

Tertiary aims were to complete a further audit after the initial lockdown period to examine how activity recovers and to assess the impact of lessons learned. This formed Phase 2 of the project.

3. Set-up

3.1. Protocol

The full protocol for UK-FALCON Audit can be found in **Appendix 1**.

3.2. Funding

Leicester Hospitals Charity provided funding to cover the NIHR Biomedical Research Centre Data staff costs and the REDCap data platform. All other activity related to this project was cost neutral. The total amount granted was £9,300.

The funders had no role in the design, analysis or reporting of the audit.

3.3. Recruitment

Following agreement of collaboration between the BOFAS Scientific and Outcomes committees to the project proposal, a request was made to the BOFAS membership for an expression of interest to partake in the audit. A total of 73 centres initially expressed an interest to take part in the audit via the BOFAS administrator. The audit was approved and registered as a clinical audit at the lead centre Leicester (Ref No. 10795). To participate, each local project lead needed to confirm local audit approval and sign a data processing agreement form **(Appendix 1).** A lead consultant and trainee per site were encouraged to take part.

Once agreements were in place, the BOFAS administrator sent the data collection (Excel) spreadsheet to each site to populate with the required data. Registered sites had access to data support, a help sheet, and a walkthrough video **(Appendix 1).**

The final list of units and collaborators contributing data to the UK-FALCON Audit is listed in **Appendix 2**.

4. Methods

4.1. Design

Multicentre retrospective national audit.

4.2. Setting

UK-based audit in patients who underwent foot and ankle surgery between the 13th January to 31st July 2020 – examining time periods pre- UK national lockdown, during lockdown (23rd March to 11th May 2020) and post-lockdown.

4.3. Participants

All patients 16 years of age or over undergoing foot and ankle surgery in an operating theatre during the audit period included from 43 participating centres in England, Scotland, Wales, and Northern Ireland.

4.4. Data Protection

A data processing agreement **(Appendix 1)** was drawn up in line with EU standards (*Regulation (EU) 2016/679*) and GDPR regulations (*Directive 95/46/EC*). This was ratified by the **BOFAS Caldicott Guardian** (Mr Stephen Bendall), the **BOFAS Senior Information Risk Officer** (Mr Paul Halliwell), and the **BOFAS Data Protection Officer** (Ms Jo Millard). The agreement was sent to each participating trust, to be signed by their data protection officer. The principle investigator at each site was responsible for registering the audit locally and ensuring data handling on site met the requirements.

4.5. Data Collection

Two data sheets required completion at each site, the first indicating if the site had 'blue' pathways, 'green' pathways, or both (defined as a split site). If the site had launched 'green' pathways, date of commencement was required. A 'blue' pathway was defined as all patients who were admitted to an acute hospital which has an accident and emergency/medical admissions unit where COVID-19 patients were also being admitted. However, foot and ankle procedures termed to have been undertaken with prevention processes in place to contracting COVID-19 (e.g. segregated clean unit, isolation period perioperative etc) was termed to have been undertaken on a 'green' pathway. Centres which do not admit acute patients (i.e. purely elective units) were also termed 'green' pathways.

The second data sheet comprised of the main data set where patient demographics such as sex, age, ethnicity, American Society of Anaesthesiologists (ASA) physical status classification were collected. 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. COVID-19 related complications and treatment of COVID-19 were entered as categorical data and free text where more information was required.

Surgery related variables were included. The foot and ankle diagnoses were 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. Comorbidities were entered as binary data (yes/ no) into columns for current smoker, asthma/COPD, cancer, chronic kidney disease, cardiac disease, dementia, or other comorbidities to be entered as free text.

The secondary outcomes included surgical-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 0-7 and died on day 8-30 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.

4.6. Data Validation

Patient identifiable data was anonymised, and each registered site was required to submit an encrypted password protected version of their data sheet to a secure nhs.net account at the lead site (Leicester). Data validation was completed by the NIHR Leicester Biomedical Research Centre team via Excel.

4.7. Data Cleansing

Any queries or missing data were referred to the site personnel for amendment / clarification. Once data had been verified, this was added to **REDCap** - Research Electronic Data Capture web application (REDCap, Vanderbilt, Tennessee). The complete REDCap dataset was exported into SPSS – Statistical Package for the Social Sciences, for analysis.

4.8. Statistical Analysis

All data was assessed using **SPSS Version 26.0** (SPSS Inc., IBM, Chicago, IL). Analysis was carried out in accordance with STROBE guidelines.

Continuous variables were tested for normality and presented as means and 95% confidence intervals whereas categorical and qualitative variables were expressed as numbers and percentages. The Student t-test and ANOVA was 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 analysed using the Chi-square 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.

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 demographics to match with were chosen based on those which differed significantly between groups on ANOVA. The ratio of 1:3 was chosen 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 matched data. The results were reported as odds ratios (OR) with 95% confidence intervals (95% CI). In general, a two-sided $p<0.05$ was considered statistically significant. The primary adjusted model included preoperative variables to identify predictors of 30-day mortality.

4.9. Regional Analysis

All regions in the UK were classified into single hierarchical classification of spatial units, defined by the nomenclature of territorial units for statistics (NUTS) used for statistical production across the European Union (EU). We also analysed cumulative COVID-19 infection rate per region. This was calculated as the cumulative number of positive COVID-19 cases from the first confirmed case in this audit per region. This was expressed as a percentage of the total number of cases performed from the date of the first COVID-19 positive case in the same region.

5. Results

5.1. Inclusions and Exclusions

A total of 7,413 cases were submitted from 43 centres across the UK. Patients who had multiple operations during the audit period were identified and patients who did not meet the inclusion criteria were excluded. A total of 6,644 patients were left for analysis (**Figure 1**).

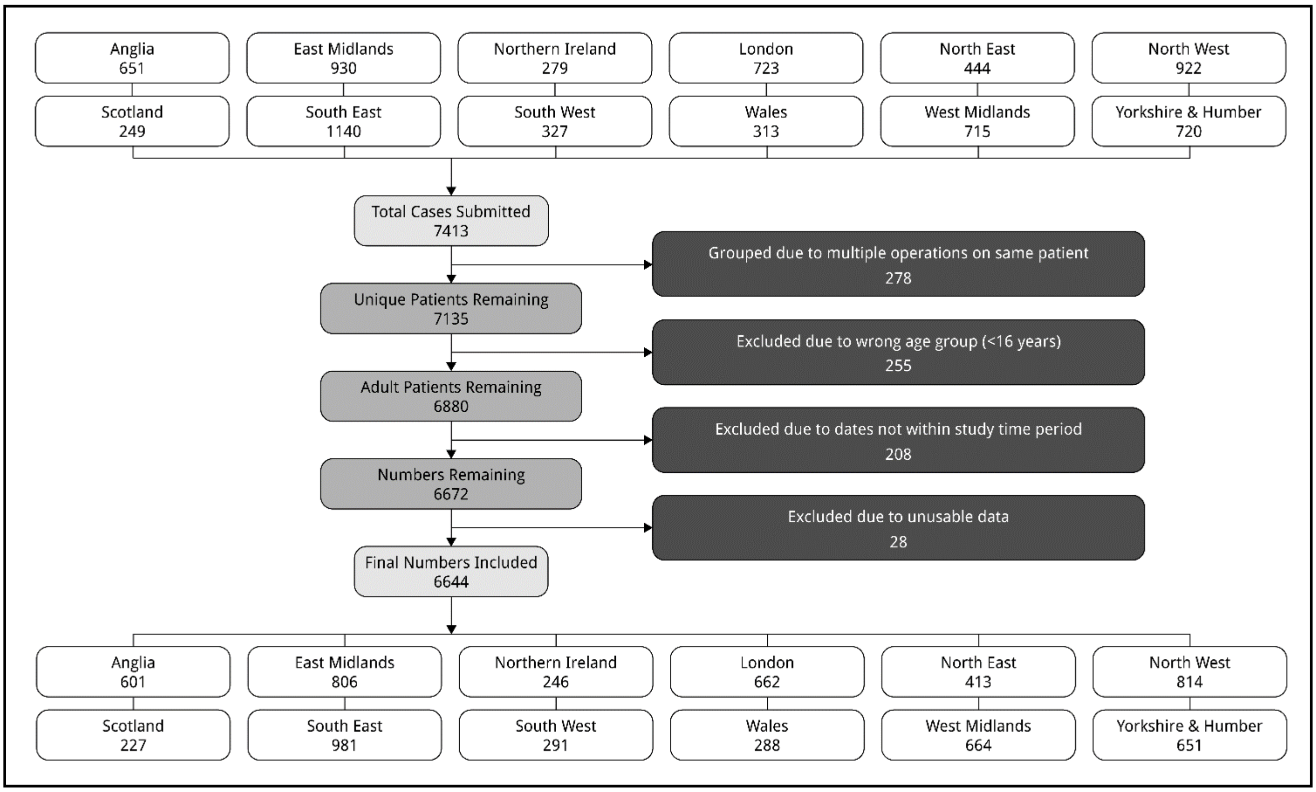

Figure 1: Total number of cases submitted per region and final number of patients included after merging / exclusions

5.2. Data Submitted and Completion Rate

All regions in the UK were represented, with the highest number of cases submitted from the South East (981 episodes) and the lowest number of cases submitted from Scotland (227 episodes). 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 **Appendix 3**. All COVID-19 specific cases had 97% completion of continuous data and 100% completion rate of categorical data. Normality tests were completed for all continuous variables as illustrated in **Appendix 4**. Majority of continuous variables were normally distributed regardless of subset breakdown apart from age, length of stay and duration of surgery for patients positive for COVID-19 and for overall mortality.

5.3. COVID-19 Infections

In total 35 patients contracted COVID-19 infection (0.53%).

All except one case were diagnosed after their surgical procedure. The one patient who developed COVID-19 pre-operatively was a trauma patient aged 32 years with ASA grade 2 (hypertension and asthma). They sustained their injury after their diagnosis of COVID 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 5 days post-operatively.

The percentage of cases of COVID-19 infection seen in various groups and time periods is depicted in **Table 1**. More COVID-19 positive cases were seen in trauma and diabetic patients ($p < 0.001$) with the highest percentage being in diabetic patients during lockdown (10%). Post-lockdown the COVID-19 infection rate was 0.16%.

