Intramedullary nail fixation versus locking plate fixation for adults with a fracture of the distal tibia: the UK FixDT RCT

Matthew L Costa, 1,2,3* Juul Achten, 1,3
Susie Hennings, 1 Nafisa Boota, 1 James Griffin, 1
Stavros Petrou, 1 Mandy Maredza, 1 Melina Dritsaki, 3
Thomas Wood, 2 James Masters, 2,3 Ian Pallister, 4
Sarah E Lamb 1,3 and Nick R Parsons 1 on behalf of the UK FixDT trial investigators

¹Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK ²Department of Trauma and Orthopaedics, University Hospitals Coventry and Warwickshire NHS Trust, Coventry, UK

Declared competing interests of authors: Matthew L Costa is a member of the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) General Board and reports grants from the trauma industry (Stryker Corporation, X-Bolt Orthopaedics, Onbone, Smith & Nephew plc, Heraeus Holding GmbH and DePuy Synthes Companies); grants from the AO Foundation; and grants from NIHR and the European Union outside the submitted work. Sarah E Lamb was a member of the NIHR HTA Additional Capacity Funding Board, NIHR HTA End of Life Care and Add-on Studies, NIHR HTA Prioritisation Group and NIHR HTA Trauma Board during this study.

Published May 2018 DOI: 10.3310/hta22250

Plain English summary

The UK FixDT RCT

Health Technology Assessment 2018; Vol. 22: No. 25

DOI: 10.3310/hta22250

NIHR Journals Library www.journalslibrary.nihr.ac.uk

³Oxford Trauma, Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, Oxford, UK

⁴Medical School, Swansea University, Swansea, Wales

^{*}Corresponding author matthew.costa@ndorms.ox.ac.uk

Plain English summary

The shin bone (tibia) is the most commonly broken major bone in the leg. Injuries in the lower part of the shin bone (distal tibia) nearly always require hospital admission and usually require surgery, resulting in prolonged periods (months) away from work and social activities.

Existing research suggested that modern 'locking' plate fixation and intramedullary (IM) nail fixation are the most common types of operation performed for this fracture. However, it was not clear which provides the better outcome for patients.

In this study, we asked 321 adult patients, who were having surgery for a fracture of the distal tibia, to have either IM nail fixation or locking plate fixation. The decision about which type of fixation to use was made using randomisation, which is a process similar to tossing a coin. The patients reported their own outcome at 3, 6 and 12 months after their fracture using the Disability Rating Index (DRI). We also collected information on quality of life, complications and costs from patient-completed questionnaires and other NHS sources.

The DRI score of both groups of patients improved in the months after their surgery, although patients were not back to normal, even 1 year later. The patients who had IM nail fixation of their tibial fracture recovered more quickly than the patients with locking plate fixation, but there were no differences between the treatments after 6 months. There was no difference in the number of complications suffered by each group, but further surgery was more common in the locking plate group. The economic analysis showed that IM nail fixation was cheaper than locking plate fixation.

This important study shows that IM nail fixation provides slightly better quality of life for patients in the 12 months following a fracture of the distal tibia and costs less than locking plate fixation. If surgery to fix the distal tibia is required, IM nail fixation is the preferred treatment.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Health Technology Assessment journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 11/136/04. The contractual start date was in March 2013. The draft report began editorial review in March 2017 and was accepted for publication in November 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Costa et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Technology Assessment Editor-in-Chief

Professor Hywel Williams Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk