

AWARD NUMBER: W81XWH-18-1-0083

TITLE: Addressing Neuromuscular Deficits for Improved Outcomes in Ankle
Rehabilitation

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14. ABSTRACT The primary purpose of this study will seek to identify lateral ankle sprain (LAS) patients that do not respond to physical rehabilitation under a traditional medical model and who subsequently develop chronic ankle instability (CAI). The proposed study will evaluate established clinical outcomes along with innovative measures of brain and spinal cord function and ankle joint stability during a one-year follow-up after injury. Our hypothesis is that patients who develop CAI within one-year after injury will demonstrate poorer clinical outcomes, larger alterations in innovative measures of brain and spinal cord function, and early ankle joint cartilage turnover compared to the LAS patients that develop into Copers. The secondary purpose of this study will be to transition the results to methods that can be applied in multiple rehabilitation settings across civilian and military treatment facilities. We will determine which clinical measures are most related to the advanced brain and spinal cord measures.						
15. SUBJECT TERMS Lateral ankle sprain; sensorimotor; musculoskeletal treatment; physical readiness						
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1. INTRODUCTION

Lateral ankle sprains (LAS) are the most commonly reported injury in military and civilian populations. Up to 70% of those who sustain a LAS will develop chronic ankle instability (CAI), with re-injury and persistent functional disability. In the military, those who suffer from CAI typically have less service time prior to discharge as a function of the physical limitations imposed by the ankle injury. Many with LAS history will develop ankle joint degeneration, marked by changes in its cartilage and has been shown even in young adults. This suggests the need to determine why some individuals follow the cascade of events of sustaining a LAS, to developing CAI, to developing osteoarthritis. A strong contribution to CAI appears to be related to lingering changes in the structure of the brain, which impacts efficient cortical regulation of overall body control. Standard of care (SOC) for LAS typically consists of symptom management or activity modification and a recovery protocol to improve motion and strength of the ankle but does not typically address central nervous system (CNS) deficiencies. However, the high rate of CAI suggests the SOC may not be sufficient. The purpose of this study is to compare the success of an innovative sensorimotor ankle rehabilitation training (SMART) protocol to mitigate the CNS deficiencies that likely lead to CAI and ankle joint degeneration. Ultimately, this study will utilize an integrative medicine approach (brain/spinal cord influence on neuromusculoskeletal injury rehabilitation) to address a common issue (why some people respond to treatment and are able to return to normal activities, while others do not) associated with LAS. This will improve the ability to disrupt the cascading transition from LAS to potential joint degeneration. This innovative and integrative approach to rehabilitation will significantly impact the short and long-term health and well-being of those affected by LAS.

2. KEYWORDS

Lateral ankle sprain; sensorimotor; musculoskeletal treatment; physical readiness

3. ACCOMPLISHMENTS

Major Goals and Accomplishments

SOW Goals	Timeline	Achieved
Major Task 1: Administrative Objectives	Months	Y/N
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	Y
Finalize consent form & human subjects protocol	1-3	Y
Coordinate with Sites for IRB protocol submission	1-3	Y
Coordinate with Sites for University of Kentucky IRB review	1-6	Y
Coordinate with Sites for University of North Carolina IRB review	1-6	Y
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	Y
<i>Milestone Achieved: Local IRB approval at UK, UNC and BAMC</i>	3	Y
<i>Milestone Achieved: HRPO approval for all protocols and local IRB approval through University of Kentucky.</i>	18	Y
Coordinate with Sites for job descriptions design	1-4	Y
Advertise and interview for project related staff	1-5	Y
Coordinate for space allocation for new staff	1-6	Y
Coordinate with Sites for Independent Evaluators hiring and trainings	5-11	Y
Coordinate with Sites for training Independent Evaluators until 100% concordance	8-11	Y
<i>Milestone Achieved: Research staff trained</i>	8-11	Y
Quarterly Reports to USAMRMC	Quarterly	Y
Annual Reports to USAMRMC	Annually	Y
Major Task 2: Technical Objectives		
Finalize assessment measurements	1-4	Y
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-6	Y
<i>Milestone Achieved: 1st participant consented, screened and enrolled at each site</i>	7-8	Y
Subject recruitment. Participants complete follow-up assessments upon completion of physical therapy for acute LAS	7-32	Y
Complete follow-up assessments 6 months after completion of physical therapy	13-38	N
Complete follow-up assessments 12 months after completion of physical therapy	19-44	N
Milestone Achieved: All participants enrolled and follow-up assessments completed	44	N
Data Analysis: Clinical, CNS, and MRI outcomes	7-48	N
Data interpretation and dissemination	36-48	N
<i>Milestone Achieved: Report findings from completed assessments</i>	36-48	N
Coordinate with Sites for annual IRB report for continuing review	Annually	Y
Submit amendments, adverse events and protocol deviations as needed	As Needed	N

Summary

Human Subject Protections

Summary from Year 1: Approval of human subject protections was initiated in MAY 18 between the IRB offices of UK, UNC and WBAMC. Reliance agreements were discussed to recognize UK as the primary site for the study for all IRB offices. Initial approval of the study was obtained by the UK IRB on 10 MAY 18. Initial HRPO documents were submitted 4 JUN 18. Notification of receipt and initiation of review was received from Brittane Foy at MPMC on 11 JUN 18. Initial HRPO Administrative Review was received 2 AUG 18. Responses and supporting documents were returned to Brittane Foy 10 AUG 18. Second HRPO Administrative Review was received 5 NOV 18. Much of the 2nd Administrative Review required coordination and revisions to documents relative to WBAMC. From NOV 18 to JAN 19, Dr. Gribble coordinated with Larissa Schmersal, WBAMC Human Protections Administrator, to address requested revisions, as well as begin preparing CLAR materials to be submitted from WBAMC after HRPO review. By the end of Year 1 period (15 MAR 19), HRPO approval was not yet received.

Summary from Year 2: During Year 2, after a 4th HRPO Administrative Review was completed in MAY 19, initial HRPO approval was received 5 JUL 19. During JUL and AUG 19, Dr. Gribble prepared and submitted substantive changes to the protocol, including a site-PI change at WBAMC (CPT Golden) and modifications to the shared consent form. The Amendment Approval was received 6 SEP 19. Enrollment commenced in OCT 19. In JAN 20 during the UK IRB annual review, an oversight was discovered in the previously approved consent form related to HIPAA language that was not allowable by UK. Dr. Gribble worked with UK IRB, Dr. Schmersal and HRPO personnel during JAN 20 to modify the consent form to remove the HIPAA language and an Amendment Request was submitted 1 FEB 20, and approval of this amendment was received 11 MAR 20. Previously enrolled participants at all sites were re-consented with the new consent form. The HRPO Continuation Review was submitted in conjunction with the Amendment approval described above and was approved 11 MAR 20.

During Year 3, a simple modification request was submitted to the UK IRB and approved on 6 APR 20 to expand recruitment methods to “word of mouth” at all sites. This was to allow broader recruitment potential, particularly in light of COVID-19 restrictions in operations that had begun in MAR 20. In SEP 20, UK allowed researchers to submit resumption of research plans that involved university facilities and previously approved IRB protocols. Dr. Gribble submitted a request to resume operations of the SMART study within the UK Sports Medicine Research Institute, with prescribed COVID-19 screening procedures of research personnel and participants, restrictions of number of personnel present with limitations of contact under 6 feet to less than 15 minutes, and utilization of personal protective equipment and cleaning procedures. This allowed the study team at UK to bring enrolled participants into the laboratory for 6 and 12-month follow-up testing during this reporting period. Also, with this approved resumption plan, we were allowed to enroll new participants under these guidelines; however, no new referrals for enrollment were received during this time period at UK, which we attribute to the societal restrictions from COVID-19. The UNC site underwent

similar modifications to research operations during this same time period and were able to enroll one new participant. The WBAMC site remained operational but with restrictions. However, the departure of Ms. Katie Roberts and the vacancy in the Clinical Research Coordinator position limited any new enrollments at this site during the reporting period.

In SEP 20, CPT Golden informed Dr. Gribble that he would be leaving WBAMC due to transfer orders, and that his replacement, CPT Shawn Stoute, had been named. Dr. Gribble and CPT Stoute began communications in SEP 20 regarding assuming the role of site-PI at WBAMC and Dr. Larissa Schmersal at WBAMC IRB was informed. After review at WBAMC, the substantive change for the site-PI change was filed with the UK IRB and approval was received on 10 OCT 20 (see Appendix). Subsequent to the IRB approval, Dr. Gribble prepared and submitted a substantive change request for the site-PI change to HRPO on 21 OCT 20. Approval from HRPO was provided on 2 NOV 20 (see Appendix).