		Pre lockdown	Lockdown	Post lockdown	Total
Trauma					
COVID-19	Negative	1413	687	1481	3581
	Positive	12	13	3	28
Total		1425	700	1484	3609
Percentage		0.84%	1.86%	0.20%	0.78%
Diabetic					
COVID-19	Negative	92	27	84	203
	Positive	1	3	0	4
Total		93	30	84	207
Percentage		1.08%	10.00%	0.00%	1.93%
Elective					
COVID-19	Negative	2476	30	319	2825
	Positive	3	0	0	3
Total		2479	30	319	2828
Percentage		0.12%	0.00%	0.00%	0.11%
Overall COVID-19 Infection Rate		0.40%	2.11%	0.16%	0.53%

Table 1: Percentage of COVID-19 positive patients by Trauma / Diabetic / Elective pathway type and by Lockdown period. No elective or diabetic patient contracted COVID-19 after lockdown

Patients contracting COVID-19 were older (64.46 years *vs.* 51.83 years, $p < 0.001$), have a higher ASA grade ($p < 0.001$) and have a higher overall number of co-morbidities ($p < 0.001$). COVID-19 patients also tended to present with an increased NCEPOD urgency ($p < 0.001$). Although interesting findings, they do not indicate causality.

There was no association between number of procedures and COVID-19 infection, and there was no association between being on a blue or green pathway and acquiring COVID-19 (**Table 2**).

Details of propensity matching are given in **Appendix 5**. Matching for age, ASA and co-morbidities, the incidence of COVID-19 was found to be lower in elective patients and post-lockdown in all pathway types ($p < 0.001$)

		Pathways		Chi Square Test (p value)
		Blue	Green	
COVID-19	No	4620	1893	0.055
	Yes	30	5	
Percentage		0.65%	0.26%	
Mortality - all cause	No	4594	1892	**0.028**
	Yes	17	1	
Percentage		0.37%	0.05%	
Mortality - COVID-19 Related	No	22	4	0.752
	Yes	8	1	
Percentage		26.67%	20.00%	

Table 2: Comparison of COVID-19 infection rate and mortality rate by admission pathway type

5.4. COVID-19 versus Mortality (Primary Outcome)

The overall 30-day all cause-mortality was 0.41% (27 patients). Excluding COVID-19 patients the mortality rate was 0.27%, and the mortality rate in all patients with COVID-19 was 25.71% (9 patients). This difference was statistically significant ($p < 0.001$).

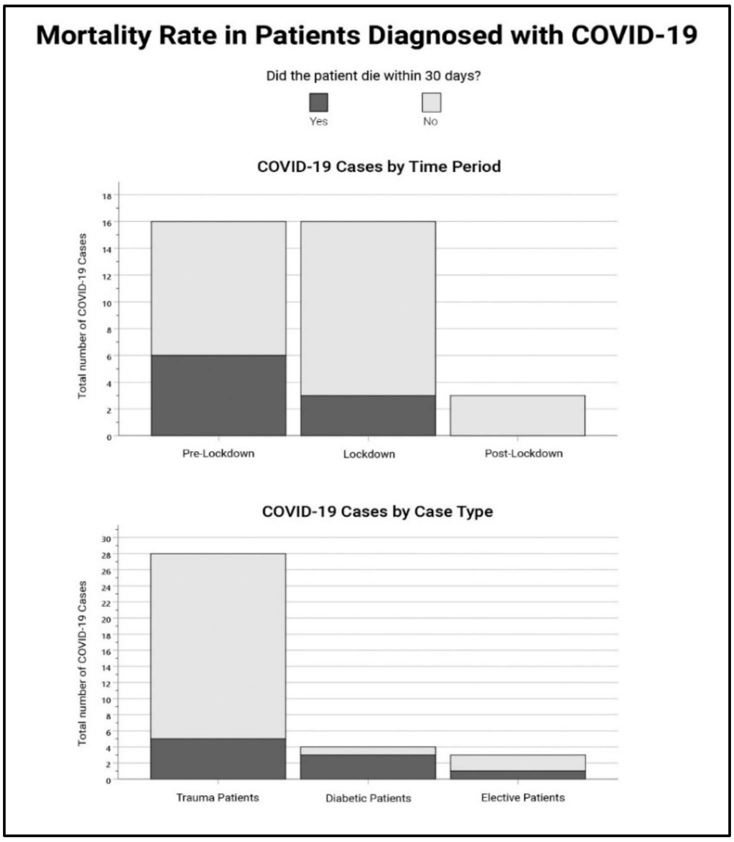

Figure 2: Mortality rate in patients diagnosed with COVID-19: differences by time-period and by type of surgical pathway

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 as there have not been any COVID-19 related deaths in the post-lockdown time-period (**Figure 2**).

The mortality rate was highest in patients on the diabetic foot pathway (75%, 3 deaths). 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 (100%, although there was only 1 patient in this subgroup). The further breakdown of numbers depending on surgical type and time-period is illustrated in **Table 3**.

	30-day Mortality	Pre-lockdown	Lockdown	Post-lockdown	Total
Trauma					
COVID-19 negative	No	1402	678	1479	3559
	Yes	7	6	0	13
COVID-19 positive	No	8	12	3	23
	Yes	4	1	0	5
Total		1421	697	1482	3600
COVID-19 negative mortality rate		0.50%	0.88%	0.00%	0.36%
COVID-19 positive mortality rate		33.33%	7.69%	0.00%	17.86%
All-cause mortality rate		0.77%	1.00%	0.00%	0.50%
Diabetic					
COVID-19 negative	No	91	27	82	200
	Yes	1	0	2	3
COVID-19 positive	No	0	1	0	1
	Yes	1	2	0	3
Total		93	30	84	207
COVID-19 negative mortality rate		1.09%	0.00%	2.38%	1.48%
COVID-19 positive mortality rate		100%	66.67%	0.00%	75%
All-cause mortality rate		2.15%	6.67%	2.38%	2.90%
Elective					
COVID-19 negative	No	2475	30	318	2823
	Yes	1	0	1	2
COVID-19 positive	No	2	0	0	2
	Yes	1	0	0	1
Total		2479	30	319	2828
COVID-19 negative mortality rate		0.04%	0.00%	0.31%	0.07%
COVID-19 positive mortality rate		33.33%	0.00%	0.00%	33.33%
All-cause mortality rate		0.08%	0.00%	0.31%	0.11%

Table 3: Breakdown of COVID-19 status *versus* 30-day mortality rate for patient on different pathways and at different time periods.

On propensity matched regression analysis (1:3 matching), the strongest independent risk for mortality was a positive diagnosis of COVID-19 (odds ratio = 11.7, 95% confidence intervals = 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 odd's ratio of 39.31, compared to elective surgery however urgency was not significant overall. Further details of the logistic regression analysis performed may be found in **Appendix 6**.

This suggests that a person contracting COVID-19 has a roughly 12 times greater risk of dying within 30 days of surgery, independent of any other risk factors.

5.5. Impact of COVID-19 Infection on Patients

Patients contracting COVID-19 had a longer length of stay (14.06 days *vs.* 3.74 days, p < 0.001).

Respiratory complications were seen in 18 of 35 patents with COVID-19 (51.43%); of these 6 cases (17.14%) were minor and 12 (34.29%) were major. Renal complications were reported in 6 cases (17.14%). These complications were more common in patients undergoing diabetic foot surgery. This is summarised in **Figure 3** along with the treatment required by patients contracting COVID-19.

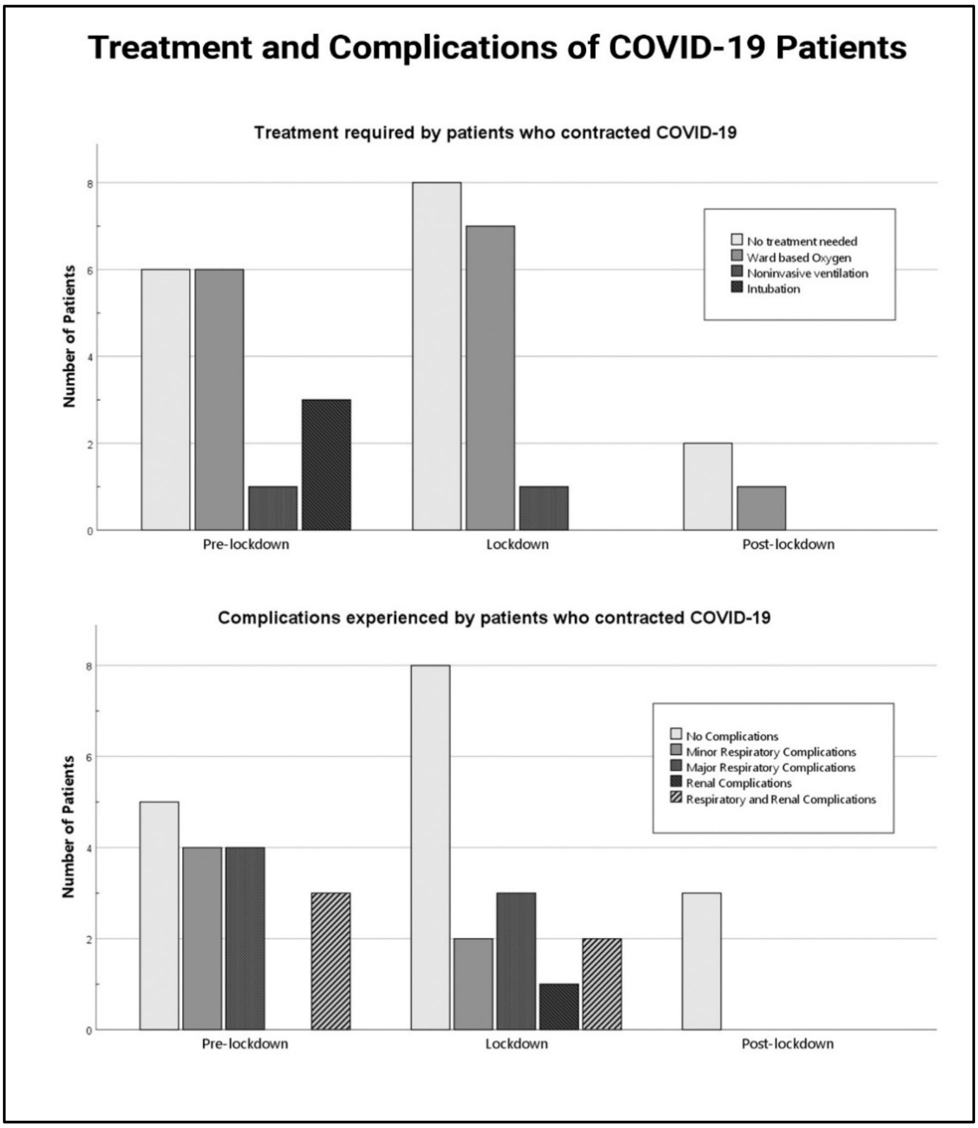

Figure 3: Treatment required by patients contracting COVID-19 and complications experienced by these patients; split by time-period

5.6. Overall Complication and Infection Rate

Across all surgical procedures there was an incidence of surgical complications of 6.07% (403 patients) and an incidence of non-surgical complications of 2.05% (136 cases). The highest incidence of both surgical and non-surgical related complications occurred in the diabetic foot and ankle surgery group (14.98% and 14.49% respectively). The only risk factors for surgical complications was urgent surgery (OR = 7.473, $p < 0.001$) and presence of dementia (OR = 2.83, $p = 0.023$). Non-surgical complications were found to be higher in COVID-19 patients as discussed in the previous section (OR = 5.22, $p = 0.009$), and in patients who died (OR = 5.19, $p = 0.013$). Non-surgical complications were also associated with a slightly longer length of stay (OR = 1.029, $p < 0.001$)

The rate of superficial surgical infections correlated slightly with increased delay from injury to surgery (OR = 1.002, $p = 0.006$) and increased length of procedure (OR = 1.003, $p = 0.022$). There was a slightly stronger correlation between superficial infections and smoking (OR = 1.81, $p = 0.004$) and diabetes (OR = 1.85, $p = 0.035$). There were no associations with deep infection and any factor. There was also no difference between surgical complication rate and infection rate and audit time-period, suggesting that these factors were not affected by changes put in place to mitigate against COVID-19, apart from perhaps an increased duration of surgery, which was seen during the lockdown period.

