Sacral nerve stimulation versus FENIX™ magnetic sphincter augmentation for adult faecal incontinence

This project was funded by the National Institute for Health Research Health Technology Assessment (project number 12/35/07)
Faecal Incontinence

- 3 – 8% adult population
- More common with advancing age
- 2\textsuperscript{nd} commonest admission to nursing home
- Impacts on social, physical, and mental well-being
- Substantial burden on NHS resources
Sacral Nerve Stimulation

- NICE 2007 recommended
  "trial of SNS be considered in patients in whom sphincter surgery is deemed inappropriate"
- 2-stage procedure
  - i) PNE ii) Permanent InterStim
Sacral Nerve Modulation

Popular and well accepted
• Minimally invasive technique
• Well cited success rates ~70%
• Minimal morbidity 5 – 26%

Cost-effective
• Initial costs
  • Direct costs ~ £9,000
  • Indirect costs ~£12,959
• Cost of colostomy ~£27,000 over 5 years
• Cost-effective – ICER £25,070
Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence

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*Br J Surg 2013; 100; 1430-47*

Success and cure rates

<table>
<thead>
<tr>
<th>Reference</th>
<th>Median follow-up (months)</th>
<th>No. at baseline</th>
<th>No. at follow-up</th>
<th>% at follow-up</th>
<th>&gt; 50% improvement in FI episodes per week (%)</th>
<th>100% continence (%)</th>
<th>&gt; 50% improvement in FI episodes per week (%)</th>
<th>100% continence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary*</td>
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<td></td>
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<tr>
<td>Short term</td>
<td>12 (6–12)</td>
<td>29 (12–106)</td>
<td>100 (56–100)</td>
<td>79 (69–83)</td>
<td>42 (21–68)</td>
<td></td>
<td>63 (33–66)</td>
<td>36 (8–68)</td>
</tr>
<tr>
<td>Medium term</td>
<td>25 (17–36)</td>
<td>37 (15–169)</td>
<td>100 (64–100)</td>
<td>80 (65–88)</td>
<td>40 (5–74)</td>
<td></td>
<td>58 (52–81)</td>
<td>32 (4–74)</td>
</tr>
<tr>
<td>Long term</td>
<td>56 (44–118)</td>
<td>21 (9–91)</td>
<td>79 (21–100)</td>
<td>84 (75–100)</td>
<td>35 (4–52)</td>
<td></td>
<td>54 (50–58)</td>
<td>20 (2–48)</td>
</tr>
</tbody>
</table>

Only 86 patients with long term FU data

Quality of Life

- Most report significant improvement in all domains of QoL
- Not ITT analysis
Fenix Continence Restoration System

- CE marked 2011
- Minimally invasive
- Augments natural anal sphincter
- £4K per implant
- Limited clinical data – suggests safe & effective
Surgical Technique

- Single perineal incision
- Tunnel in the ischioanal fossa just beneath the levator ani
- Sizing tool for model selection
- Implant and verify with fluoroscopy
Fenix Registry

Cleveland Clinic Incontinence Score

* $P \leq 0.001$

* $^1P=0.002$

n.s. = 0.068
Fenix Registry

FI Quality of Life

![Bar chart showing the quality of life before and after surgery for different categories: lifestyle, coping, depression, embarrassment, and total. The chart includes error bars and notes the significance levels with asterisks: *P ≤ 0.001, *P = 0.002, and *P = 0.004.]
Current evidence on safety and efficacy of a magnetic bead band for faecal incontinence is limited. If further evidence supports the efficacy of this procedure, it has the potential to significantly improve quality of life for appropriately selected patients.