Dr. Gribble submitted documentation for an annual continuation review to the UK IRB on 8 DEC 20. Approval from the UK IRB was received on 10 DEC 20. Dr. Gribble submitted the notification of the UK IRB continuation review to HRPO on 5 JAN 21. Approval from HRPO was provided on 14 JAN 21 (see Appendix). Dr. Gribble alerted Ms. Katelyn Murter that on the approval documentation, CPT Golden was listed incorrectly as the WBAMC contact list, which was acknowledged and corrected to CPT Stoute (see Appendix).

Personnel

Dr. Kyle Kosik was promoted within the University of Kentucky from a post-doctoral research fellow to an assistant professor in the JUL 20.

Mrs. Katie Roberts left her position as Clinical Research Coordinator at the WBAMC site on 1 SEP 20 to accompany her husband who received a transfer order from Ft. Bliss to another military installation. The open position has been advertised through the Geneva Foundation, related professional organizations websites, and multiple social media outlets. Dr Gribble has received 10 applications to the position from SEP 20 - MAR 21. After initial email communication with the applicants when the materials were received, 5 applicants were offered a phone interview with Dr. Gribble; and 3 were then invited to participate in Zoom calls with SMART team members (Stoute, Kosik, Heebner, Bain). One applicant was offered the position in JAN 21, but declined due to a competing job offer. A second applicant was offered the position in MAR 21, but declined due to personal reasons prohibiting a move to El Paso. The recruiting process for this position is ongoing.

In OCT 20, CPT Golden began transitioning out of WBAMC for a transfer effective DEC 20 and was replaced at WBAMC by CPT Shawn Stoute. Dr. Gribble worked with CPT Golden and CPT Stoute OCT-DEC 20 for the transfer of this position within the study. A substantive change was filed with UK IRB and approved on 20 OCT 20. A substantive change was then filed with HRPO and approved on 2 NOV

20 (see Appendix). Subsequently, CPT Stoute assumed the role of Site-PI for WBAMC for the project in NOV 20.

Equipment Acquisition

No equipment acquisitions took place in Year 2 of the project.

SOP Procedures and Site Visit

Site visits by Dr. Gribble to WBAMC and UNC were discussed with site personnel, but all plans were suspended when COVID-19 related travel restrictions emerged and persisted throughout the reporting period.

Opportunities for Training and Professional Development

Nothing to Report

Dissemination of Results to Communities of Interest

Nothing to Report

Plan for Next Reporting Period

As of this report, 10 participants have been enrolled across the three sites (UK: 4, UNC: 4; WBAMC: 2). Due to an 18-month delay in initial HRPO approval followed by a 12-month interruption from COVID-19 restrictions that began in MAR 20, our goal of 50% enrollment and completion of interventions by the end of CY 19 had to be modified. We will continue to aggressively recruit; however, our sites have been experiencing considerable reductions in expected referrals since the global pandemic began. A recent published paper demonstrated that Emergency Department census for orthopedic injuries has been significantly down in the United Kingdom since the pandemic began (see Appendix), which mirrors what our study sites have been experiencing. We are encouraged that during the pandemic-driven shut-down, the UK and UNC sites were still able to maintain research facility operations at a modified level. This allowed one new participant to be enrolled at UNC and complete the intervention. At UK, we were able to complete the intervention for two participants enrolled just before the pandemic began. During this reporting period, some 6-month and 12-month follow-up sessions were completed at UK and UNC. We anticipate that additional follow-up sessions of previously enrolled participants will proceed successfully during this next reporting period. We anticipate that our enrollment numbers will increase in the CY 21, but our intended timeline for study completion of enrollment and 1year follow-ups by the end of CY 21 will have to be modified. Because of this, we anticipate discussing the possibility of no-cost extension periods in order to complete the objectives of the study successfully.

4. IMPACT

Impact on Principal Disciplines of the Project

Nothing to Report

Impact on Other Disciplines

Nothing to Report

Impact on Technology Transfer

Nothing to Report

Impact on Society Beyond Science and Technology

Nothing to Report

5. CHANGES/PROBLEMS

Changes in Approach and Rationale

Nothing to Report

Actual or Anticipated Problems or Delays

We had an 18-month delay in the start of our enrollment while waiting for initial HRPO approval and amendments of our study protocols. A detailed summary of the timeline seeking HRPO approval is provided in our previous annual reports.

We anticipated that in Year 3, there would be delays in additional enrollment due to the COVID-19 outbreak that began to affect the United States in FEB 20. In anticipation, we explored and prepared methods to maintain enrollment growth, but there were very few referrals to our study, which we attribute to the societal restrictions in place. At UK and UNC, university restrictions were in place for many months, preventing utilization of the research facilities through the summer of 20. However, we were able to pivot to a telehealth format to complete interventions on 2 participants previously enrolled before COVID-restrictions began. Fortunately, research operations were allowed to resume in fall 20, with appropriate limitations and safety guidelines, in time for the data collection sessions to commence such that we did not forfeit opportunities to obtain follow-up data on previously enrolled participants.

The Clinical Research Coordinator, Mrs. Katie Roberts, serving at the WBAMC site resigned her position for personal reasons on 1 SEP 20 to accompany her husband who received a transfer order from Ft. Bliss to another military installation. Significant effort has been made to fill this position, but with COVID-19 restrictions still in place SEPT 20-MAR 21, and with El Paso, TX exhibiting some of the highest numbers of COVID-19 during this time period, it has been very challenging to find a qualified replacement that was willing to relocate to one

of the largest hotspots of reported COVID-19 cases in the country during this reporting period. A new site-PI, CPT Stoute, was secured at WBAMC as of 2 NOV 20. However, without the CRC, recruitment for this site has been halted as the site-PI cannot conduct the interventions due to blinding considerations as part of the study design. When the new CRC is in place, we anticipate study activity will increase significantly at WBAMC.

In spite of our efforts and alternative strategies, the COVID-19 pandemic has created a significant delay in study operations over the last 12 months. We are hopeful that in the coming year, these barriers will lessen and our trajectory of accomplishing study objectives will resume.

Changes in Expenditures

With the vacancy of the Clinical Research Coordinator 1 SEP 20 – 14 MAR 21, there were no study related expenditures on the Geneva Foundation sub-award related to this position during these months.

At UK, due to interrupted operations, Dr. Gribble decreased the effort of some study personnel and his own effort. This included declines for Dr. Gribble (20% to 16%), and Nathan Johnson (15% to 10%).

At UK, Dr. Kosik received funding from another research grant, allowing his effort to be modified on the SMART study from 89% to 79%.

The stipend and tuition for the spring semester for Ms. Katie Bain, doctoral student research assistant at UK, was paid through funds from the UK College of Health Sciences Office of Research in an effort to preserve funds for later study operations.

These all lead to creating some surplus in the operating budget which the Dr. Gribble as PI envisions could be used if no-cost extension periods are granted.

Changes in Use or Care of Human Subjects

Nothing to Report

6. PRODUCTS, INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Publications, Conference Papers, and Presentations

Nothing to Report

Websites or Other Internet Sites

Nothing to Report

Technologies or Techniques

Nothing to Report

Inventions, Patent Applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**Individuals Working on Project**

Name:	Phillip Gribble
Project Role:	Principal Investigator
Nearest person month worked:	2
Contribution to Project:	Provide scientific oversight to the project and direct activities at UK, UNC and WBAMC. Assumes responsibility for the scientific integrity of the project; works closely with the site-PIs to ensure validity of the data and observations from the investigators. Ensure compliance with specific terms and conditions of the award as stated in the award notification. Supervise and co-mentor graduate student researchers.
Funding Support:	N/A
Name:	Nick Heebner
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Assist with data collection, interpretation and analysis
Funding Support:	N/A
Name:	Matt Hoch
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Assist with data interpretation and analysis
Funding Support:	N/A

Name:	Nathan Johnson
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Assist with data collection, interpretation and analysis
Funding Support:	N/A
Name:	David Powell
Project Role:	Co-Investigator
Nearest person month worked:	0
Contribution to Project:	Assist with data interpretation.
Funding Support:	N/A
Name:	Kyle Kosik
Project Role:	Co-Investigator
Nearest person month worked:	5
Contribution to Project:	Coordinate data collection sessions at UK. Assist with recruitment. Assist with data collection, interpretation and analysis
Funding Support:	N/A
Name:	Katherine Bain
Project Role:	Graduate Research Assistant
Nearest person month worked:	4.5
Contribution to Project:	Coordinate intervention sessions at UK. Assist with recruitment. Assist with data collection, interpretation and analysis
Funding Support:	1.5 months support on UK account
Name:	Erik Wikstrom
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Site PI at UNC. Provides oversight to all activities at UNC. Maintains communication with PI. Contributes to data interpretation and analysis from

	all sites.
Funding Support:	N/A
Name:	Katie Roberts
Project Role:	Co-Investigator
Nearest person month worked:	5
Contribution to Project:	Clinical Research Coordinator. Coordinate intervention sessions at WBAMC. Assist with recruitment at WBAMC. Assist with data collection, interpretation and analysis at WBAMC. Maintains communication with site-PI at WBAMC and study PI at UK.
Funding Support:	N/A

Change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period

NEW

Mathew Hoch

Title: (OR190060) Optimizing Functional Outcomes for Patients with Chronic Ankle Instability Using Foot Intensive Rehabilitation (FIRE)

Role: Principal Investigator

Time Commitments: 32%, 3.84 person months

Supporting Agency: United States Department of Defense

Performance Period: 09/01/2020 – 09/30/2024

Level of Funding:

Sub-Awards: University of Virginia, Naval Health Research Center

Goals: The purpose of this randomized controlled trial is to demonstrate that a novel Foot Intensive Rehabilitation (FIRE) protocol will create more effective clinical outcomes compared to standard of care rehabilitation for patients with chronic ankle instability.