5.7. Impact of COVID-19 on Activity

Overall mean activity during lockdown was 24.44% of pre-lockdown activity with decreases in trauma, diabetic, and elective surgery. Separating procedures by type of case (trauma, elective and diabetic surgery), the greatest loss of activity across the UK was in elective surgery. There were, however, significant decreases in trauma and diabetic surgery during lockdown, which subsequently returned to normal levels, post-lockdown. The change in elective surgery, however, was most marked with only 1.73% activity during lock down and 10.72% activity post lockdown as compared to pre-lockdown, although a gradual increase was seen throughout the post-lockdown period. This can be seen in **Figure 4** and **Table 4**.

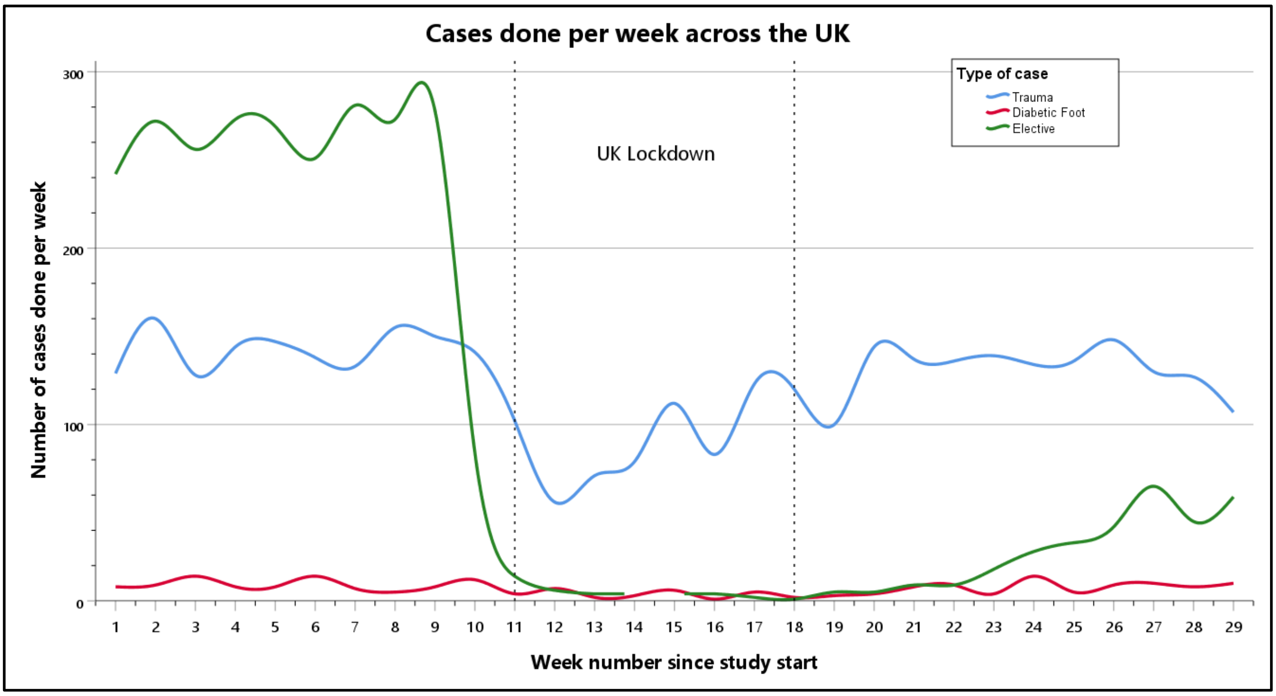

Figure 4: Graphical representation of cases per week categorised by type of surgery. Period of lockdown is highlighted between weeks 11 and 18 of the audit.

Time Period	Total	Mean cases per week	95% Confidence Intervals		ANOVA (p value)
			Lower	Upper	
Trauma					
Pre-Lockdown	1425	142.50	134.79	150.21	< 0.001
Lockdown	700	89.42	67.41	111.45	
Post-Lockdown	1484	129.83	120.69	138.97	
Diabetic					
Pre-Lockdown	93	247.90	205.74	290.06	< 0.001
Lockdown	30	4.29	-0.17	8.74	
Post-Lockdown	84	26.58	12.47	40.70	
Elective					
Pre-Lockdown	2479	9.30	7.14	11.46	0.007
Lockdown	30	4.00	2.00	6.00	
Post-Lockdown	319	7.17	4.90	9.43	

Table 4: Mean number of patients across the UK undergoing each type of surgery per week over the different time periods in this audit

5.8. Regional Differences in COVID-19 Infection Rate

The first confirmed case of COVID-19 infection across the audit occurred at week 7 (week commencing 24th February 2020) in the South East Region. There was a significant difference in timing of COVID-19 infection peaks and cumulative COVID-19 infections between regions. The overall national peak infection rate was 1.37%, occurring during the final week of lockdown. The differences in regional peaks is represented in **Figure 5**.

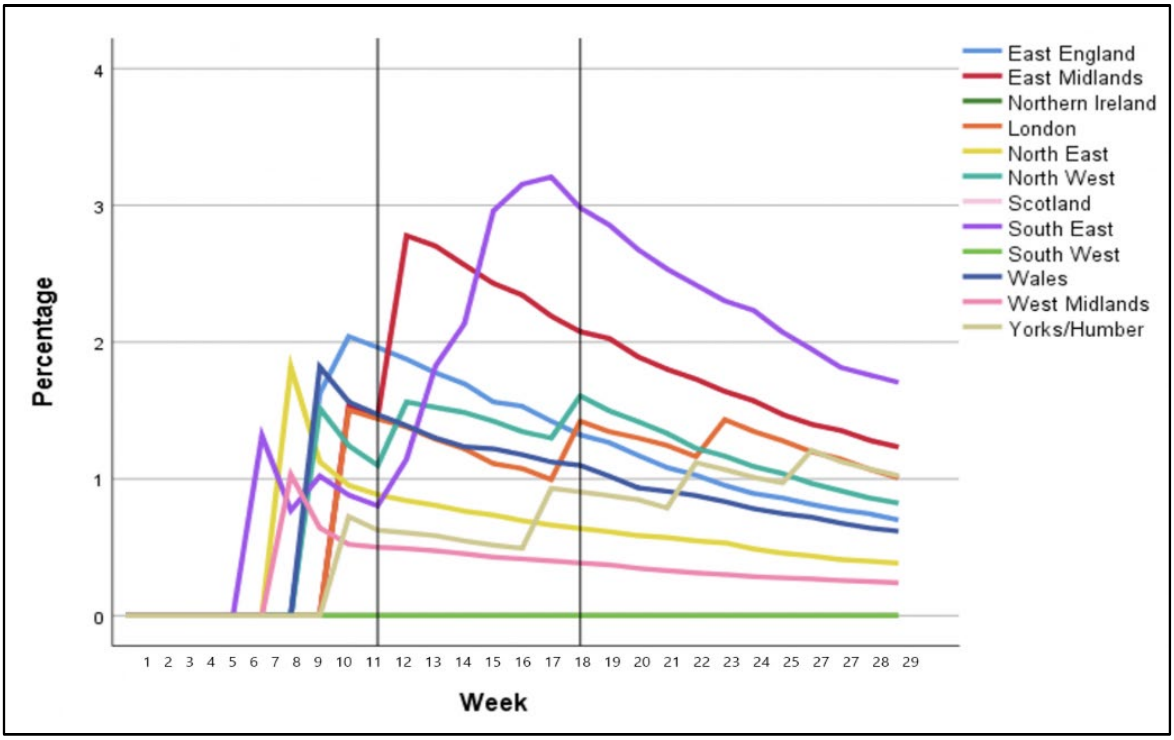

Figure 5: Cumulative percentage of number of positive COVID-19 cases per surgical episode from the first confirmed case in the audit over time (weeks). Vertical bars indicate the lockdown period.

Although most cases were clustered between weeks 8 and 12 (weeks commencing 2nd March 2020 and 30th March 2020), the South East COVID-19 positive cases peaked later at week 17 (week commencing 4th May 2020), and the North West peaked at week 18 (week commencing 11th May 2020). In the Yorkshire and Humber region the majority of cases (75%) occurred post-lockdown, with their final case occurring at week 26 (week commencing 6th July 2020).

The rate of COVID-19 infections also varied significantly between regions ($p < 0.001$) with the highest percentage of COVID-19 positive cases being reported in the South East region (1.12%), and no cases being reported in Scotland, Northern Ireland and the South West regions. This difference in rates is shown in **Figure 6**. South East England also had the highest peak cumulative infection rate (3.21%).

