

# Clinical effectiveness and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study – results from the PROSPECT Study

Cathryn Glazener,<sup>1\*</sup> Suzanne Breeman,<sup>1</sup>  
Andrew Elders,<sup>2</sup> Christine Hemming,<sup>3</sup> Kevin Cooper,<sup>3</sup>  
Robert Freeman,<sup>4</sup> Anthony Smith,<sup>5</sup> Suzanne Hagen,<sup>2</sup>  
Isobel Montgomery,<sup>6</sup> Mary Kilonzo,<sup>7</sup> Dwayne Boyers,<sup>1,7</sup>  
Alison McDonald,<sup>1</sup> Gladys McPherson,<sup>1</sup>  
Graeme MacLennan<sup>1</sup> and John Norrie<sup>1</sup>

<sup>1</sup>Health Services Research Unit, University of Aberdeen, Aberdeen, UK

<sup>2</sup>Nursing, Midwifery and Allied Health Professionals Research Unit, Glasgow Caledonian University, Glasgow, UK

<sup>3</sup>Aberdeen Royal Infirmary, Aberdeen, UK

<sup>4</sup>Derriford Hospital, Plymouth, UK

<sup>5</sup>St Mary's Hospital, Manchester, UK

<sup>6</sup>Patient representative, Aberdeen, UK

<sup>7</sup>Health Economics Research Unit, University of Aberdeen, Aberdeen, UK

\*Corresponding author

**Declared competing interests of authors:** Robert Freeman reports personal fees from speaker fees for Astellas and Pfizer, outside the submitted work. John Norrie reports non-financial support from Health Technology Assessment (HTA) Commissioning Board and personal fees from the National Institute for Health Research (NIHR) HTA and Efficacy and Mechanism Evaluation (EME) Editorial Board, outside the submitted work. He is a member of the NIHR Journals Library Editorial Group. Andrew Elders reports a grant from the NIHR HTA programme during the conduct of the study; his institution (Glasgow Caledonian University) is due to receive payment for statistical analysis from the University of Aberdeen using funds from their NIHR grant.

Published December 2016

DOI: 10.3310/hta20950

## Plain English summary

### Results from the PROSPECT Study

Health Technology Assessment 2016; Vol. 20: No. 95

DOI: 10.3310/hta20950

NIHR Journals Library [www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)

## Plain English summary

About 10% of women have pelvic organ prolapse surgery, and one-third require a further operation. To improve prolapse repair results, surgeons used synthetic mesh and graft materials to reinforce the repair because this had worked well for hernia repairs. This study aimed to provide evidence on whether or not the use of these materials are more effective than a standard/traditional repair.

We compared a standard repair with a standard repair supported with a synthetic non-absorbable mesh inlay or mesh inserted using a kit, or a semi-absorbable biological graft inlay. We asked women about their prolapse and other symptoms, assessed their prolapse measurements and compared the results between the different procedures.

Most women reported that their prolapse symptoms and quality of life improved after surgery. We found that all of the surgical options worked equally well, but mesh or graft surgery was more expensive. Adverse effects were similar in all groups, but some women who had synthetic mesh (around 1 in 20) needed extra surgery, typically to remove a small portion of the mesh. The need for further prolapse surgery was similar for all groups. Results in non-randomised women were similar to randomised women, suggesting that the overall results would apply to most UK women who are having prolapse surgery.

Overall, we found no benefit to women who were having mesh or graft material in the first 2 years, and the costs were higher. Some women did require additional minor surgery for synthetic mesh exposure. Participants will be followed up for at least 6 years after surgery to determine longer-term costs and consequences.



ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

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

Editorial contact: [nhredit@southampton.ac.uk](mailto:nhredit@southampton.ac.uk)

The full HTA archive is freely available to view online at [www.journalslibrary.nihr.ac.uk/hta](http://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](http://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 15/141/01. The contractual start date was in September 2009. The draft report began editorial review in September 2015 and was accepted for publication in February 2016. 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. 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.

© Queen's Printer and Controller of HMSO 2016. This work was produced by Glazener *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. 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](http://www.journalslibrary.nihr.ac.uk)), produced by Prepress Projects Ltd, Perth, Scotland ([www.prepress-projects.co.uk](http://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 Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

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

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

**Professor Matthias Beck** Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

**Professor Aileen Clarke** Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

**Dr Tessa Crilly** Director, Crystal Blue Consulting Ltd, UK

**Dr Eugenia Cronin** Senior Scientific Advisor, Wessex Institute, UK

**Ms Tara Lamont** Scientific Advisor, NETSCC, UK

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

**Professor Geoffrey Meads** Professor of Health Sciences Research, Health and Wellbeing Research Group, 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 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](http://www.journalslibrary.nihr.ac.uk/about/editors)

**Editorial contact:** [nihredit@southampton.ac.uk](mailto:nihredit@southampton.ac.uk)