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A multicentre national study of the effectiveness of virtual fracture clinic management of orthopaedic trauma during the COVID-19 pandemic (MAVCOV): a cross-sectional study protocol

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Aims

Virtual fracture clinics (VFCs) are advocated by recent British Orthopaedic Association Standards for Trauma and Orthopaedics (BOASTs) to efficiently manage injuries during the COVID-19 pandemic. The primary aim of this national study is to assess the impact of these standards on patient satisfaction and clinical outcome amid the pandemic. The secondary aims are to determine the impact of the pandemic on the demographic details of injuries presenting to the VFC, and to compare outcomes and satisfaction when the BOAST guidelines were first introduced with a subsequent period when local practice would be familiar with these guidelines.

Methods

This is a national cross-sectional cohort study comprising centres with VFC services across the UK. All consecutive adult patients assessed in VFC in a two-week period pre-lockdown (6 May 2019 to 19 May 2019) and in the same two-week period at the peak of the first lockdown (4 May 2020 to 17 May 2020), and a randomly selected sample during the 'second wave' (October 2020) will be eligible for the study. Data comprising local VFC practice, patient and injury characteristics, unplanned re-attendances, and complications will be collected by local investigators for all time periods. A telephone questionnaire will be used to determine patient satisfaction and patient-reported outcomes for patients who were discharged following VFC assessment without face-to-face consultation.

Ethics and dissemination

The study results will identify changes in case-mix and numbers of patients managed through VFCs and whether this is safe and associated with patient satisfaction. These data will provide key information for future expert-led consensus on management of trauma injuries through the VFC. The protocol will be disseminated through conferences and peer-reviewed publication. This protocol has been reviewed by the South East Scotland Research Ethics Service and is classified as a multicentre audit.

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Introduction

Virtual fracture clinics (VFCs), initiated by Glasgow Royal Infirmary in 2011,[1,2] are being increasingly used by hospitals across the UK to efficiently manage orthopaedic injuries.[3-7] VFCs have become a popular alternative to face-to-face fracture clinics to cope with the rising numbers of unselected patients with minor injuries not requiring further investigation or intervention, in light of the British Orthopaedic Association Standards for Trauma (BOAST) 7 guidelines. These state that patients should be seen in a new fracture clinic within 72 hours of presentation with the injury.[8]

The global outbreak of COVID-19 has precipitated the rapid development and evolution of VFCs nationally due to necessities for safe hospital distancing.[9,10] The shift to virtual clinics is advocated by the British

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Table I. Inclusion and exclusion criteria for the study.

Inclusion criteria	Exclusion criteria
Adult patients (≥ 18 years), no upper age limit	Paediatric patients
All consecutive patients managed in a participating VFC during 6 May 2019 to 19 May 2019 and from 4 May 2020 to 17 May 2020	Patients with significant cognitive impairment precluding the ability to consent to the telephone questionnaire
A random sample of patients from the 'second wave' of the pandemic in October 2020	

VFC, virtual fracture clinic.

Orthopaedic Association (BOA) in the recently published COVID-19 BOAST guidelines which stipulate 1) patient-initiated follow-up should be the default, with booked appointments only where this is unavoidable; and 2) follow-up appointments should be delivered by telephone or video call if at all possible.[11] The BOA has also acknowledged there will be an increased emphasis on nonoperative management and minimizing outpatient visits amid the current pandemic.[11]

At present, over 50 orthopaedic units have implemented the VFC model.[2] However, there is a paucity of evidence reporting the outcomes of patients with injuries safely managed in a VFC with no further face-to-face assessment. Local practice and patient pathways also vary from hospital to hospital.[12] There are currently no multicentre or national studies which describe patient outcomes of VFC management, and none which further evaluate the VFC outcomes in the context of the BOAST guidelines pertaining to the COVID-19 pandemic.

The primary aim of this national multicentre study is to assess the impact of the COVID-19 pandemic and BOAST guidelines on patient satisfaction and clinical outcome following VFC assessment. The secondary aims are to determine the impact of the pandemic on variation in practice; patient demographic details; nature of injuries presenting to the VFC, including number of injuries, nature, and injury type; and to compare satisfaction and clinical outcomes of VFC assessment.

Methods

Study setting. This is a national multicentre cross-sectional study of VFCs across the UK comprising retrospective clinical data collection and prospective patient-reported outcome data collection. All consecutive adult patients managed in a VFC during 6 May 2019 to 19 May 2019, and from 4 May 2020 to 17 May 2020, will be eligible for the study. A random sample of patients during the second wave in the month of October 2020 will also be eligible for inclusion. Local investigators, supervised by a consultant orthopaedic surgeon, will complete data collection for the specified time periods. Specific inclusion and exclusion criteria will be applied (Table I).

