NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

Treating faecal incontinence by applying heat energy to the anal wall

Faecal incontinence occurs when a person loses (often only partially) voluntary control of their bowel movements, resulting in leakage of faeces. The condition may relate to inadequate formation of the anus from birth. It can also relate to diseases of the nervous system (such as spina bifida, spinal cord injury, multiple sclerosis), pelvic organ prolapse, or previous pelvic surgery or radiotherapy. In women, another cause is injury to the anal canal during childbirth. In this procedure, radiofrequency energy is applied to the anal wall, with the aim of inducing muscle changes to improve muscle tone and help control bowel movement.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2010.

Procedure name

- Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

Specialty societies

- The Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

Faecal incontinence occurs when a person loses the ability to control their anal sphincter and bowel movements resulting in leakage of faeces and/or gas.

Faecal incontinence can have a number of underlying causes affecting either the anatomy or function of the anal sphincter. The condition may relate to inadequate formation of the anus from birth. It can also be caused by neurological, or spinal disease or injury (for example, spina bifida, multiple sclerosis, stroke, or spinal cord injury), pelvic organ or rectal prolapse, previous pelvic organ surgery or radiotherapy. Perineal injury during vaginal delivery is a common cause in women.

Faecal incontinence is associated with a high level of physical disability and social stigma. Its true incidence may be under-reported because of the sensitive nature of the condition.

Typically, first-line treatment is conservative, including dietary management and antidiarrhoeal medication. If these are not successful, pelvic floor muscle or anal sphincter training may be used.

If conservative treatments have been unsuccessful, surgery is sometimes recommended. Options include sphincter repair, sacral nerve stimulation, stimulated graciloplasty (creation of a new sphincter from other suitable muscles), anorectal or transabdominal implantation of an artificial anal sphincter, and permanent colostomy.

What the procedure involves

The aim of this procedure is to deliver radiofrequency energy to the anal sphincter muscles. The exact mechanism of action has not been adequately described. It is believed that the procedure aims to cause a degree of fibrosis, so tightening the ring of muscle that forms the sphincter. It is intended to be less invasive than alternative surgical treatments.

Prophylactic antibiotics and enema preparation are usually used, and the procedure is usually done with sedation and local anaesthesia. Under direct visualisation, a specially designed transparent catheter which houses needle electrodes is inserted into the anus at the level of the dentate line. The needle electrodes deliver heat generated by radiofrequency energy to the anal sphincter muscle under temperature feedback control using temperature sensors. Mucosal irrigation by chilled water is also used for cooling. Needle electrodes are typically applied to the anal sphincter tissue on each quadrant sequentially. The same process is repeated sequentially at 3 to 5 levels above and below the dentate line, approximately 1 cm apart. Patients are normally able to resume normal activities within a few days. Symptom improvement is expected to occur around 6 weeks after treatment.

Instruments to assess disease severity and measuring symptoms

Faecal incontinence disease severity instruments include:

The 'Cleveland Clinic Florida Fecal Incontinence score' (CCF-FI) (also referred to as the Wexner or Jorge-Wexner score) is a composite score which combines 5 parameters: lifestyle changes; need to wear a pad; frequency of incontinence to each of gas, liquid, and solid. It is measured from a patient-completed questionnaire in which each parameter is given a score from 0 to 4 with 0 indicating its absence and 4 indicating daily presence. These values are added to give a score ranging from 0 to 20 (0 indicating perfect control, 10 to 15 indicating moderate incontinence and greater than 15 indicating severe incontinence).

The 'Vaizey incontinence score' is a modification of the CCF-FI score which incorporates an assessment of the ability to defer defaecation, and the use of antidiarrhoeals, and reduces emphasis on the need to wear a pad. The score ranges from 0 to 24 with '0' indicating perfect continence and '24' indicating total incontinence.

The 'Fecal incontinence quality of life questionnaire' (FIQL) is a scale based on a patient-completed questionnaire with 29 questions grouped into 4 components: lifestyle, coping, depression, and embarrassment. Each aspect is valued between 1 and 4 with 1 being very affected and 4 being not affected.

The 'Fecal Incontinence Severity Index' (FISI) is based on clinical assessment or a patient self-report outside of the clinical setting. It is calculated from a 20-cell type and frequency matrix: 4 types of leakage (gas, mucus, liquid stool, solid stool) and 5 different frequencies (1 to 3 times per month, once per week, twice per week, once per day, twice or more per day). Higher scores indicate worse faecal incontinence.

Generic quality of life or health status instruments such as the Short Form 36 Health Survey (SF-36) are also used.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence. Searches were conducted of the following databases, covering the period from their commencement to 25 January 2011: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with faecal incontinence.
Intervention/test	Endoscopic radiofrequency therapy of the anal sphincter.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 148 patients from 7 case series[1,2,3,4,5,6,7] and 1 case report of a safety event[8].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Efron JE (2003)[1]

Case series
USA
Recruitment period: not reported
Study population: patients with FI for at least 3 months
n = 50
Mean age: 61.1 years
Sex: 86% female
Cause of FI: associated with event in 39.6%; 88.4% (38/43) of female patients had history of pregnancy with vaginal delivery (16 required forceps at least once and 24 had episiotomy in at least 1 delivery and 15 had immediate postpartum repair)
Mean duration of FI: 14.9 years

Patient selection criteria: FI at least once per week for at least 3 months with failure of medical and/or surgical management to resolve symptoms
Exclusion criteria: inflammatory bowel disease, active anal fissure, constipation or chronic diarrhoea, collagen vascular diseases, fistula or abscess, pelvic irradiation, pregnancy, history of laxative abuse, unstable psychiatric disorder