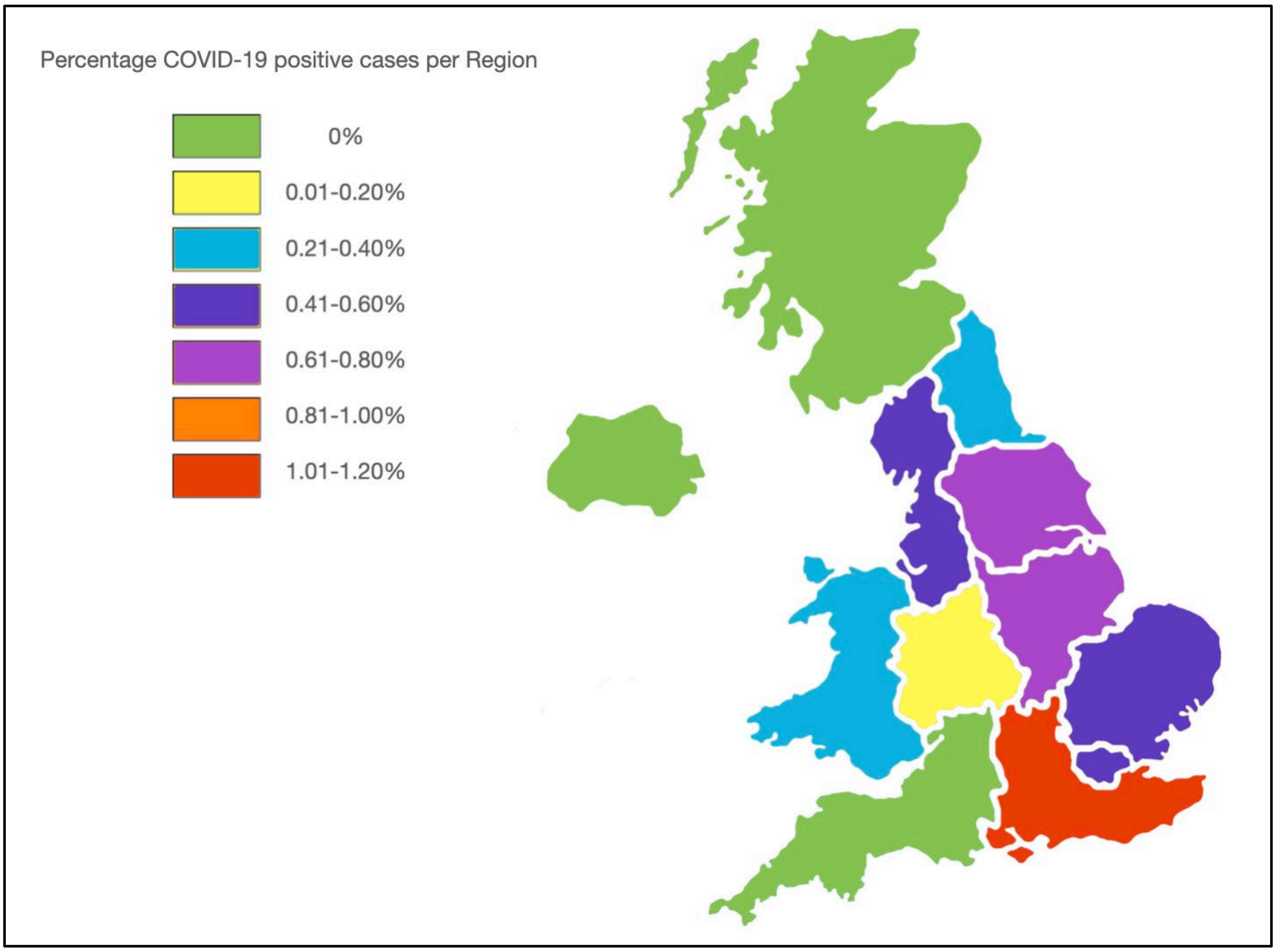

Figure 6: Infographic heatmap illustrating the rate of COVID-19 infection across each region of the UK. The key represents the colour coding of different percentage of infection rate.

5.9. Regional Differences in Activity

There was marked regional variation in numbers of cases performed, but the proportion of decrease in cases during and after lockdown was comparable between all regions. The overall foot and ankle surgery activity in the submitted centres fell from an average of 399.70 (95% confidence interval = 356.56 to 442.84) cases per week pre-lockdown, to 97.71 (95% confidence interval = 75.23 to 120.20) cases per week during lockdown and then up to 163.58 (95% confidence interval = 145.72 to 181.45) cases per week post lockdown.

Accounting for the differences in number of submitting centres in each region and the size of each centre, there was no significant difference between each region in the activity lost during lockdown or recovery post-lockdown. This can be seen in **Figure 7**. Here it can be seen that three regions had significant outliers at Week 10 indicating that they had started to reduce their surgical activity levels earlier than other regions. Similarly, outliers in the lockdown period indicated that Yorkshire and Humber activity reduction occurred later than the other regions and recommencement of surgical activity was earlier in the South West compared to other regions.

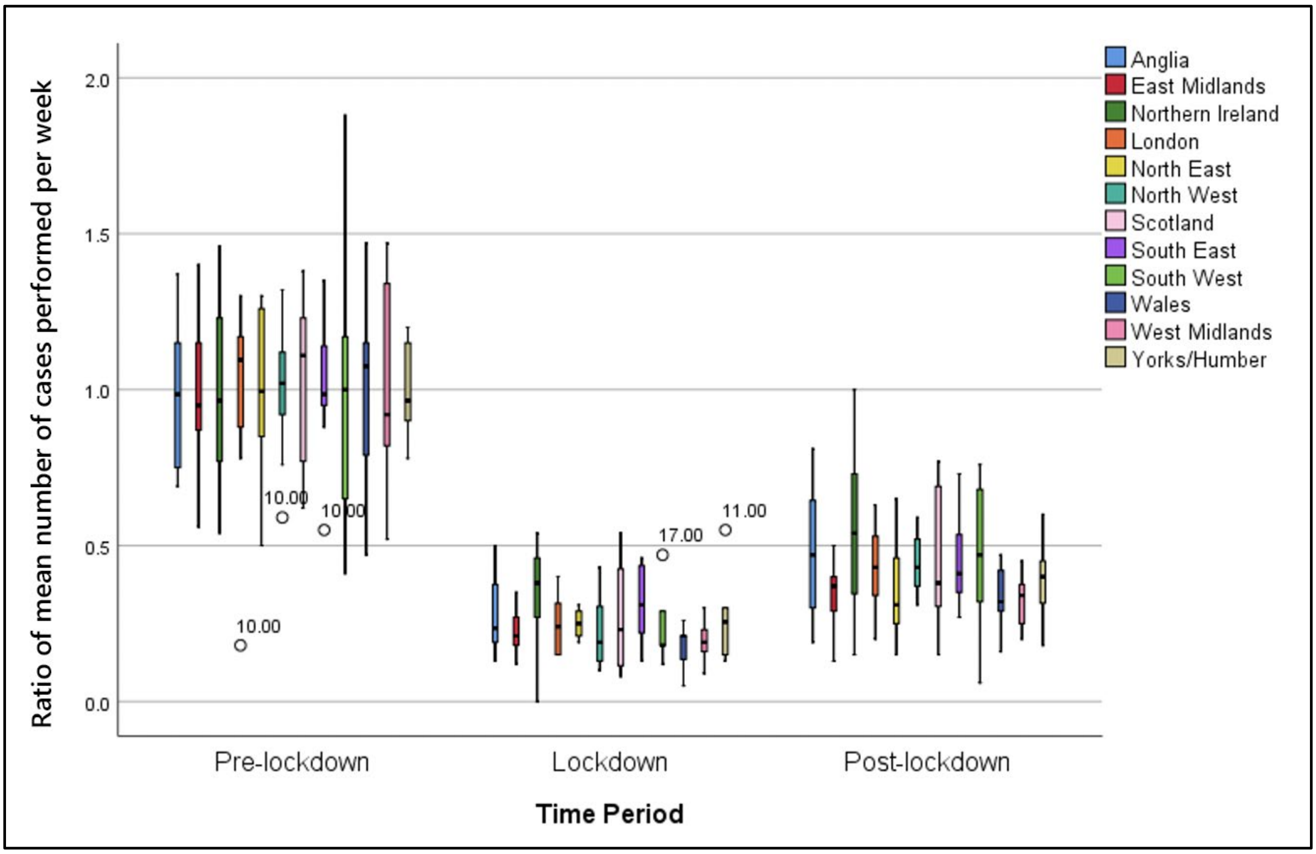

Figure 7: Graphical representation of average percentage of total cases per week for each region, over time periods pre-lockdown, lockdown, and post-lockdown. Using the average number of cases per region pre-lockdown to equate to 1, the lockdown and post-lockdown periods are calculated as a percentage of this.

5.10. Changes in Case Mix

Details of the change in case mix of trauma, diabetic and elective activity can be seen in **Appendix 7**.

With regards to trauma, and when taking each anatomical location as a percentage of total foot and ankle trauma submitted, there was a significant increase in the proportion of malleolar fractures and calcaneal fractures treated surgically in lockdown as compared to pre-lockdown, and a decrease in the percentage of Achilles ruptures. The overall numbers and percentages normalised to pre-lockdown levels post-lockdown.

There was no change in proportions of types of diabetic surgery performed over the three time periods apart from a decrease in abscess drainage during lockdown.

In elective surgery there was a decrease in the proportion of forefoot surgery performed from 49.74% pre-lockdown to 36.85% post-lockdown ($p < 0.001$). This difference was made up for by a small increase in percentage of all other operation types.

5.11. Green and Blue Pathways

Overall, the vast majority of elective patients were managed on green pathways, and most trauma on blue pathways. Prior to lockdown electives were managed roughly 50% : 50% on green : blue pathways, but post lockdown this ratio shifted to 20% : 80% for green : blue pathways ($p < 0.001$). For trauma and diabetic patients 80% continue to be managed on blue pathways. There was no significant difference in incidence of symptomatic COVID-19 cases between patients managed on green and blue pathways.

5.12. Other effects seen

The average length of surgery increased by 21 minutes during lockdown (26% increase) and by 16 minutes after lockdown (20% increase), compared to pre-lockdown durations ($p < 0.001$). On the whole, trauma cases took longer than elective and diabetic cases, but this trend was seen even when considering just trauma cases and is likely a reflection of the additional precautions put in place to mitigate against infection.

After lockdown there was a reduction in the number of patients undergoing surgery under a combination of regional and general anaesthesia, in favour of just regional anaesthesia ($p < 0.001$). There were also fewer injections being performed after lockdown ($p < 0.001$) and fewer day case procedures ($p < 0.001$). The latter two may be linked and it may also reflect a skew toward more complex, urgent work, and less forefoot work.

6. Interpretation

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 0.53%.

In our audit, COVID-19 infections occurred in both blue and green pathways, with no significant difference between the pathways, however there was a trend toward reduced numbers in green pathways. Before lockdown there were three positive COVID-19 cases in elective foot and ankle surgery, of which one died. Therefore, the use of ‘safe’ pathways and the reinstitution of elective practice should not be considered as without risk.

In patients positive for COVID-19, there was a 25.71% chance of mortality with a 12-fold increase in odds ratio. This rate is similar to previous studies from other specialities[1-3] and therefore foot and ankle surgery should not be considered as lower risk.

The mortality rate across the three time periods has significantly reduced, with no cases of deaths related to COVID-19 reported after lockdown. Previous studies only report on the early stages of the pandemic.[1-3] This audit may therefore provide unique insight into an improving trend in the management of COVID-19, but further work will be required to validate this. Possible reasons for the improvements seen include reducing prevalence in the population, triaging of surgical practice and an improvement in the care of the respiratory sequalae of the COVID-19 infection.

