



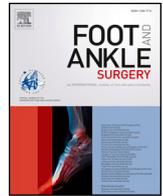
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Contents lists available at ScienceDirect

Foot and Ankle Surgery

journal homepage: www.journals.elsevier.com/foot-and-ankle-surgery

Rate of COVID-19 infection and 30 day mortality between blue and green (dedicated COVID-19 safe) pathways: Results from phase 1 and 2 of the UK foot and ankle COVID-19 national (UK-FALCoN) audit

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ARTICLE INFO

Article history:

Received 26 September 2021

Received in revised form 5 January 2022

Accepted 23 February 2022

Keywords:

UK-FALCON

COVID-19

SARS-Cov-2

Foot and ankle surgery

National audit

Pathways

Mortality

ABSTRACT

Objectives: The primary aim was to determine the differences in COVID-19 infection rate and 30-day mortality in patients undergoing foot and ankle surgery between different treatment pathways over the two phases of the UK-FALCON audit, spanning the first and second UK national lockdowns.

Setting: This was an ambispective (retrospective Phase 1 and prospective Phase 2) national audit of foot and ankle procedures in the UK in 2020 completed between 13th January 2020 and 30th November 2020.

Participants: All adult patients undergoing foot and ankle surgery in an operating theatre during the study period were included from 46 participating centres in England, Scotland, Wales and Northern Ireland. Patients were categorised as either a green pathway (designated COVID-19 free) or blue pathway (no protocols to prevent COVID-19 infection).

Results: 10,846 patients were included, 6644 from phase 1 and 4202 from phase 2. Over the 2 phases the infection rate on a blue pathway was 1.07% (69/6470) and 0.21% on a green pathway (9/4280). 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 ($p = .109$), lockdown ($p = .923$) or post-lockdown ($p = .577$)). 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 (Odds Ratio 0.077, $p < .001$). There was no significant difference in COVID-19 related mortality between pathways.

Conclusions: 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 to using green pathways in reducing the risk to patients undergoing foot and ankle surgery.

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1. Introduction

Informed consent 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

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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. We reported on the first COVID-19 wave in the UK on our phase 1 study from the UK FaCoN audit, which was undertaken to observe the national surgical activity in foot and ankle surgery during the period of national lockdown. This audit revealed a significant reduction in surgical activity during 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 provided data regarding COVID-19 perioperative infection and mortality to aid discussions 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 pathways’ or COVID-19 free pathways) 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 prioritise cases, optimisation 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].

1.1. Aims and objectives

The primary aim of our study was to determine the differences in COVID-19 infection and 30-day mortality rate in patients undergoing foot and ankle surgery between green (COVID-19 safe pathway) and blue COVID-19 pathway over the two phases of the UK-FaCoN audit, spanning the first and second UK national lockdowns.

2. Methods

2.1. Study Design

This was an ambispective (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. All patients aged 16 years and over who underwent a foot and ankle surgical procedure in an operating theatre from a participating trust were included in the audit.

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. These thresholds are in keeping with previous COVID-19 surgical studies [2,3,12–14].

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 [4,5]. All patients were admitted to hospital, and the days in hospital before discharge were recorded. All cases which were admitted and discharged on the day of surgery were recorded as zero days.

2.2. 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. Data queries and missing data were resolved with the submitting trust where possible. The final data was then uploaded to the Research Electronic Data Capture web application (REDCap, Vanderbilt, Tennessee).

Phase 2 followed the protocol of Phase 1, which has been previously published [2,3]. 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. Full details of the protocol can be found in the supplementary material.

COVID-19 identification was 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 diagnosed with COVID-19 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 2020–22nd March 2020), ‘Phase 1 Lockdown’ (23rd March 2020–11 th May 2020), and ‘Phase 1 Post-lockdown’ (12th May 2020–31 st July 2020). For Phase 2 there were 2 subcategories: ‘Phase 2 Pre-lockdown’ (1st August 2020–4 th November 2020) and ‘Phase 2 Lockdown’ (5th November 2020–30 th 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 were captured as 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.