Technique: Secca procedure with injection</td>
<td>Number of patients analysed: 50
Cleveland Clinic Florida Fecal Incontinence score
These scores improved in a steady gradual manner from 1 to 3 to 6 months.
<table>
<tr><th>Mean baseline score</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>14.6 ± 3.4</td><td>11.1 ± 4.9</td><td>< 0.0001</td></tr>
</table>
(significance persisted with ITT was applied: p < 0.0001)
FIQL scores
These scores improved in a steady gradual manner from 1 to 3 to 6 months in all 4 scores (they were significant from 3 months).
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.5 ± 1</td><td>3.1 ± 0.8</td><td>< 0.0001</td></tr>
<tr><td>Coping</td><td>1.9 ± 0.7</td><td>2.4 ± 0.9</td><td>< 0.0001</td></tr>
<tr><td>Depression</td><td>2.8 ± 0.9</td><td>3.3 ± 0.9</td><td>< 0.0001</td></tr>
<tr><td>Embarrassment</td><td>1.9 ± 0.8</td><td>2.5 ± 1</td><td>< 0.0001</td></tr>
</table>
(significance persisted with ITT was applied: p < 0.0001)
SF-36 quality of life scores
<table>
<tr><th></th><th>Mean baseline score (SD)</th><th>Mean score at 6 months (SD)</th><th>p value</th></tr>
<tr><td>Social function subscore</td><td>64.3 (34.4)</td><td>77.3 (28.8)</td><td>0.003</td></tr>
</table>
</td>
<td>Intraoperative side-effects
During device insertion
8% (4/50) had mild discomfort.
6% (3/50) had moderate discomfort requiring additional local anaesthesia, and anal dilation without further event (these patients had previous surgery altering the structure of the anal canal).
During radiofrequency energy delivery
6% (3/50) had ‘moderate’ pain.
2% (1/50) had ‘severe’ pain (for all these patients, additional local anaesthetic was given without additional events).

Significant postoperative complications
• Anal mucosal ulceration occurred in 2 patients 2 to 3 weeks after treatment requiring 2 to 3 weeks of local wound care. In 1 this was superficial and in the other this occurred with underlying muscle injury. The first had improved continence and no adverse sequelae but the second had ongoing anal pain and worsened</td>
<td>Follow-up issues:
• Follow-up at baseline and 6 months.
• 1 was unable to complete follow-up because of stercoral perforation requiring colostomy 3 months after surgery from a car accident, and 3 for personal circumstances such as reluctance to travel.
Study design issues:
• 5 centres.
• Patients discontinued platelet inhibiting medications 7 days before treatment and were not permitted to restart until 3 weeks after treatment.
• ITT analysis was performed using baseline data.
• Mucosal ulceration in 2 patients occurred early in the trial prompting the development of mucosal cooling in the protocol; no further events occurred after the change in protocol.
• Patient discomfort was measured by the physician.
Study population issues:
• 14 had previous haemorrhoid surgery and 2 had previous fistula surgery
• Previous unsuccessful surgeries</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>of local anaesthetic and intravenous sedation
Follow-up: 6 months

Conflict of interest/source of funding: study sponsored by Curon Medical Inc</td>
<td>
<table>
<tr><td>Emotional well being subscore (mental health)</td><td>65.8 (24)</td><td>73.8 (21.1)</td><td>0.02</td></tr>
<tr><td>Mental health composite</td><td>45.2 (13.9)</td><td>49 (11.7)</td><td>0.03</td></tr>
<tr><td>Physical health composite</td><td>42.5 (11.4)</td><td>43.2 (11.2)</td><td>0.6</td></tr>
</table>
(significant of social function, mental health and mental health composite scores parameters persisted with ITT was applied: same p values)
14-day diary responses
• Significant improvements from baseline to 6 months in days with FI (mean 10 to 7.3, p < 0.0001) and gas incontinence (mean 6.6 to 4.4, p < 0.0001).
• Pad use did not decrease but pad soiling improved (7.3 to 5.7 days, p = 0.05).
• Days with FI related to urgency, fear with urgency, and fear alone were all significant improved at 6 months (for example, days patients feared soiling was improved by more than 50%: 5.8 to 2.4 days, p < 0.0001).
Patient-determined success (VAS)
When asked to grade their symptoms at 1, 3 and 6 months using a 10-cm VAS (0 cm = no improvement and 10 cm = complete resolution), the mean score was 4.3 ± 3.5 cm for the entire group corresponding to a 43% resolution of symptoms.
60% of patients were considered responders (at least 10% improvement). In this group of responders, the median score was 70% resolution of symptoms.
2 opted to have colostomy to control existing symptoms (n = 2).
Anorectal manometry
</td>
<td>
incontinence at last follow-up.
• Delayed bleeding (after 30 days) occurred in 1 patient from a haemorrhoidal vein requiring suture ligation.

Minor postoperative complications
<table>
<tr><th></th><th>Frequency*</th></tr>
<tr><td>Antibiotic-associated diarrhoea</td><td>12% (6/50)</td></tr>
<tr><td>Minor bleeding</td><td>10% (5/50)</td></tr>
<tr><td>Transient worsening of FI</td><td>8% (4/50)</td></tr>
<tr><td>Anal pain*,**</td><td>10% (5/50)</td></tr>
<tr><td>Fever without signs of perianal infection</td><td>4% (2/50)</td></tr>
<tr><td>Vomiting, constipation, groin swelling and headache</td><td>2% (1/50) for each</td></tr>
</table>
*calculated by analyst
** 1 on day 2 and 2 occurred 2 to 3 weeks later; all treated with oral pain medication with complete resolution within 1 to 5 days
</td>
<td>for FI: 18% (9/50) overlapping sphincter repair and 4% (2/50) artificial bowel sphincter implantation.</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	There were no differences in resting or squeeze pressure, rectal sensation, pudendal nerve motor latency, or sphincter defects on endoanal ultrasound between baseline and 6 months. However, a number of centres had manometric device malfunctions. 1 centre showed a significant reduction in average initial rectal threshold volume (41 ± 12 to 24 ± 21 ml, p = 0.005).		

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ruiz D (2010)[2]

Case series
USA
Recruitment period: 2003 to 2004
Study population: patients with FI for at least 3 months refractory to treatments
n = 24
Mean age: 72.8 years (of 16 patients available for follow-up)
Sex: 95.8% female
Cause of FI: all females had vaginal deliveries (4 required forceps and 8 also had episiotomy); others included aging and trauma from previous anorectal surgeries.
Patient selection criteria: FI for at least 3 months and had failed conservative management and/or prior surgery
Exclusion criteria: inflammatory bowel disease, active anal fissure, constipation or chronic diarrhoea, collagen vascular diseases, anal fistula or perianal sepsis, pelvic irradiation, pregnancy, history of laxative abuse, unstable psychiatric disorder

Technique: Secca procedure with intravenous sedation and injection of local anaesthetic
Follow-up: 12 months
Conflict of interest/source of funding: 1 of the authors is the consultant for C.R. Bard, Inc; Medtronic Inc; Ethicon Inc and Incontinence Devices Inc</td>
<td>Number of patients analysed: 16

Cleveland Clinic Florida Fecal Incontinence score
<table>
<tr><th>Mean baseline score</th><th>Mean score at 12 months</th><th>p value</th></tr>
<tr><td>15.6 ± 3.2</td><td>12.9 ± 4.5</td><td>< 0.035</td></tr>
</table>
25% (4/16) had worsening of their FI.
12.5% (2/16) had no improvement.
Of those with improvement, 12.5% (2/16) had 50% or more improvement in this score and 43.8% (7/16) had 20% or greater improvement at 12 months follow-up.
37.5% (6/16) patients improved to a score below 10 and overall, 62.5% (10/16) patients had a score of less than 15, indicating moderate FI.

