NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of stapled transanal rectal resection for obstructed defaecation syndrome

Obstructed defaecation syndrome is characterised by the urge to pass faeces but an impaired ability to do so. It may be caused by a structural problem in the rectum. Common symptoms include constipation, excessive straining, pain and bleeding after passing faeces. In stapled transanal rectal resection (STARR), two circular staplers or a specific stapling device are used to remove the damaged part of the rectum and join the remaining parts back together.

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 November 2009.

Procedure name

- Stapled transanal rectal resection for obstructed defaecation syndrome.

Specialty societies

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

Obstructed defaecation syndrome (ODS) is a complex and multifactorial condition, characterised by an urge to defecate but an impaired ability to expel

the faecal bolus. Symptoms include: unsuccessful faecal evacuation attempts, excessive straining, pain, bleeding after defaecation and a sense of incomplete faecal evacuation. ODS is often associated with structural defects in the rectum such as rectocele (herniation of rectum into vagina), internal rectal prolapse (intussusception) and perineal descent. Women, particularly multiparous women, are more likely to present with symptoms of ODS than men.

Conservative treatment such as diet, biofeedback, laxatives, and pelvic floor retraining improves symptoms in the majority of patients with ODS. Surgery may be considered in patients for whom conservative treatments have failed and where there is an underlying structural abnormality, such as rectocele.

Various surgical procedures can be used to correct the underlying condition, taking an abdominal, vaginal or laparoscopic approach. However, many of these procedures have high recurrence and complication rates, and are often unsuitable for patients who have rectocele with intussusception.

New procedures including single stapled transanal prolapsectomy, perineal levatorplasty (STAPL), laparoscopic ventral mesh sacrocolporectopexy and double stapled transanal rectal resection procedure (STARR) have been proposed to address structural abnormalities associated with ODS.

What the procedure involves

Prior to undergoing STARR, patients are given prophylactic antibiotics and usually receive bowel preparation. The procedure is performed with the patient under spinal or general anaesthesia. Details of the procedure vary according to the method of stapling.

A circular anal dilator is introduced into the anal canal and secured with skin sutures. If a two-stapler technique is being used, then two methods have been described to retract the prolapsing rectum into the stapler housing: 2 or 3 traction sutures are either placed in a semi-circumferential manner at intervals above the anorectal junction. Alternatively 3 traction sutures are placed at the apex of the prolapse in the 10, 12 and 2 o’clock positions. The posterior rectal wall is protected with a spatula. A circular stapler is introduced into the rectum and the open head positioned above the level of the proximal suture. Traction is applied to the sutures to prolapse the redundant rectal wall into the anvil of the stapler. The stapler is then fired to perform the anterior rectal resection.

The procedure is repeated for the posterior rectal resection. Either two or three semi-circumferential sutures are placed posteriorly above the anorectal junction, or three sutures are placed at the 4, 6 and 8 o’clock positions. The anterior rectum is protected with a spatula, the second stapler is inserted into the anorectum, traction is applied on the sutures, and the stapler is fired to produce a complete full-thickness rectal resection. Any bleeding at the circumferential staple line is controlled with interrupted sutures.

If a dedicated stapler device is used, a number of short running sutures are used circumferentially to obtain control of the selected prolapsing tissue.

Another single suture is then placed, involving the entire length of the prolapsing rectal wall and knotted tightly. This suture is held in traction, the stapler device is positioned and fired to open the prolapsed rectal wall laterally. The stapler is then fired a number of times to complete the circumferential resection.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to STARR for ODS. Searches were conducted of the following databases, covering the period from their commencement to 13 July 2009: 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 obstructed defaecation syndrome.
Intervention/test	Stapled transanal rectal resection.
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 3530 patients from 2 RCTs, 1 non-randomised comparative study, 7 case series and 1 case report[1–10]. One of the case series is a report from the European STARR registry, which includes 2838 patients[4].

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 stapled transanal rectal resection for obstructed defaecation syndrome

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lehur PA (2008)[1]

Randomised controlled trial

France, Italy and UK

Recruitment period: 2004–5

Study population: women with ODS associated with rectal intussusception and/or rectocele

n = 119 (59 STARR, 60 biofeedback)
Mean age: 56 years
Sex: 100% (119/119) female

Patient selection criteria: women aged 18 years or older with ODS (minimum ODS score of 7 out of 24 on structured interview-led questionnaires including 7 ODS symptoms scored 0–3 and 1 score for lifestyle alteration) and candidates for surgical treatment. An adequate external sphincter function on rectal examination and evidence of anterior rectocele and/or rectal intussusception on dynamic defaecography also were required. Main exclusion criteria comprised clinically evident external sphincter injury, faecal incontinence, enterocele requiring surgery, and anterior defect, colpocele or cystocele requiring a combined surgical approach. Patients who had been previously treated with biofeedback were also excluded from entry to the study.</td>
<td>Number of patients analysed:
93 (54 STARR vs 39 control) evaluable patients;
50 (31 STARR vs 19 control) per-protocol patients