Specific Aims: Aim 1: Determine the effect of FIRE on recurrent ankle sprain rates, frequency of ankle giving way episodes, and perceived CAI symptom severity. Aim 2: Determine the effect of FIRE on sensorimotor function in CAI patients. Aim 3: Determine the effect of FIRE on health-related quality of life in CAI patients.

Point of Contact: Akua Roach, PhD, PRORP, Program Manager,

akua.roach.civ@mail.mil

NEW

Phillip Gribble

Title: (OR190060) Optimizing Functional Outcomes for Patients with Chronic Ankle Instability Using Foot Intensive Rehabilitation (FIRE)

Role: Co-Investigator

Time Commitments: 5%, 0.6 person months

NEW

Nick Heebner

Title: (OR190060) Optimizing Functional Outcomes for Patients with Chronic Ankle Instability Using Foot Intensive Rehabilitation (FIRE)

Role: Co-Investigator

Time Commitments: 10%, 1.2 person months

NEW

Kyle Kosik

Title: Physical Rehabilitation Through Telehealth for an Ankle Sprain: A Randomized Controlled Trial

Role: Principal Investigator

Time Commitments: 8%, 1 person month

Supporting Agency: NATA Research & Education Foundation

Performance Period: 06/15/2020 to 06/30/2023

Level of Funding:

Goals: The *overall objectives* of this study are to compare levels of acute pain and disability; quantify use of pain medication; and evaluate the perceived barriers to implementing a 2-week telehealth intervention or usual care for ankle sprain patients discharged from the Emergency Department.

Specific Aims: Aim 1: Compare levels of pain and disability among ankle sprain patients (age 15-35 years) discharged from the ED that complete either a 2-week telehealth intervention or a usual care protocol. Aim 2: Compare opioid and non-opioid medication utilization among ankle sprain patients (age 15-35 years) discharged from the ED that complete either a 2-week telehealth intervention or a usual care protocol. Aim 3: Compare patient perceived barriers to implementing a 2-week telehealth intervention and the usual care for an ankle sprain among patients (age 15-35 years) discharged from the ED.

Point of Contact: Jennifer Earl-Boehm, PhD, ATC, Chair, Research Committee, 800.879.6282

Other Involved Partner Organizations

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS**Collaborative Awards**

Nothing to Report

Quad Chart

Addressing neuromuscular deficits for improved outcomes in ankle sprain rehabilitation

Program: Joint Program Committee 8/Clinical & Rehabilitative Medicine Research Program

Funding Opportunity Number: W81XWH-17-DMRDP-CRMRP-NMSIRRA



PI: Gribble, Phillip A

Org: University of Kentucky

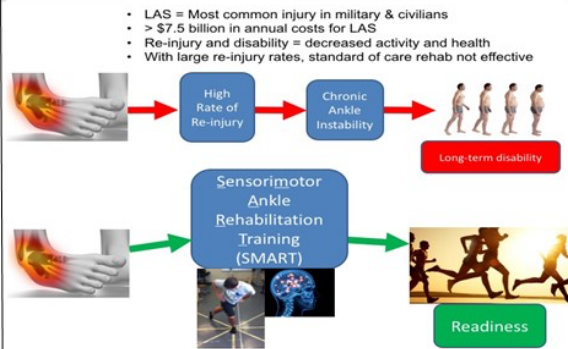
Award Amount: \$2.5 million

Study/Product Aim(s)

- Aim #1:** Determine if a novel sensorimotor ankle rehabilitation training (SMART) protocol improves clinical outcomes (patient-reported function and quality of life, lateral ankle sprain (LAS) re-injury rates, postural control, ankle ROM) and ankle joint integrity (articular cartilage turnover) in LAS patients.
- Aim #2:** Determine if SMART improves innovative measures of central nervous system (CNS) function (corticospinal excitability and brain white matter integrity) in LAS patients.
- Aim #3:** Delineate the association between explanatory mechanistic measures (corticospinal excitability and brain white matter integrity) and the hypothesized improvements in clinical and ankle joint integrity in LAS patients receiving SMART.

Approach

We will compare SMART protocol against a standard of care protocol to demonstrate successful 1-year outcomes and lower rates of re-injury and disability. We expect improvement in clinical outcomes, CNS function and joint health, improving health in LAS patients, bringing translational application to military personnel.



Timeline and Cost

Activities	CY	18	19	20	21
Regulatory/human subjects		█			
Participant enrollment, intervention implementation, post-testing			█	█	
1-year follow up testing				█	█
Analysis of clinical, sensorimotor and MRI outcomes		█	█	█	█
Estimated Budget (\$K)		\$745	\$565	\$580	\$610

Goals/Milestones

CY19 Goal – 25% enrollment

Post-testing complete on 25% of sample

Analysis of outcomes begins

CY20 Goals – 100% enrollment

Post-testing complete on 100% of sample

1 year follow up complete on 50% of sample

Analysis of outcomes continues

CY21 Goal – Completion of follow-up and outcomes analysis

1 year follow up complete on 100% of sample

Analysis of outcomes at all time points of 100% of sample

CY22 Goal

Dissemination of data

APPENDICES

- A. Letter – 20 OCT 20 from UK IRB to Dr. Phillip Gribble Re: approval of modification request to reflect substantive change of site-PI at WBAMC (page 18)
- B. Email – 2 NOV 20 from Ms. Andrea Kline to Dr. Phillip Gribble Re: HRPO approval of substantive change request (page 19)
- C. Letter – 10 DEC 20 from UK IRB to Dr. Phillip Gribble Re: approval of UK IRB Continuation Review (page 22)
- D. Email – 14 JAN 21 from Ms. Katelyn Murter to Dr. Phillip Gribble Re: HRPO approval of IRB Continuation Review (page 23)
- E. Email – 14 JAN 21 from Ms. Katelyn Murter to Dr. Phillip Gribble Re: acknowledgement of need to correct contact information for site-PI at WBAMC per HRPO approval (page 26)
- F. Published paper – Sephton et al, *The effect of COVID-19 on a Major Trauma Network. An analysis of mechanism of injury pattern, referral load and operative case-mix. In press* (page 32)



Modification Review

Approval Ends:
1/15/2021

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Modification Request

DATE: 10/20/2020

On 10/20/2020, the Medical Institutional Review Board approved your request for modifications in your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

In addition to IRB approval, you must also meet the requirements of the [VPR Resumption of Research Phased Plan](#) (i.e., waiver for Phase 1, training & individualized plan submission for Phases 2-4) before resuming/beginning your human subjects research. If your modification request necessitated a change in your approved informed consent/assent form(s), the new IRB approved consent/assent form(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]

Note that at Continuation Review, you will be asked to submit a brief summary of any modifications approved by the IRB since initial review or the last continuation review, which may impact subject safety or welfare. Please take this approved modification into consideration when preparing your summary.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

Subject: A-20657.1c, Amendment Approval Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Monday, November 2, 2020 at 4:02:20 PM Eastern Standard Time

From: Kline, Andrea J CIV USARMY MEDCOM USAMRMC (USA)

To: Stoute, Shawn M CPT USARMY MEDCOM BAMC (USA)

CC: 'kcarter.1@uky.edu', Office of Sponsored Projects Administration, Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (USA), Gribble, Phillip A., Meinberg, Christopher L CIV USARMY MEDCOM USAMRAA (USA), Ghannadian, D Jason CIV USARMY MEDCOM CDMRP (USA), Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (USA), Murter, Katelyn D CTR (USA)

CAUTION: External Sender

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Amendment for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by CPT Shawn M. Stoute, William Beaumont Army Medical Center, El Paso, Texas, in Support of the Proposal Submitted by Phillip A. Gribble, PhD, University of Kentucky, Lexington, Kentucky, Proposal Log Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Number A-20657.1c

1. The subject protocol received initial approval by the U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) on 5 July 2019.
2. An amendment to this no greater than minimal risk protocol was received by the HRPO on 28 October 2020. The University of Kentucky Institutional Review Board (IRB) approved the amendment on 20 October 2020.
3. The amendment allows for a change in the Principal Investigator from CAPT Andrew P. Golden to CPT Shawn Stoute.
4. The change proposed in the amendment has been reviewed by the HRPO and found to be acceptable. The HRPO approves the protocol amendment.
5. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil. Failure to comply could result in suspension of funding.
 - a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in the IRB of Record, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. A copy of the IRB continuing review approval letter must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the IRB is due no later than 15 January 2021. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrhc.other.hrpo@mail.mil), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

6. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

7. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

8. The HRPO point of contact for this action is Katelyn Murter, BA, Human Subjects

Protection Scientist, at 301-619-7839, DSN 343-7839, or katelyn.d.murter.ctr@mail.mil.

ANDREA J. KLINE, MS, CIP
Deputy Director
Human Research Protection Office
Office of Research Protections
U.S. Army Medical Research and Development Command

Note: The official copy of this memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 810 Schreider Street, Fort Detrick, MD 21702-5000. Signed copies will be provided upon request.

CLASSIFICATION: UNCLASSIFIED



XP Continuation Review

Approval Ends:
12/9/2021

IRB Number:
44172

TO: Phillip Gribble, PhD, ATC
Health Sciences - Rehabilitati
PI phone #: 859- 218-0885

PI email: phillip.gribble@uky.edu

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval for Continuation

DATE: 12/10/2020

On 12/10/2020, the Medical Institutional Review Board approved your protocol entitled:

Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation

Approval is effective from 12/10/2020 until 12/9/2021 and extends to any consent/assent form, cover letter, and/or phone script. In addition to IRB approval, you must also meet the requirements of the [VPR Resumption of Research Phased Plan](#) (i.e., waiver for Phase 1, training & individualized plan submission for Phases 2-4) before resuming/beginning your human subjects research. If applicable, the IRB approved consent/assent document(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review (CR)/Administrative Annual Review (AAR) request which must be completed and submitted to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "[PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research](#)" available in the online Office of Research Integrity's [IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

Subject: A-20657.1a, A-20657.1b, and A-20657.1c, Continuing Review Acknowledgement Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

Date: Thursday, January 14, 2021 at 9:47:34 AM Eastern Standard Time

From: Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA)

To: Gribble, Phillip A., Wikstrom, Erik A., Golden, Andrew P CPT USARMY MEDCOM BAMC (USA)

CC: 'kcarter.1@uky.edu', Office of Sponsored Projects Administration, Bennett, Jodi H CIV USARMY FUTURES COMMAND (USA), Meinberg, Christopher L CIV USARMY FUTURES COMMAND (USA), Ghannadian, D Jason CIV USARMY FUTURES COMMAND (USA), Schmursal, Larissa A CIV USARMY MEDCOM WBAMC (USA), Kline, Andrea J CIV USARMY FUTURES COMMAND (USA), Larson, Karen, Brown, Joe, Odam, Kimberly L CIV USARMY FUTURES COMMAND (USA), Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA)

CAUTION: External Sender

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Acknowledgement of the Continuing Review Documents for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip A. Gribble, PhD, University of Kentucky (UK), Lexington, Kentucky, Erik Wikstrom, PhD, University of North Carolina (UNC), Chapel Hill, North Carolina, and CAPT Andrew P. Golden, William Beaumont Army Medical Center (WBAMC), El Paso, Texas, Proposal Log Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Numbers A-20657.1a (UK Site), A-20657.1b (UNC Chapel Hill Site), and A-20657.1c (WBAMC Site)

1. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 5 July 2019.
2. The USAMRDC ORP HRPO received the UK Institutional Review Board (IRB) approval on 12 January 2021. The UNC, Chapel Hill and the WBAMC are relying on the review provided by the UK Institutional Review Board (IRB). The UK IRB approved continuation of the subject protocol on 10 December 2020; this approval will expire on 9 December 2021.
3. This correspondence serves to acknowledge the HRPO receipt of the continuing review documents for the protocol. No further action related to this continuing review is needed. The documents in support of this continuing review will be placed in the HRPO file.
4. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to usarmy.detrick.medcom-usamrhc.other.hrpo-cr-documents@mail.mil. Failure to comply could result in suspension of funding.
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 - b. A copy of the IRB continuing review approval letter must be submitted to the HRPO as soon as possible after receipt of approval. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

5. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

6. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this study is Katelyn Murter, BA, Human Subjects Protection Scientist, at 301-619-7839, DSN 343-7839, or Katelyn.d.murter.ctr@mail.mil.

Regards,

Katelyn D. Murter, BA
Human Subjects Protection Scientist
General Dynamics Health Solutions
Human Research Protection Office
Office of Research Protections
U.S. Army Medical Research and Development Command
Fort Detrick, Maryland

Phone: 301-619-7839, DSN: 343-7839

Email: Katelyn.d.murter.ctr@mail.mil

To notify HRPO of changes to the conduct of DoD-supported research due to COVID-19:
usarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil or 301-619-2165

Need Guidance?

See: [https://nam04.safelinks.protection.outlook.com/?](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmrdc.amedd.army.mil%2Findex.cfm%2Fcollaborate%2Fresearch_protections%2Fhrpo%2Ffaqs&data=04%7C01%7Cphillip.gribble%40uky.edu%7Cd211c4ded55840744aa308d8b89b6c72%7C2b30530b69b64457b818481cb53d42ae%7C0%7C0%7C637462324991989781%7CUnknown%7CTWFpbGZsb3d8eyJWljiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IjE6IjEhaWwiLCJXVCI6ImN0%3D%7C3000&data=CGyfkYrGZY%2FdLZAT70KpuurdSiv%2FlxpOE9PaliyzWDM%3D&reserved=0)

[url=https%3A%2F%2Fmrdc.amedd.army.mil%2Findex.cfm%2Fcollaborate%2Fresearch_protections%2Fhrpo%2Ffaqs&data=04%7C01%7Cphillip.gribble%40uky.edu%7Cd211c4ded55840744aa308d8b89b6c72%7C2b30530b69b64457b818481cb53d42ae%7C0%7C0%7C637462324991989781%7CUnknown%7CTWFpbGZsb3d8eyJWljiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IjE6IjEhaWwiLCJXVCI6ImN0%3D%7C3000&data=CGyfkYrGZY%2FdLZAT70KpuurdSiv%2FlxpOE9PaliyzWDM%3D&reserved=0](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmrdc.amedd.army.mil%2Findex.cfm%2Fcollaborate%2Fresearch_protections%2Fhrpo%2Ffaqs&data=04%7C01%7Cphillip.gribble%40uky.edu%7Cd211c4ded55840744aa308d8b89b6c72%7C2b30530b69b64457b818481cb53d42ae%7C0%7C0%7C637462324991989781%7CUnknown%7CTWFpbGZsb3d8eyJWljiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IjE6IjEhaWwiLCJXVCI6ImN0%3D%7C3000&data=CGyfkYrGZY%2FdLZAT70KpuurdSiv%2FlxpOE9PaliyzWDM%3D&reserved=0)

CLASSIFICATION: UNCLASSIFIED

Subject: RE: [Non-DoD Source] RE: A-20657.1a, A-20657.1b, and A-20657.1c, Continuing Review
Acknowledgement Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)
Date: Thursday, January 14, 2021 at 10:06:55 AM Eastern Standard Time
From: Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA)
To: Gribble, Phillip A.

CAUTION: External Sender

CLASSIFICATION: UNCLASSIFIED

Hi Phillip,

Thank you for catching this, I apologize for the oversight. I have made sure to update our list of study contacts.

Take care,

Katelyn D. Murter, BA
Human Subjects Protection Scientist
General Dynamics Health Solutions
Human Research Protection Office
Office of Research Protections
U.S Army Medical Research and Development Command
Fort Detrick, Maryland

Phone: 301-619-7839, DSN: 343-7839
Email: Katelyn.d.murter.ctr@mail.mil

To notify HRPO of changes to the conduct of DoD-supported research due to COVID-19:
usarmy.detrick.medcom-usamrmc.mbx.COVID-19@mail.mil or 301-619-2165

Need Guidance?

See: https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmrdd.amedd.army.mil%2Findex.cfm%2Fcollaborate%2Fresearch_protections%2Fhrpo%2Ffaqs&data=04%7C01%7CPhillip.Gribble%40uky.edu%7C88ce9b987eb0422d924708d8b89e2e1f%7C2b30530b69b64457b818481cb53d42ae%7C0%7C0%7C637462336811323928%7CUnknown%7CTWFpbGZsb3d8eyJWljiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IklhaWwiLCJXVCi6Mn0%3D%7C1000&data=yMqsuGYmYcdQE8%2F%2F7Rxqts3GaEgBeNI4fWla99r2mys%3D&reserved=0

-----Original Message-----

From: Gribble, Phillip A. [<mailto:phillip.gribble@uky.edu>]
Sent: Thursday, January 14, 2021 10:00 AM
To: Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA) <katelyn.d.murter.ctr@mail.mil>; Wikstrom, Erik A. <ewikstro@email.unc.edu>; Stoute, Shawn M CPT USARMY MEDCOM WBAMC (USA) <shawn.m.stoute.mil@mail.mil>
Cc: Office of Sponsored Projects Administration <OSPA@uky.edu>; Bennett, Jodi H CIV USARMY FUTURES COMMAND (USA) <jodi.h.bennett.civ@mail.mil>; Meinberg, Christopher L CIV USARMY FUTURES COMMAND (USA) <christopher.l.meinberg.civ@mail.mil>; Ghannadian, D Jason CIV USARMY FUTURES COMMAND (USA) <darius.j.ghannadian.civ@mail.mil>; Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA)

<larissa.a.schmersal.civ@mail.mil>; Kline, Andrea J CIV USARMY FUTURES COMMAND (USA)
<andrea.j.kline.civ@mail.mil>; Larson, Karen <klars2@uky.edu>; Brown, Joe <joe.brown@uky.edu>; Odam, Kimberly
L CIV USARMY FUTURES COMMAND (USA) <kimberly.l.odam.civ@mail.mil>
Subject: [Non-DoD Source] RE: A-20657.1a, A-20657.1b, and A-20657.1c, Continuing Review Acknowledgement
Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Katelyn,

Thank you very much for the update and approval information of the continuing review.

I wanted to note that I have copied CPT Shawn Stoute on this reply as the recent replacement for CPT Andrew Golden as the site PI at WBAMC. This change was approved 20 OCT 20 by the UK IRB as a modification request and received HRPO approval on 2 NOV 20. I noticed that CPT Golden was still on the list of contacts in the email, but CPT Stoute had not been added, so I wanted to make sure I included him.

Thank you again,

Phillip

Phillip Gribble, PhD, ATC, FNATA

Chair and Professor

University of Kentucky

Department of Athletic Training & Clinical Nutrition, College of Health Sciences

210 Charles T. Wethington Building

Lexington, KY 40536-0200

859-218-0885 <tel:859-218-0885 >

phillip.gribble@uky.edu

-----Original Message-----

From: Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA) <katelyn.d.murter.ctr@mail.mil>

Sent: Thursday, January 14, 2021 9:48 AM

To: Gribble, Phillip A. <phillip.gribble@uky.edu>; Wikstrom, Erik A. <ewikstro@email.unc.edu>; Golden, Andrew P CPT USARMY MEDCOM BAMC (USA) <andrew.p.golden3.mil@mail.mil>

Cc: 'kcarter.1@uky.edu' <kcarter.1@uky.edu>; Office of Sponsored Projects Administration <OSPA@uky.edu>; Bennett, Jodi H CIV USARMY FUTURES COMMAND (USA) <jodi.h.bennett.civ@mail.mil>; Meinberg, Christopher L CIV USARMY FUTURES COMMAND (USA) <christopher.l.meinberg.civ@mail.mil>; Ghannadian, D Jason CIV USARMY FUTURES COMMAND (USA) <darius.j.ghannadian.civ@mail.mil>; Schmersal, Larissa A CIV USARMY MEDCOM WBAMC (USA) <larissa.a.schmersal.civ@mail.mil>; Kline, Andrea J CIV USARMY FUTURES COMMAND (USA) <andrea.j.kline.civ@mail.mil>; Larson, Karen <klars2@uky.edu>; Brown, Joe <joe.brown@uky.edu>; Odam, Kimberly L CIV USARMY FUTURES COMMAND (USA) <kimberly.l.odam.civ@mail.mil>; Murter, Katelyn D CTR USARMY FUTURES COMMAND (USA) <katelyn.d.murter.ctr@mail.mil>

Subject: A-20657.1a, A-20657.1b, and A-20657.1c, Continuing Review Acknowledgement Memorandum (Proposal Log Number DM170430, Award Number W81XWH-18-1-0083) (UNCLASSIFIED)

CAUTION: External Sender

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Acknowledgement of the Continuing Review Documents for the Protocol, "Addressing Neuromuscular Deficits for Improved Outcomes in Ankle Rehabilitation," Submitted by Phillip A. Gribble, PhD, University of Kentucky (UK), Lexington, Kentucky, Erik Wikstrom, PhD, University of North Carolina (UNC), Chapel Hill, North Carolina, and CAPT Andrew P. Golden, William Beaumont Army Medical Center (WBAMC), El Paso, Texas, Proposal Log Number DM170430, Award Number W81XWH-18-1-0083, HRPO Log Numbers A-20657.1a (UK Site), A-20657.1b (UNC Chapel Hill Site), and A-20657.1c (WBAMC Site)

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2. The USAMRDC ORP HRPO received the UK Institutional Review Board (IRB) approval on 12 January 2021. The UNC, Chapel Hill and the WBAMC are relying on the review provided by the UK Institutional Review Board (IRB). The UK IRB approved continuation of the subject protocol on 10 December 2020; this approval will expire on 9 December 2021.
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4. The Principal Investigator must provide the following post-approval submissions to the HRPO via email tousarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil < Caution-<mailto:usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil> > . Failure to comply could result in suspension of funding.

a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in the IRB of Record, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

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7. The HRPO point of contact for this study is Katelyn Murter, BA, Human Subjects Protection Scientist, at 301-619-7839, DSN 343-7839, [orKatelyn.d.murter.ctr@mail.mil](mailto:Katelyn.d.murter.ctr@mail.mil) < Caution-<mailto:Katelyn.d.murter.ctr@mail.mil> > .

Regards,

Katelyn D. Murter, BA

Human Subjects Protection Scientist

General Dynamics Health Solutions

Human Research Protection Office

Office of Research Protections

U.S Army Medical Research and Development Command Fort Detrick, Maryland

Phone: 301-619-7839, DSN: 343-7839

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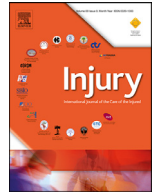
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The effect of COVID-19 on a Major Trauma Network. An analysis of mechanism of injury pattern, referral load and operative case-mix

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ABSTRACT

Purpose: The aim of this study was to evaluate changes in both mechanism and diagnoses of injuries presenting to the orthopaedic department during this lockdown period, as well as to observe any changes in operative case-mix during this time.

Methods: A study period of twelve weeks following the introduction of the nationwide "lockdown period", March 23rd – June 14th, 2020 was identified and compared to the same time period in 2019 as a "baseline period". A retrospective analysis of all emergency orthopaedic referrals and surgical procedures performed during these time frames was undertaken. All data was collected and screened using the 'eTrauma' management platform (Open Medical, UK). The study included data from a five NHS Foundation Trusts within North West London. A total of 6695 referrals were included for analysis.

Results: The total number of referrals received during the lockdown period fell by 35.3% (n=2631) compared to the same period in 2019 (n=4064). Falls remained proportionally the most common mechanism of injury across all age groups in both time periods. The proportion sports related injuries compared to the overall number of injuries fell significantly during the lockdown period (p<0.001), however, the proportion of pushbike related accidents increased significantly (p<0.001). The total number of operations performed during the lockdown period fell by 38.8% (n=1046) during lockdown (n=1732). The proportion of patients undergoing operative intervention for Neck of Femur (NOF) and ankle fractures remained similar during both study periods. A more non-operative approach was seen in the management of wrist fractures, with 41.4% of injuries undergoing an operation during the lockdown period compared to 58.6% at baseline (p<0.001).

Conclusion: In conclusion, the nationwide lockdown has led to a decrease in emergency orthopaedic referrals and procedure numbers. There has been a change in mechanism of injuries, with fewer sporting injuries, conversely, there has been an increase in the number of pushbike or scooter related injuries during the lockdown period. NOF fractures remained at similar levels to the previous year. There was a change in strategy for managing distal radius fractures with more fractures being treated non-operatively.

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Introduction

In December 2019, an epidemic of a novel coronavirus (COVID-19) emerged, with its geographical epicentre in Wuhan City, China.

At present more than 12.5 million cases and more than 560,000 deaths have been recorded worldwide [1]. In Britain social distancing measures were first introduced on March 16th followed by a nationwide lockdown on March 23rd 2020 [2]. Lockdown measures included instructions for individuals to stay at home bar visits out for essential food shopping and limited exercise, closing of non-essential businesses and a ban on social gatherings [2]. The over-riding aim of the nationwide lockdown was to the reduce spread

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of the virus and ease the burden on an already stretched National Health Service (NHS). Part of the NHS strategy was to maximise both in-patient and critical care capacity [3] through postponement of all non-urgent elective operations and rapid discharge of all hospital in-patients, who were medically fit to leave. Alongside this, there was mass redeployment of healthcare staff, rapid assessment and triage (RAT) protocols within emergency departments and conversion of surgical theatres into make-shift critical care units [4].