Service survey. A service survey will be administered at each participating VFC to assess duration of service implementation, grade of staff involved, presence of treatment protocol, dissemination of patient information resources, and alterations to VFC practice secondary to the COVID-19-related lockdown restrictions. The survey responses will be used as a quality scoring tool to independently assess the quality of data at each VFC.

Retrospective data collection. All consecutive adult patients from the pre-lockdown cohort and the lockdown-restricted cohort will be retrospectively identified from VFC databases and other hospital records. All information collected is routinely available from medical records, including images from the Picture Archiving and Communication System (PACS; Insignia Medical Systems, UK). Data will be collected by local investigators using an electronic proforma held under secure NHS computer access, and data anonymized prior to transfer to the central study team atthe University of Edinburgh.

Patient and injury characteristics comprising age, sex, type of injury, mechanism of injury, place of injury, and orthopaedic immobilization technique used prior to referral will be collected. Waiting time for VFC review and grade of staff making decisions at the VFC will be audited against the BOAST 7 guidelines.[8] The VFC management decision and the grade of staff providing verbal information to the patient will also be collected.

The outcome measures from retrospective data collection will include the rates of unplanned re-attendance, complications, and any subsequent change in management within a three-month follow-up period in patients who have been discharged from VFC without a face-to-face appointment. Additional outcome measures will include the evaluation of demographic changes in injury incidence, characteristics of injury sustained, and variation in practice as a consequence of the COVID-19-related lockdown compared with a similar time pre-lockdown.

Patient telephone questionnaire. Patients in the pre- and lockdown cohorts discharged without a face-to-face fracture clinic appointment, and a random sample of patients discharged during the second wave of the pandemic in October 2020, will be identified and contacted by the investigators to complete a telephone questionnaire. The goal of the telephone questionnaire is to supplement retrospective data with patient-reported outcome measures to assess patient outcome and satisfaction with VFC care. Potential participants will be checked for eligibility using patient records. A standardized telephone transcript will be used to seek verbal consent and administer the questionnaire (Figure 1). The reason for collecting

1	Rate your pain when you first came into hospital with your injury in [month-year] on a scale from 0 to 10. 0 being no pain and 10 being the worst pain imaginable.	0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10
2	Rate your pain now on average for the injury you had.	0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10
	Regarding your treatment in the virtual fracture clinic for your injury:	
3	How well did your orthopaedic treatment relieve your pain?	Very good / Good / Neither good nor poor / Poor / Very poor
4	How well did your orthopaedic treatment increase your ability to perform regular activities? [If patient asks, give example of writing, walking up the stairs etc.]	Very good / Good / Neither good nor poor / Poor / Very poor
5	How well did your orthopaedic treatment allow you to perform heavy work or sport activities?	Very good / Good / Neither good nor poor / Poor / Very poor
6	How satisfied are you with the virtual fracture clinic?	Very satisfied / Satisfied / Neither satisfied nor dissatisfied / Dissatisfied / Very dissatisfied
7	Thinking about the virtual fracture clinic, how was your experience of our service?	Very good / Good / Neither good nor poor / Poor / Very poor / Don't know
8	How likely are you to recommend the virtual fracture clinic to friends and family if they needed similar care and treatment?	Extremely likely / Likely / Neither likely nor unlikely / Unlikely / Extremely unlikely / Don't know
9	Would you have preferred the virtual fracture clinic or to attend a face-to-face hospital appointment for the injury you had?	Virtual fracture clinic / Face-to-face appointment / No preference
10	Did you receive an information leaflet relevant to your injury when you were first discharged from A&E / Minor Injuries Unit in [month-year]?	Yes / No / Not sure
11	How satisfied were you with the information on the leaflet?	Very satisfied / Satisfied / Neither satisfied nor dissatisfied / Dissatisfied / Very dissatisfied / Not applicable
12	Did you receive a telephone call from the hospital just after your injury in [month-year]?	Yes / No / Not sure
13	How satisfied were you with the information provided over the phone?	Very satisfied / Satisfied / Neither satisfied nor dissatisfied / Dissatisfied / Very dissatisfied / Not applicable
14	Were you aware that there was a helpline number to contact if you encountered problems?	Yes / No
15	Did you ever contact the virtual fracture clinic for further advice after being discharged?	Yes / No / Not sure
16	Did you visit your GP or return to hospital for your injury after being discharged?	GP / Hospital / GP and hospital / No
17	[If re-attended] What was the main reason of re-attendance?	Pain or concern (not due to a further episode of trauma) / Pain or concern (due to a further episode of trauma) / Conservative management (e.g. plaster/splint/sling) problem / Unable to manage at home / Wound problem
18	[If re-attended] When did you first return to GP or hospital?	Within / after three months following initial discharge
19	Is there anything about the virtual fracture clinic that would have made your experience better?	Free text

Fig. 1

Telephone questionnaire and associated scoring system.