2.3. 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 1 and Phase 2, and their subphases, had differing numbers of patients and the duration of subphases was different. Therefore, in order

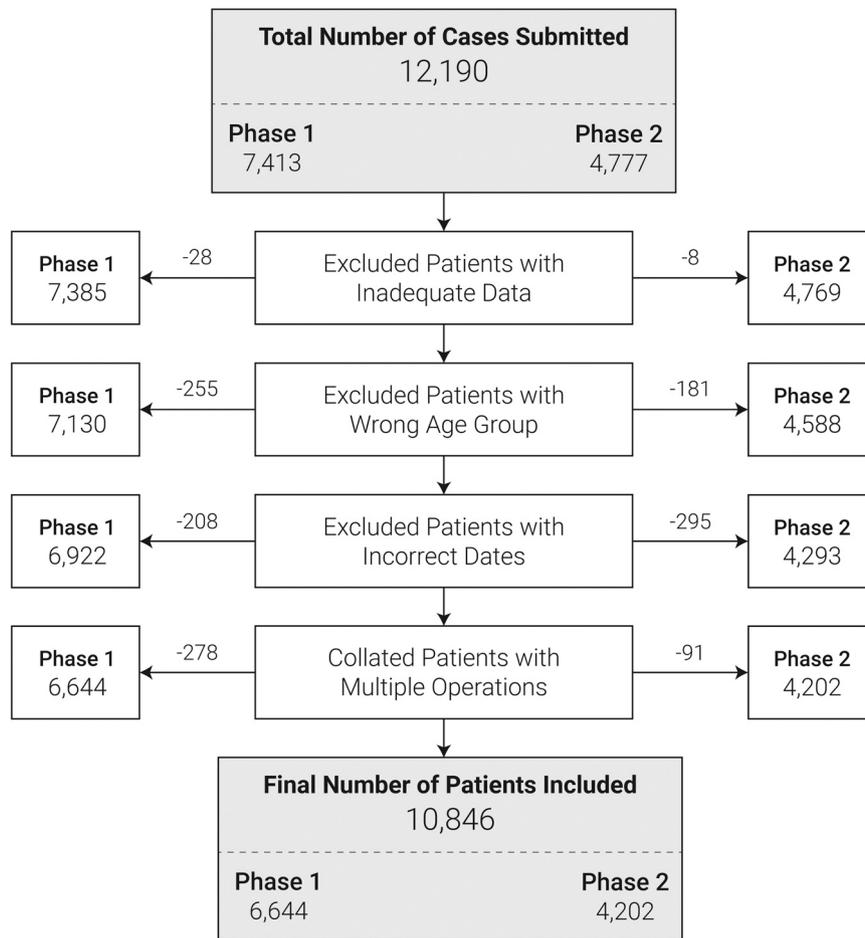


Fig. 1. – Flow chart depicting the sizes of the datasets and exclusions for Phase 1 and Phase 2.

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).

2.4. 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.

3. Results

From across the UK a total of 46 sites submitted data on 12,190 cases. A total of 43 sites participated in Phase 1 and 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 10,846 patients were available for analysis: 6644 from Phase 1 and 4202 from Phase 2. The breakdown of exclusions is illustrated in Fig. 1. In total a complete dataset was available for 9750

Table 1

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.

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 *

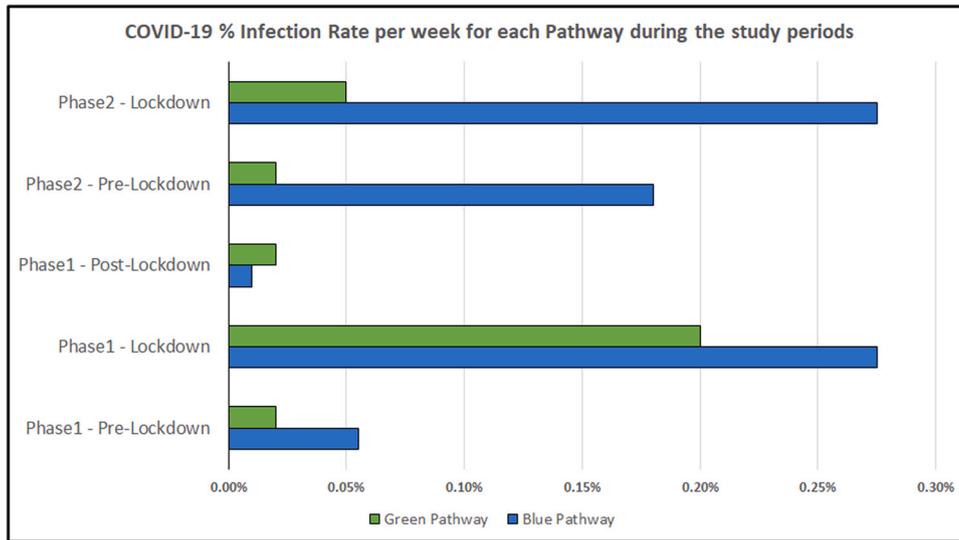


Fig. 2. – Graph illustrating the proportion of patients diagnosed with COVID-19 infections on blue and green pathways for each subphase of the study; expressed as a percentage of infections per patient per week.

patients (89.9%). The most common missing variables were ethnicity and length of surgery, accounting for 8.5% (918 cases) and 5.5% (600 cases) of missing data, respectively. For patients contracting COVID-19, details were available for comorbidities, mortality, complications, and COVID-19 treatment for all patients. All patients included in this study were admitted to a ward on either a blue or green pathway.