There was no difference between surgical complications and infections related to the foot and ankle following surgery between the time periods of pre-lockdown, lockdown, and post-lockdown. This suggests that any system changes that have occurred during or post-lockdown, do not appear to have increased the risk of complications or infection in patients.

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 this difference of *‘complicated’* diabetes as termed by Gougoulias *et al.* where the act of undergoing diabetic surgery is evidence to the presence of chronic poor glycaemic control.[4] Regardless, our audit has shown the significant increase in risk diabetic surgery incurs in this time of COVID-19 and therefore all effort needs to be made in prevention of foot and ankle complications that may result in surgical requirement.

This audit also looked at cumulative infection rates which peaked at week 18 (highest peak in the South East region which peaked at 3.21% COVID-19 infection rate at week 17). This corroborates the finding that infection rate was lower post-lockdown (0.16% overall).

Examining activity, we have seen significant reductions in all cases during the COVID-19 pandemic in the UK from March to August 2020. Using the UK national lockdown period for reference, the urgent cases (trauma and diabetic surgery) recovered to normal pre-lockdown levels post-lockdown. However, in elective surgery there was a gradual recovery, which by the end of the audit had only reached 22.18% of the pre-lockdown average cases per week. There were no significant differences in average activity across all regions, indicating possible similar restrictions nationally to elective recovery. With the rapid recovery of urgent surgery as compared to elective surgery, the transfer of resources away from elective surgery in the short term is likely a major factor in preventing the return to normal elective practice. In the UK, elective orthopaedics was planned to resume in a three-phased manner, as recommended by the BOA, however, further increases in COVID-19 cases nationally make these plans possibly unachievable in the short term.

Although there were significant differences between regions regarding COVID-19 infection rates and peaks of infections, there was no difference in the average proportionate decrease in number of cases performed in trauma, elective and diabetic surgery across the regions.

There are multiple factors related to the differences in national trauma activity between the three time periods, with the most likely contributor being social immobility and change in activities that could cause injury due to national lockdown. To a lesser extent the rationing of surgical time and patients opting for non-operative management would also influence the reduced numbers of surgical trauma cases. Despite guidance on the ethical effects of decision making in COVID-19, promoting that decisions made were reasonable in the circumstances, the rationing of care appears to have been mitigated by the overall reduction in the trauma volume seen. Only Achilles tendon ruptures significantly reduced in numbers and percentage of surgical trauma; this may indicate that in conditions where satisfactory results are possible without surgical management, the risk of COVID-19 infection has had its greatest influence.

Our audit has shown a return to normal levels of diabetic surgery practice in the post-lockdown period, with only a two-month period of affected activity. There has been no increase in minor or major amputation rate nationally or in the proportions of types of cases performed for diabetic foot surgery.

As expected, the number of elective procedures significantly decreased during UK national lockdown due to government guidance. The ratio of forefoot, midfoot and hindfoot cases did not change significantly post lockdown as compared to pre-lockdown, which might have been expected if prioritisation of cases occurred on reinstitution of elective practice. However, the proportion of forefoot surgery did change from almost 50% pre-lockdown to 37% post-lockdown. In our national audit there were positive cases in the elective surgical cohort of patients, two of which occurred in forefoot surgery. Therefore, foot and ankle elective surgery should not be seen as without risk.

1. Collaborative C. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. *Lancet* 2020; **396**(10243): 27-38

2. Muñoz Vives JM, Jornet-Gibert M, Cámara-Cabrera J, et al. Mortality Rates of Patients with Proximal Femoral Fracture in a Worldwide Pandemic: Preliminary Results of the Spanish HIP-COVID Observational Study. *The Journal of bone and joint surgery American volume* 2020; **102**(13): e69.

3. Kayani B, Onochie E, Patil V, et al. The effects of COVID-19 on perioperative morbidity and mortality in patients with hip fractures. *Bone Joint J* 2020; **102-B**(9): 1136-45.

4. Gougoulias N, Oshba H, Dimitroulias A, Sakellariou A, Wee A. Ankle fractures in diabetic patients. EFORT Open Rev 2020; **5**(8): 457-63.

7. Audit Limitations

This audit has limitations. 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 audit 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 non-operatively; 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. Additionally, the national setup for diabetic surgery in the UK is variable, with vascular surgery sharing the responsibility for the patients. Therefore, depending on local setup, some patients would have undergone surgery not under foot and ankle and would therefore not been included in this dataset.

We included patients who had COVID-19 between seven days prior and 30 days after their procedure; it is not currently known whether one week is sufficient to reduce the peri-operative risk. It may be that we have therefore not captured complications in patients who had COVID pre-operatively, but longer than seven days prior to surgery. However, our protocol is in line with other large, published studies such as COVIDSurg.

The number of COVID-19 patients is likely an underestimation. In the early phase of our audit 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 post-operatively and developed COVID-19 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 6000 patients the data presented is likely to be 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.

There were significant differences in age, ASA grade and co-morbidity profile between patients who died and contracted COVID-19 versus those who did not. These factors are to be expected, but to mitigate for 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.

Finally, this audit cannot determine whether the relationship between increasing age and co-morbidities and contracting COVID-19 is causative.

8. Key Messages for BOFAS Members

This national audit in foot and ankle surgery has indicated that the overall COVID-19 infection rate across 6,644 patients was 0.53% (35 patients), with the cumulative percentage of COVID-19 infection of 1.37%, peaking at week 18. This indicates that COVID-19 infection was uncommon (although not insignificant) in foot and ankle patients even at the peak of lockdown; roughly 1 in 200 patients contracting COVID-19 overall, but ranging from 1 in 50 during lockdown to 1 in 600 after lockdown.

There was, however, a significant mortality rate in those who contracted COVID-19 of 25.71% (9 patients) and contracting COVID-19 increased the risk of 30-day mortality by roughly 12 times.

Overall surgical complications and post-operative infection rate remained unchanged during the period of this audit. Patients and treating clinicians should be aware of the risks to enable informed decisions.

We noted a significant regional variation in COVID-19 infection rates and peak of COVID-19 infections across the country with the highest rate being seen in the South East; this data may be useful in planning response to subsequent waves.

National surgical activity significantly reduced for all cases during lockdown, however in the post-lockdown period there was normalisation of activity in trauma and diabetic surgery with less than a quarter of elective activity resuming by the end of the audit. The marked decrease in, and slow recovery of elective activity seen will need to be considered when planning for restoration of elective foot and ankle services in subsequent waves.

8.1. Take-home points

- A marked decrease was seen in elective activity followed by a slow recovery which will need to be considered when planning restoration of elective foot and ankle services.

- There was significant regional variation in COVID-19 rates across the country, nevertheless cumulative rates of infection suggest that in some regions the risk of contracting COVID-19 in patients undergoing foot and ankle surgery is not insignificant.

- For patients undergoing foot and ankle surgery who contracted COVID-19, the mortality rate remains high, comparable to other studies in other specialities.

- Patients should therefore be appropriately counselled and national and local guidelines for prevention should be strictly adhered to, to minimise the risk of peri-operative COVID-19 infection.

9. Recommendations and Next Steps

The findings of this report should be made readily available to the BOFAS members and foot and ankle surgeons worldwide. This may be done via this report and publication of data. To this end 2 clinical papers have been submitted for peer reviewed publication.

The first paper examines the rate of COVID-19 related mortality and the changes in complication and infection rate during this period. The second paper reports on the regional variation of COVID-19 seen during the audit period.

Most elective surgery is now being performed on green pathways but in our audit, type of pathway did not affect the rate of COVID-19 infection, and further work may need to be done to determine how effective pathways are (Phase 2).

There has been an increase in length of surgery which showed a slight improvement by the end of the audit period. Further work will also be required to determine whether operative time recovers to pre-lockdown levels, and if not this information will be useful in planning longer term allocation of resources.

Phase 2 Report

10. Introduction for Phase 2

The activity of consenting and proceeding with surgical intervention during the COVID-19 pandemic has been an evolving and difficult process. In the setting of reduced resources and unknown risk of perioperative COVID-19 infection to the patient and healthcare professionals, decisions to initially limit elective surgery were undertaken by multiple governing bodies.[1] In the UK, NHS England asked NHS hospitals to reduce all elective activity, to the point of postponing all non-urgent elective procedures by the 15th of April 2020, for a period of at least three months. We reported on the first COVID-19 wave in the UK on our Phase 1 study from the UK FAlCoN audit, which revealed national surgical activity in foot and ankle surgery had significantly reduced during the period of lockdown, however in the post-lockdown period there was normalisation of activity in trauma and diabetic foot and ankle surgery.[2] Less than a quarter of elective activity had resumed to its pre-lockdown levels by the end of the study. The audit also gave us data regarding COVID-19 perioperative infection and mortality to enable the process of informed consent.[3]

In an attempt to enable safe resumption of elective activity, the British Orthopaedic Association (BOA) and the National Institute for Health and Care Excellence (NICE) produced recommendations on recovery pathways. [4,5] Development of COVID-19 safe pathways (otherwise termed 'green pathway' or COVID-19 free pathway) forms the basis of the recommendations. Ding et al published the guiding principles for restarting elective surgeries in a safe and acceptable manner which included up-to date disease awareness, projection, a fair and transparent system to prioritize cases, optimization of peri-operative workflows and continuous data gathering.[6] Despite this, published results on COVID-19 safe pathways have been limited. To date, one large multicentre study and three small single centre studies have reported on the apparent success of COVID-19 safe pathways.[7-11]

1. Bansal, V; Mahapure, KS; Mehra, I, et al. Mortality Benefit of Convalescent Plasma in COVID-19: A Systematic Review and Meta-Analysis. Front Med (Lausanne) 2021;**8**:624924
2. BOA: Re-starting non-urgent trauma and orthopaedic care: Full guidance, British Orthopaedic Association, **2020**.
3. Chang, JS; Wignadasan, W; Pradhan, R, et al. Elective orthopaedic surgery with a designated COVID-19-free pathway results in low perioperative viral transmission rates. Bone Jt Open 2020;**1**(9):562-567.
4. Chui, K; Thakrar, A; Shankar, S. Evaluating the efficacy of a two-site ('COVID-19' and 'COVID-19-free') trauma and orthopaedic service for the management of hip fractures during the COVID-19 pandemic in the UK. Bone Jt Open 2020;**1**(6):190-197.
5. COVIDSurg Collaborative. Delaying surgery for patients with a previous SARS-CoV-2 infection. Br J Surg 2020;**107**(12):e601-e602.
6. COVIDSurg Collaborative. Elective surgery cancellations due to the COVID-19 pandemic: global predictive modelling to inform surgical recovery plans. Br J Surg 2020;**107**(11):1440-1449.
7. COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. Lancet 2020;**396**(10243):27-38.
8. Ding, BTK; Tan, KG; Oh, JY; Lee, KT. Orthopaedic surgery after COVID-19 - A blueprint for resuming elective surgery after a pandemic. Int J Surg 2020;**80**:162-167.
9. Editors, PM. Observational studies: getting clear about transparency. PLoS 383 Med 2014;11(8):e1001711.
10. England, PH: COVID-19 Symptoms, **2020**.
11. Glasbey, JC; Bhangu, A. Elective Cancer Surgery in COVID-19-Free Surgical Pathways During the SARS-CoV-2 Pandemic: An International, Multicenter, Comparative Cohort Study. J Clin Oncol 2020:**Jco**2001933.