These changes led to several logistical challenges for many trauma and orthopaedic centres. Whilst the overall priority was to maximise resources for managing the COVID-19 outbreak; there remained an ongoing responsibility to ensure that emergency orthopaedic care continued. The British Orthopaedic Association (BOA) released guidelines for the management of traumatic injuries and urgent orthopaedic conditions during the coronavirus pandemic [5]. The overall outpatient strategy was an increased emphasis on managing patients non-operatively whilst minimising outpatient visits, therefore, reducing exposure risk to both clinicians and patients. For those injuries requiring urgent surgery the approach was aimed at avoiding hospital admission where possible, alongside utilisation of day-case facilities and repurposing of elective centres to provide trauma care [5]. With patients self-isolating at home and driving less frequently, lockdown measures were expected to reduce the number of injuries sustained. The pandemic offered a unique insight into injury patterns, trauma workload and the effectiveness of rapid re-modelling of major trauma networks.

The aim of this study was to evaluate changes in both mechanism and diagnoses of the emergency cases presenting to the orthopaedic department during this lockdown period, as well as to observe any changes in operative case-mix during this time. The secondary aim was to observe the impact on emergency orthopaedic referrals and procedure numbers as well as the change in patient flow between the Major Trauma Centres and the Trauma Units within the Network.

Methods

The initial twelve weeks of the "lockdown period" (Mar 23rd – June 14th) were compared to the same time period in 2019 (baseline period) across an urban major trauma network. This included data from five large NHS Trusts; Imperial College Healthcare NHS Trust, London North West University Healthcare NHS Trust, The

Hillingdon Hospitals NHS Foundation Trust, Chelsea and Westminster Hospital NHS Foundation Trust and West Hertfordshire Hospitals NHS Trust. Together, these trusts form the North West London trauma network and receive the vast majority of trauma referrals in the region. A retrospective analysis of all emergency orthopaedic referrals and procedures performed during these periods was undertaken. All data was collected and screened using the Pathpoint™ eTrauma platform (Open Medical, UK), a modern cloud-based patient management platform used in all the hospital sites for incoming referrals alongside the documentation and planning of operations. All acute orthopaedic referrals and operations during the study periods were included for further analysis. Exclusion criteria were non-emergency/semi-elective referrals, virtual or other direct fracture clinic referral and any elective operations performed.

For each acute trauma referral; age, mechanism of injury and diagnosis were recorded. For each surgical procedure undertaken; date of injury, date of surgery, diagnosis of injury and operation performed were collected. Across the 2 periods, a total of 6695 orthopaedic referrals met the inclusion criteria and were considered for analysis. Mechanism of injury and diagnoses were coded by the inputting clinician using the Snomed CT vocabulary, the recognised international standard for medical terminology utilised in computer systems.

The study population was determined by the number of eligible patients referred via the eTrauma database and by our pre-defined study periods. Diagnoses of new referrals and type of procedure performed were described in terms of absolute number and percentages. To establish significance of difference between the average number of referrals and average number of procedures performed per week, an unpaired, two tailed t-test was used. Mechanism of injury and operation performed were allocated to sub-categories to allow for comparison. To determine changes in diagnosis and mechanism of injury as well as operative case mix, a Fisher's exact test was performed.

To further analyse changes to operative practice, three key injuries were studied in further detail; neck of femur (NOF), distal radius and ankle fractures, with the aim of establishing if there was a change in non-operative versus operative management of these injuries. Ankle injuries were divided into open and closed injuries for further comparison. Injuries sustained as part of poly-trauma were excluded in this section of analysis. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using XL Stat (Addinsoft, New York, USA).

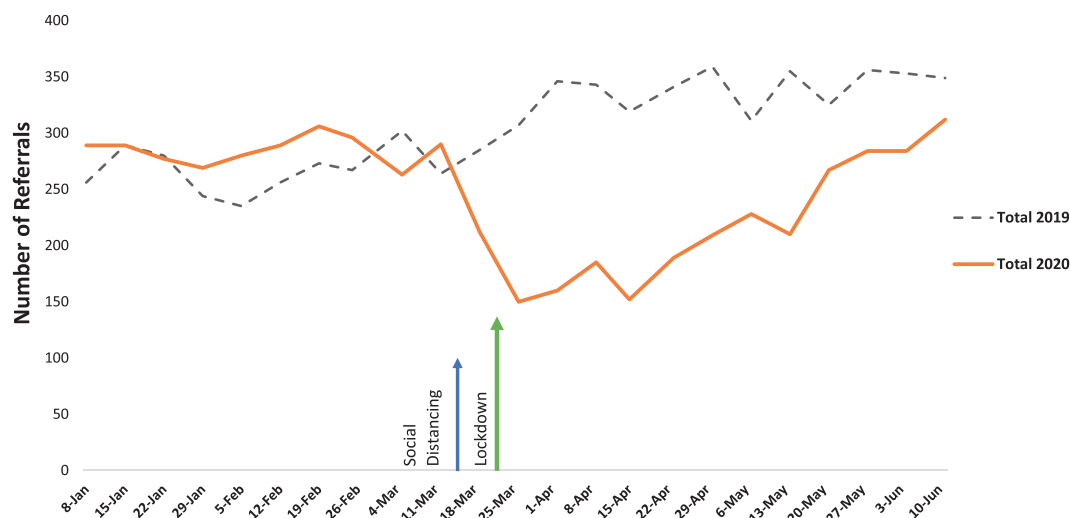


Fig. 1. Week by week comparison of number of referrals received between 2019 and 2020 across combined hospital sites

Results

Number of referrals

The total number of referrals received during the lockdown period (n=2631) fell by 35.3% compared to the same period in 2019 (n=4064). The average number of referrals per week, across all hospital sites, fell significantly from 339 referrals (SD=18.4) to 219 referrals per week (SD=55.9) during the lockdown period (p<0.001). Significant reductions in average number of referrals were seen across all hospital sites. The average age of referrals remained similar between baseline and lockdown periods; with an average age of 53.4 years (SD=27.7) and 53.0 years (SD=28.2), respectively (p=0.412). A week by week comparison of combined referral load between 2019 and 2020 across all hospital sites is displayed in Fig. 1; data from January to March has been included in Figures for schematic purposes. Gradual recovery towards baseline referral figures began approximately after six weeks.

Mechanism of injury

Falls remained proportionally the most common mechanism of injury across all age groups accounting for 42.9% (n=1735) of injuries during the baseline period and 52.8% (n=1379) of injuries during the lockdown period. The proportion of pushbike / scooter accidents significantly increased during the lockdown period to 4.8% of injuries compared to 2.4% at baseline (p<0.001). The proportion of sports related injuries also significantly fell during the lockdown period from 6.2% to 3.6% (p<0.001). Atraumatic injuries consisting of soft tissue infections, atraumatic joint pain and crystal arthropathies; were proportionally lower during the lockdown at 18.1% compared to 25.2% in 2019 (p<0.001). The overall numbers of patients injured by all other mechanisms was reduced during the lockdown; however, no significant difference was found in the overall proportion of injuries between the two study periods. The trends in mechanism of injury sustained between 2019 and 2020 periods are displayed in Table 1.

Looking at paediatric trauma (0-18 years) the number of pushbike/scooter related accidents increased during the lockdown, representing a proportionally significant increase from 4.7% of injuries at baseline to 10.7% of injuries during lockdown (p<0.001). The proportion of sports accidents and atraumatic injuries however were significantly lower during the lockdown (p<0.01).

In younger patients of working age (19-30 years), there was a significant increase in the proportion of pushbike / scooter related injuries from 5.7% at baseline to 10.2% during the lockdown (p=0.039). No other differences were found in mechanism of injury pattern between the two groups. In older patients of working age (31-65 years), the number of falls injuries decreased during lockdown (435 in 2019 and 358 in 2020), although its proportion amongst all injuries was significantly higher during the lockdown period (31.7% in 2019 and 40.0% in 2020; p<0.001). There was a significant increase in the proportion of pushbike / scooter related injuries from 3.0% at baseline to 5.6% during the lockdown (p=0.003). The proportion of sports accidents injuries however were significantly lower during the lockdown at 3.8% of injuries compared to 7.3% of injuries in 2019 (p<0.001). The proportion of atraumatic injuries in this age group significantly decreased from 28.5% of injuries in 2019 to 24.3% of injuries in 2020 (p=0.033).

For the elderly population (over 65 years), again falls remained the most common mechanism with 902 (55.0%) injuries in 2019 and 722 (68.4%) injuries in 2020, which represented a significant increase in the proportion of injuries sustained during the lockdown period (p<0.001). The proportion of road traffic accidents during the lockdown was significantly reduced in over 65-year olds

Table 1 Comparison of mechanism of injury by age.