3.1. COVID-19 infection

There were 78 positive COVID-19 cases across the entire audit. Overall, there were 69 positive COVID-19 cases in 6470 patients

(1.07%) on blue pathways. There were 9 positive COVID-19 cases in 4271 patients (0.21%) on green pathways. The overall reduction in COVID-19 positive cases in the green pathways as compared to the blue pathways was statistically significant ($P < .001$). Table 1 and Fig. 2 illustrate the proportion of patients on blue and green pathways at differing points in the study, and the associated COVID-19 infection rates. Overall, during Phase 1 there was no statistically significant difference in COVID-19 infection rate between patients on blue and green pathways. However, 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 0.027–0.215).

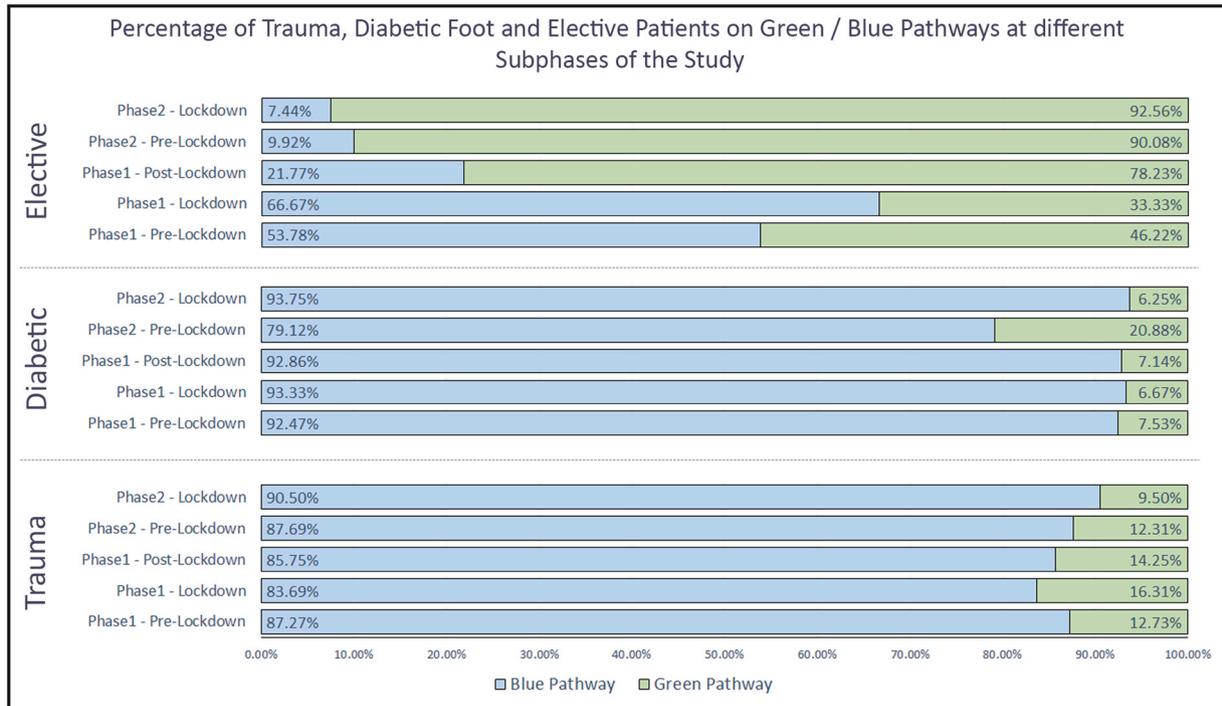


Fig. 3. – Bar graph illustrating the percentage of patients on blue and green pathways for various subphases of the study. The percentages are shown for each category of patient: elective, diabetic foot, and trauma.