11. Phase 2 Set-up

Phase 2 was between 1st September 2020 and 30th November 2020 and captured the second UK national lockdown. For the purposes of categorisation, patients were considered to be in the COVID-19 positive cohort if they were first diagnosed with COVID-19 infection between 7 days prior to their surgery and 30 days after their surgery. Patients who did not contract COVID-19 or who contracted COVID-19 outside of this time window were analysed in the non-COVID-19 cohort. Patients were also categorised by whether they were managed on a COVID-19 safe pathway (“green” pathway), or a non-COVID-19 safe pathway (“blue” pathway), in line with recommendations from the BOA and the NICE.

12. Phase 2 Methods

12.1. Design

Prospective national audit of foot and ankle procedures in the UK in the year 2020.

12.2. Setting

From across the UK a total of 46 sites submitted data. For Phase 2 there were 2 subcategories: 'Phase 2 Pre-lockdown' (1st August 2020 to 4th November 2020) and 'Phase 2 Lockdown' (5th November 2020 to 30th November 2020).

12.3. Participants

All patients aged 16 years and over who underwent a foot and ankle surgical procedure in an operating theatre from 37 participating centres in England, Scotland, Wales, and Northern Ireland. Many of these centres had taken part in phase 1 of the audit.

12.4. Data Protection

The same data processing agreement (Appendix 1) was used for Phase 2. The agreement was sent to each participating trust, to be signed by their data protection officer. The principal investigator at each site was responsible for registering the audit locally and ensuring data handling on site met the requirements.

12.5. Data Collection

Data was collected and anonymised by each participating NHS trust and transmitted securely to the primary trust site (University Hospitals of Leicester NHS trust). Data governance was dictated by the European general data protection regulations and the study was approved and registered as a clinical audit in the lead centre (Ref No. 10795). In addition, each participating trust obtained local audit approval.

Data was collected at the originating trusts on a purpose-designed encrypted spreadsheet. This was securely transferred to the lead trust and data was checked for integrity.

COVID-19 identification were standardised as per national government guidelines. For Phase 2, this meant that the diagnosis of COVID-19 was based on laboratory detection of SARS-Cov-2 viral RNA by quantitative RT-PCR. In the early part of Phase 1 limited testing was available and therefore patients were included on the basis of typical clinical or radiological features.15

For both phases, time periods were subcategorised to reflect their relationship to the UK National Lockdowns. Therefore, for Phase 1 there were 3 subcategories: 'Phase 1 Pre-lockdown' (13th January 2020 to 22nd March 2020), 'Phase 1 Lockdown' (23rd March 2020 to 11th May 2020), and 'Phase 1 Post-lockdown (12th May 2020 to 31st July 2020). For Phase 2 there were 2 subcategories: 'Phase 2 Pre-lockdown' (1st August 2020 to 4th November 2020) and 'Phase 2 Lockdown' (5th November 2020 to 30th November 2020).

The designation of the pathway type (green / blue) each patient followed was determined by each contributing trust in line with national guidance and according to their specific protocols. Criteria for a green pathway included: isolation and testing of patients prior to admission for surgery, operating in protected theatres, and segregation of patients from patients on blue pathways.

Demographics and data regarding admission, length of surgery and length of stay was captured as categorical data, continuous data, or dates. Pathway type, COVID-19 category, and treatment type for patients contracting COVID-19 were collected as categorical data. Further categorical data was captured detailing whether patients underwent surgery for trauma, elective procedures, or emergency diabetic foot conditions; this was further subcategorised by anatomical region and type of procedure. Patient co-morbidities, ASA grade, type of anaesthetic, urgency of surgery, complications and mortality were also captured.

12.6. Data Validation

Data validation was completed by the NIHR Leicester Biomedical Research Centre team via Excel.

After our experience with Phase 1, minor modifications were made to the data collection spreadsheet and data guide to improve consistency of data reported. Data was collected on demographics, co-morbidities, physiological condition, operative treatment, complications, COVID-19 status, and patient pathway

12.7. Data Cleansing

Any queries or missing data were referred to the site personnel for amendment / clarification. Once data had been verified, this was added to REDCap - Research Electronic Data Capture web application (REDCap, Vanderbilt, Tennessee). The complete REDCap dataset was exported into SPSS – Statistical Package for the Social Sciences, for analysis.

12.8. Statistical Analysis

This study was conducted in accordance with STROBE guidelines.16 Continuous variables are presented as means with 95% confidence intervals (95% CI); categorical data as presented as number and percentages. Data was tested for normality and parametric continuous data was analysed using an independent samples t-test and ANOVA. Categorical data was analysed using a chi-squared test (Fisher's exact test used for sample sizes less than 5). Where appropriate Odds Ratios are presented with 95% confidence intervals. For all statistical analysis, a two-tailed p value of <0.05 was considered significant.

Phase 2 subphases, had differing numbers of patients and the duration of subphases was different. Therefore, in order to make more accurate comparisons, the incidence of COVID-19 has been expressed as a percentage of infections per patient per week. All data was analysed using SPSS version 26.0 (SPSS Inc, IBM, Chicago, IL).

13. Phase 2 Results

13.1. Data Submitted and Completion Rate

37 sites supplied data for Phase 2. After exclusion of cases in accordance with the audit protocol and collating data on patients who had multiple operations, a total of 4,202 patients were available for analysis. The breakdown of exclusions is illustrated in **Figure 8**. The most common missing variables were ethnicity and length of surgery. For patients contracting COVID-19, details were available for comorbidities, mortality, complications, and COVID-19 treatment for all patients.

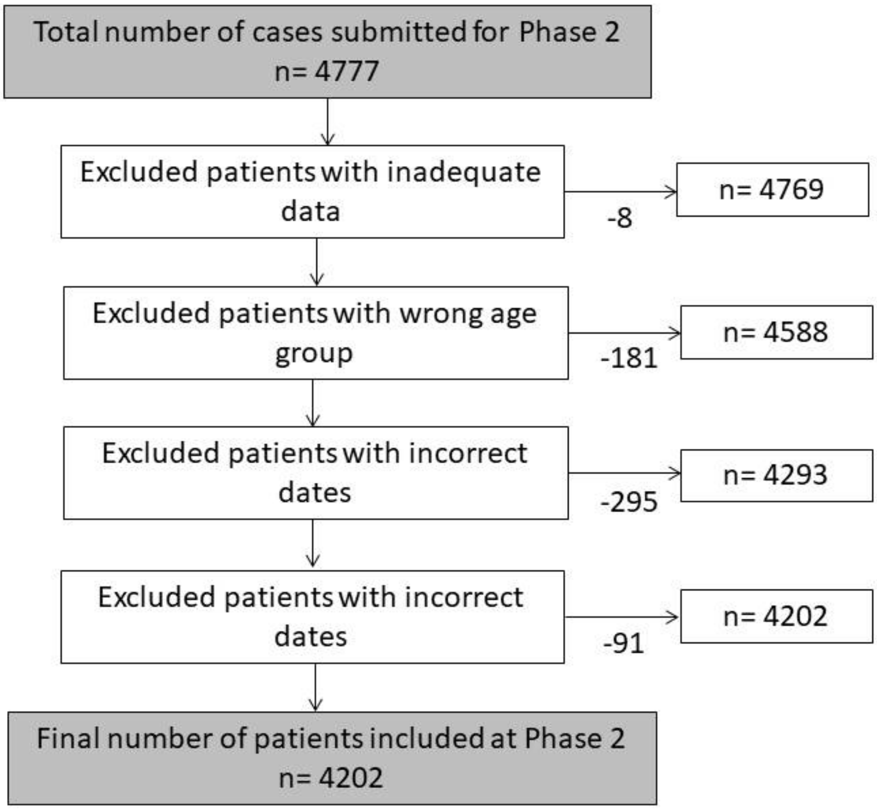

Figure 8. Reasons for exclusion of data cases in phase 2

13.2. COVID-19 Infections

There were 43 positive COVID-19 cases across the phase 2 audit. Overall, there were 39 positive COVID-19 cases in 1820 patients (2.14%) on blue pathways. There were 4 positive COVID-19 cases in 2382 patients (0.17%) on green pathways. During Phase 2, being on a green pathway was associated with a significantly lower incidence of contracting COVID-19 (Odds ratio: 0.077, 95% CI 0.027 to 0.215) (**Table 5**).

Subphase	Blue Pathway			Green Pathway			Fisher's Exact Test (p)
	Total Patients	COVID-19 Patients	% COVID-19 Infections	Total Patients	COVID-19 Patients	% COVID-19 Infections	
Phase 1 - Pre-Lockdown	2636	14	0.53%	1313	2	0.15%	0.109
Phase 1 – Lockdown	633	14	2.21%	126	2	1.59%	0.923
Phase 1 - Post-Lockdown	1381	2	0.14%	459	1	0.22%	0.577
Phase 2 - Pre-Lockdown	1357	24	1.77%	1693	3	0.18%	<0.001*
Phase 2 - Lockdown	463	15	3.24%	689	1	0.15%	<0.001*

Table 5: Breakdown of patients who were diagnosed with COVID-19 by pathway type and subphase of the audit. Due to the small numbers involved Fisher's exact test was used. '*' denotes statistical significance.

13.3. Type of surgery

Figure 9 further illustrates the proportion of trauma, elective, and diabetic foot patients on blue and green pathways during the various subphases and the COVID-19 infection rate. The percentage of trauma patients on a green pathway reduced from 14.04% in Phase 1 to 11.62% in Phase 2 (p = 0.015). At the same time, the percentage of diabetic foot patients on a green pathway increased from 7.25% in Phase 1 to 17.07% in Phase 2 (p = 0.010). However, the biggest change was in elective patients where 49.73% were on green pathways in Phase 1 and 90.83% were on green pathways in Phase 2 (p < 0.001).

