Sacral nerve stimulation versus the magnetic sphincter augmentation device for adult faecal incontinence: the SaFaRI RCT

David G Jayne,1* Annabelle E Williams,2 Neil Corrigan,3 Julie Croft,3 Alison Pullan,3 Vicky Napp,3 Rachel Kelly,3 David Meads,4 Armando Vargas-Palacios,4 Adam Martin,4 Claire Hulme,5 Steven R Brown,6 Karen Nugent,7 Jen Lodge,8 David Protheroe,9 Sushil Maslekar,10 Andrew Clarke,11 Pasha Nisar12 and Julia M Brown3

1Academic Surgery, Leeds Institute of Medical Research at St James’s, University of Leeds, Leeds, UK  
2Colorectal and General Surgery, Milton Keynes University Hospital, Milton Keynes, UK  
3Clinical Trials Research Unit, Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK  
4Academic Unit of Health Economics, Leeds Institute of Health Sciences, University of Leeds, Leeds, UK  
5Health Economics Group, Institute of Health Research, University of Exeter Medical School, Exeter, UK  
6Department of Colorectal Surgery, Northern General Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK  
7University of Southampton, Southampton, UK  
8Bowel Health and Pelvic Floor Dysfunction Community Urology and Colorectal Service (CUCS), Leeds Community Healthcare NHS Trust, Leeds, UK  
9Department of Liaison Psychiatry, Leeds General Infirmary, Leeds and York Partnership NHS Foundation Trust, Leeds, UK  
10St James’s Hospital, Leeds Teaching Hospitals NHS Trust, Leeds, UK  
11Poole Hospital NHS Foundation Trust, Poole, UK  
12St Peter’s Hospital, Ashford and St Peter’s Hospitals NHS Foundation Trust, Chertsey, UK

*Corresponding author d.g.jayne@leeds.ac.uk
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Plain English summary

Faecal incontinence is a distressing condition for patients, and surgery is recommended if symptoms are having an effect on quality of life. One of the treatments recommended for faecal incontinence by the National Institute for Health and Care Excellence is sacral nerve stimulation, which aims to improve continence by stimulating the nerves to the back passage. A newer treatment involves surgery to implant a string of magnetic beads around the anal canal using the FENIX™ device (Torax Medical, Minneapolis, MN, USA). The aim of this study was to assess the benefits and risks of the FENIX device compared with sacral nerve stimulation.

The SaFaRI study aimed to recruit 350 participants with faecal incontinence, but was stopped early because of the manufacturer withdrawing the FENIX device for strategic reasons. In total, we recruited 99 participants. Fifty participants were allocated to receive the FENIX device and 49 participants were allocated to receive sacral nerve stimulation. The observed success rates with both devices were low: at 18 months following their entry into the study, 6 out of 41 (14.6%) participants in the FENIX group and 4 out of 39 (10.3%) participants in the sacral nerve stimulation group had the device both in use and producing a benefit. A total of 5 out of 50 (10.0%) participants allocated to receive the FENIX device did not have a device implanted, and 15 out of 45 (33.3%) participants who did have the FENIX device implanted needed to have it removed because of complications during the 18-month follow-up period. A total of 21 out of 49 (42.9%) participants allocated to receive sacral nerve stimulation did not have a permanent sacral nerve stimulation device implanted, and 0 of the 28 who did have a permanent sacral nerve stimulation device implanted needed to have it removed during the 18-month follow-up period. The costs associated with the FENIX device were higher because of a greater number of participants experiencing complications, meaning that the FENIX device is unlikely to be cost-effective in the treatment of faecal incontinence compared with sacral nerve stimulation.
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This report

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