



ORTHOPAEDIC TRAUMA ASSOCIATION
Education •• Research •• Service
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Website: <http://www.ota.org>

SECTION 1

PROPOSAL RESEARCH GRANT APPLICATION



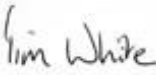


Application Detailed Instructions Link

Total Amount Requested: \$19997

DATE: 14th June 2021

This request is made by the undersigned, who also agree(s) to comply with the following:

- (1) Funds granted as a result of the request are to be expended for the purposes set forth herein.
- (2) All reports or original investigations supported by any grant made as a result of this request shall acknowledge support provided by the Orthopaedic Trauma Association.
- (3) Reports will be made as required and necessary records and accounts, including financial and property controls, will be maintained and made available to the Orthopaedic Trauma Association.

NAME	TITLE	DEPARTMENT	SIGNATURE
Principal Investigator: Andrew D. Duckworth	Senior Clinical Lecturer and Honorary Consultant Orthopaedic Trauma Surgeon	Centre for Population Health Sciences, Usher Institute @ Bioquarter, University of Edinburgh Edinburgh Orthopaedics, Royal Infirmary of Edinburgh	 Phone: +447769701875 Fax: NA E-mail: andrew.duckworth@ed.ac.uk
OTHER INVESTIGATORS ASSOCIATED WITH PROJECT:			
Mr Samuel G. Molyneux	Consultant Orthopaedic Trauma Surgeon	Edinburgh Orthopaedics, Royal Infirmary of Edinburgh	
Mr Timothy O. White	Consultant Orthopaedic Trauma Surgeon	Edinburgh Orthopaedics, Royal Infirmary of Edinburgh	
Mr Nicholas D. Clement	Consultant Orthopaedic Surgeon	Edinburgh Orthopaedics, Royal Infirmary of Edinburgh	
Miss Katrina R. Bell	Clinical Research Fellow	Edinburgh Orthopaedics, Royal Infirmary of Edinburgh	

Institution Name and Address:

- 1. Edinburgh Orthopaedics and SORT-IT, Royal Infirmary of Edinburgh, 51 Little France Crescent, Old Dalkeith Road, Edinburgh, EH16 4SA**
- 2. University of Edinburgh, Centre for Population Health Sciences, Usher Institute @ Bioquarter, 9 Little France Road, Edinburgh BioQuarter, Edinburgh, EH16 4UX**

SECTION 2

ABSTRACT OF RESEARCH PLAN

PROJECT TITLE:

eFORRCE (*Elderly-Fixation Of the Radius: Radiological and Clinical Evaluation*): *A prospective randomised superiority trial of surgical versus conservative management for unstable fractures of the distal radius in patients aged 65 and older.*

Abstract of research plan: Please provide an abstract of 250 words or less with 5 underlined phrases for a project summary. Please avoid summaries of past accomplishments and the use of the first person. The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

eFORRCE is a prospective randomised superiority trial of surgical versus conservative management for unstable fractures of the distal radius in patients aged 65 and older. The primary aim is to quantify and draw inferences on the primary outcome measure, the Patient-Rated Wrist Evaluation (PRWE), at one-year post-injury between surgical fixation and conservative treatment. Secondary outcome measures include the PRWE at other time points, EQ-5D-3L, Quick Disabilities of Arm, Shoulder and Hand (QuickDASH) score, Visual Analog Scale (VAS) pain score, a health economic analysis, complications, grip strength, range of motion and a radiographic assessment.

From a power analysis, 184 patients (92 in each arm) will be enrolled. In our centre, patients with displaced distal radius fractures routinely undergo closed reduction and cast application under intravenous regional anaesthesia (Bier's block) in the Emergency Department. Patients will be potentially eligible for inclusion if their fracture is unable to be reduced to a satisfactory position or if it initially reduces but subsequently becomes unsatisfactory on radiographs taken at clinic reviews one week or two weeks post-injury. After gaining informed consent, they will be randomised in a 1:1 ratio to either open reduction and internal fixation (ORIF) or conservative management, with six weeks in a below elbow cast. Patients will be reviewed in clinic at one week, two weeks, six weeks, 12 weeks and complete a postal questionnaire at 26 and 52 weeks. The study is anticipated to take three years to complete from first patient recruited to last patient one-year postal questionnaire review.

SECTION 3

FACILITIES – Laboratory Space and Major Equipment

Please provide an accurate description of laboratory facilities and major equipment available at the grantee's institution that will support this project. Please recall the list of supplies and support that the grantee's institution, or grant funds other than those from the OTA, are expected to provide: [click to see the list](#)

1. Laboratory space
 - Laboratory not required but research offices based in orthopaedic outpatient clinic are already in place and provided by NHS Lothian/SORT-IT Research Charity
 - Dynamometers are available and require recalibration
2. Maintenance service, including maintenance, supplies and service contracts
 - All in place and provided by NHS Lothian/SORT-IT Research Charity (offices on NHS premises)
3. Telephone services
 - All in place and provided by NHS Lothian/SORT-IT Research Charity
4. Library service, including subscriptions to periodicals and the purchase of books
 - In place and provided by the University of Edinburgh (See Point 11 please)
5. Laboratory furniture and office equipment
 - All in place and provided by NHS Lothian/SORT-IT Research Charity
6. Salary of principal investigator, co-principal investigator and of secretarial personnel
 - Salary of PI paid for by University of Edinburgh
 - Salary of secretarial personnel covered by NHS Lothian
7. Worker's compensation, public liability or other hazard and special insurance
 - Covered by study sponsor (University of Edinburgh/NHS Lothian jointly)
8. Employee group life, disability, medical expense or hospitalization insurance
 - Not applicable for our public healthcare system
9. Hospital bed expense, nursing or related services, even though used for research studies
 - Provided by NHS Lothian as routine care. The study will not differ from standard care in terms of these provisions.
10. Indirect Costs
 - Not applicable
11. Tuition expenses of personnel on grant
 - Self-funded higher degrees fees with University of Edinburgh

SECTION 4

RESEARCH PLAN

Click for Research Plan Instructions

A. SCIENTIFIC AIMS (not exceed 400 words)

The main research question is whether operative intervention in the form of open reduction and internal fixation (ORIF) results in improved outcomes in elderly patients with displaced distal radius fractures when compared to conservative management.

Primary Aim

The aim of this trial is to quantify and draw inferences on the primary outcome measure, the Patient-Rated Wrist Evaluation (PRWE) at one-year (52 weeks) post injury between surgical fixation AND conservative treatment for displaced fractures of the distal radius in elderly patients (≥ 65 yrs of age).

The primary null hypothesis is that there will be no difference in the primary outcome (PRWE at one year) between surgical fixation and conservative management.