Table 2 Breakdown of patients who were diagnosed with COVID-19 by surgery type, pathway, and subphase of the audit. Numbers within subgroups are too few for meaningful statistical analysis.

Subphase	Trauma Pathway				Diabetic Foot Pathway				Elective Pathway			
	Blue Pathway		Green Pathway		Blue Pathway		Green Pathway		Blue Pathway		Green Pathway	
	Total	COVID-19 %	Total	COVID-19 %	Total	COVID-19 %	Total	COVID-19 %	Total	COVID-19 %	Total	COVID-19 %
Phase 1 -Pre-Lockdown	1241	11	0.89%	181	1	0.55%	1309	2	0.15%	1125	1	0.09%
Phase 1 -Lockdown	585	11	1.88%	114	2	1.75%	20	0	0%	10	0	0%
Phase 1 -Post-Lockdown	1234	2	0.16%	205	1	0.49%	69	0	0%	248	0	0%
Phase 2 -Pre-Lockdown	1118	21	1.88%	157	2	1.27%	167	0	0%	1517	0	0%
Phase 2 -Lockdown	381	15	3.94%	40	1	2.50%	52	0	0%	647	0	0%

3.2. Type of surgery

Fig. 3 and Table 2 further illustrate 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 1–11.62% in Phase 2 ($p = .015$). At the same time, the percentage of diabetic foot patients on a green pathway increased from 7.25% in Phase 1–17.07% in Phase 2 ($p = .010$). 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 ($p < .001$). Tables 3 and 4.

3.3. Mortality

The total 30-day mortality rate for the entire audit was 0.36% (39/10,741). 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% (4/4280). In comparing the pathways, the difference observed in all-cause mortality rate was statistically significant ($p < .001$). Overall 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 3. 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 ($p = .008$). The differences between the pathways on all the recorded continuous variables are shown in Table 3. Although there were statistically significant differences in the number of operations, age, time from 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 clinically meaningful differences. The differences between the pathways on all the recorded categorical variables are shown in Table 5. All showed significant differences between the pathways; however the National Confidential Enquiry into Patient Outcome and Death classification (NCEPOD) and type of anaesthetic were the only meaningful differences illustrating the high level of elective activity occurring in the green pathways. The differences in reported comorbidities are illustrated in Table 6. Although a number of comorbidities showed a statistical difference between the pathways, no meaningful differences were found.

4. Discussion

According to the results of the present study, there are clear differences over the two phases of the UK-FAICoN audit in COVID-19 infection rate; and there was 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%v3.6%; aOR, 0.53; 95% CI, 0.36–0.76) [17]. 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 Glasbey et al. was completed in a similar time frame to our phase 1 study, thus

Table 3
Breakdown of mortality (all cause and 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. *** denotes statistical significance.

	Blue Pathway			Green Pathway			p Value
	Number	%	Total	Number	%	Total	
All Cause Mortality							
Phase 1 Prelockdown	14	0.53%	2632	1	0.08%	1313	0.542
Phase 1 Lockdown	8	1.27%	630	1	0.79%	126	0.542
Phase 1 Post Lockdown	3	0.22%	1379	0	0.00%	459	0.422
Phase 2 Prelockdown	8	0.59%	1357	2	0.12%	1693	0.025 *
Phase 2 Lockdown	2	0.43%	463	0	0.00%	689	0.161
Non COVID-19 Related Mortality							
Phase 1 Prelockdown	9	0.34%	2618	0	0.00%	1311	0.034 *
Phase 1 Lockdown	5	0.81%	616	1	0.81%	124	0.735
Phase 1 Post Lockdown	3	0.22%	1377	0	0.00%	458	0.422
Phase 2 Prelockdown	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 1 Prelockdown	5	35.71%	14	1	50.00%	2	0.625
Phase 1 Lockdown	3	21.43%	14	0	0.00%	2	0.650
Phase 1 Post Lockdown	0	0.00%	2	0	0.00%	1	
Phase 2 Prelockdown	1	4.17%	24	0	0.00%	3	0.889
Phase 2 Lockdown	1	6.67%	15	0	0.00%	1	0.938

further data collection at time periods similar to our phase 2 may increase the magnitude of difference in COVID-19 infection rate they observe between pathways [17].

