Surgical treatments compared with early structured physiotherapy in secondary care for adults with primary frozen shoulder: the UK FROST three-arm RCT

Stephen Brealey,1 Matthew Northgraves,1 Lucksy Kottam,2 Ada Keding,1 Belen Corbacho,1 Lorna Goodchild,3 Cynthia Srikesavan,4 Saleema Rex,1 Charalambos P Charalambous,5,6 Nigel Hanchard,7 Alison Armstrong,8 Andrew Brooksbank,9 Andrew Carr,4 Cushla Cooper,4 Joseph Dias,8 Iona Donnelly,9 Catherine Hewitt,1 Sarah E Lamb,4 Catriona McDaid,1 Gerry Richardson,10 Sara Rodgers,1 Emma Sharp,9 Sally Spencer,11 David Torgerson,1 Francine Toye12 and Amar Rangan1,2,4*

1York Trials Unit, Department of Health Sciences, University of York, York, UK
2The James Cook University Hospital, South Tees Hospitals NHS Foundation Trust, Middlesbrough, UK
3The Physiotherapy Practice, South Shields, UK
4Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Botnar Research Centre, University of Oxford, Oxford, UK
5Department of Orthopaedics, Blackpool Victoria Hospital, Blackpool, UK
6School of Medicine, University of Central Lancashire, Preston, UK
7School of Health & Life Sciences, Teesside University, Middlesbrough, UK
8University Hospitals of Leicester NHS Trust, Leicester, UK
9Glasgow Royal Infirmary, Glasgow, UK
10Centre for Health Economics, University of York, York, UK
11Postgraduate Medical Institute, Edge Hill University, Ormskirk, UK
12Physiotherapy Research Unit, Oxford University Hospitals NHS Foundation Trust, Oxford, UK

*Corresponding author amar.rangan@york.ac.uk

Declared competing interests of authors: Lucksy Kottam reports grants from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme for other work during the conduct of this study. South Tees Hospitals NHS Foundation Trust receives an educational grant to the Department of Trauma and Orthopaedic Surgery from DePuy Synthes (Warsaw, IN, USA: part of the Johnson & Johnson Medical Devices group). It also receives payment from DePuy Synthes for Lucksy Kottam as a study co-ordinator for the GLOBAL ICON Stemless Shoulder System Post Market
Clinical Follow Up Study: CT 1401. These payments are outside and unrelated to the submitted work. Catherine Hewitt is a member of the NIHR HTA Commissioning Board. Catriona McDaid receives funding from the British Orthopaedic Association (2014 to present). She is a member of the NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2017 to present). Sarah E Lamb reports membership of the following boards: HTA Additional Capacity Funding Board 2012–15, HTA Clinical Trials Board 2010–15, HTA End of Life Care and Add on Studies Board 2015, HTA Funding Boards Policy Group (formerly Clinical Studies Group) 2010–15, HTA Maternal, Neonatal and Child Health Methods Group 2013–15, HTA Post-board funding teleconference 2010–15, HTA Primary Care Themed Call Board 2013–14, HTA Prioritisation Group 2010–15 and the NIHR Clinical Trials Unit Standing Advisory Committee 2012–16. Amar Rangan reports other grants from the NIHR HTA programme, Orthopaedic Research UK (London, UK) and Horizon 2020 during the conduct of the study. South Tees Hospitals NHS Foundation Trust receives an educational grant to the department from DePuy Synthes. The institution also receives payment from DePuy Synthes for Amar Rangan as the co-ordinating investigator for the GLOBAL ICON Stemless Shoulder System Post Market Clinical Follow Up Study: CT 1401. These are outside and unrelated to the submitted work. Joseph Dias reports grants from NIHR during the conduct of the study, outside the submitted work.

Published December 2020
DOI: 10.3310/hta24710

Plain English summary
The UK FROST three-arm RCT
Health Technology Assessment 2020; Vol. 24: No. 71
DOI: 10.3310/hta24710

NIHR Journals Library www.journalslibrary.nihr.ac.uk
**Plain English summary**

Frozen shoulder occurs when the soft tissue envelope around the shoulder joint becomes inflamed, scarred and contracted, making movement painful and stiff. It affects around 1 in 10 people and is more common in women. Most patients are treated in the community. Those who do not improve are offered treatments in hospital. This includes costly and invasive surgical options. It is unclear which treatment provides the best patient outcomes and is cost-effective.

UK FROST (UK FROzen Shoulder Trial) comprised 503 patients (from 35 UK hospitals) who randomly received one of three commonly offered treatments for frozen shoulder:

1. early physiotherapy to restore movement, including a steroid injection for pain relief
2. manipulation under anaesthesia, to stretch and tear the tight capsule to restore movement, and a steroid injection followed by physiotherapy
3. arthroscopic capsular release, which uses keyhole surgery, including manipulation, to restore movement, followed by physiotherapy with pain medication.

No important differences were found between the three treatments in shoulder function or pain at 12 months. Fewer patients who received arthroscopic capsular release required further treatment, and patients who received arthroscopic capsular release had slightly better shoulder function and pain outcomes than those who received the manipulation procedure or early physiotherapy. This improvement, however, was unlikely to be of clinical benefit to patients. Arthroscopic capsular release had slightly higher risks and substantially higher costs. Six serious complications were reported in patients who received arthroscopic capsular release (mostly owing to co-existing health problems) and two were reported in patients who received manipulation under anaesthesia. Physiotherapy was the least expensive treatment, but patients who received manipulation under anaesthesia had slightly better general health than those who received physiotherapy. Early physiotherapy with steroid injection could be accessed quicker than the surgical alternatives. Manipulation under anaesthesia cost more than physiotherapy but provided the best value for money. Patients in the study wanted early access to medical help to improve their shoulder problems.
Health Technology Assessment

ISSN 1366-5278 (Print)
ISSN 2046-4924 (Online)
Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and 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

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 13/26/01. The contractual start date was in October 2014. The draft report began editorial review in October 2019 and was accepted for publication in June 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. This report has been published following a shortened production process and, therefore, did not undergo the usual number of proof stages and opportunities for correction. 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 2020. This work was produced by Brealey 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).
Editor-in-Chief of Health Technology Assessment and NIHR Journals Library

Professor Ken Stein  Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor John Powell  Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. 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 (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, 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  Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson  Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont  Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, 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  Emeritus Professor of Wellbeing Research, University of Winchester, UK

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

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

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

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