Secondary Aims

The secondary aims of this trial are:

- To quantify and draw inferences in the PRWE score at all time points (baseline, 6, 12, 26 and 52 weeks) between surgery AND conservative treatment for displaced fractures of the distal radius in elderly patients (≥ 65 yrs of age)
- To quantify and draw inferences in the EQ-5D-3L (a validated assessment of Health-related Quality of Life) rate at all time points
- To quantify and draw inferences in the QuickDASH score at all time points
- To quantify and draw inferences in the VAS pain score at all time points
- To investigate, using appropriate statistical and economic analysis methods, the healthcare resource use, and comparative cost effectiveness at one year (52 weeks)
- To quantify and draw inferences in the complication rate at one-year (52 weeks) post injury
- To quantify and draw inferences in grip strength at 12 weeks
- To quantify and draw inferences in the range of motion at 12 weeks
- To compare radiographic parameters at all time points

B. BACKGROUND & SIGNIFICANCE (not to exceed 400 words)

Distal radius fractures are the most commonly treated fractures by orthopaedic surgeons, 41.8% of which occur in patients aged 65yrs or older.¹ There is evidence to suggest that in the elderly improved radiographic parameters may not correlate with improved functional outcomes for the patient.² If fixation is not superior to conservative management, this could reduce the number of procedures required and the potential morbidity and costs associated with them. The ageing population is posing considerable challenges in terms of healthcare provision, thus increasing the importance of finding ways to cost-effectively manage injuries common in this group, whilst also maximizing function and minimizing dependency. This aligns with the OTA mission statement to promote excellence in the care of the injured patient.

There is heterogeneity amongst the findings of the existing RCTs comparing non-operative management with ORIF of distal radius fractures, with areas for improvement in terms of the methodologies used. Some studies have found significantly better outcomes in operatively managed patients, whilst others found only early differences, or no difference at all.³⁻⁹ Additionally, many of these studies used the limb-specific DASH score instead of the joint-specific PRWE. Increasingly, PRWE is becoming the patient reported outcome measure of choice when assessing the outcome of distal radius fracture treatment, with better construct validity and responsiveness compared to the DASH score.^{10,11} An adequately powered PRCT with the PRWE as the primary outcome measure would meaningfully add to the current literature in this area.

An additional consideration is the large variation amongst the population that we would consider elderly, both in terms of medical comorbidities and functional demands. Selecting the most appropriate treatment by differentiating chronological from physiological and functional age is key to optimizing outcome whilst also minimizing morbidity from interventions that are unlikely to improve outcome. There are tools which can be used to help assess function and the development of frailty in the elderly, primarily developed by geriatricians.¹² With the aforementioned heterogeneity in conclusions from previous studies, we plan to utilize the Clinical Frailty Score (CFS) and PRISMA-7 to determine if frailty has a predictable influence on outcome.^{13,14} To the knowledge of the authors, this has not previously been studied and may explain the mixed conclusions of the current literature. Depending on our findings, it may be that the less frail patients have better outcomes with operative intervention, but that frail patients do not as they have lower pre-injury functional demands.

C. PREVIOUS WORK DONE ON THE PROJECT (Not to exceed 400 words)

Prior to the project commencing, the literature surrounding the factors which contribute to distal radius fracture instability and subsequent displacement was reviewed as part of an invited book chapter entitled 'Predictors of Instability and Secondary Displacement After Conservatively Managed Distal Radius Fractures' in the book 'Radius Fractures Evidence Based Medicine'.¹⁵ Increasing age, particularly above age 60, and dorsal comminution were the factors with the highest quality evidence supporting their relationship to fracture displacement risk.

We have carried out a systematic review of the literature in this area and locally we have performed a retrospective review of a consecutive series of operatively managed adult distal radius fractures treated at our institution in a single year to determine the rate of complications and the re-intervention rate. Increasing age was one of the factors significantly associated with developing a complication. Given the increased risk of complications associated with surgery and the positive outcomes reported in the literature following conservative management, we felt that this added weight to the argument that non-operative management of displaced fractures should be considered in older patients. This retrospective study has been accepted for podium presentation at the OTA in 2021.

We are currently in the data collection phase a retrospective review of patient-reported outcomes and their relation to radiographic outcome. This focuses on a single year cohort of adult distal radius fractures treated at our institution with a minimum of 4 years follow-up. As aforementioned, there is evidence to suggest that the elderly can achieve a satisfactory functional outcome without what would widely be considered as a satisfactory radiographic appearance.² Whilst our study includes all adult patients, we plan to compare the effect of radiographic outcome on long-term functional outcome between the elderly and non-elderly population in this large cohort.

As part of preparation for the study it has been discussed and undergone a peer review with our centre's orthopaedic trauma consultant body, with all being in support. We have asked elderly patients who have sustained a distal radius fracture in the past for comments on the study. They have agreed in principle to participating in such a study and felt that the patient-reported outcomes measures that will be used were acceptable in terms of content and time taken to complete. A statistician with extensive experience in orthopaedic trials has contributed to the study protocol and has devised the randomisation, the power analysis and the statistical analysis plan.

D. METHOD (not to exceed 1200 words and 4 pages)

eFORRCE is a prospective randomised superiority trial of surgical versus conservative management for unstable fractures of the distal radius in patients aged ≥ 65 yrs. We plan to enrol 184 patients with a displaced fracture of the distal radius, as determined by our power analysis (see Statistical plan below). We currently manage approximately 450 potentially eligible cases per year in our centre. Based on previous experience of RCTs and enrolment rates, we provisionally expect recruitment to take two years with total completion time for the trial three years. We have done some preliminary PPI work and this has suggested patients would be willing to recruit to the trial, with previous trials in this area possible.³⁻⁹ Our institution has an established track record of delivering trials of this design comparing non-operative and operative management.^{16,17,18}

Patient identification (Figure 1)

In our center patients with displaced distal radius fractures routinely undergo closed reduction and cast application under intravenous regional anaesthesia (Bier's block) in the ED. Patients will be eligible for inclusion if their fracture is unable to be reduced to a satisfactory position or if it initially reduces, but subsequently displaces to an unsatisfactory position on radiographs taken at clinic reviews one week or two weeks post-injury. An unsatisfactory position will be defined as one or more of carpal malalignment, dorsal angulation >10 degrees from the anatomical position, radial shortening >2 mm, intra-articular step >2 mm or intra-articular gap >5 mm. The other *inclusion criteria* are patients ≥ 65 yrs of age, a dorsally angulated fracture, that the surgeon believes that the patient is suitable for surgical fixation, and that the operation date is within three weeks of the date of injury. Patients of all genders and ethnicities will be eligible for inclusion. *Exclusion criteria* include patients unable to provide informed consent, associated upper limb injuries, open fractures of Gustilo-Anderson grade II or higher, persisting neurovascular deficit requiring operative intervention, off-ended or severely displaced fractures despite attempted reduction that are deemed to require surgery by the treating surgeon, non-residents and patients unable to comply with follow up, including English-language patient reported outcome measures.

Eligible participants will be identified by a member of the treating clinical team either in the ED or the outpatient clinic. They will then be approached by a clinical research fellow who is also a trauma and orthopaedic surgery registrar to begin the informed consent process. Patients will be provided with a patient information sheet (PIS), given time to read this and the opportunity to ask questions. Patients will be able to take as much time as they require to consider their participation, provided that their surgery could be completed within three weeks of their injury. After providing informed written consent, patients will be randomised and baseline data collected, including demographic data, injury-related information and frailty scoring (Clinical Frailty Scale and PRISMA-7).^{13, 14}

Randomization

Patients will be randomised in a 1:1 ratio using sealed envelopes to receive either surgical management with ORIF or non-operative management with a cast. An independent statistician employed through the University of Edinburgh will produce a computer-generated randomisation schedule using a block randomisation with a random block size. Randomisation will be stratified based on the fracture AO classification to ensure as far as possible that there are equal numbers of type A and C fractures in each treatment arm. Two separate randomisation lists will be produced, one for type A fractures and a second for type C fractures. A member of staff independent from the trial will use this list to create opaque sequentially sealed envelopes for each list containing a participant identification number and the treatment allocation. To aid identification and ensure that the next randomisation envelope is taken from the appropriate list, the fracture type (A or C) will be stated on the front of the envelopes with differently colored stickers for each arm.