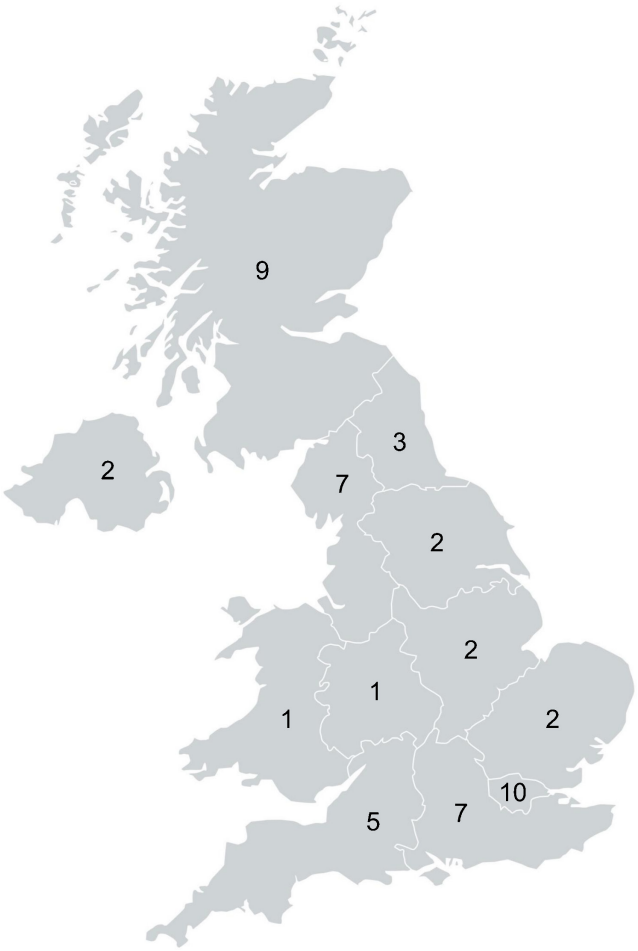

Fig. 2

Number of hospitals with virtual fracture clinic services recruited by region in the UK. Regional map reproduced with permission from Shutterstock.

patient-reported outcome data for the lockdown cohort and the second wave cohort is to compare how VFC practice and patient outcome changed from when the COVID-19-related BOAST guidelines were first introduced to when they were established, and when centres became familiar with the change in VFC discharge practice.

Pain at presentation of injury and at the time of questionnaire will be assessed with the Numeric Pain Rating Scale (0 to 10). Patients will be asked if they have used the VFC helpline and attended their general practice or hospital at any point to seek further advice following discharge and their clinical indication for re-attendance.

Patient satisfaction data will be obtained using the following questions, answered on a five-point Likert scale (very good, good, neither good nor poor, poor, very poor) (Figure 1). Patients will indicate if they would prefer the VFC or a face-to-face fracture clinic appointment for the same injury should they have it again. The NHS Friends and Family Test,[13] a national patient experience questionnaire widely used by NHS England and the Care Quality Commission,[14] will also be used to collect patient feedback on the VFC service.

Investigators. The study will assess the outcomes of a nationally representative sample of patients who have undergone VFC assessment and management of their injuries. As of 31 October 2020, 51 hospitals with VFC services (39 in England, nine in Scotland, two in Northern Ireland, and one in Wales) have been recruited to participate in this study (Figure 2).

The study will be undertaken by local investigators who will be responsible for ensuring that study approvals are in place, identifying and including all eligible patients, administering the telephone questionnaire, and the accurate completion and submission of data. Data collection at each hospital is supervised by a consultant orthopaedic surgeon who will also complete the local service survey. Investigators will undertake in-depth training via regular webinars and receive published guidance prior to commencing data collection, to maximize homogenous data collection techniques.

The British Orthopaedic Trainees' Association (BOTA) and National Student Association of Medical Research (NSAMR) will support the central study team at the

Table II. Strengths and limitations of the study.