Guidelines instituted by the UK national governing bodies on the formation of green pathways did not occur until after the first UK national lockdown [4,5]. Prior to this time, hospitals arranged “green” pathways based on local policies and availability of resources as reported in a number of small studies [7–9]. A number of authors concluded that the use of “COVID-19 free” pathways (green pathways) were key to the resumption of elective services [7,8,10]. In the first phase of our study, 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 2382 patients (0.16%) on the green pathway and 39 COVID-19 perioperative infections in 1820 patients (2.14%) on the blue pathway. This 13-fold difference 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 studied. 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 [18–21]. In addition, developing technology including the use of telemedicine consults have improved patients access to clinicians and may become important tools to measure post-operative outcomes or pre-surgical clinical evaluations in the future [22].

When comparing both the categorical and continuous data variables between the pathways collected in the audit, the majority were statistically significant. However, the clinical differences were

Table 4
Breakdown of continuous data variables between pathways. *** denotes statistical significance.

Continuous Data	Pathway type	Number	Mean	Std. Deviation	p Value
Number of Operations	Blue	6470	1.05	0.263	<0.001 *
	Green	4280	1.02	0.186	
Age (years)	Blue	6470	51.75	18.279	<0.001 *
	Green	4280	53.29	17.112	
Time from Injury / Listing to Surgery (days)	Blue	6297	43.02	560.274	<0.001 *
	Green	4261	414.45	3428.639	
Length of Stay (days)	Blue	6460	4.82	9.83	<0.001 *
	Green	4270	1.64	8.819	
Length of Operation (mins)	Blue	6150	85.6	55.048	<0.001 *
	Green	4050	77.67	58.634	
Total number of comorbidities	Blue	6461	1	1.228	<0.001 *
	Green	4280	0.9	1.062	
COVID - Time from surgery to COVID (days)	Blue	69	8.75	9.98	0.161
	Green	10	4.1	7.49	

Table 5
Breakdown of categorical data variables between pathways. *** denotes statistical significance.

Categorical Data			Pathway type		Total	p Value
			Blue	Green		
Gender	Female	Count	3525	2593	6118	<0.001 *
		%	54.50%	60.60%	56.90%	
	Male	Count	2945	1687	4632	
		%	45.50%	39.40%	43.10%	
Did patient have more than one surgery?	No	Count	6150	4231	10381	<0.001 *
		%	95.10%	98.90%	96.60%	
	Yes	Count	320	49	369	
		%	4.90%	1.10%	3.40%	
Length of Admission	Day Case	Count	2128	2710	4838	<0.001 *
		%	32.94%	63.47%	45.09%	
	1 Night Stay	Count	1124	813	1937	
		%	17.40%	19.04%	18.05%	
	2–7 Days	Count	2023	557	2580	
		%	31.32%	13.04%	24.04%	
	1–4 weeks	Count	1008	149	1157	
%		15.60%	3.49%	10.78%		
>4 weeks	Count	177	41	218		
	%	2.74%	0.96%	2.03%		
CEPOD	Immediate	Count	72	3	75	<0.001 *
		%	1.10%	0.10%	0.70%	
	Urgent	Count	3053	398	3451	<0.001 *
		%	47.30%	9.30%	32.10%	
	Expedited	Count	1753	391	2144	<0.001 *
%		27.10%	9.10%	20.00%		
Elective	Count	1580	3487	5067	<0.001 *	
	%	24.50%	81.50%	47.20%		
Type of Anaesthetic	Local	Count	412	519	931	<0.001 *
		%	6.50%	12.20%	8.80%	
	Regional	Count	1343	649	1992	<0.001 *
		%	21.10%	15.30%	18.80%	
	General	Count	3973	2150	6123	<0.001 *
%		62.40%	50.50%	57.70%		
Combined GA / Regional	Count	634	936	1570	<0.001 *	
	%	10.00%	22.00%	14.80%		

small. The patients on the green pathway were older, more likely to be female, had lower number of operations per patient, had longer time between listing and surgery, had shorter length of stay and had fewer comorbidities. These differences are likely to represent the significantly greater elective patient numbers in the green pathways than trauma and diabetic surgical patients. These differences are more apparent toward the end of the study period as the shift from blue to green pathways for elective patients becomes greater. The most obvious differences between the pathways is in the CEPOD categorisation (the coding of urgency of surgery in the UK) and the length of stay. The majority of blue pathway patients were in the urgent category (47.30%) as compared to the green pathway patients who were mostly elective (81.50%). Similarly, although all patients in this study were admitted to a ward pre- and post-operatively, 50.34% of patients on a blue pathway were either a day case or overnight stay, versus 82.51% of patients on a green pathway (63.47% were day case).