Interventions

Conservatively managed patients will be initially immobilized in a below-elbow plaster of Paris backslab, followed by completion of this at one week and then change to a synthetic cast at the two week clinic review, which will be in place for a further four weeks (total time in case 6 weeks). Surgically managed patients will undergo volar locked plating, with post-operative immobilization at the discretion of the treating surgeon. This will routinely be a splint for 10-14 days followed by early active motion.

Outcomes

The primary outcome measure is the patient-rated wrist evaluation (PRWE) score at 52 weeks.^{19,20} The PRWE assesses wrist function based on the patient's pain and disability. Secondary outcome measures include the PRWE at other time points, EQ-5D-3L, Quick Disabilities of Arm, Shoulder and Hand (QuickDASH) score²¹, visual analog scale (VAS) pain score, a health economic analysis, complications, grip strength, range of motion and a radiographic assessment. Patients will be followed up at 2, 6, 12, 26 and 52 weeks with radiographs and grip strength measurement at 6 and 12 weeks, and patient reported outcome measures from 6 weeks onwards. Follow-up at the 26- and 52-week timepoints will be remote through a questionnaire.

Statistical plan

The primary outcome measure will be the PWRE, a continuous variable that follows a normal (Gaussian-shaped) distribution. This study is designed to determine a clinically relevant mean difference of 11 points between the two cohorts at one year after enrolment.²⁰ A power analysis indicates that a total sample size of 141 (71 in each group) subjects will provide 90% statistical power to detect significant differences (0.05) in PWRE scores, assuming an effect size of 0.55 (mean difference of 11 points, standard deviation of 20 points) using a two-sided, two-sample Student's t-test.²⁰ To account for a loss to follow-up rate of 30%, we anticipate enrolling 92 subjects in each group for a total sample size of 184 patients.

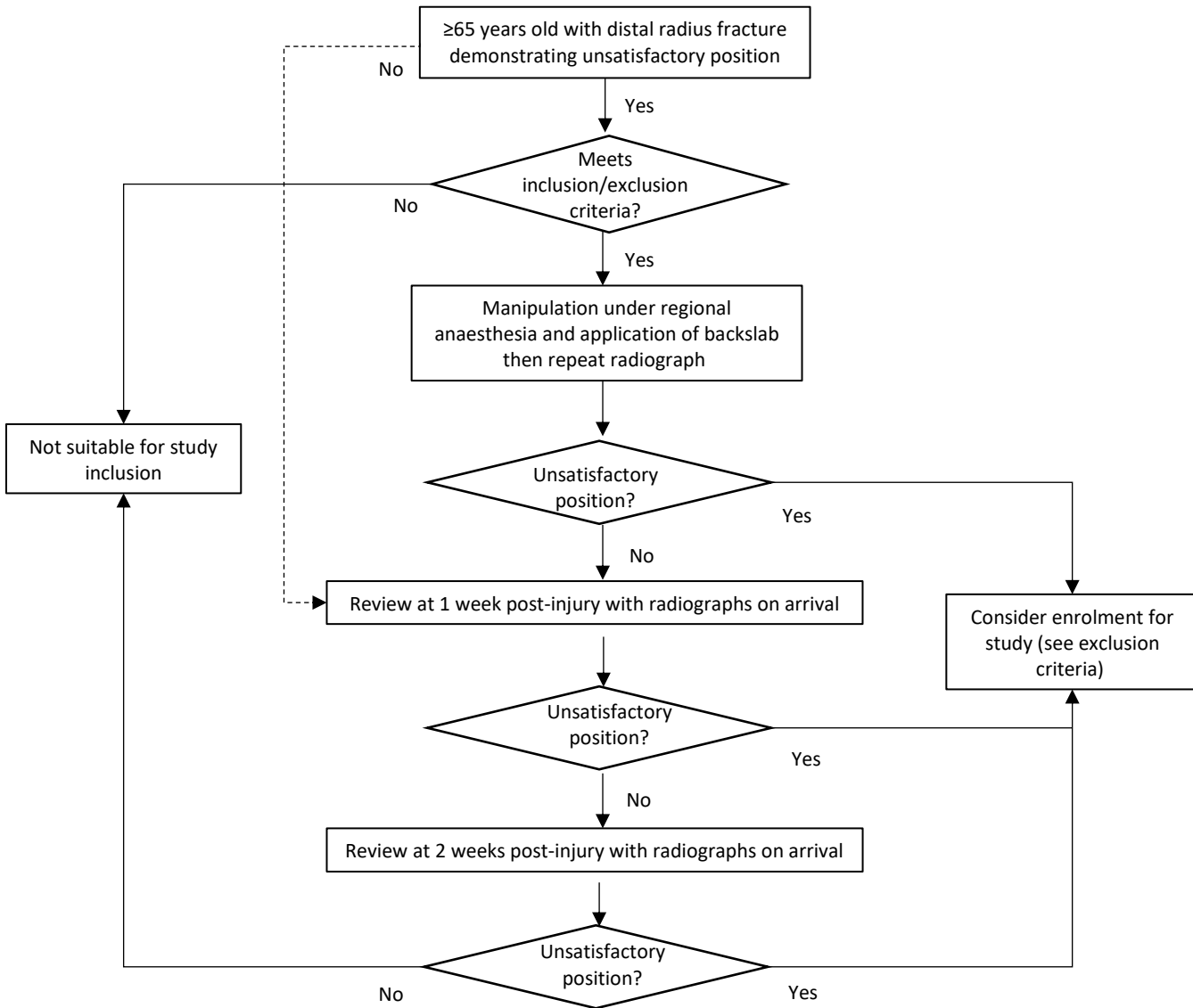
Where variables are continuous, descriptive statistics will be presented and this will provide number of observations, number of missing observations, mean, standard deviation, median, 25th centile, 75th centile, maximum and minimum. Where variables are categorical, we will present the number and % of each treatment arm. Comparison of PWRE at one year (primary outcome) between treatment arms will be analysed using a two-sample t-test. Descriptive analysis of measures at each time point will be presented split by treatment arm and comparisons will be made in a similar way to the primary outcome. Grip strength and range of motion at 12 weeks will be corrected using the non-affected side and then comparison of the corrected values will be made between treatment arms using a two-sample t-test. The comparison of complications and radiological success will be made between treatment arms using a binomial test for the comparison of proportions and we will present the difference in percentage between groups accompanied by the 95% CI for the difference and p-value associated with the comparison. For time to return to work and sports, we will analyse this using a Kaplan-Meier survival curve and present this along with the log-rank statistic comparing the two treatment arms. We will also present a breakdown of the number of drop-outs by treatment arm and if appropriate compare this rate using a binomial test for the comparison of proportions. The sample size calculation accounts for a 30% loss to follow-up rate. Analysis will be on an intention-to-treat basis.