FIQL scores
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>Mean score at 12 months</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.6 ± 0.85</td><td>3.0 ± 0.9</td><td>0.0035</td></tr>
<tr><td>Coping</td><td>1.6 ± 0.4</td><td>2.2 ± 1.0</td><td>0.0095</td></tr>
<tr><td>Depression</td><td>2.5 ± 0.7</td><td>2.8 ± 0.8</td><td>0.058</td></tr>
<tr><td>Embarrassment</td><td>1.3 ± 0.4</td><td>2.2 ± 1.0</td><td>0.0005</td></tr>
</table>
</td>
<td>Complications
4 complications occurred related to the preparation for the procedure:
• 1 had nausea and vomiting from orally ingested enema.
• 1 had mild allergic reaction to prophylactic antibiotics.
• 1 had abscess formation at local anaesthetic injection site resolved with drainage (no other details provided).
• 1 had urinary tract infection.

4 patients had complications related to the procedure:
• 2 had postoperative bleeding within days of the procedure but these resolved spontaneously.
• 1 had constipation which resolved with laxatives.
• 1 had diarrhoea and bleeding which resolved.

There were no late complications.</td>
<td>Follow-up issues:
• Follow-up at baseline and then at 12 months.
• 8 patients were lost to follow-up at 12 months

Study design issues:
• Patients from 3 institutions.
• All patients maintained their low-residue or high-fibre diets after the procedure.

Study population issues:
• Prior treatments were conservative in most (for example, dietary modification, fibre supplements, biofeedback) but 3 patients (13%) had prior overlapping anal sphincter for FI (not otherwise described).
• All had had antidiarrhoeal agents before the procedure.

Other issues:
• Preoperative examination included proctologic evaluation.</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Walega P (2009)[3]

Case series
Poland
Recruitment period: 2001 to 2008
Study population: patients with symptomatic end-stage FI refractory to conservative treatment
n = 20
Mean age: 59 years
Sex: 70% female
Cause of FI: injury during labour or proctological procedure (n = 12), idiopathic anal sphincter (n = 4) or likely neurogenic disturbance or rectoanal coordination (n = 4)

Exclusion criteria: loss of sphincter muscle no more than 1/3 of anal circumference, systematic contraindications (haemorrhagic diathesis, generalised infection, systematic diseases, pregnancy)
Technique: Secca procedure with intravenous sedation and local anaesthetic

Follow-up: 6 months
Conflict of interest/source of funding: study was paid for by Polish Ministry of Science and Higher Education</td>
<td>Number of patients analysed: 20
Jorge-Wexner scale
<table>
<tr><th>Mean score at baseline</th><th>Mean score at 3 months</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>12.1 ± 2.5</td><td>9.1 ± 2.53</td><td>9.3 ± 2.59</td><td>< 0.05</td></tr>
</table>
Fecal Incontinence Severity Index
<table>
<tr><th>Mean score at baseline</th><th>Mean score at 3 months</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>36.9 ± 9.25</td><td>34.9 ± 4.57</td><td>35.2 ± 6.33</td><td>NS</td></tr>
</table>
(all but 1 patient who had no change in score had a better score after the procedure, though not significant)
FIQL scores
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>Mean score at 3 months</th><th>Mean score at 6 months</th></tr>
<tr><td>Lifestyle</td><td>1.96 ± 0.51</td><td>1.95 ± 0.5</td><td>1.9 ± 0.52</td></tr>
<tr><td>Coping</td><td>1.67 ± 0.52</td><td>1.76 ± 0.69</td><td>1.96 ± 0.43</td></tr>
<tr><td>Depression</td><td>2.1 ± 0.55</td><td>2.29 ± 0.37</td><td>1.97 ± 0.47</td></tr>
<tr><td>Embarrassment</td><td>1.79 ± 0.75</td><td>1.89 ± 0.64</td><td>1.61 ± 0.63</td></tr>
</table>
(the study text states that the scores were significant from baseline to 6 months but the table shows that they were not significant)
Anorectal manometry
There were significant increases in basal and squeeze anal pressure, and high pressure zone length from baseline to follow-up (from 34.23 ± 14.79 to 42 ± 13.55 mm Hg, 73.15 ± 33.8 to 96.69 ± 52 mm Hg, and 2.07 ± 0.33 to 2.43 ± 0.28 cm, respectively; p < 0.05, 0.05 and 0.001, respectively).
Recto-anal inhibitory reflex returned in all but 6 patients at 6 months. It was normal in 6 and paradoxical in 6 (the study did</td>
<td>Complications
Mild complications in the postoperative period which did not require surgical intervention:
• 1 patient with small submucosal haematoma
• 1 patient with superficial anal mucosal erosion (no more details provided)
• 1 patient had transient fever of 38 degrees from the third to fifth day postoperatively.
Another patient presented with a profound defect of tissue at the place of the needle insertion 3 weeks after the procedure. This required surgery, healing completely within the next 6 months.</td>
<td>Follow-up issues:
• Follow-up scheduled at 3, 6, 12 and 24 months after the procedure including clinical exam, assessment of defaecation control, quality of life and manometric studies.

Study design issues:
• Patients assessed for inclusion with defaecation control, subjective impression and results of functional, electrophysiological and imaging studies.</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	not report about the other 2 patients).		