	0-18 years n (%)		19-30 years n (%)		31-65 years n (%)		65+ years n (%)		Total n (%)		p-value
	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	
	n=623	n=438	n=406	n=225	n=1374	n=896	n=1640	n=1055	n=4043	n=2614	
Assault or altercation	2 (0.3)	1 (0.2)	26 (6)	8 (4)	28 (2)	25 (3)	7 (0.4)	2 (0.2)	63 (2)	36 (1)	0.496
Crush Injury	7 (1)	7 (2)	5 (1)	2 (0.9)	15 (1)	10 (1)	1 (0.1)	4 (0.4)	28 (0.7)	23 (0.9)	0.081
Fall	307 (49)	238 (54)	91 (22)	61 (27)	435 (32)	358 (40)	902 (55)	722 (68)	1735 (43)	1379 (53)	<0.001
Impact from falling object / projectile	3 (0.5)	3 (0.7)	8 (2)	2 (0.9)	7 (0.5)	9 (1)	2 (0.2)	3 (0.3)	21 (0.5)	17 (0.7)	0.685
Injury from sharp object	11 (2)	9 (2)	26 (6)	15 (7)	51 (4)	26 (3)	13 (0.8)	5 (0.5)	101 (2)	55 (2)	0.468
Low energy impact	19 (3)	20 (5)	13 (3)	9 (4)	72 (5)	22 (3)	30 (2)	16 (2)	134 (3)	67 (3)	0.091
Machinery Accident	1 (0.2)	1 (0.2)	1 (0.2)	2 (0.9)	4 (0.3)	2 (0.2)	1 (0.1)	0 (0)	7 (0.2)	5 (0.2)	1.000
Pushbike / scooter accident	29 (5)	47 (11)	23 (6)	23 (10)	41 (3)	50 (6)	5 (0.3)	5 (0.5)	98 (2)	125 (5)	<0.001
Road Traffic Accident	12 (2)	8 (2)	52 (13)	27 (12)	98 (7)	61 (7)	35 (2)	8 (0.8)	197 (4.9)	104 (4)	0.091
Sports Accident	93 (15)	35 (8)	53 (13)	25 (11)	100 (7)	34 (4)	6 (0.4)	0 (0)	252 (6)	94 (4)	<0.001
Atraumatic	99 (16)	40 (9)	70 (17)	37 (16)	391 (29)	218 (24)	459 (28)	179 (17)	1019 (25)	474 (18)	<0.001
Mechanism of injury not specified	40 (6)	29 (7)	38 (9)	14 (6)	132 (10)	81 (9)	178 (11)	111 (11)	388 (10)	235 (9)	0.799

Fisher's Exact Test performed for all statistical analysis. % values, rounded to nearest decimal place. Statistically significant results are highlighted in bold.

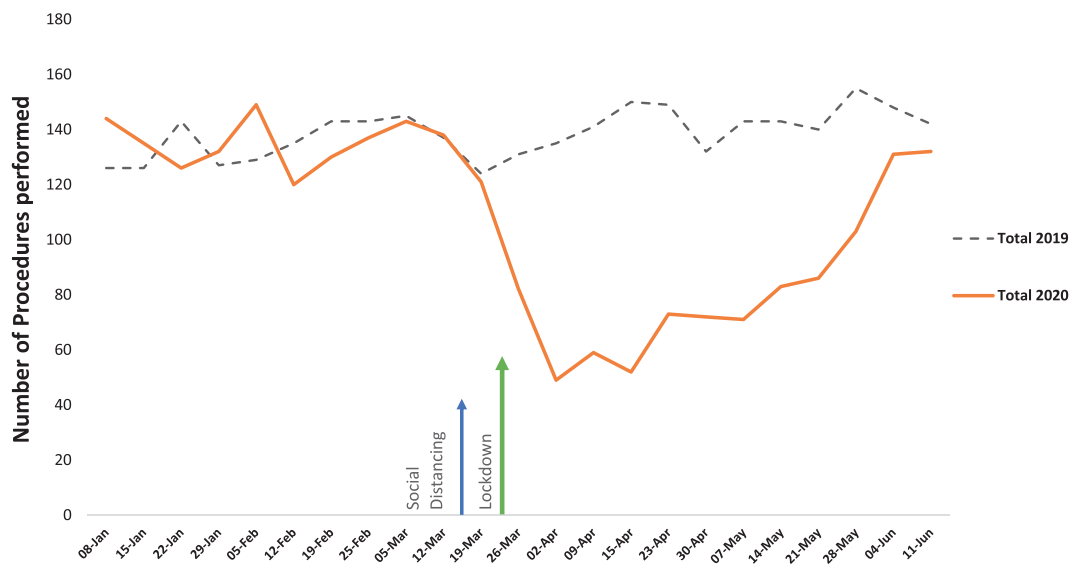


Fig. 2. Week by week comparison of number of operations performed between 2019 and 2020 across combined hospital sites

Table 2
Comparison of injury pattern of referrals

	2019 n (%)	2020 n (%)	p-value*
Spinal injuries (including thoracic cage)	164 (4)	118 (4)	0.456
Upper limb injuries	1050 (46)	709 (27)	0.478
Pelvic injuries	101 (3)	70 (3)	0.752
Neck of femur fractures	410 (10)	327 (12)	0.005
Lower limb injuries	820 (20)	571 (21)	0.218
Open fractures	86 (2)	52 (2)	0.661
Polytrauma (≥ 2 injuries in ≥ 2 areas)	9 (0.2)	13 (0.5)	0.079
Compartment Syndrome	6 (0.1)	4 (0.2)	1.000
Other (soft tissue infections, metalwork etc.)	1418 (35)	799 (30)	<0.001

*Fisher's exact test performed for all statistical analysis. Statistically significant results are highlighted in bold.

(2.1% to 0.8%; $p=0.005$); along with the proportion of atraumatic injuries (28.0% compared to 17.0% at baseline; $p<0.001$).

Diagnosis of injuries sustained

The number of NOF fractures reduced during the lockdown period (410 in 2019 and 327 in 2020), meaning that the proportion of NOF fractures to total number of injuries sustained increased significantly from 10.1% to 12.3% during the lockdown period ($p=0.005$). The proportion of "other" non-bony injuries (soft tissue infections, metalwork complications etc) also significantly decreased during the lockdown (34.9% to 30.0%; $p<0.001$). Polytrauma injury, defined as two or more significant injuries in two or more areas of the body, increased in overall numbers during the lockdown, however, this was not found to be significant ($p=0.079$). Overall numbers of all other sub-category of injuries were reduced during the lockdown; but no significant changes in proportion of injuries were found. Trends in the diagnosis of injury sustained are outlined in Table 2.

Number of operations

The total number of operations performed during the lockdown period fell by 38.8% ($n=1046$) compared with the same period in 2019 ($n=1732$). A week by week comparison of combined number of operations performed between 2019 and 2020 across all hospital sites is displayed in Fig. 2; data from January to March has been included in Figures for schematic purposes. The average number of

operations performed each week, across all hospital sites, fell significantly from 144 (SD=7.3) procedures per week in 2019 to 87.2 (SD=27.3) procedures per week in the lockdown period ($p<0.001$). A total of 31 NOF fracture patients were transferred to an external specialist elective centre that had been repurposed to provide surgical trauma care. Patient repatriation records were analysed to identify the procedure performed and included in overall analysis of number and case-mix of operations performed.

Operative Case-mix

Operative case-mix appears to have varied slightly from the baseline period in 2019. The proportion of NOF fracture operations increased significantly during the lockdown period to 27.2% of operations, up from 21.1% at baseline ($p<0.001$). There was a significant increase in the proportion of arthroplasty operations performed ($p<0.001$)(Table 3). There was a significant increase in the proportion of dynamic hip screw operations performed during the lockdown period to 7.1% from 4.7% in 2019 ($p=0.011$), otherwise, the NOF operative case-mix remained similar between the two study periods. Considering non-NOF related operations, the operative case mix for all other operations remained relatively similar. There were fewer spinal operations performed across all sites during the lockdown at 0.5% of operations; which represented a significant fall from 1.3% of baseline period procedures ($p=0.031$). The total number of operations performed for all other categories fell over the lockdown period, however, no statistical difference was found in case-mix proportions (Table 3).