E. REFERENCES (not to exceed 2 pages)

1. Court-Brown CM, Clement ND. The Epidemiology of Musculoskeletal Injury. In: Tortnetta Paul III, Ricci WM, Ostrum RF, McQueen MM, McKee MD, Court-Brown CM, editors. *Rockwood and Green's Fractures in Adults*. 9th ed. London; Wolters Kluwer; 2020. p. 123-187
2. Blakeney WG. Stabilization and treatment of Colles' fractures in elderly patients. *Clin Interv Aging*. 2010;5:337-44.
3. Arora R, Lutz M, Deml C, Krappinger D, Haug L, Gabl M. A prospective randomized trial comparing nonoperative treatment with volar locking plate fixation for displaced and unstable distal radial fractures in patients sixty-five years of age and older. *J Bone Joint Surg Am*. 2011 Dec 7;93(23):2146-53.
4. Bartl C, Stengel D, Bruckner T, Gebhard F. The Treatment of Displaced Intra-articular Distal Radius Fractures in Elderly Patients. *Dtsch Aerzteblatt Online*. 2018;(10).
5. Martinez-Mendez D, Lizaur-Utrilla A, de-Juan-Herrero J. Intra-articular distal radius fractures in elderly patients: a randomized prospective study of casting versus volar plating. *J Hand Surg Eur Vol*. 2018;43(2):142-7.
6. Saving J, Severin Wahlgren S, Olsson K, Enocson A, Ponzer S, Sköldenberg O, et al. Nonoperative Treatment Compared with Volar Locking Plate Fixation for Dorsally Displaced Distal Radial Fractures in the Elderly. *J Bone Jt Surg [Internet]*. 2019 Jun;101(11):961-9. Available from: <http://insights.ovid.com/crossref?an=00004623-201906050-00002>
7. Mulders MAM, Walenkamp MMJ, Van Dieren S, Goslings JC, Schep NWL. Volar plate fixation versus plaster immobilization in acceptably reduced extra-articular distal radial fractures: A multicenter randomized controlled trial. *J Bone Jt Surg - Am Vol*. 2019;101(9):787-96.
8. Sirniö K, Leppilähti J, Ohtonen P, Flinkkilä T. Early palmar plate fixation of distal radius fractures may benefit patients aged 50 years or older: a randomized trial comparing 2 different treatment protocols. *Acta Orthop*. 2019;90(2):123-8.
9. Lawson A, Naylor JM, Buchbinder R, Ivers R, Balogh ZJ, Smith P, et al. Surgical plating vs closed reduction for fractures in the distal radius in older patients A randomized clinical trial. *JAMA Surg*. 2021;2170:1-9.
10. Hoang-Kim A, Pegreff F, Moroni A, Ladd A. Measuring wrist and hand function: Common scales and checklists. *Injury [Internet]*. 2011;42(3):253-8. Available from: <http://dx.doi.org/10.1016/j.injury.2010.11.050>
11. Changulani M, Okonkwo U, Keswani T, Kalairajah Y. Outcome evaluation measures for wrist and hand - Which one to choose? *Int Orthop*. 2008;32(1):1-6.
12. British Geriatrics Society. Frailty: what's it all about? [Internet] London: British Geriatrics Society; 2019 [updated 2018 May 23; cited 2021 Jan 9]. Available from: <https://www.bgs.org.uk/resources/frailty-what's-it-all-about>
13. So RKL, Bannard-Smith J, Subbe CP, Jones DA, Van Rosmalen J, Lighthall GK. The association of clinical frailty with outcomes of patients reviewed by rapid response teams: an international prospective observational cohort study. *Crit Care*. 2018;22(1):1-9.
14. Raïche M, Hébert R, Dubois MF. PRISMA-7: A case-finding tool to identify older adults with moderate to severe disabilities. *Arch Gerontol Geriatr*. 2008;47(1):9-18.
15. Chapter 9: Predictors of Instability and Secondary Displacement After Conservatively Managed Distal Radius Fractures. Bell KR, White TO, Molyneux SG, Duckworth AD. In: *Distal Radius Fractures Evidence Based Medicine*, 1st ed. Editors: Buijze GA, Jupiter J, Chammas M. Oxford: Elsevier, 2021.
16. Oliver WM, Carter TH, Graham C, White TO, Clement ND, Duckworth AD, Molyneux SG. A prospective randomised

- controlled trial of operative versus non-operative management of fractures of the humeral diaphysis: the HUmeral Shaft Fracture FIXation (HU-FIX) Study protocol. *Trials*. 2019 Aug 5;20(1):475. doi: 10.1186/s13063-019-3576-0. PMID: 31383027
17. Duckworth AD, Clement ND, White TO, Court-Brown CM, McQueen MM. Plate Versus Tension-Band Wire Fixation for Olecranon Fractures: A Prospective Randomized Trial. *J Bone Joint Surg Am*. 2017 Aug 2;99(15):1261-1273. doi: 10.2106/JBJS.16.00773.PMID: 28763412
 18. Robinson CM, Goudie EB, Murray IR, Jenkins PJ, Ahktar MA, Read EO, Foster CJ, Clark K, Brooksbank AJ, Arthur A, Crowther MA, Packham I, Chesser TJ. Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. *J Bone Joint Surg Am*. 2013 Sep 4;95(17):1576-84. doi: 10.2106/JBJS.L.00307.PMID: 24005198
 19. MacDermid JC. Development of a scale for patient rating of wrist pain and disability. *J Hand Ther [Internet]*. 1996;9(2):178–83. Available from: [http://dx.doi.org/10.1016/S0894-1130\(96\)80076-7](http://dx.doi.org/10.1016/S0894-1130(96)80076-7)
 20. Walenkamp MMJ, de Muinck Keizer RJ, Goslings JC, Vos LM, Rosenwasser MP, Schep NWL. The Minimum Clinically Important Difference of the Patient-rated Wrist Evaluation Score for Patients With Distal Radius Fractures. *Clin Orthop Relat Res* 2015;473(10):3235–41.
 21. Beaton DE, Wrigth JG, Katz JN. Development of the Quickdash. *J Bone Jt Surgery-American Vol*. 2005;87(5):1038–46.

Figure 1: Flowchart illustrating the recruitment process.



SECTION 5

BIOGRAPHICAL SKETCH

Not to exceed two pages for each person. Copy and paste below the two Bio-Sketch pages for each additional Investigator.