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Takahashi-Monroy T (2008)[4]
Case series
Mexico
Recruitment period: not reported
Study population: patients presenting to centre with FI for at least 3 months refractory to other treatments
n = 19
Mean age: 57.1 years, Sex: 94.7% female
Cause of FI: 15 of the 18 women in the study had previous vaginal delivery (3 requiring forceps and 9 episiotomy) (cause of FI not reported in others)
Mean duration of FI: 7.9 years
Patient selection criteria: at least 1 episode per week for at least 3 months, dissatisfaction with 1 or more conservative treatments
Exclusion criteria: previous FI surgery, inflammatory bowel disease, Crohn’s disease, collagen vascular disease, active anal fissure, fistula or abscess, constipation or chronic diarrhoea as sole contributor, abnormal blood coagulation or active use of anticoagulant or antiplatelet therapy, previous pelvic irradiation, pregnancy, history of laxative abuse, unstable psychiatric disorders
Technique: Secca procedure with sedation and local anaesthetic
Follow-up: 5 years
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 19
Cleveland Clinic Florida Fecal Incontinence score
<table>
<tr><th>Mean baseline score</th><th>Mean score at 5 years</th><th>p value</th></tr>
<tr><td>14.37</td><td>8.26</td><td>< 0.00025</td></tr>
</table>
Scores became significantly different 2 months after the procedure with a plateau at 60 months.16 patients had a > 50% reduction at 5 years. There was no significant difference in scores from 24 to 60 months.
From 24 months, all but 1 patient maintained or improved in score (the other patient had a decrease from 24 to 60 months).
FIQL questionnaire
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>Mean score at 5 years</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.43</td><td>3.16</td><td>< 0.00075</td></tr>
<tr><td>Coping</td><td>1.73</td><td>2.6</td><td>< 0.00083</td></tr>
<tr><td>Depression</td><td>2.24</td><td>3.15</td><td>< 0.0002</td></tr>
<tr><td>Embarrassment</td><td>1.56</td><td>2.51</td><td>< 0.0003</td></tr>
</table>
(no change in scores from 2 and 5 year follow-up)
SF-36 quality of life scores
<table>
<tr><th>Mean baseline score</th><th>Mean score at 5 years</th><th>p value</th></tr>
<tr><td>36</td><td>60</td><td>< 0.05</td></tr>
</table>
The mental component summary had a trend towards improvement but the physical component did not change during follow-up.</td>
<td>Complications
Delayed bleeding in 31.6% (6/19) patients with 1 requiring anoscopy and suture ligation to control the bleeding (percentage calculation by the analyst; location of bleeding and exact timing not specified).
There were no long-term complications.</td>
<td>Follow-up issues:
• Not reported
Study design issues:
• First 10 patients were reported on in earlier publications (included in appendix A). These patients had slightly different treatment protocol (treatment at 5 instead of 4 levels).
Study population issues:
• 7 patients had previous rectal, anal or colon surgery and 5 had previous haemorrhoid surgery.</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lefebure B (2008)[5]
Case series
France
Recruitment period: 2005 to 2006
Study population: patients with FI for at least 3 months refractory to medical and/or surgical therapies
n = 15
Mean age: 53 years
Sex: 93% female

Cause of FI: all females had previous vaginal deliveries (mean 2.13 deliveries; 6 requiring forceps, 7 episotomy and 8 postpartum repair)
Mean duration of FI: 70 months
Patient selection criteria: had FI at least once per week for at least 3 months and had attempted alternative treatments but were not satisfied with them
Exclusion criteria: significant external sphincter defect suited for sphincter repair, collagen vascular disease, inflammatory bowel disease, fistula or abscess, active anal fissure, constipation or chronic diarrhoea as major contributor to FI, pelvic irradiation, pregnancy, history of laxative abuse, unstable psychiatric disorder
Technique: Secca procedure with general anaesthetic
Follow-up: 1 year
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 15
Cleveland Clinic Florida Fecal Incontinence score-Wexner score
<table>
<tr><th>Mean baseline score</th><th>Mean score at 1 year</th><th>p value</th></tr>
<tr><td>14.07</td><td>12.33</td><td>0.02</td></tr>
</table>
9 patients had an improvement and 6 had no change or worsening of score.
With a clinical response rate as > 50% reduction in Wexner score, patient response rate was 13%.
With a > 20% reduction in Wexner score, patient response rate was 26%.
This score did not change at the 3, 6 and 12 months which the patients were followed up.
FIQL questionnaire
<table>
<tr><th>FIQL component</th><th>Mean score at baseline</th><th>Mean score at 12 months</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.3 ± 1</td><td>2.05 ± 0.86</td><td>0.48</td></tr>
<tr><td>Coping</td><td>1.77 ± 0.69</td><td>1.82 ± 0.77</td><td>0.92</td></tr>
<tr><td>Depression</td><td>1.92 ± 0.62</td><td>2.33 ± 0.74</td><td>0.01</td></tr>
<tr><td>Embarrassment</td><td>2.49 ± 1.43</td><td>1.62 ± 0.80</td><td>0.09</td></tr>
</table>
Anorectal manometry
<table>
<tr><th></th><th>Mean score at baseline</th><th>Mean score at 12 months</th><th>p value</th></tr>
<tr><td>Resting pressure (cm H_20)</td><td>52.9 ± 19.7</td><td>42.5 ± 20.4</td><td>0.07</td></tr>
<tr><td>Squeeze pressure (cm H_20)</td><td>92.1 ± 40.7</td><td>85.5 ± 17.5</td><td>0.44</td></tr>
<tr><td>Maximum rectal distension (ml)</td><td>179.6 ± 38.5</td><td>177.7 ± 41.6</td><td>0.59</td></tr>
</table>
</td>
<td>Complications
There were no cases of bleeding during or immediately after the procedure.
There were no long-term complications at 12 months' follow-up.</td>
<td>Follow-up issues:
• Followed-up at 3, 6, and 12 months.
• None lost to follow-up.

Study population issues:
• 2 had previous haemorrhoid surgery and 1 had previous fistula surgery.
• Previous unsuccessful surgeries for incontinence included overlapping sphincter repair in 13% (2/15), artificial bowel sphincter repair implantation in 13% (2/15) and explantation in 13% (2/15) explanted, and sacral nerve stimulation in 53% (8/15).</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Felt-Bersma RJ (2007)[6]