Rates of operative management

The proportion of NOF fractures that were managed operatively remained similar; 87.2% of fractures were operated on compared to 89.0% in the same time period in 2019 ($p=0.491$). The percentage of all acutely referred ankle fractures undergoing operative management was 65.0% at baseline falling slightly to 57.8% during the lockdown period ($p=0.168$). On further analysis, the proportion of open ankle fractures undergoing operative management remained at 100% during the lockdown period. Operative intervention for closed ankle fractures also remained at similar rates with 62.8% undergoing operative intervention at baseline compared to 54.2% during the lockdown period ($p=0.105$). A more conservative approach was seen in wrist fracture management with 41.4% of in-

Table 3
Comparison of operative case mix

	2019 n (%)	2020 n (%)	p-value*
<i>Neck of femur fracture management</i>			
Total	365 (21)	285 (27)	<0.001
Arthroplasty (THR/Hemi)	155 (9)	148 (14)	<0.001
DHS	82 (5)	74 (7)	0.011
IM Nailing	50 (3)	29 (3)	0.907
Cannulated Screws	14 (0.8)	8 (0.8)	1.000
Generic ORIF (subtype not listed)	39 (2.3)	18 (2)	0.408
Operation not specified	25 (1)	8 (0.8)	0.147
<i>Other Operations (excluding neck of femur management)</i>			
Arthroplasty	31 (2)	10 (1)	0.103
ORIF	556 (32)	333 (32)	0.900
IM Nailing	63 (4)	36 (3)	0.833
External Fixation	28 (2)	27 (3)	0.091
Joint washout	53 (3)	27 (3)	0.485
Washout/debridement of soft tissues	88 (5)	47 (5)	0.524
MUA of joint	178 (10)	92 (9)	0.210
Removal of metalwork	61 (4)	50 (5)	0.110
Spinal operations	23 (1)	5 (0.5)	0.031
Fasciotomy	2 (0.1)	0 (0)	0.530
Other (tendon/ligament repairs, I&D, removal of FB etc.)	165 (10)	80 (8)	0.098
Operation not specified	119 (7)	54 (5)	0.075

THR, total hip replacement; DHS, dynamic hip screw; IM, intramedullary; ORIF, open reduction internal fixation; MUA, manipulation under anaesthesia; I&D, incision and drainage; FB, foreign body

Fisher's exact test performed for all statistical analysis

Statistically significant results are highlighted in bold

juries undergoing an operation during the lockdown period compared to 58.6% at baseline ($p < 0.001$). Operative management of all three injury subsets is shown in Table 4. Note that analysis of ankle and wrist operative management does not include fractures considered stable by initial reviewing clinician and therefore referred directly to fracture clinic without acute orthopaedic referral.

Discussion

This study demonstrates a rapid and profound change in the overall numbers of orthopaedic trauma referrals occurring during the lockdown period. The fall number of acute trauma referrals from 4064 the year before to 2631 represented a 35.3% reduction in total referral load. This likely represents a change in societal behaviour during lockdown; either from a reduction in the number of injuries sustained due to social distancing measures or reduced attendance to emergency departments. According to NHS England data there has been a decrease in overall emergency department admissions, with monthly attendance rates falling between 29.4% to 56.6% between March and June 2020, compared to the same periods last year [6-9]. The main concern regarding this decrease is that individuals may avoid presenting with serious or life-threatening conditions [10], however, this also may mean a reduction in the number individuals presenting with lower energy traumatic injuries.

Falls remained the most common mechanism of injury across all age groups. The largest proportion of falls injuries to overall injuries were seen in the 31-65-year-old and geriatric age groups. This may be due to more elderly individuals continuing to have falls, trips and slips in and around the home, with little effect of social isolation on reducing incidence of such injuries.

The total number of road traffic accidents in our study fell by 47.2% during the nationwide lockdown with the greatest reduction seen in the elderly population. During the coronavirus outbreak the number of road traffic users in the UK has decreased by as much as 73% according to cabinet office data from March 2020 [11]. This

decrease in road travel follows the advice from the UK government on avoiding non-essential travel and only travelling for work-based purposes. Alongside this companies and workers have been encouraged to work from home if possible, thus reducing overall road traffic numbers [2]. Despite the government limiting exercise and lower overall road traffic users during the lockdown there was an increase in the number of cycling accidents during the lockdown period. The number of cycling related injuries increased during the lockdown period. The reduced vehicle numbers combined with favourable weather in April and May is likely to have increased the number of cyclists taking to the road. Whilst cycling has been advocated during lockdown periods, as part of our once a day exercise regime, there have been concerns raised regarding cyclist riding excessive distances unnecessarily and the potential burdens of injuries on the NHS [12].

The proportion of sports related injuries fell during in the lockdown period with the greatest reduction seen in under 18-year olds. This likely correlates with the governments closure of schools, gymnasiums and banning of group events leading to fewer physical education activities and no sporting competitions. Previously atraumatic injuries constituted a large proportion of referrals at 25.2% which fell to 18.1% during lockdown. This subcategory of referrals consisted predominantly of soft tissue infections, atraumatic joint pain and crystal arthropathies which often do not require admission to hospital. Significant reductions in the number of atraumatic referrals were seen in the paediatric and elderly populations, which may represent family members avoiding the risk of attending emergency departments, unless deemed absolutely necessary [10]. It may also be the case that a large number of these referrals were managed conservatively within the community or via telecommunications, such as the NHS 111 service.

Upper limb injuries constituted the most common injury pattern both at baseline and during the lockdown period. Lower limb injuries were the second most common injury pattern in both study periods at just over 20% of injuries. There was no significant difference in proportion of injuries for both of these subcategories. NOF fractures are the commonest reason for admission to an orthopaedic trauma ward. The vast majority of these are usually 'fragility fractures' of individuals with underlying bone disease (osteoporosis or osteopenia) [13]. The National Hip Fracture Database reports the average age of individuals sustaining a NOF fracture as >80 years for both men and women. NOF fracture numbers were relatively unaffected by the social distancing measures. As previously mentioned, falls remained the most common mechanism of injury in the elderly population meaning that low energy impacts in patients own homes still resulted in NOF fractures.

There was a 38.8% reduction in the number of procedures performed during the lockdown period. Mass postponement of all non-urgent cases and conversion of surgical theatres into make-shift critical care units [4] has left reduced space for trauma cases across all three sites. Strict infection control guidelines have been implemented for suspected or positive COVID-19 patients with additional cleaning and safety precautions required [14]. Further to this, the anaesthetic time for intubation has increased due to vital safety precautions needed for aerosol generating procedures (e.g. intubation), aiming to reduce the risk of transmission to anaesthetists and their supporting team [15]. These changes overall, have meant a slower and less efficient trauma list during the lockdown period, thus reducing the number of procedures that can be performed.

Alongside this, there is the question of a change in approach to more conservative management strategies. The BOAST guidelines advocated a shift to non-operative management strategies where possible but did outline that some injuries that undergo non-operative management may require later reconstruction [5]. Overall operative case-mix was otherwise similar to 2019, how-

Table 4
Analysis of operative management rates of specific injuries

Diagnosis	No. of injuries (n)		No. of injuries undergoing operative management (n)		Proportion of injuries undergoing operative management (%)		p-value*
	2019	2020	2019	2020	2019	2020	
Neck of femur#	410	327	365	285	89.0	87.2	0.491
Wrist#	324	210	190	87	58.6	41.4	<0.001
Ankle #							
Total	246	154	160	89	65.0	57.8	0.168
Open injuries	15	12	15	12	100.0	100.0	1.000
Closed Injuries	231	142	145	77	62.8	54.2	0.105

#, fracture

Fisher's exact test performed for all statistical analysis unless stated

Statistically significant results are highlighted in bold

ever, there was a significant reduction in spinal surgeries whilst the number of external fixation procedures remained the same. This may represent a delay in non-essential surgeries and prioritisation of limited trauma list space.

The percentage of NOF and ankle fractures undergoing operative intervention remained similar in both study periods. The number of open ankle fractures undergoing intervention remained at 100%. Distal radius fracture saw a significant fall in the number of injuries receiving operative management from 58.6% of injuries at baseline to 41.4% of injuries during the lockdown period. It is not known whether this was related to an increased conservative approach to these fractures as per the BOA guidance.

Limitations and future areas of research

One of the key limitations of this study due to the short study period analysed we were unable to assess the functional outcomes on patients managed non-operatively. Future studies will be needed to assess the morbidity and functional outcomes resulting from this more conservative approach during the lockdown period. A further limitation of our study is its reliance on accurate data coding. Due to the substantial number of referrals and injuries analysed we relied upon data codes for referrals, mechanism of injury and procedure performed making the assumption that these had all been entered correctly by the individual inputting the data.

Conclusion

In conclusion, the nationwide lockdown has led to a decrease in emergency orthopaedic referrals and associated injuries. There has been a change in mechanism of injuries and a reduction in the overall number of acute trauma procedures performed. This study should provide some insights to facilitate policy writing during the recovery phase and may help guide decision making regarding orthopaedic trauma care if lockdown measures are re-instated or similar emergency pandemics are encountered in the future. The impact of the outbreak on elective orthopaedic management and the longer-term impact on NHS services and its staff remains to be seen.

Declarations

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Patient and Public Involvement

No patients or members of the public were involved in the design, or conduct, or reporting, or dissemination plans of our research.

Data Sharing Agreement

No additional data are available

Conflicts of interest/competing interests

All authors declare no conflicts of interest/competing interests. Senior author PM declares employment as director of Open Medical Ltd. MS declares conflict as non-employed director of Open Medical Ltd.

Authors Contributions

PM, MS and RB conceived the idea for the study and contributed to study design. NF, KD, RB, DN, KS, TS, NS made contributions to acquisition of data for further analysis. BS, PM and MS contributed to data analysis with all authors contributing to the interpretation of results. The manuscript was drafted by BS, PM and MS with all authors contributing to its critical revision and approved the final version to be published.

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