NAME Andrew D. Duckworth	TITLE Senior Clinical Lecturer and Honorary Consultant Orthopaedic Trauma Surgeon	BIRTHDATE (Mo., Day, Yr.) January 31st 1982	
PLACE OF BIRTH (City, State. Country) Leeds, Yorkshire, UK	NATIONALITY (If non-US citizen indicate visa status) British	SEX (right click on the check in box/properties/default value/checked) Male <input checked="" type="checkbox"/> Female <input type="checkbox"/>	
EDUCATION (Begin with baccalaureate training and include postdoctoral.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Edinburgh, UK	BSc	2003	Medical Sciences (Neuroscience)
University of Edinburgh, UK	MBChB	2006	Medicine
University of Edinburgh, UK	MSc	2010	Surgical Sciences
University of Edinburgh, UK	PhD	2016	Proximal forearm fractures
RELATIONSHIP TO PROPOSED PROJECT Chief Investigator (CI)	MAJOR RESEARCH INTEREST Trauma, Upper limb		
HONORS			
OTHER RESEARCH SUPPORT			
RESEARCH AND/OR PROFESSIONAL EXPERIENCE My current post is as a Senior Clinical Lecturer at the University of Edinburgh and Honorary Consultant Orthopaedic Trauma Surgeon at the Royal Infirmary of Edinburgh. I have authored over 130 peer-reviewed publications as well as a number of book chapters. I have been Principal Investigator for five completed or currently recruiting randomized controlled trials and am the Co-Chief Investigator for the MOTION trial that was recently awarded NIHR funding (£1,833,804.93). I am also co-applicant and PI for the NIHR funded SOFFT trial (£1,737,362.39).			
Employment Nov 2020 – Present Honorary Consultant Orthopaedic Trauma Surgeon, Royal Infirmary of Edinburgh Nov 2020 – Present Senior Clinical Lecturer at the University of Edinburgh Jan 2018 – Nov 2020 Consultant Orthopaedic Trauma Surgeon, Royal Infirmary of Edinburgh Aug – Dec 2017 Upper Limb Fellow, Wrightington Upper Limb Unit, Wrightington 2008 – 2017 Specialty Registrar, Trauma and Orthopaedics, South East Scotland 2010 – 2011 Clinical Research Fellow, SORT-IT, Edinburgh 2006 – 2008 Foundation Doctor, South Each Scotland			

Relevant Publications & Randomized Controlled Trials (*Published = 134, H-Index = 36, i10 Index = 77*)

PubMed Link: <https://pubmed.ncbi.nlm.nih.gov/?term=duckworth+ad&sort=date>

- MOTION Trial. *What is the clinical-effectiveness and cost-effectiveness of surgery with medial opening wedge high tibial osteotomy (HTO) compared with nonsurgical treatment in the management of osteoarthritis (OA) of the knee in patients younger than 60 years?*
 - Co-Chief Investigator
 - Funder: NIHR/HTA (£1,833,804.93)
- SOFFT Trial. *Simple Olecranon Fracture Fixation: Suture fixation versus tension band wiring for simple olecranon fracture fixation - a multi-centre randomised controlled trial*
 - Co-applicant, Principal Investigator and Trial Monitoring Group (TMG) Member
 - Funder: NIHR/HTA (£1,737,362.39)
 - Trial commenced: November 2019 (ISRCTN87904264)
- HuFIX Trial. *Humeral shaft fracture FIXation: A single centre prospective randomised controlled trial of operative versus non-operative management of fractures of the humeral diaphysis*
 - Co-Principal Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma (£100,000.00)
 - Trial commenced: September 2018 (NCT03689335)
 - Oliver WM, Carter TH, Graham C, White TO, Clement ND, **Duckworth AD**, Molyneux SG. A prospective randomised controlled trial of operative versus non-operative management of fractures of the humeral diaphysis: the HUmeral Shaft Fracture FIXation (HU-FIX) Study protocol. *Trials. 2019 Aug 5; 20(1):475.*
- MOON Trial. *Medial malleolus Operative Or Non-operative: A single centre prospective randomized controlled trial of operative versus nonoperative management of associated medial malleolus fractures in unstable fracture dislocations of the ankle joint*
 - Co-Principal Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma and Acumed® (£100,000.00)
 - Trial commenced: October 2017 (NCT03362229)
 - Carter TH, Oliver WM, Graham C, **Duckworth AD**, White TO. Medial malleolus: Operative Or Non-operative (MOON) trial protocol - a prospective randomised controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fractures of the ankle. *Trials. 2019 Sep 12; 20(1):565.*
- A Randomized Controlled Trial Comparing Traditional Plaster Cast Rehabilitation With Functional Walking Boot Rehabilitation for Acute Achilles Tendon Ruptures
 - Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma (£50,000.00)
 - Trial completed: July 2019 (NCT02598843)
 - Maempel JF, Clement ND, **Duckworth AD**, Keenan OJF, White TO, Biant LC. A Randomized Controlled Trial Comparing Traditional Plaster Cast Rehabilitation With Functional Walking Boot Rehabilitation for Acute Achilles Tendon Ruptures. *Am J Sports Med. 2020 Sep; 48(11):2755-2764.*
- ACORN Trial. *AcromioClavicular Open Reduction versus Nonoperative: A single centre prospective randomised controlled trial to compare open reduction and tunnelled suspensory device fixation versus nonoperative treatment for the management of acute grade III and IV acromioclavicular joint dislocations*
 - Investigator
 - Funder: Arthrex© (£64,000)
 - Trial completed: January 2018 (ISRCTN47376242)
 - Murray IR, Robinson PG, Goudie EB, **Duckworth AD**, Clark K, Robinson CM. Open Reduction and Tunnelled Suspensory Device Fixation Compared with Nonoperative Treatment for Type-III and Type-IV Acromioclavicular Joint Dislocations: The ACORN Prospective, Randomized Controlled Trial. *J Bone Joint Surg Am. 2018 Nov 21; 100(22):1912-1918.*

- FaB Trial. Fractures and Bisphosphonates: *A multi-centre double-blind, randomised placebo-controlled trial on the effect of alendronic acid on healing and clinical outcomes of wrist fractures*
 - Investigator
 - Funder: Arthritis Research UK (£723,692)
 - Trial completed: December 2015 (EudraCT ID: 2011-000988-28)
 - **Duckworth AD**, McQueen MM, Tuck CE, Tobias JH, Wilkinson JM, Biant LC, Pulford EC, Aldridge S, Edwards C, Roberts CP, Ramachandran M, McAndrew AR, Cheng KC, Johnston P, Shah NH, Mathew P, Harvie J, Hanusch BC, Harkess R, Rodriguez A, Murray GD, Ralston SH. Effect of Alendronic Acid on Fracture Healing: A Multicenter Randomized Placebo-Controlled Trial. *J Bone Miner Res.* 2019 Jun; 34(6):1025-1032.
- A prospective, randomised, controlled, multicentre, international trial comparing the fibular nail with open reduction and internal fixation for unstable ankle fractures in younger patients
 - Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma (£50,000.00)
 - Trial completed: February 2015 (ISRCTN54687269)
 - White TO, Bugler KE, Olsen L, Holck Lundholm L, Holck K, Lindegaard Madsen B, **Duckworth AD**. A prospective, randomised, controlled, two-centre, international trial comparing the fibular nail with open reduction and internal fixation for unstable ankle fractures in younger patients. *J Orthop Trauma.* 2021 Apr 17. doi: 10.1097/BOT.0000000000002140. *Online ahead of print.*
- Prospective randomized trial of plate fixation versus tension band wire for olecranon fractures
 - Co-Principal Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma (£36,000)
 - Trial completed: January 2016 (ClinicalTrials.gov ID NCT01391936)
 - **Duckworth AD**, Clement ND, White TO, Court-Brown CM, McQueen MM. Plate Versus Tension-Band Wire Fixation for Olecranon Fractures: A Prospective Randomized Trial. *J Bone Joint Surg Am.* 2017 Aug 2; 99(15):1261-1273.
- Prospective randomized trial of non-operative versus operative management of olecranon fractures in the elderly
 - Co-Principal Investigator
 - Funder: Scottish Orthopaedic Research Trust into Trauma (£22,000)
 - Trial completed: December 2015 (ClinicalTrials.gov ID NCT01397643)
 - **Duckworth AD**, Clement ND, McEachan JE, White TO, Court-Brown CM, McQueen MM. Prospective randomised trial of non-operative versus operative management of olecranon fractures in the elderly. *Bone Joint J.* 2017 Jul; 99-B(7):964-972.
- The influence of vitamin C on the outcome of distal radial fractures: *a double-blind, randomized controlled trial*
 - Investigator
 - Funder: Chief Scientist's Office for Scotland and the Scottish Orthopaedic Research Trust into Trauma (£142,603)
 - Trial completed: July 2008 (EudraCT 2005-003635-46)
 - Ekrol I, **Duckworth AD**, Ralston SH, Court-Brown CM, McQueen MM. The influence of vitamin C on the outcome of distal radial fractures: a double-blind, randomized controlled trial. *J Bone Joint Surg Am.* 2014 Sep 3; 96(17):1451-9.