Case series
Netherlands
Recruitment period: not reported
Study population: women with FI for at least 6 months refractory to conservative treatment
n = 11
Mean age: 61 years
Sex: 100% women
Cause of FI: all but 1 had previous vaginal delivery (4 with episiotomy, 1 straining and 1 had 3rd sphincter rupture); 2 had hysterectomy and 1 had bladder fixation
Mean duration of FI: 12 years
Stool frequency: 0 to 1 per day (1), 1 per day (3), 2 per day (4), once per 3 days (2), 3-4 per day (1)
Patient selection criteria: a Vaizey incontinence score of at least 12, failure of conservative treatment (diet modifications, antidiarrhoeals, physiotherapy)
Exclusion criteria: proctitis or inflammatory bowel disease, chronic diarrhoea, chronic constipation, overflow incontinence, previous ileoanal or coloanal anastomosis, rectal prolapse, anal stenosis, anal fissures or fistulae, pelvic radiation, coagulation disorders or use of anticoagulants, large sphincter defects and anal stenosis
Technique: Secca procedure with conscious sedation and local anaesthesia
Follow-up: 1 year</td>
<td>Number of patients analysed: 11
Vaizey incontinence score
<table>
<tr><th>Follow-up</th><th>Mean score (SD)</th></tr>
<tr><td>Preoperative</td><td>19 (2)</td></tr>
<tr><td>3 months</td><td>15 (4)*</td></tr>
<tr><td>6 months</td><td>15 (4)</td></tr>
<tr><td>12 months</td><td>15 (4)</td></tr>
</table>
*from preoperative to 3 months, p = 0.03 (significance not reported for other time periods)
5 patients were considered to have improved and 1 was considered to have slightly improved.
Patient satisfaction
Those who improved were very pleased with the treatment. 4 patients said they felt the urge and now had more time to get to the toilet (5 minutes rather than 1 minute).
Anorectal manometry and rectal compliance
<table>
<tr><th></th><th>Mean score at baseline</th><th>Mean score at 3 months</th><th>p value</th></tr>
<tr><td colspan="4">In those who improved (n = 6) :</td></tr>
<tr><td>Maximum basal pressure (mm Hg)</td><td>36 (20)</td><td>31 (17)</td><td>NS</td></tr>
<tr><td>Maximum squeeze pressure (mm Hg)</td><td>32 (23)</td><td>34 (16)</td><td>NS</td></tr>
<tr><td>Maximum tolerance (ml)</td><td>218 (86)</td><td>198 (51)</td><td>NS</td></tr>
<tr><td>Urge to defaecate (ml)</td><td>167 (86)</td><td>155 (45)</td><td>NS</td></tr>
<tr><td colspan="4">In those not improved (n = 5)</td></tr>
<tr><td>Maximum basal pressure (mm Hg)</td><td>36 (9)</td><td>34 (17)</td><td>NS</td></tr>
<tr><td>Maximum squeeze pressure (mm Hg)</td><td>27 (18)</td><td>32 (15)</td><td>NS</td></tr>
</table>
</td>
<td>Intraoperative side-effects
2 patients had slight pain and 1 had moderate pain during the procedure.

Postoperative side-effects
<table>
<tr><th></th><th>Frequency</th></tr>
<tr><td>Slightly painful anus for 1 to 2 days</td><td>72.7% (8/11)</td></tr>
<tr><td>Moderate pain for 1 to 2 days</td><td>18.2% (2/11)*</td></tr>
<tr><td>Severe pain for 1 week</td><td>9.1% (1/11)*</td></tr>
<tr><td>Haematoma and/or minor bleeding for 2 to 7 days</td><td>45.5% (5/11)</td></tr>
<tr><td>Antibiotic-associated diarrhoea</td><td>27.3% (3/11)</td></tr>
<tr><td>Transient worsening of FI</td><td>9.1% (1/11)*</td></tr>
</table>
*% calculated by analyst
There were no major side effects.</td>
<td>Follow-up issues:
• Evaluation at 6 weeks, 3, 6 and 9 months and 1 year. 3D Ultrasound at 6 weeks and 3 months. Anal manometry and rectal compliance at 0 and 3 months.
• Loss to follow-up not reported.

Study design issues:
• Patients with haemorrhoids or mucosal prolapse were treated first with rubber band ligation 6 weeks before treatment.

Study population issues:
• There were no differences in biological characteristics between responders and non-responders.
• 3 also had urinary incontinence

Other issues:
• Patients had colonoscopy in their previous work-up and had preoperative 3D ultrasound.</td>
</tr>
</table>

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

Study details	Key efficacy findings				Key safety findings	Comments
Conflict of interest/source of funding: not reported	Maximum tolerance (ml)	203 (82)	189 (82)	NS		
	Urge to defaecate (ml)	212 (80)	185 (61)	NS		

Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kim (2009)[7]

Case series
Korea
Recruitment period: 2006 to 2006
Study population: patients with FI for 6 months to 12 years
n = 8
Median age: 59 years
Sex: 87.5% female
Causes of FI: vaginal delivery (n = 2), low anterior resection for rectal cancer (n = 2) and surgery for urinary incontinence (n =1), prolonged constipation (n = 2) and iatrogenic FI but with prior history of haemorrhoidectomy (n = 1)

Patient selection criteria: solid or liquid anal incontinence for more than 1 month, previous unsatisfactory conservative treatments
Exclusion criteria: not reported

Technique: Secca procedure as an inpatient procedure with local anaesthetic

Follow-up: 6 months

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 8
Faecal Incontinence Severity Index (FISI)
<table>
<tr><th>Mean score at baseline</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>35.1</td><td>25.6</td><td>0.885</td></tr>
</table>
(1 patient had increasingly worse score during the follow-up evaluations)
FIQL
<table>
<tr><th>FIQL component</th><th>Mean baseline score</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>Lifestyle</td><td>2.64</td><td>2.65</td><td>NS</td></tr>
<tr><td>Coping</td><td>2.35</td><td>2.35</td><td>NS</td></tr>
<tr><td>Depression</td><td>2.55</td><td>2.77</td><td>NS</td></tr>
<tr><td>Embarrassment</td><td>2.25</td><td>2.46</td><td>0.006</td></tr>
</table>
Cleveland Clinic Florida Fecal Incontinence score
<table>
<tr><th>Mean score at baseline</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>13.6</td><td>9.9</td><td>NS</td></tr>
</table>
Patient satisfaction
5 were reported to be dissatisfied or answered ‘poor’ on a questionnaire (which included 4 scores: excellent, good, fair and poor).
1 patient without complications and 2 with anal bleeding and anal mucosal discharge, respectively, were satisfied with treatment.</td>
<td>Complications
87.5% (7/8) developed complications associated with the procedure:
• 3 had anal bleeding
• 1 had anal pain
• 1 had anal mucosal discharge
• 2 had both anal bleeding and pain
(time of occurrence for these outcomes was not reported; all resolved with conservative management)</td>
<td>Follow-up issues:
• At 1, 3 and 6 months after procedure.
Study design issues:
• Patient inclusion/exclusion criteria for this study were different from the other studies. This study included a patient with previous pelvic radiotherapy for rectal cancer and 3 with chronic constipation.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: FI, faecal incontinence; FIQL, fecal incontinence quality of life; ITT, intention to treat; NS, not significant; SD, standard deviation; SF-36, short form (36) health survey; VAS, visual analogue scale</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr><td></td><td>Anorectal manometry
<table>
<tr><th></th><th>Mean score at baseline</th><th>Mean score at 6 months</th><th>p value</th></tr>
<tr><td>Resting pressure (mm Hg)</td><td>22.1</td><td>16.9</td><td>NS</td></tr>
<tr><td>Squeeze pressure (mm Hg)</td><td>112.0</td><td>96.0</td><td>NS</td></tr>
<tr><td>Maximum tolerated volume (ml)</td><td>173</td><td>130</td><td>NS</td></tr>
</table></td><td></td><td></td></tr>
<tr><td>Adverse event reported in Maude (FDA) database (2004)[8]

