Total ankle replacement versus ankle arthrodesis for patients aged 50–85 years with end-stage ankle osteoarthritis: the TARVA RCT

Andrew J Goldberg,[1,2,3*] Kashfia Chowdhury,[4] Ekaterina Bordea,[4] James Blackstone,[4] Deirdre Brooking,[2] Elizabeth L Deane,[4] Iva Hauptmannova,[2] Paul Cooke,[5] Marion Cumbers,[2] Simon S Skene[6] and Caroline J Doré[4] on behalf of the TARVA Study Group[†]

[1]Institute of Orthopaedics & Musculoskeletal Science, Division of Surgery, University College London, London, UK
[2]Department of Research & Innovation, Royal National Orthopaedic Hospital, London, UK
[3]MSK Lab, Sir Michael Uren Hub, Imperial College London, London, UK
[4]Comprehensive Clinical Trials Unit, Institute of Clinical Trials and Methodology, University College London, London, UK
[5]Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Trust, Oxford, UK
[6]Surrey Clinical Trials Unit, University of Surrey, Guildford, UK

*Corresponding author Andy.goldberg@nhs.net
[†]The names of the TARVA Study Group members can be found at www.anklearthritis.co.uk

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/PTYJ1146.

Primary conflicts of interest: Andrew J Goldberg declares the following competing interests: American Orthopaedic Foot and Ankle Society (board or committee member; 2012–present), British Orthopaedic Foot & Ankle Society (board or committee member; 2011–present), National Joint Registry (board or committee member; 2010–present), Foot and Ankle International and Foot and Ankle Orthopaedics (editorial or governing board; 2014–present), Stryker (previously Wright Medical Technology, Inc.; Memphis, TN, USA) (paid presenter or speaker), Standing CT (stock or stock options) and X-Bolt Orthopaedics (Dublin, Ireland) (unpaid consultant)..

Published March 2023
DOI: 10.3310/PTYJ1146

Plain language summary

Total ankle replacement versus ankle arthrodesis

Health Technology Assessment 2023; Vol. 27: No. 5
DOI: 10.3310/PTYJ1146

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

Plain language summary

Each year, over 29,000 patients with ankle osteoarthritis seek a specialist opinion, of whom 4000 undergo NHS surgical treatment. The main surgical treatments for severe ankle osteoarthritis are total ankle replacement or arthrodesis (i.e. ankle fusion). Both are known to be good treatments to relieve pain, and each has its advantages. Total ankle replacement is a more popular patient choice than ankle fusion. When deciding whether to undergo ankle replacement or fusion, patients consult various sources, but the majority of them rely on the advice of their surgeon to make a final decision. To the best of our knowledge, there has never been a high-quality randomised clinical trial comparing these two treatments and there are no published guidelines on the most suitable management.

In this study, 303 patients were randomised to a type of ankle surgery: 138 in the total ankle replacement arm and 144 in the ankle fusion arm received surgery. We found that both total ankle replacement and ankle fusion improved patients' walking ability, but we did not find a statistically significant difference between the treatment arms based on our primary outcome measure at 1 year. When we considered the type of total ankle replacement implant, we found that the implant most commonly used in the NHS (a fixed-bearing two-component implant) had better outcomes at 1 year than ankle fusion. Both total ankle replacement and ankle fusion appear to be safe. However, there were more wound-healing issues and nerve injuries in the total ankle replacement arm than in the ankle fusion arm. Twelve per cent of patients experienced bone non-union in the ankle fusion arm, but only 7.1% experienced symptoms.

We estimate that there is a 69% chance that total ankle replacement would be cost-effective compared with ankle fusion at the National Institute for Health and Care Excellence's cost-effectiveness threshold of £20,000 per quality-adjusted life-year gained over a patient's lifetime. This study provides the NHS with important information that could help to obtain the best possible outcome for patients with severe ankle arthritis.

Copyright © 2023 Goldberg *et al*. This work was produced by Goldberg *et al*. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaption in any medium and for any purpose provided that it is properly attributed. See: https://creativecommons.org/licenses/by/4.0/. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 4.014 and is ranked 27th (out of 108 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2021 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), Embase (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded (Clarivate , Philadelphia, PA, USA).

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.

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

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

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.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 16/78/04. The contractual start date was in May 2018. The draft report began editorial review in November 2020 and was accepted for publication in May 2021. 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 and Care 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, 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, the HTA programme or the Department of Health and Social Care.

Copyright © 2023 Goldberg *et al*. This work was produced by Goldberg *et al*. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaption in any medium and for any purpose provided that it is properly attributed. See: https://creativecommons.org/licenses/by/4.0/. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

Published by NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress, final files produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).

NIHR Journals Library Editor-in-Chief

Dr Cat Chatfield Director of Health Services Research UK

NIHR Journals Library Editors

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HSDR, PGfAR, PHR journals) and Editor-in-Chief of HSDR, PGfAR, PHR journals

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 Consultant in Public Health, Delta Public Health Consulting Ltd, UK

Dr Peter Davidson Interim Chair of HTA and EME Editorial Board. Consultant Advisor, School of Healthcare Enterprise and Innovation, University of Southampton, UK

Ms Tara Lamont Senior Adviser, School of Healthcare Enterprise and Innovation, University of Southampton, UK

Dr Catriona McDaid Reader in Trials, 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 Emeritus Professor of Wellbeing Research, University of Winchester, UK

Professor James Raftery Professor of Health Technology Assessment, School of Healthcare Enterprise and Innovation, University of Southampton, UK

Dr Rob Riemsma Consultant Advisor, School of Healthcare Enterprise and Innovation, University of Southampton, UK

Professor Helen Roberts Professor of Child Health Research, Child and Adolescent Mental Health, Palliative Care and Paediatrics Unit, Population Policy and Practice Programme, UCL Great Ormond Street Institute of Child Health, London, 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 Ken Stein Professor of Public Health, University of Exeter Medical School, UK

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

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

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