Presentations

I have personally presented or contributed to work in over 160 national and international presentations.

SECTION 5

BIOGRAPHICAL SKETCH

Not to exceed two pages for each person. Copy and paste below the two Bio-Sketch pages for each additional Investigator.

NAME Samuel G. Molyneux	TITLE Consultant Orthopaedic Trauma Surgeon	BIRTHDATE (Mo., Day, Yr.) January 31st 1977	
PLACE OF BIRTH (City, State. Country) Blantyre, Malawi	NATIONALITY (If non-US citizen indicate visa status) British	SEX (right click on the check in box/properties/default value/checked) Male <input checked="" type="checkbox"/> Female <input type="checkbox"/>	
EDUCATION (Begin with baccalaureate training and include postdoctoral.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Newcastle Medical School	BMedSci	2001	Medical Sciences
Newcastle Medical School	MBBS	2002	Medicine
University of Teeside	MSc	2009	Evidence Based Orthopaedics
RELATIONSHIP TO PROPOSED PROJECT Additional investigator		MAJOR RESEARCH INTEREST	
HONORS			
OTHER RESEARCH SUPPORT			
RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.) I am a Consultant in Trauma and Orthopaedic Surgery at the Royal Infirmary of Edinburgh. I have a specialist interest in wrist and hand injuries, upper limb injury and pelvic / acetabular fractures, and run a regional tertiary referral service for these injuries. I also have a specialist interest in coordinating our major trauma care and liaise regularly with other regions and teams to maximise the efficiency of our major trauma network.			
Employment 2013 – Present Consultant Trauma and Orthopaedic Surgeon, Royal Infirmary of Edinburgh 2012 – 2013 Orthopaedic Trauma Fellowship, Vancouver General Hospital, Canada 2006 – 2012 Orthopaedic Specialty Training 2002 – 2006 House Officer Training			

Publications (15, 5 most recent)

PubMed Link: <https://pubmed.ncbi.nlm.nih.gov/?term=Molyneux+SG&sort=pubdate&size=200>

Oliver WM, Rhatigan D, Mackenzie SP, White TO, Duckworth AD, Molyneux SG. Outcome following mini-open lower limb fasciotomy for chronic exertional compartment syndrome. *Eur J Orthop Surg Traumatol.* 2021 Mar 6. doi: 10.1007/s00590-021-02919-z. Online ahead of print. PMID: 33675406

Stirling PHC, Broll RD, Molyneux SG, Oliver CW, McQueen MM, Duckworth AD. Percutaneous fixation of acute scaphoid waist fractures: Long-term patient-reported functional outcomes and satisfaction at a mean of 11 years following surgery. *Hand Surg Rehabil.* 2021 Jun;40(3):293-298. doi: 10.1016/j.hansur.2021.02.002. Epub 2021 Feb 27. PMID: 33652139

Oliver WM, Searle HKC, Ng ZH, Molyneux SG, White TO, Clement ND, Duckworth AD. Factors associated with humeral shaft nonunion. *J Shoulder Elbow Surg.* 2021 Feb 23:S1058-2746(21)00134-8. doi: 10.1016/j.jse.2021.01.029. Online ahead of print. PMID: 33636324

Oliver WM, Searle HKC, Ng ZH, Wickramasinghe NRL, Molyneux SG, White TO, Clement ND, Duckworth AD. Fractures of the proximal- and middle-thirds of the humeral shaft should be considered as fragility fractures. *Bone Joint J.* 2020 Nov;102-B(11):1475-1483. doi: 10.1302/0301-620X.102B11.BJJ-2020-0993.R1. PMID: 33135447

Stirling PHC, Oliver WM, Ling Tan H, Brown IDM, Oliver CW, McQueen MM, Molyneux SG, Duckworth AD. Patient-reported outcomes after corrective osteotomy for a symptomatic malunion of the distal radius. *Bone Joint J.* 2020 Nov;102-B(11):1542-1548. doi: 10.1302/0301-620X.102B11.BJJ-2020-0848.R3. PMID: 33135431

Presentations

I have presented nationally and internationally on over 20 occasions.

Randomised Controlled Trials/Research

HU-FIX: operative fixation versus conservative management of humeral shaft fractures.

This is a randomised controlled trial comparing the outcomes of treatment for humeral shaft fractures. We are aiming to recruit 70 patients to this trial, which is currently in progress. I am the senior author.

SECTION 5

BIOGRAPHICAL SKETCH

Not to exceed two pages for each person. Copy and paste below the two Bio-Sketch pages for each additional Investigator.

NAME Timothy O. White	TITLE Consultant Orthopaedic Trauma Surgeon	BIRTHDATE (Mo., Day, Yr.) November 1st 1970	
PLACE OF BIRTH (City, State. Country) Ras Al Khaimah, UAE	NATIONALITY (If non-US citizen indicate visa status) British	SEX (right click on the check in box/properties/default value/checked) Male <input checked="" type="checkbox"/> Female <input type="checkbox"/>	
EDUCATION (Begin with baccalaureate training and include postdoctoral.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Sheffield	BMedSci	1993	Anaesthesia
University of Sheffield	MBCbB	1995	Medicine
University of Edinburgh	MD	2005	Systemic response to trauma
RELATIONSHIP TO PROPOSED PROJECT Additional investigator		MAJOR RESEARCH INTEREST Trauma	
HONORS			
OTHER RESEARCH SUPPORT			
RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)			
<p>I am a Consultant Orthopaedic Trauma Surgeon and the Director of Orthopaedic Trauma at the Royal Infirmary of Edinburgh. I am an Honorary Senior Lecturer in the Department of Orthopaedic and Trauma Surgery at the University of Edinburgh. With ten consultant colleagues, I have responsibility for all emergency trauma admissions from the Edinburgh region as well as tertiary referrals from farther afield. I have published over 70 papers in peer reviewed journals and several book chapters, and supervise higher degree students for the University of Edinburgh.</p> <p>Employment</p> <p>2006 – Present Consultant Orthopaedic Trauma Surgeon, NHS Lothian</p> <p>Year – Present Director of Orthopaedic and Trauma Surgery, Royal Infirmary of Edinburgh</p> <p>2012 – Present Director and Secretary Scottish Orthopaedic Research Trust into Trauma (National research charity which runs the Symposium and funds two Research Fellows annually, and a standing research staff) Director Edinburgh International Trauma Symposium and Instructional Course</p>			

SECTION 5**BIOGRAPHICAL SKETCH (continued)**

2005 – 2006	Orthopaedic Trauma Fellowship, Vancouver General Hospital, Canada
1996 – 2005	Surgical training – basic then higher orthopaedic, South East Scotland Deanery
1995 – 1996	House Officer Training, Royal Hallamshire Hospital, Sheffield

Publications (over 70, 5 most recent)

PubMed Link: <https://pubmed.ncbi.nlm.nih.gov/?term=White+TO&sort=pubdate&size=200>

Hall AJ, Clement ND, MacLulich AMJ, Ojeda-Thies C, Hoefler C, Brent L, White TO, Duckworth AD. IMPACT of COVID-19 on hip fracture services: A global survey by the International Multicentre Project Auditing COVID-19 in Trauma & Orthopaedics. *Surgeon*. 2021 May 24:S1479-666X(21)00092-5. doi: 10.1016/j.surge.2021.04.007. Online ahead of print. PMID: 34103268

White TO, Bugler KE, Olsen L, Lundholm LH, Holck K, Madsen BL, Duckworth AD. A prospective, randomised, controlled, two-centre, international trial comparing the fibular nail with open reduction and internal fixation for unstable ankle fractures in younger patients. *J Orthop Trauma*. 2021 Apr 17. doi: 10.1097/BOT.0000000000002140. Online ahead of print. PMID: 33878069

Ng ZH, Downie S, Makaram NS, Kolhe SN, Mackenzie SP, Clement ND, Duckworth AD, White TO. 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. *Bone Jt Open*. 2021 Mar;2(3):211-215. doi: 10.1302/2633-1462.23.BJO-2020-0191.R1. PMID: 33752474 Free PMC article.

Oliver WM, Rhatigan D, Mackenzie SP, White TO, Duckworth AD, Molyneux SG. Outcome following mini-open lower limb fasciotomy for chronic exertional compartment syndrome. *Eur J Orthop Surg Traumatol*. 2021 Mar 6. doi: 10.1007/s00590-021-02919-z. Online ahead of print. PMID: 33675406

Oliver WM, Searle HKC, Ng ZH, Molyneux SG, White TO, Clement ND, Duckworth AD. Factors associated with humeral shaft nonunion. *J Shoulder Elbow Surg*. 2021 Feb 23:S1058-2746(21)00134-8. doi: 10.1016/j.jse.2021.01.029. Online ahead of print. PMID: 33636324

Randomised Controlled Trials/Research

I am an investigator in several on-going Randomised Controlled Trials (see below). I have on-going research projects into the biomechanical stability of ankle fracture fixation, the outcomes after tibial plateau fracture. I have laboratory studies into chondrocyte susceptibility to mechanical and thermal injury. I have an on-going collaboration with the Department of Medicine for the Elderly into the causes and effects of delirium, and Critical Care in the development of protocols for restricted blood transfusion.

SECTION 5**BIOGRAPHICAL SKETCH**

Not to exceed two pages for each person. Copy and paste below the two Bio-Sketch pages for each additional Investigator.

NAME Nicholas D. Clement		TITLE Consultant Orthopaedic Surgeon		BIRTHDATE (Mo., Day, Yr.) June 16th 1978													
PLACE OF BIRTH (City, State, Country) Sunderland, UK		NATIONALITY (If non-US citizen indicate visa status) British		SEX (right click on the check in box/properties/default value/checked) Male <input checked="" type="checkbox"/> Female <input type="checkbox"/>													
EDUCATION (Begin with baccalaureate training and include postdoctoral.)																	
INSTITUTION AND LOCATION		DEGREE	YEAR CONFERRED	FIELD OF STUDY													
Newcastle University, UK		MBBS	2005	Medicine													
University of Sunderland, UK		PhD	2015	Orthopaedics													
University of Edinburgh, UK		MD	2020	Elderly Trauma													
RELATIONSHIP TO PROPOSED PROJECT Additional investigator			MAJOR RESEARCH INTEREST Hip and knee arthroplasty, elderly fracture care														
HONORS																	
OTHER RESEARCH SUPPORT																	
RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)																	
<p>I am a consultant orthopaedic trauma surgeon in the Royal Infirmary of Edinburgh specialising in hip and knee arthroplasty, and elderly fracture care. I have higher degrees of MD and PhD for work looking at outcomes following elderly fractures and arthroplasty. I have published over 200 papers in peer reviewed journals and several book chapters, and supervise higher degree students for the University of Edinburgh.</p> <p>Employment</p> <table> <tr> <td>January 2018 – Present</td> <td>Consultant Orthopaedic Trauma Surgeon, NHS Lothian</td> </tr> <tr> <td>August 2017 – January 2018</td> <td>Arthroplasty Fellow, Freeman Hospital, Newcastle, UK</td> </tr> <tr> <td>August 2013 – Present</td> <td>Clinical Tutor, University of Edinburgh</td> </tr> <tr> <td>August 2007 – July 2017</td> <td>Specialty Registrar Trauma and Orthopaedic Surgery Southeast Scotland training programme</td> </tr> <tr> <td>March 2011 – January 2012</td> <td>Scottish Orthopaedic Research Trust Into Trauma Research Fellow</td> </tr> <tr> <td>August 2005 – July 2007</td> <td>Foundation Doctor, Sunderland Royal Hospital</td> </tr> </table>						January 2018 – Present	Consultant Orthopaedic Trauma Surgeon, NHS Lothian	August 2017 – January 2018	Arthroplasty Fellow, Freeman Hospital, Newcastle, UK	August 2013 – Present	Clinical Tutor, University of Edinburgh	August 2007 – July 2017	Specialty Registrar Trauma and Orthopaedic Surgery Southeast Scotland training programme	March 2011 – January 2012	Scottish Orthopaedic Research Trust Into Trauma Research Fellow	August 2005 – July 2007	Foundation Doctor, Sunderland Royal Hospital
January 2018 – Present	Consultant Orthopaedic Trauma Surgeon, NHS Lothian																
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August 2013 – Present	Clinical Tutor, University of Edinburgh																
August 2007 – July 2017	Specialty Registrar Trauma and Orthopaedic Surgery Southeast Scotland training programme																
March 2011 – January 2012	Scottish Orthopaedic Research Trust Into Trauma Research Fellow																
August 2005 – July 2007	Foundation Doctor, Sunderland Royal Hospital																

Prizes

Arthroscopy Journal Prize 2015	Best comparative study (\$5,000)
PanCeltic Meeting 2015	Best research presentation
S.C.O.T. winter meeting 2015	Best research presentation
Manske Award 2014	Most impactful paediatric upper limb research paper published 2013
S.C.O.T. winter meeting 2014	Best research presentation
BESS Leicester 2013	Ian Kelly prize for best presentation
S.C.O.T. summer meeting 2013	Best research presentation
S.C.O.T. summer meeting 2012	Best research presentation
Regional Research Symposium 2010	Best research presentation
Prostrakan Travelling fellowship 2009	Best review presentation

Publications (over 200, 5 most recent)

PubMed Link: <https://pubmed.ncbi.nlm.nih.gov/?term=Clement+ND&sort=pubdate&size=200>