Case report of safety
n = 1
Technique: Secca procedure

Time of occurrence: 1 week after the procedure</td><td colspan="2">Anticoagulants were discontinued before the procedure, and reinstated after the procedure. The procedure was performed with no complications. 1 week following the procedure, the patient presented to emergency room with rectal bleeding requiring blood transfusion. Further examination revealed circumferential ulcerations above the dentate line, which were oversewn. The patient was discharged with bleeding resolved, and no further sequelae. The event was not reported to have been related to device malfunction.</td><td></td></tr>
</table>

Efficacy

Health status and disease severity outcomes

FIQL scores

The case series of 50 patients reported significantly improved mean scores in all components of the FIQL score from baseline to 6-month follow-up in the per protocol and intention-to-treat analyses (per protocol analysis: lifestyle from 2.5 to 3.1, coping from 1.9 to 2.4, depression from 2.8 to 3.3 and embarrassment from 1.9 to 2.5; $p \leq 0.0001$ for each and for intention-to-treat)[1].

The case series of 24 patients reported significantly improved scores in the lifestyle, coping and embarrassment components of the FIQL score from baseline to 12 month follow-up (2.6 to 3, $p = 0.0035$; 1.6 to 2.2, $p = 0.0095$; and 1.3 to 2.2, $p = 0.0005$, respectively)[2].

The case series of 19 patients reported a significant improvement in all components of the FIQL score from baseline to 5-year follow-up (lifestyle from 2.43 to 3.16, $p < 0.00075$; coping from 1.73 to 2.6, $p < 0.00083$; depression from 2.24 to 3.15, $p < 0.0002$ and embarrassment from 1.56 to 2.51, $p < 0.0003$)[4].

The case series of 15 patients showed significant results in only the depression component of the FIQL score, while the case series of 8 showed significant results in only the 'embarrassment' component baseline to 1 year or 6 months follow-up, respectively (from 1.92 to 2.33 [$p = 0.01$] and 2.25 to 2.46 [$p = 0.006$])[5,7].

Cleveland Clinic Florida Fecal Incontinence score (CCF-FI)

The case series of 50, 24, 20, 19, and 15 patients reported a significantly improved CCF-FI score from baseline to 6 months, 12 months, 6 months, 5 years, and 1 year follow-up, respectively (from 14.6 to 11.1 [$p < 0.0001$]; 15.6 to 12.9 [$p < 0.035$], 12.1 to 9.3 [$p < 0.05$], 14.37 to 8.26 [$p < 0.00025$] and 14.07 to 12.33 [$p = 0.02$], respectively)[1,2,3,4,5].

The case series of 8 patients reported a difference in CCF-FI score from baseline to 6 months but this was not significant (13.6 to 9.9)[7].

Quality of life assessed with SF-36

The case series of 50 patients reported significantly improved social function (64.3 to 77.3) emotional well-being (65.8 to 73.8) subscores and mental health composite (45.2 to 49) from the SF-36 from baseline to 6 months follow-up ($p = 0.003$, 0.02 and 0.03, respectively; significance persisted with the intention-to-treat analysis)[1].

The case series of 19 patients reported a significantly improved mental component summary in the SF-36 scores from 36 to 60 from baseline to 5 years ($p < 0.05$)[4].

Patient satisfaction

A case series of 11 patients reported that 5 patients who had improved continence and 1 who had slightly improved continence were pleased with their treatment. Four patients said they had more time to get to the toilet when they felt the urge to defaecate (5 minutes rather than 1 minute)[6].

A case series of 8 patients reported that 5 patients were dissatisfied with their treatment[7].

Physiological measurements

The case series of 50 patients reported no differences in resting or squeeze pressure, rectal sensation, pudendal nerve motor latency, or sphincter defects on endoanal ultrasound at 6 months follow-up. However, 1 centre showed a significant reduction in average initial rectal threshold volume (41 ± 12 to 24 ± 21 ml, $p = 0.005$)[1].

The case series of 20 patients reported significant increases in basal and squeeze anal pressure, and high pressure zone length from baseline to follow-up (from 34.23 ± 14.79 to 42 ± 13.55 mm Hg, 73.15 ± 33.8 to 96.69 ± 52 mm Hg, and 2.07± 0.33 to 2.43 ±0.28, respectively; $p < 0.05$, 0.05 and 0.001, respectively)[3].

The case series of 15, 11 and 8 patients reported no significant differences in anorectal manometry measurements from baseline to 12, 3, and 6 months follow-up, respectively[5,6,7].

Safety

Mucosal ulceration/erosion

The case series of 50 patients reported anal mucosal ulceration in 2 patients 2 to 3 weeks after treatment. In 1 this was superficial, and in the other this occurred with underlying muscle injury. These were treated with 2 to 3 weeks of local wound care resulting in an improvement in continence in the first patient, but the second had ongoing anal pain and worsened incontinence at the last follow-up[1].

The case series of 20 patients reported that 1 patient had postoperative superficial mucosal erosion but this was considered a mild complication and did not require surgical intervention (no more details provided)[3].

Constipation or diarrhoea

The case series of 50 and 11 reported antibiotic-associated diarrhoea in 12% (6/50) and 28% (3/11) of patients, respectively. The case series of 50 reported constipation in 2% (1/50) of patients (treatment and resolution for these events was not described)[1,6].

The case series of 24 patients reported constipation and diarrhoea in 1 patient each. The first patient was treated with laxatives and the diarrhoea in the second patient resolved spontaneously[2].

Bleeding

The case series of 50 patients reported secondary haemorrhage in 1 patient from a haemorrhoidal vein 30 days after the procedure requiring surgical ligation[1].

The case series of 19 patients reported secondary haemorrhage in 6 patients; 1 patient required anoscopy and suture ligation to control the bleeding (location and exact timing of bleeding not reported)[4].

The case series of 24, 20 and 11 patients reported postoperative bleeding and/or haematoma in 8% (2/24), 5% (1/20), and 45% (5/11) of patients, respectively. In the first 2 studies, this resolved spontaneously without surgical intervention and was not reported to have negative sequelae in the second study[2,3,6].