Clinicians should offer all eligible patients entry into the HTA trial – 12/35/07

The procedure should only be performed in units specializing in the assessment and treatment of faecal incontinence.
SaFaRI

Objectives

• Short-term safety and efficacy of FENIX and SNS

• Impact of FENIX and SNS on QoL and cost effectiveness
SaFaRI

Primary outcome
• Proportion of patients with FENIX or SNS in situ at 18-months follow-up with device working and with ≥50% improvement in CCIS

Secondary outcomes
• Length of stay
• Complications
• Re-interventions
• Constipation
• QoL
• Cost effectiveness
SaFaRI

Design
• UK, multi-centre, prospective, parallel-group, randomised controlled, unblinded study

Eligibility
• Failed medical management
• Moderate to severe FI
  • Incontinence > 6 months, suffering ≥2 incontinent episodes per week
SaFaRI

**Sample size**
- 350 participants to detect at least 20% in percentage of success at 18-months post-randomisation between FENIX and SNS at 5% significance, 90% power
- Success – device in situ and working with ≥50% CCIS improvement
- Allows 20% loss to follow-up

**Recruitment**
- 2-years
- 24 surgeons recruiting 15 patients
SaFaRI

Site eligibility
• NHS hospital providing specialist treatment for FI with membership of ACPGBI
• Experience in SNS
• Facilities to perform endoscopy, manometry, EAUS

Surgeon eligibility
• Performed minimum of 10 SNS
• Minimum 1 observed FENIX + 2 performed FENIX
• Moderate to severe FI
  • Incontinence > 6 months, suffering ≥2 incontinent episodes per week
Patient Identification: adult patients with FI who have failed conservative therapy

Inclusion criteria: aged ≥ 18 years; FI for >6 months; incontinent episodes of ≥2 per week; suitable candidate for surgery; anal sphincter defect <180°; willing and able to give informed consent and co-operate with follow-up.

CONSENT

Baseline: demographics, co-morbidity, FI medication, investigations (flexible sigmoidoscopy, anorectal manometry and endoanal ultrasound), CCIS, FIQoL, and obstructive defecation (OD) score, SF12, EQ-5D, healthcare economics (HE)

RANDOMISATION (1:1)
Minimised by: surgeon, sex (M/F), CCIS score and degree of anal sphincter defect

Sacral Nerve Stimulation (SNS)
n = 175

Temporary SNS trial

2 wk FU (complications (Cx), CCIS, HE)

No permanent SNS implant

Permanent SNS implant

Magnetic Anal Sphincter (MAS)
n = 175

MAS surgical implant

2wk FU (Cx, CCIS, HE)

6, 12 and 18 month FU post-randomisation:
FI medication, complications, CCIS, OD-score, FIQoL, SF12, EQ-5D, healthcare economics.
FENIX™ MSA Device Funding

- The FENIX™ MSA device was classed as an NHS treatment cost in line with the DoH’s AcoRD guidance.

- No process in place for funding of NHS treatment costs through NHS England

- QIPP proposal developed and submitted to NHSE in Q1 2015

- Signed off by NHSE centrally - then filtered out to NHSE regional teams – Q2 2015

- Knock on effect on site set-up
  - Sites unable to submit local applications until funding resolved
## SaFaRI Sites

<table>
<thead>
<tr>
<th>SaFaRI Sites</th>
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<tbody>
<tr>
<td>St James's University Hospital</td>
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<tr>
<td>University Hospital of North Durham</td>
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<tr>
<td>Southampton General Hospital</td>
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<tr>
<td>Northern General Hospital, Sheffield</td>
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<tr>
<td>St Peter's Hospital</td>
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<tr>
<td>Poole Hospital</td>
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<tr>
<td>Royal Devon &amp; Exeter Hospital</td>
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<tr>
<td>Churchill Hospital (Oxford)</td>
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<tr>
<td>Wythenshawe Hospital</td>
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<tr>
<td>Good Hope Hospital</td>
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<tr>
<td>University College London Hospital</td>
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<tr>
<td>Manchester Royal Infirmary</td>
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SaFaRI Recruitment
Summary

• SaFaRI addresses an important research question

• Provides a rigorous and safe evaluation of a new technology that could save the NHS money

• 12 months behind schedule due to national FENIX™ MSA device funding issues

• Recruitment picking up with resolution of funding issues and timely opening of sites
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