Mean modified ODS score (evaluable population)
<table>
<tr><th>Follow-up</th><th>STARR (n = 54)</th><th>Biofeedback (n = 39)</th></tr>
<tr><td>Baseline</td><td>16.2</td><td>14.4</td></tr>
<tr><td>12 months (last observation carried forward)</td><td>4.7</td><td>10.2</td></tr>
</table>
Mean modified ODS score (per-protocol population)
<table>
<tr><th>Follow-up</th><th>STARR (n = 31)</th><th>Biofeedback (n = 19)</th></tr>
<tr><td>Baseline</td><td>16.1</td><td>14.2</td></tr>
<tr><td>12 months</td><td>4.7</td><td>10.9</td></tr>
</table>
Successful treatment in evaluable patients (defined as a decrease in ODS score of ≥ 50 % at 1 year)
• STARR = 82% (44/54)
• Biofeedback = 33% (13/39), p < 0.0001
Successful treatment in per-protocol population
• STARR = 81% (25/31)
• Biofeedback = 26% (5/19), p < 0.001

Mean change in ODS score
<table>
<tr><th>Follow-up</th><th>STARR (n = 31)</th><th>Biofeedback (n = 19)</th></tr>
<tr><td>6 months</td><td>-11.7</td><td>-4.9</td></tr>
<tr><td>12 months</td><td>-11.5</td><td>-4.2</td></tr>
</table>
Mean change in PAC-QOL score at 12 months
• STARR = -37.1
• Biofeedback = -11.4</td>
<td>Adverse events
• STARR = 14.8% (8/54)
• Biofeedback = 1.9% (1/52) (anal pain during training sessions)

Adverse events in STARR patients included local infection, anorectal pain, incontinence, bleeding, urinary infection, depression (actual numbers not stated in paper).

One STARR patient withdrew because of incontinence that needed further investigation.

‘Serious adverse events’
• 12-hour postoperative bleeding (n = 1), managed under general anaesthesia with additional sutures at the site of haemorrhage.
• Pain in the right upper abdominal quadrant several weeks after surgery (n =1), required hospital care but was not considered to be related to STARR procedure.</td>
<td>Follow-up issues:
• 14% (8/59) STARR and 50% (30/60) control patients withdrew before 6 months; 16 of the biofeedback-treated patients who withdrew cited unsatisfactory results of the procedure.
• Only 42% (50/119) of patients were followed up per-protocol to visit 6 at 12 months (52% of STARR patients and 32% of control patients). Any patient who failed to complete the 12-month assessment (15 months after start of treatment) within ± 2 weeks was excluded from the per-protocol population.
• 92% (54/59) STARR patients and 65% (39/60) control patients had evaluable data at the end of the study.
Study design issues:
• Modified ODS score used the sum of individual scores for 7 symptoms and 1 score for lifestyle alteration. Each point is scored 0 to 3 according to frequency of symptom (never = 0, less than once weekly = 1, 1–6 times weekly = 2, every day = 3) or time needed to evacuate (< 5 min = 0, 6–10 min = 1, 11–20 min = 2, > 20 min = 3)
• Secondary outcomes included PAC–QOL, consisting of 28 questions scored from 0 to 4, with a total of 0 (best) to 112.

• Patients were randomised to one</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lehur PA (2008) cont.

Technique: STARR procedure performed using two circular staplers (PROXIMATE®, Ethicon Endo-Surgery). Biofeedback therapy comprised training twice per week for 10–24 electromyographic-based treatment sessions during a 3-month period.

Follow-up: 15 months

Conflict of interest/source of funding: not reported</td>
<td>Number of STARR patients with score > 0 for individual symptoms
<table>
<tr><th>Symptom</th><th>Number of patients at baseline with score > 0</th><th>Number of patients at 12 months with score > 0</th></tr>
<tr><td>Medication to evacuate</td><td>40</td><td>8</td></tr>
<tr><td>Evacuation difficulties</td><td>54</td><td>17</td></tr>
<tr><td>Digitation</td><td>43</td><td>8</td></tr>
<tr><td>Time to evacuate</td><td>43</td><td>12</td></tr>
<tr><td>Lifestyle alteration</td><td>49</td><td>31</td></tr>
</table>
Median patient reported success scores (interquartile range)
• STARR (n = 51) = 8 (6–10)
• Biofeedback (n = 34) = 4 (3–6),
p < 0.0001 (between groups)