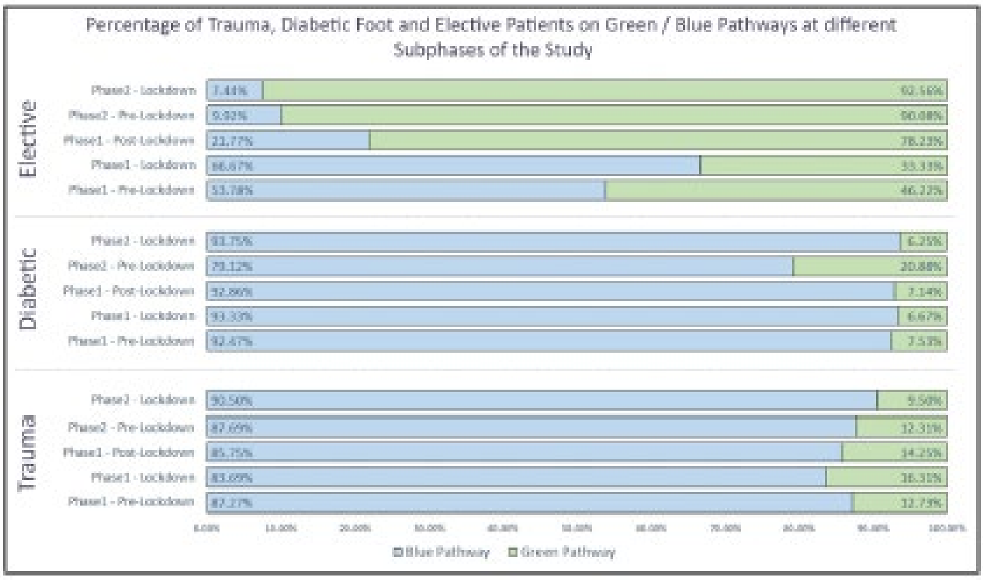

Figure 9. Bar chart of trauma, diabetic and elective patients on green/ blue pathways

13.4. Mortality

The total 30-day mortality rate for the entire audit was 0.36% (39/10,846). The blue pathway had a 30-day mortality rate of 0.54% (35/6426), and the green pathway 30-day mortality rate was 0.09% (4/4,280). In comparing the pathways, the mortality rate was statistically significant (p<.001). Mortality in patients who were diagnosed with COVID-19 was 14.10% (11/78). Comparing the mortality in COVID-19 patients between pathways showed no statistically significant difference (p=.784). A breakdown of mortality rate by time period sub-phases and pathway can be seen in **Table 6**.

	Blue Pathway			Green Pathway			
	Number	%	Total	Number	%	Total	p Value
Non COVID-19 Related Mortality							
Phase 2 Pre-lockdown	7	0.53%	1333	2	0.12%	1690	0.044*
Phase 2 Lockdown	1	0.22%	448	0	0.00%	688	0.394
COVID-19 Related Mortality							
Phase 2 Pre-lockdown	1	4.17%	24	0	0.00%	3	0.889
Phase 2 Lockdown	1	6.67%	15	0	0.00%	1	0.938

Table 6: Breakdown of mortality (COVID-19 and non-COVID-19 related) with pathway type, and subphase of the audit. Numbers within subgroups are too few for meaningful statistical analysis. Due to the small numbers involved Fisher's exact test was used.

The COVID-19 related mortality rate reduced from 25.71% (9/35) in the first phase of the study to 4.65% (2/43) in the second phase of the study. This reduction in mortality was statistically significant (p=0.008). Although there were statistically significant differences in number of operations, age, time form injury/listing, length of stay, length of operation and number of comorbidities, only time from injury/listing and length of stay could be considered to show meaningful differences. All showed significant differences between the pathways, however CEPOD and type of anaesthetic were the only meaningful differences illustrating the high level of elective activity occurring in the green pathways. Although a number of comorbidities showed a statistical difference between the pathways, no meaningful differences were found.

14. Phase 2 Interpretation

One of the primary aims of Phase 2 was to determine the differences in COVID-19 infection and 30-day mortality rate in patients undergoing foot and ankle surgery between green and blue COVID-19 pathways. Our findings have shown a significant reduction in COVID-19 infection in patients undergoing surgery in dedicated COVID-19 preventative pathways (green pathways). There was also a reduction in the overall 30-day all-cause mortality rate in the green pathway as compared to the blue pathway, although there was no difference in COVID-19 related mortality between the pathways. Our results are similar to the findings by Glasbey *et al.* who in an international multicentre comparative cohort study between different pathways on patients undergoing elective cancer surgery found a reduced COVID-19 infection rate in COVID-19-free surgical pathways (2.1% vs 3.6%; aOR, 0.53; 95% CI, 0.36 to 0.76).[1] However, the difference of COVID-19 infection rate between pathways in our study, was of a greater magnitude. This may be the result of either a difference in patient types, with a higher infection rate being expected in cancer patients undergoing surgery, or the timing of the data collection. The early phases of our study showed no difference in COVID-19 infection rate between the pathways, however the later phases did. The study by Glasby et al was completed in a similar time frame to our Phase 1 study, thus further data collection at time periods similar to our phase 2 may increase the magnitude of difference of COVID-19 infection rate between the pathways.[1]

Guidelines instituted by the UK national governing bodies on the formation of green pathways did not occur until after the first UK national lockdown. Prior to this time, hospitals arranged “green” pathways based on local policies and availability of resources. A number of authors concluded that the use of “COVID-19 free” pathways (green pathways) were key to the resumption of elective services.[2,3] In the first Phase of the audit, we did not find significant differences in COVID-19 infection rate between pathways. This is most likely due to the non-establishment of clear guidelines and varying degrees of COVID-19 in the first UK COVID-19 wave. Lessons learnt from the first wave enabled successful creation and institution of COVID-19 pathways, which in the second phase allowed clear pathway distinctions and some elective activity to recommence. Our study has shown that in the second phase there were only four COVID-19 perioperative infections in 2,382 patients (0.16%) on the green pathway and 39 COVID-19 perioperative infections in 1,820 patients (2.14%) on the blue pathway. This was statistically significant.

Although the overall all-cause mortality between pathways revealed a significant increase in mortality in the blue pathway as compared to the green, the COVID-19 related mortality was not significantly different. The most significant factor influencing mortality related to COVID-19 was the time period. Our study on the first wave reported a COVID-19 related mortality of 25.71% (9/35).3 However, this significantly reduced to 4.65% (2/43) in the second wave as reported in the current study. In our first study, we had already indicated a reduction in mortality rate across the sub-phase time periods, and this reduction has continued into the second phase. The trend toward the reduction in mortality has been associated with the rapidly evolving treatment of COVID-19 complications, including the use of antivirals, anti-inflammatory drugs and immunomodulation therapies, dexamethasone, convalescent plasma, and the early start of anticoagulant regimens.[4]

1. Glasbey, JC; Bhangu, A. Elective Cancer Surgery in COVID-19-Free Surgical Pathways During the SARS-CoV-2 Pandemic: An International, Multicenter, Comparative Cohort Study. J Clin Oncol 2020:Jco2001933.
2. Chang, JS; Wignadasan, W; Pradhan, R, et al. Elective orthopaedic surgery with a designated COVID-19-free pathway results in low perioperative viral transmission rates. Bone Jt Open 2020;**1**(9):562-567.
3. Chui, K; Thakrar, A; Shankar, S. Evaluating the efficacy of a two-site ('COVID-19' and 'COVID-19-free') trauma and orthopaedic service for the management of hip fractures during the COVID-19 pandemic in the UK. Bone Jt Open 2020;**1**(6):190-197.
4. Ruggeri, A; Landoni, G; Ciceri, F. Trend towards reduction in COVID-19 in-hospital mortality. Lancet Reg Health Eur 2021;**3**:100059.

15. Phase 2 Audit Limitations

Although it is the largest audit of its kind in foot and ankle surgery in the UK, it still does not fully represent the UK practice. However, with a large cohort size the data presented may be considered a satisfactory surrogate for UK practice. As stated in Phase 1 section, patients were included who had COVID-19 between seven days prior and 30 days after their procedure. This has become the standard metric for perioperative infection, however, there may still be patients who fall outside this period who had a perioperative infection. In first 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, in Phase 2, non-symptomatic SARS-Cov-2 testing had become more widespread thus increasing the possible incidence of detection of SARS-Cov-2, thus increasing the incidence of reported COVID-19 infection. Although the pathways were defined by national guidance, earl phases of the study relied on local guidelines. Therefore, the study may not fully represent the pathways they have been allocated to.

16. Take home messages for BOFAS members from Phase 2 of the audit

There was a reduction in the perioperative COVID-19 infection rate when using designated COVID-19 green pathways in phase 2 of the audit. The audit shows a developing success in using green pathways in reducing the risk to patients undergoing foot and ankle surgery. Appendix 1: UK-FALCON Audit Protocol, Data Sheet and Links

Appendix 1: Links to UK-FALCON Protocols / Resources

The BOFAS webpage for the UK-FALCON Audit (including FAQ) can be accessed here:

https://www.bofas.org.uk/Outcomes/UK-FALCON-Audit

The protocol for the UK-FALCON Audit can be accessed here:

https://drive.google.com/file/d/1he5y4hyg9mh1WDZc_FAR33PQRJlmCV90/view?usp=sharing

The data sharing agreement for the UK-FALCON Audit can be accessed here:

https://drive.google.com/file/d/1qqZjqFfwraWpJ-PVE8tJP404fOJxPBA5/view?usp=sharing

The help sheet for the UK-FALCON Audit can be accessed here:

https://drive.google.com/file/d/1O8dncDGBOjQoWbZNPj7OdJhoOqFyN7pc/view?usp=sharing

The video walkthrough for data entry for the UK-FALCON Audit can be accessed here:

https://drive.google.com/file/d/1ukKSxoJey-AKoWsoVH9U_Dmel1AAI1Xr/view?usp=sharing

The datasheet for the UK-FALCON Audit can be accessed here:

https://drive.google.com/file/d/1XrcGrsZXL1-SiJEfmfeqk4uk41F5phYg/view?usp=sharing

Appendix 2: Participating Sites and Investigators

Site	Contributors
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York Hospitals NHS Trust	Charlie Jowett / Mohamed Mahmoud / Gunay Cryer / Stuart Place