The case series of 8 reported anal bleeding which was associated with the procedure in 5 patients (in 2 this was accompanied with pain) which resolved with conservative management[7].

A case report from the FDA Maude database reported rectal bleeding requiring blood transfusion 1 week after the procedure in a patient who stopped anticoagulants for the procedure. Further examinations of this patient revealed circumferential ulcerations above the dentate line, which were oversewn. The patient was discharged with bleeding resolved, and no further sequelae[8].

Pain

The case series of 50 patients reported mild discomfort during device insertion in 8% (4/50) of patients and moderate discomfort requiring additional local anaesthesia and anal dilation in 6% (3/50) of patients. During the procedure, 6% (3/50) were reported to have ‘moderate’ pain and 2% (1/50) ‘severe’ pain, both requiring additional local anaesthetic[1].

The same study reported postoperative anal pain in 10% (5/50) of patients.

The case series of 11 patients reported slightly painful anus for 1 to 2 days in 73% (8/11), moderate pain for 1 to 2 days in 18% (2/11) and sever pain for 1 week in 9% (1/11)[6].

The case series of 8 patients reported postoperative anal pain in 1 patient[7].

Other

The case series of 50 patients reported fever without signs of perianal infection in 4% (2/50) and vomiting, groin swelling and headache in 1 patient for each[1].

The case series of 50 and 11 patients reported transient worsening of faecal incontinence in 8% (4/50) and 9% (1/11) of patients, respectively[1,6].

The case series of 24 patients reported complications related to the preparation of the procedure in 1 patient each of nausea and vomiting from orally ingested enema, mild allergic reaction to prophylactic antibiotics, abscess formation at the local anaesthetic site which resolved with drainage, and urinary tract infection[2].

The case series of 20 patients reported 1 patient presented with a profound tissue defect at the place of the needle insertion 3 weeks after the procedure. This required surgery and had healed completely within 6 months. The same study reported transient fever from the third to fifth day postoperatively[3].

The case series of 8 patients reported anal mucosal discharge in 1 patient (no other details provided)[7].

Validity and generalisability of the studies

- There are no comparative published studies on this procedure.
- Follow-up is usually short-term but in 1 study was up to 5 years[4].
- There is some variation in the inclusion/exclusions criteria in the studies: the length of faecal incontinence symptoms prior to treatment (most had symptoms for at least 3 months[1,2,4,5] but 2 included patients with symptoms for at least 6 months[6,7]), presence of chronic constipation (excluded in all but 1 study[7]), previous surgery for faecal incontinence (exclusion criteria in only some of the studies), and previous pelvic radiotherapy (excluded in all but 1 study[7]). The study that excluded patients with chronic constipation and pelvic radiotherapy did not report positive outcomes after the procedure as most of the other studies did so patient selection is probably an important element in treating patients with this procedure.
- Across a range of patient-reported outcome measures, some patients with a significant improvement in scores have residual moderate faecal incontinence after the procedure, so it is difficult to determine if the results are clinically significant. Considering the social stigma and adverse impact on quality of life of this condition, a small improvement in scores may be highly significant for patients.

Existing assessments of this procedure

In 2004, the Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIP) produced a horizon scanning report on this procedure recommending that:

> "Limited evidence exists on the safety and efficacy of the delivery of radio-frequency to the anal canal for the treatment of faecal incontinence. However, long-term safety and efficacy data from randomised controlled trials will be required before this procedure can be widely accepted. Due to limited use of this procedure, it is recommended that the procedure be monitored, and a further assessment be undertaken in 6 months."

No further follow-up or update of this guidance could be found.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedures guidance 276 (2008). Available from www.nice.org.uk/guidance/IPG276
- Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007). Available from www.nice.org.uk/guidance/IPG210
- Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006). Available from www.nice.org.uk/guidance/IPG159
- Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004) Available from www.nice.org.uk/guidance/IPG66
- Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004). Available from www.nice.org.uk/guidance/IPG99

Clinical guidelines

- Faecal incontinence. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/guidance/CG49

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr David Bartolo, Mr Richard Cohen, Association of Coloproctology of Great Britain and Ireland; Dr Anton Emmanuel, British Society of Gastroenterology.

- The Advisers varied in their opinion on the status of the procedure: one considered it established practice, another considered it to be a minor

variation of an existing procedure, unlikely to alter the procedure's safety and efficacy, and another considered it to be novel and of uncertain safety and efficacy.
- The comparator is injection of artificial materials to bulk the anus.
- None of the Advisers have performed the procedures but one was about to perform the procedure.
- Anecdotal events or events known from reports include haemorrhage (acute or delayed), mucosal ulceration, and anal stenosis.
- Theoretical adverse events include damage to anus.
- Key efficacy outcomes include an improvement in continence/faecal control, fewer episodes of incontinence and improved quality of life.
- One Adviser highlighted the lack of randomised data and that the follow-up in most studies is only in the short term.
- Another Adviser highlighted that despite modest improvements in questionnaire scores, there is little improvement in actual symptoms burden.
- Training in the procedure should include preceptorship.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- There was reference to an American randomised controlled trial comparing the procedure with sham in some of the literature but this study was not indexed in any of the routinely checked clinical trials databases.

References

1. Efron JE, Corman ML, Fleshman J et al. (2005) Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. Diseases of the Colon and Rectum 46: 1606–16.

2 Ruiz D, Pinto RA, Hull TL et al. (2010) Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? Diseases of the Colon and Rectum 53:1041–6.

3 Walega P, Jasko K, Kenig J et al. (2009) Radiofrequency waves in the treatment of faecal incontinence: Preliminary report. Proktologia 10: 134–43.

4 Takahashi-Monroy T, Morales M, Garcia-Osogobio S et al. (2008) SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. Diseases of the Colon and Rectum 51: 355–9.

5 Lefebure B, Tuech JJ, Bridoux V et al. (2008) Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. International Journal of Colorectal Disease 23: 993–7.

6 Felt-Bersma RJ, Szojda MM, Mulder CJ (2007) Temperature-controlled radiofrequency energy (SECCA) to the anal canal for the treatment of faecal incontinence offers moderate improvement. European Journal of Gastroenterology and Hepatology 19: 575–80.

7 Kim DW, Yoon HM, Park JS et al. (2009) Radiofrequency energy delivery to the anal canal: is it a promising new approach to the treatment of fecal incontinence? American Journal of Surgery 197: 14–8.