Although there have been no factors identified directly related to the development of COVID-19 infection, there are clinical determinants to the severity of COVID-19. Li et al. conducted a systematic review finding the clinical factors related to the severity of COVID-19 infection included patients who were male, with advanced age, obesity, a history of smoking, hypertension, diabetes, malignancy, coronary heart disease, hypertension, chronic liver disease, chronic obstructive pulmonary disease and chronic kidney disease [23]. Our review found minimal differences between the pathways in regard to comorbidities. Therefore, the differences seen in COVID-19

infections between the pathways should not be assumed to be in relation to other patient factors.

4.1. Limitations

Our audit has limitations. This was an audit with both retrospective (phase 1) and prospective (phase 2) of observational data, which underwent retrospective analysis. 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 of over 10,000 patients we feel that the data presented is a satisfactory surrogate for UK practice. As stated in our first study, we included patients 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; during earlier phases of the study, the pathways were determined by local guidelines. Therefore, the reported pathways in early sub-phases of the

Table 6
Breakdown of recorded comorbidities between pathways. *** denotes statistical significance.

Comorbidities			Pathway type		Total	p Value
			Blue	Green		
Smoker	No	Count	5590	3887	9477	0.003 *
		%	89.10%	90.90%	89.80%	
	Yes	Count	684	389	1073	
		%	10.90%	9.10%	10.20%	
Asthma / Chronic Obstructive Pulmonary Disease	No	Count	5709	3706	9415	0.008 *
		%	88.40%	86.60%	87.70%	
	Yes	Count	752	573	1325	
		%	11.60%	13.40%	12.30%	
Malignancy	No	Count	6277	4130	10407	0.068 *
		%	97.20%	96.50%	96.90%	
	Yes	Count	184	149	333	
		%	2.80%	3.50%	3.10%	
Chronic Kidney Disease	No	Count	6202	4176	10378	<.001 *
		%	96.00%	97.60%	96.60%	
	Yes	Count	259	103	362	
		%	4.00%	2.40%	3.40%	
Cardiac Conditions	No	Count	5864	3894	9758	0.681
		%	90.80%	91.00%	90.90%	
	Yes	Count	597	385	982	
		%	9.20%	9.00%	9.10%	
Dementia	No	Count	6395	4263	10658	<.0001 *
		%	99.00%	99.60%	99.20%	
	Yes	Count	65	16	81	
		%	1.00%	0.40%	0.80%	
Diabetes	No	Count	5702	3957	9659	<.0001 *
		%	88.30%	92.50%	89.90%	
	Yes	Count	759	322	1081	
		%	11.70%	7.50%	10.10%	
Hypertension	No	Count	5183	3376	8559	0.096
		%	80.20%	78.90%	79.70%	
	Yes	Count	1278	903	2181	
		%	19.80%	21.10%	20.30%	
Peripheral Vascular Disease	No	Count	6266	4225	10491	<.0001 *
		%	97.00%	98.70%	97.70%	
	Yes	Count	195	54	249	
		%	3.00%	1.30%	2.30%	
Previous Stroke	No	Count	6073	4085	10158	<.0001 *
		%	94.00%	95.50%	94.60%	
	Yes	Count	388	194	582	
		%	6.00%	4.50%	5.40%	
Other Comorbidities	No	Count	4462	3130	7592	<.0001 *
		%	69.10%	73.10%	70.70%	
	Yes	Count	1999	1150	3149	
		%	30.90%	26.90%	29.30%	

study may not fully represent the pathways as we consider them now.

5. Conclusion

There was a five-fold overall reduction in the perioperative COVID-19 infection rate when using designated COVID-19 green pathways. However, the success of the pathways only became significant in phase 2 of the study where the reduction in COVID-19 infection rate was 13-fold. There was no difference in COVID-19 related mortality between the pathways, however the COVID-19 mortality rate markedly improved over the course of the study period. The study shows a developing success in using green pathways in reducing the risk to patients undergoing foot and ankle surgery and should be continued as elective services resume.

CRedit authorship contribution statement

Mr Karan Malhotra: drafting, final approval, analysis and interpretation of data, writing. Mr Jitendra Mangwani: Conception of work, drafting, final approval, analysis and interpretation of data,

writing. Linzy Houchen-Wollof: final approval, analysis and interpretation of data, writing. Prof Lyndon W Mason: Conception of work, drafting, final approval, analysis and interpretation of data, writing.

Acknowledgements

This work was supported by Leicester Hospitals Charity, (ref 7681).

Appendix. UK - FalCoN Audit Collaborators

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