Appendix 3: Completeness of data sets

Variables Recorded	Data Available for *(out of 6644)*
Continuous Variables	• *= incomplete*
Age	6644
Number of Operations (Calculated)	6644
Time from injury / listing to surgery (Calculated - days)	* 6405
Length of Stay (Calculated - days)	*6625
Length of Surgery (mins)	*6145
Number of co-morbidities (calculated)	*6635
COVID Specific	*(out of 35 cases)*
Time from surgery to COVID diagnosis (days)	*34
Categorical Variables	• *= incomplete*
COVID Positive (Y/N)	6644
Gender (Y/N)	6644
Ethnicity	*6122
Foot & Ankle Diagnosis	*6641
Trauma / Diabetic Foot / Elective	*6641
Invasiveness of Surgery (MUA / Percutaneous / Open, etc)	*6642
Urgency of Surgery (NCEPOD)	*6639
Type of Anaesthetic (LA / Regional / General)	*6472
ASA Grade (1-5)	*6264
Pathway Type (Blue / Green)	*6548
Smoking Status (Y/N)	*6404
Comorbidities (Y/N)	*6635
Asthma / COPD	*6635
Active Malignancy	*6635
Chronic Kidney Disease	*6635
Cardiac History	*6635
Dementia	*6634
Diabetes	*6635
Hypertension	*6635
Peripheral Vascular Disease	*6635
Stroke	*6635
Other	*6635
Infection (None / Superficial / Deep)	*6635
Complications (None / Surgical / Non-surgical)	*6634
Mortality (Y/N and Within 7 days / Within 30 days)	*6634
COVID Specific	*(out of 35 cases)*
Method of Diagnosis (swab / symptoms)	35
Minor Pulmonary Complications (Y/N)	35
Major Pulmonary Complications (Y/N)	35
Renal Complications (Y/N)	35
Treatment (Level of support required)	35
Period of Treatment (Pre-lockdown / Lockdown / Post-lockdown)	6644

Appendix 4: Normality and Summary of Continuous Data

Normality assessed for continuous variables using the Kolmogorov-Smirnov test ($p < 0.05$ indicates normally distributed)

Variable	Total	By COVID-19 Infection	By Mortality	By Lockdown Period	By Trauma / Elective / Diabetic Pathway	By Green / Blue Pathway
Age	<0.001	0.2	0.2	<0.001	0.021	<0.001
Number of Operations (Calculated)	<0.001	0.014	<0.001	<0.001	<0.001	<0.001
Time from injury / listing to surgery (Calculated - days)	<0.001	0.006	<0.001	<0.001	<0.001	<0.001
Length of Stay (Calculated - days)	<0.001	<0.001	0.2	<0.001	<0.001	<0.001
Length of Surgery (mins)	<0.001	<0.001	0.2	<0.001	<0.001	<0.001
Number of co-morbidities (Calculated)	<0.001	<0.001	0.014	<0.001	<0.001	<0.001
Time from surgery to COVID-19 diagnosis (days)	-	0.073	-	-	-	-

Summary of continuous variables of the whole dataset

Summary	Mean	St Dev	Min	Max
Age	51.90	17.955	16	99
Length of Surgery (mins)	84.50	55.516	0	620
Length of Stay (days)	3.79	8.912	0	165
Number of operations each patient had	1.04	0.239	1	7
Time from listing / injury to surgery (days)	56.81	97.342	0	983
Total number of comorbidities	0.95	1.158	0	10
Time from surgery to COVID diagnosis (days)	10.38	8.985	-7	28

Appendix 5: Analysis of Propensity Matched Data

Propensity matching was done for the variables of age, ASA Grade and number of co-morbidities. These variables were chosen as they demonstrated significant differences between patients who were COVID-19 positive and those who were not. Matching was done with a 1:3 ratio. As matching was done on these variables they are not included in further analysis.

It can be noted that length of stay is prolonged in COVID-19 positive patients regardless of matching. COVID-19 positive patients also had a longer length of procedure, higher urgency and in trauma and diabetic patients. This audit cannot determine whether this demonstrates direct causality.

COVID-19 Diagnosis	Negative (Matched)	Positive	p
Number	105	35	-
Means of Continuous Variables			
Number of Operations	1.04	1.03	0.794
Length of Stay	8.01	14.06	**0.037**
Operation Length	78.89	107.08	**0.025**
Descriptors for Categorical Variables of Significance			
Urgency (NCEPOD)	Higher COVID-19 rate in patients who had urgent surgery		**0.001**
Complications	Higher COVID-19 rate in patients who had non-surgical complications		**< 0.001**
Mortality	Higher Mortality rate in patients with COVID-19		**< 0.001**
Trauma / Elective	High COVID-19 rates in trauma patients and diabetic patients		**0.001**
Time Period (Pre/Post Lockdown)	Highest COVID rates during lockdown		**< 0.001**

Appendix 6: Binomial Logistic Regression Analyses

Binomial logistic regression analysis was conducted on variables found to have a likely correlation on linear regression, and those variables felt to be of particular significance. Logistic regression was performed on propensity matched data for patients with COVID-19 positive status and for matched data for patients with 30-day mortality.

Variables included in regression models

- 30-day Mortality	(Binary)	(For COVID-19 model)
- COVID-19 Status	(Binary)	(For mortality model)

- NCEPOD	(Categorical data)
- Type of Anaesthesia	(Categorical Data)
- Pathway type (Elective / Diabetic / Elective)	(Categorical Data)
- Infection	(Categorical Data)
- Complications	(Categorical Data)
- Type of Case	(Categorical Data)

COVID-19 Model

Model pseudo R-squared value	=	0.426	(p < 0.001)
Model accuracy of predicting COVID-19 negative status	=	98.1%	
Model accuracy of predicting COVID-19 positive status	=	37.5%	
Overall COVID-19 model accuracy	=	83.7%	

30-day Mortality Model

Model pseudo R-squared value	=	0.481	(p < 0.001)
Model accuracy of predicting 'Alive' status	=	94.7%	
Model accuracy of predicting Mortality status	=	50.0%	
Overall COVID-19 model accuracy	=	83.2%	

Key Significant Predictors

- If a patient died, they were ~40 times more likely to have had COVID-19 than a patient who did not die
  (OR = 39.85, 95% CI 2.97 to 534.22, p = 0.005)

- If a patient had a non-surgical complication, they were ~15 times more likely to have had COVID-19 than a patient without similar complications
  (OR = 14.86, 95% CI 1.34 to 164.23, p = 0.028)

- If a patient had COVID-19, they were ~12 times more likely to die within 30-days of surgery
  (OR = 11.71, 95% CI 1.55 to 88.74, p = 0.017)

- If a patient had Urgent surgery, they were ~40 times more likely to die than an elective patient
  (OR = 39.31, 95% CI 1.32 to 1175.24, p = 0.034)

Appendix 7: Changes in Case Mix After Lockdown

The following data summarises the mean numbers of patients undergoing specific types of surgery each week of the audit period across the UK. The percentage representation of all cases performed in the specific pathway are also presented.

Trauma		Mean procedures per week	ANOVA (p-value)	Percentage of all procedures during time period	Chi-Squared (p-value)
Distal Tibia	Pre-lockdown	9.90	0.215	6.98%	0.174
	Lockdown	7.57		8.38%	
	Post-lockdown	8.67		6.84%	
Malleolar	Pre-lockdown	97.60	**0.000**	68.48%	**0.034**
	Lockdown	64.71		72.87%	
	Post-lockdown	86.92		67.09%	
Talus	Pre-lockdown	2.00	0.497	1.45%	0.661
	Lockdown	1.86		1.87%	
	Post-lockdown	2.50		1.89%	
Calcaneus	Pre-lockdown	2.70	**0.021**	1.88%	**0.025**
	Lockdown	2.43		2.68%	
	Post-lockdown	5.08		3.82%	
Cuboid	Pre-lockdown	0.10	0.095	0.07%	0.140
	Lockdown	0.14		0.18%	
	Post-lockdown	0.50		0.40%	
Cuneiform	Pre-lockdown	2.60	0.144	1.85%	0..641
	Lockdown	1.14		1.28%	
	Post-lockdown	2.08		1.59%	
Metatarsal	Pre-lockdown	4.10	**0.030**	2.87%	0.160
	Lockdown	1.71		1.92%	
	Post-lockdown	4.50		3.41%	
Phalanges	Pre-lockdown	3.40	**0.040**	2.41%	0.330
	Lockdown	1.29		1.32%	
	Post-lockdown	3.25		2.53%	
Achilles tendon	Pre-lockdown	3.50	**0.001**	2.47%	**0.008**
	Lockdown	0.71		0.81%	
	Post-lockdown	1.50		1.14%	
Other F+A tendon	Pre-lockdown	2.20	0.340	1.57%	0.842
	Lockdown	1.43		1.50%	
	Post-lockdown	1.58		1.27%	
Other F+A Procedure	Pre-lockdown	5.70	0.067	4.02%	0.258
	Lockdown	2.14		2.49%	
	Post-lockdown	6.58		4.91%	
Wound management	Pre-lockdown	8.40	**0.024**	5.94%	0.491
	Lockdown	4.29		4.69%	
	Post-lockdown	6.67		5.11%	

Diabetic		Mean procedures per week	ANOVA (p-value)	Percentage of all procedures during time period	Chi-Squared (p-value)
Wound debridement	Pre-lockdown	2.70		31.53%	
	Lockdown	1.13	0.052	26.49%	0.898
	Post-lockdown	2.27		31.85%	
Drainage	Pre-lockdown	0.80		8.87%	
	Lockdown	0.25	**0.043**	4.58%	0.085
	Post-lockdown	1.18		15.67%	
Forefoot amputation	Pre-lockdown	4.60		45.95%	
	Lockdown	2.00	0.052	58.39%	0.317
	Post-lockdown	3.09		40.45%	
Midfoot amputation	Pre-lockdown	0.40		4.68%	
	Lockdown	0.00	0.166	0.00%	0.233
	Post-lockdown	0.73		7.74%	
BKA or above	Pre-lockdown	0.80		8.97%	
	Lockdown	0.38	0.091	10.54%	0.407
	Post-lockdown	0.36		4.29%	

Elective		Mean procedures per week	ANOVA (p-value)	Percentage of all procedures during time period	Chi-Squared (p-value)
Elective forefoot	Pre-lockdown	125.30		49.74%	
	Lockdown	1.50	**0.000**	19.79%	**0.001**
	Post-lockdown	12.36		36.85%	
Elective midfoot	Pre-lockdown	29.70		12.17%	
	Lockdown	0.50	**0.000**	6.99%	0.256
	Post-lockdown	3.36		13.65%	
Elective hindfoot	Pre-lockdown	33.90		13.55%	
	Lockdown	0.88	**0.000**	18.45%	0.704
	Post-lockdown	3.27		15.59%	
Elective tendon procedure	Pre-lockdown	11.20		4.48%	
	Lockdown	0.13	**0.000**	12.50%	0.675
	Post-lockdown	2.55		7.48%	
Other	Pre-lockdown	47.80		20.06%	
	Lockdown	0.88	**0.000**	17.26%	0.247
	Post-lockdown	7.36		26.43%