8. US Food and Drug Administration (2004) MAUDE Adverse Event Report: Curon Medical, Inc. SECCA system RF generator and electrosurgical accessories [online]. Available from www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=570930

Appendix A: Additional papers on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Takahashi T, Garcia-Osogobio S, Valdovinos MA et al. (2002) Radio-frequency energy delivery to the anal canal for the treatment of fecal incontinence. Diseases of the Colon and Rectum 45: 915–22.	Case series n = 10 Follow-up = 1 year	Improvement in symptoms at 12 months.	Patients included in Takahashi-Monroy[4]
Takahashi T, Garcia-Osogobio S, Valdovinos MA et al. (2003) Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). Diseases of the Colon and Rectum 46: 711–5.	Case series n = 10 Follow-up = 2 years	Improvement in symptoms at 2 years. (Same patients as above with longer follow-up.)	Patients included in Takahashi-Monroy[4]

Appendix B: Related NICE guidance for endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

Guidance	Recommendations
Interventional procedures	**Transabdominal artificial bowel sphincter implantation for faecal incontinence. NICE interventional procedures guidance 276 (2008).** 1.1 Current evidence on the safety and efficacy of transabdominal artificial bowel sphincter implantation for faecal incontinence is based on a small number of patients and is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake transabdominal artificial bowel sphincter implantation for faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG276publicinfo). • Audit and review clinical outcomes of all patients having transabdominal artificial bowel sphincter implantation for faecal incontinence (see section 3.1). **Injectable bulking agents for faecal incontinence. NICE interventional procedures guidance 210 (2007).** 1.1 Current evidence on the safety and efficacy of injectable bulking agents for faecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups. 1.2 Clinicians wishing to inject bulking agents for the treatment of faecal incontinence should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from

	www.nice.org.uk/IPG210publicinfo). • Audit and review clinical outcomes of all patients receiving injectable bulking agents for faecal incontinence (see section 3.1). 1.3 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence. The Institute may review the procedure upon publication of further evidence. **Stimulated graciloplasty for faecal incontinence. NICE interventional procedures guidance 159 (2006).** 1.1 Current evidence on the safety and efficacy of stimulated graciloplasty for faecal incontinence is limited, but appears sufficient to support the use of this procedure for carefully selected patients in whom other treatments have failed or are contraindicated, provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 This procedure should be performed only in specialist units by clinicians with specific training and experience in the assessment and treatment of faecal incontinence. **Artificial anal sphincter implantation. NICE interventional procedures guidance 66 (2004).** 1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. • Audit and review clinical outcomes of all patients having artificial anal sphincter implantation. 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence. 1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence. **Sacral nerve stimulation for faecal incontinence. NICE interventional procedures guidance 99 (2004).** 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for faecal incontinence appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 The procedure should only be performed in specialist

	units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.
Clinical guidelines	**Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49 (2007)** 1.8.2 People with a full-length external anal sphincter defect that is 90º or greater (with or without an associated internal anal sphincter defect) and faecal incontinence that restricts quality of life should be considered for sphincter repair. They should be given a realistic expectation of what this operation can achieve and information about possible adverse events, in both the short and long terms. 1.8.3 People with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair. 1.8.4 People undergoing anal sphincter repair should not routinely receive a temporary defunctioning stoma. 1.8.5 People undergoing anal sphincter repair should not receive constipating agents in the postoperative period and should be allowed to eat and drink as soon as they feel able to. 1.8.6 A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate (See NICE interventional procedures guidance on sacral nerve stimulation [www.nice.org.uk/IPG099]). These may be patients with intact anal sphincters, or those with sphincter disruption. In those with a defect, contraindications to direct repair may include atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor-quality muscle. 1.8.7 All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with faecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success. People being considered for sacral nerve stimulation should be assessed and managed at a specialist centre that has experience of performing this procedure. 1.8.8. If a trial of sacral nerve stimulation is unsuccessful, an individual can be considered for a neosphincter, for which the two options are a stimulated graciloplasty or an artificial anal sphincter. People should be informed of the potential benefits and limitations of both procedures. Those offered these procedures should be informed that they may experience evacuatory disorders and/or serious infection, either of which

	may necessitate removal of the device. People being considered for either procedure should be assessed and managed at a specialist centre with experience of performing these procedures. If an artificial anal sphincter is to be used, there are special arrangements that should be followed, as indicated in NICE interventional procedures guidance 66 (See NICE interventional procedures guidance on stimulated graciloplasty [www.nice.org.uk/IPG159] and artificial anal sphincter [www.nice.org.uk/IPG066]). 1.8.9 People who have an implanted sacral nerve stimulation device, stimulated graciloplasty or an artificial anal sphincter should be offered training and ongoing support at a specialist centre. These people should be monitored, have regular reviews and be given a point of contact. 1.8.10 Antegrade irrigation via appendicostomy, neo-appendicostomy or continent colonic conduit may be considered in selected people with constipation and colonic motility disorders associated with faecal incontinence. 1.8.11 A stoma should be considered for people with faecal incontinence that severely restricts lifestyle only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered. Individuals should be informed of the potential benefits, risks and long-term effects of this procedure. Individuals assessed as possible candidates for a stoma should be referred to a stoma care service.

Appendix C: Literature search for endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25/01/2011	Issue 1 of 12, January 2011
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25/01/2011	January 2011
HTA database (CRD website)	25/01/2011	January 2011
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25/01/2011	Issue 1 of 4, January 2011
MEDLINE (Ovid)	25/01/2011	1948 to Week 2 2011
MEDLINE In-Process (Ovid)	25/01/2011	January 24, 2011
EMBASE (Ovid)	25/01/2011	1980 to 2011 Week 3
CINAHL (NLH Search 2.0)	25/01/2011	January 2011
BLIC (Dialog DataStar)	28/07/2010	n/a
Zetoc	25/01/2011	January 2011

Trial sources searched on 26/07/2010 (UKCRN searched 04/08/2010)

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 22/7/2010 and 23/7/2010

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Endoscopy/
2	Endoscopes/
3	endoscop*.tw.

4	(Surg* adj3 Procedure* adj3 Endoscop*).tw.
5	(radio* adj3 frequen* adj3 (therap* or energ*)).tw.
6	secca*.tw.
7	(Temp* adj3 control* adj3 radio* adj3 frequenc*).tw.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	Fecal Incontinence/
10	((Faecal* or fecal*) adj3 incontinen*).tw.
11	(anal* adj3 sphincter* adj3 incontinen*).tw.
12	((anal* or anus*) adj3 incontinen*).tw.
13	(Anal* adj3 sphincter* adj3 function*).tw.
14	9 or 10 or 11 or 12 or 13
15	8 and 14
16	Animals/ not Humans/
17	15 not 16