Stirling PHC, Ng N, Jenkins PJ, Clement ND, Duckworth AD, McEachan JE. Hand-arm vibration and outcomes of surgery for Dupuytren's contracture. *Occup Med (Lond)*. 2021 Jun 9;kqab070. doi: 10.1093/occmed/kqab070. Online ahead of print. PMID: 34104973

Hall AJ, Clement ND, MacLulich AMJ, Ojeda-Thies C, Hofer C, Brent L, White TO, Duckworth AD. IMPACT of COVID-19 on hip fracture services: A global survey by the International Multicentre Project Auditing COVID-19 in Trauma & Orthopaedics. *Surgeon*. 2021 May 24;S1479-666X(21)00092-5. doi: 10.1016/j.surge.2021.04.007. Online ahead of print. PMID: 34103268

Ng N, Gaston P, Simpson PM, Macpherson GJ, Patton JT, Clement ND. Robotic arm-assisted versus manual total hip arthroplasty : a systematic review and meta-analysis. *Bone Joint J*. 2021 Jun;103-B(6):1009-1020. doi: 10.1302/0301-620X.103B6.BJJ-2020-1856.R1. PMID: 34058875

Clement ND, Scott CEH, Hamilton DF, MacDonald D, Howie CR. Meaningful values in the Forgotten Joint Score after total knee arthroplasty. *Bone Joint J*. 2021 May;103-B(5):846-854. doi: 10.1302/0301-620X.103B5.BJJ-2020-0396.R1. PMID: 33934639

Leow JM, Clement ND, McQueen MM, Duckworth AD. The rate and associated risk factors for acute carpal tunnel syndrome complicating a fracture of the distal radius. *Eur J Orthop Surg Traumatol*. 2021 Apr 23. doi: 10.1007/s00590-021-02975-5. Online ahead of print. PMID: 33891155

Presentations

I have presented over 40 podium presentations at regional and international meetings.

Randomised Controlled Trials/Research

I have been involved in eight randomised controlled trials previously, all of which have finished recruiting and are either published or in the process of publication.

SECTION 5

BIOGRAPHICAL SKETCH

Not to exceed two pages for each person. Copy and paste below the two Bio-Sketch pages for each additional Investigator.

NAME Katrina R. Bell		TITLE Clinical Research Fellow		BIRTHDATE (Mo., Day, Yr.) June 15 th 1990	
PLACE OF BIRTH (City, State, Country) Stirling, UK		NATIONALITY (If non-US citizen indicate visa status) British		SEX (right click on the check in box/properties/default value/checked) Male <input type="checkbox"/> Female <input checked="" type="checkbox"/>	
EDUCATION (Begin with baccalaureate training and include postdoctoral.)					
INSTITUTION AND LOCATION		DEGREE	YEAR CONFERRED	FIELD OF STUDY	
University of Edinburgh, UK		MBChB	2013	Medicine	
RELATIONSHIP TO PROPOSED PROJECT Investigator			MAJOR RESEARCH INTEREST		
HONORS					
OTHER RESEARCH SUPPORT					
RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)					
<p>I am currently taking time out of my orthopaedic training as a Clinical Research Fellow, carrying out an MD with the University of Edinburgh. This role involves recruiting to a single-centre randomised controlled trial as well as the large multi-centre NIHR funded SOFFT trial, for which I am Associate Principal Investigator. To enable me to carry out this role I have completed Good Clinical Practice (GCP) training and completed the GRANULE course.</p>					
Employment					
2020 – Present		Clinical Research Fellow, Scottish Orthopaedic Research Trust Into Trauma			
2016 – 2020		Specialty Registrar, Trauma and Orthopaedic Surgery, South East Scotland			
2015 – 2016		Clinical Development Fellow, Trauma & Orthopaedics, Royal Infirmary of Edinburgh			
2015 – 2015		Foundation Doctor, South East Scotland			

Publications*PubMed Link:*

<https://pubmed.ncbi.nlm.nih.gov/?term=Bell+KR+AND+Edinburgh&sort=pubdate&size=200>

Bell KR, White TO, Molyneux SG, Duckworth AD. Chapter 9: Predictors of Instability and Secondary Displacement After Conservatively Managed Distal Radius Fractures. In: Distal Radius Fractures Evidence Based Medicine, 1st ed. Editors: Buijze GA, Jupiter J, Chammas M. Oxford: Elsevier, 2021.

Lloyd TD, Neal-Smith G, Fennelly J, Claireaux H, Bretherton C, Carr AJ, Murphy M, Kendrick BJ, Palmer AJR, collaborators. 'Peri-operative Administration of Tranexamic Acid in Lower Limb Arthroplasty: A Multicentre, Prospective Cohort Study' *Anaesthesia*, 2020 Aug;75(8):1050-1058. PMID: **32500530**

Robinson CM, Bell KR, Murray IR. 'Open Reduction and Tunneled Suspensory Device Fixation of Displaced Lateral-End Clavicular Fractures: Medium-Term Outcomes and Complications After Treatment'. *J Bone Joint Surg Am.* 2019;101:1335-41. PMID: 31393423

Carter TH, Mackenzie SP, Bell K, Hollyer MA, Gill EC, MacDonald D, Duckworth AD, White TO. Selective fixation of the medial malleolus in unstable ankle fractures. *Injury.* 2019 Apr;50(4):983-989. PMID: 30879641

Carter TH, Mackenzie SP, Bell K, Bugler K, MacDonald D, Duckworth AD, White TO. Optimising long-term outcomes and avoiding failure with the fibula intramedullary nail. *J Orthop Trauma.* 2019 Apr;33(4):189-195. PMID: 30562254

Scott CEH, Bell KR, Ng RT, MacDonald DJ, Patton JT, Burnett R. Excellent 10-year patient-reported outcomes and survival in a single- radius, cruciate-retaining total knee arthroplasty. *Knee Surgery, Sports Traumatology, Arthroscopy.* 2019 Apr;27(4):1106-1115. PMID: 30276434

Bell KR, Clement ND, Jenkins PJ, Keating JF. A comparison of the use of uncemented hydroxyapatite-coated bipolar and cemented femoral stems in the treatment of femoral neck fractures: a case-control study. *Bone Joint J.* 2014 Mar;96-B(3):299-305. PMID: 24589782

Presentations

I have both personally presented and contributed to work presented nationally and internationally on 14 occasions.

SECTION 6

RESEARCH SUPPORT, SUBMISSIONS

Please combine the information on this page for PI and Co-PI. Add additional lines and pages as needed, there is no word limit in this section.

Prior OTA Funding to Principal Investigator or Co-P.I.:

SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF
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No Prior Funding from OTA

Research Support to Principal Investigator or Co-PI Relevant to THIS Project Past 5 Years (Include That From Own Institution):

SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF
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PI has dedicated research time for this project as part of university post.

Support To Principal Investigator or Co-PI for OTHER Research Projects:

SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF
NIHR	SOFFT Trial	3% FTE salary	2019 - 2024
NIHR	MOTION Trial	5% FTE salary	2022 - 2027

Please see PI Section 5 where further details of this can be found.

Previous Research:

SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF
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NA

Current Research:

SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF
NIHR	SOFFT Trial	3% FTE salary	2019 - 2024
NIHR	MOTION Trial	5% FTE salary	2022 - 2027

Please see PI Section 5 where further details of this can be found.

Submissions Of This Or Similar Project To Other Agencies

SUBMITTED: NA

PLANNED: NA