Strengths	Limitations
This will be the first national multicentre study evaluating the effectiveness of VFCs in the UK.	Selection and recall bias are inherent to patient telephone questionnaire.
This study will form the largest prospective, patient-reported outcome data collection to date with regards to VFC management.	
This study will recruit from a large number of trauma units to provide feedback on orthopaedic care that can direct future consensus processes to improve VFC treatment on a national basis.	

VFC, virtual fracture clinic.

University of Edinburgh with dissemination of the protocol and study findings nationally and internationally.

Sample size, statistics, and analysis. The number of VFC referrals will vary by hospital according to their catchment population. Overall, there are approximately 20 mean referrals per day based on local audit results,[5,15,16] and it is estimated that 200 patients were managed over the two-week period at each participating VFC. It is anticipated that 51 hospitals with VFC services will participate in the study, and therefore a total of 10,200 patients could be referred to the VFC. Assuming 25% patients are virtually discharged without a face-to-face fracture clinic appointment,[1,15] an estimated 2,550 patients will be approached to complete the telephone questionnaire from this lockdown cohort. A random sample of patients from the second wave cohort will also be asked to complete the telephone questionnaire. A ratio of 2:1 will be employed for the lockdown and second wave cohorts, i.e. one patient in the second wave cohort will be asked to complete the telephone questionnaire for every two patients completing the questionnaire in the lockdown cohort. It is assumed that up to 20% of patients may not respond to the telephone questionnaire. Using an effect size of 0.06 (to detect a 2% difference in satisfaction between lockdown (n = 2,040) and second wave cohorts (n = 1,020), an α of 0.05 and one degree freedom a power of 90% would be achieved.

On completion of data collection, data will be analyzed by the central study team at the University of Edinburgh. Data will be analyzed using SPSS Statistics v. 27.0 software (IBM, USA) with continuous variables analyzed using range and standard measures of central tendency (mean and standard deviation or median and interquartile range according to assessment of whether raw data is parametric or not). Any comparison between study groups will use the chi-squared test (categorical variables) and paired t-test or non-parametric Mann-Whitney U test (continuous variables) as appropriate. Statistical significance will be set at $p < 0.05$.

Ethical considerations and approval. The protocol was reviewed by the South East Scotland Research Ethics Service and a letter of exemption provided on 3 July 2020 as this is considered a multicentre audit. The study was registered with the NHS Lothian Musculoskeletal Quality Improvement Group. Local investigators will be responsible for ensuring the study is registered and approval gained from relevant local clinical audit departments, information governance, or research and development departments, as appropriate in their centre.

Patient and public involvement. A lay member of the East of Scotland Research Ethics Service (EoSRES) was consulted in the development of the study design and telephone questionnaire.

Discussion

This protocol describes the methodology for the first national multicentre observational study assessing the practice patterns, clinical outcome, and patient satisfaction of VFCs in the UK. A review of existing literature indicates there is a paucity of empirical studies evaluating the role and management of VFCs during the COVID-19 pandemic.

A number of recent articles have described the rapid adoption and evolution of VFC services during the pandemic.[9,17-20] The general principles of the VFC model as outlined by the original centre remain the same.[2,9,12] However, there is variation in practice across the UK, including the grade of staff making management decisions, provision of verbal and written information, and local treatment protocols for specific injuries.[12] Prior to the pandemic, several studies have reported good acceptability of the VFC model in their local centres in the management of specific injuries, such as fifth metacarpal fractures,[3,21] fifth metatarsal fractures,[3,22] clavicle fractures,[23] mallet finger injuries,[24] and ankle fractures.[25] However, a high index of suspicion and expertise may be required in the management of other types of injuries with lower prevalence but higher morbidity where radiographs may be misinterpreted, to avoid adverse outcomes and complications.[12,15]

This national multicentre study will assess outcomes from a large and nationally representative cohort of patients who have undergone VFC assessment and management of their injuries. The large sample size and multicentre data collection on a national scale will improve external validity regarding the outcome of VFC management. This study is pragmatic and will account for variations in routine clinical practice in all relevant

UK hospitals. It will also expand the evidence base on the spectrum of injuries that may be safely incorporated into the VFC model during and beyond the COVID-19 pandemic. Specific strengths and potential limitations of the study are summarized in Table II. The investigators hope this national collaborative will provide a quality improvement platform to streamline outpatient services to further improve clinical outcome, and generate evidence to inform future consensus or interventional studies on the effective virtual management of orthopaedic trauma.

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