Decrease in incontinence score between baseline and 12 months
• STARR = -2.8, p = 0.001
• Biofeedback = –0.4, p = 0.356
p = 0.086 (between groups)

Radiological findings on standardised defaecography
<table>
<tr><th></th><th>STARR</th><th>Biofeedback</th></tr>
<tr><td>Rectocele
Baseline
12 months</td><td>
92%(49/53)
41%(19/46)</td><td>
97% (38/39)
96% (24/25)</td></tr>
<tr><td>Intussusception
Baseline
12 months</td><td>
61%(33/54)
22%(10/46)</td><td>
51% (20/39)
24% (6/25)</td></tr>
<tr><td>Enterocele
Baseline
12months</td><td>
13% (7/53)
6% (3/44)</td><td>
2% (1/39)
0% (0/25)</td></tr>
</table>
</td>
<td></td>
<td>of the study arms, described as ‘stratified 1:1 by surgeon, with varying block sizes after baseline assessment’.
• A sample size of 206 was required to detect a 20% clinically important difference in success rates. The trial was terminated early because of slow recruitment.
• The last observation carried forward was used to impute missing values.
• Patient-reported success scale used a single, self-administered questionnaire at 12 months to assess patient satisfaction, scoring from 0 to 10.
Study population issues:
• Patients in the control group who withdrew before the visit 3 assessment had higher baseline ODS than the group as a whole. The baseline scores in the two evaluable groups were therefore slightly different.</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details

Boccasanta P et al (2004)[2]

Italy

Randomised controlled trial

Recruitment period: 1999–2001

Study population: women with outlet obstruction associated with descending perineum, intussusceptions and rectocele

n = 50 (25 STARR vs 25 STAPL)
Mean age: STARR = 54.6 years, STAPL = 53.2 years
Sex: 100% (50/50) female

Patient selection criteria: Women presenting with outlet obstruction who were non-responders to medical therapy and biofeedback. All had intussusception and rectocele and at least 3 symptoms persisting for more than 6 months. Patients were excluded if presenting with faecal incontinence, enterocele, recurrent rectocele or mega rectum, concomitant genital prolapse or cystocoele.

Technique: STARR procedure performed using two circular staplers (PPH-01, Ethicon Endo-Surgery). The first step of the STAPL procedure is the same as conventional stapled anopexy for internal rectal prolapse, followed by a perineal levatorplasty.

Mean follow-up: STARR = 22.3 months, STAPL = 23.4 months

Funding source/Conflict of interest: Study was supported by grant (non commercial)

Key efficacy findings

Number of patients analysed: **50 (25 STARR vs 25 STAPL)**

Preoperative scores are in *italics*.
Postoperative symptoms measured at 20 months.

	STARR n = 25	STAPL n = 25
Feeling of incomplete evacuation	*25 (100%)* 4 (16%)	*25 (100%)* 5 (20%)
Assistance	*23 (92%)* 4 (16%)	*22 (88%)* 4 (16%)
Painful evacuation effort	*19 (76%)* 4 (16%)	*19 (76%)* 5 (20%)
Laxatives	*14 (56%)* 3 (12%)	*13 (52%)* 3 (12%)
Enema	*9 (36%)* 2 (8%)	*10 (40%)* 2 (8%)
Abdominal pain	*5 (20%)* 2 (8%)	*6 (24%)* 3 (12%)
Bleeding	*4 (16%)* 1 (4%)	*4 (16%)* 1 (4%)
Dyspareunia	*0* 0	*0* 5 (20%)

	STARR	STAPL
Mean score: Constipation Scoring System	*18.01* 5.65	*17.95* 6.20
Mean score: Continence Grading Scale	*0.28* 0.36	*0.24* 0.20

Authors note that there were no differences between the groups except for the onset of dyspareunia.

Pain
(Absolute figures were not given in the paper).
Pain was significantly higher after STAPL, particularly from the third postoperative day (probably from perineal wound)

Key safety findings

Complications:

	STARR	STAPL
Early (< 7 days)		
Urinary retention	2 (8%)	2 (8%)
Bleeding	1 (4%)	0
Delayed healing of the wound:	-	10 (40%)
Late:		
Urge to defecate	4 (16%)	1 (4%)
Incontinence to flatus	2 (8%)	1 (4%)
Stenosis	1 (4%)	1 (4%)
Dyspareunia	0	5 (20%)

Comments

Follow-up issues:
- No patients were lost to follow-up

Study design issues:
- Originally 96 patients were recruited for conservative treatment. 67 were non-responders. From those, 17 patients were excluded from the study for reasons including genital prolapse or cystocoele (n = 5) and faecal incontinence (n = 4).
- Study powered at 0.8
- Randomisation: Assigned using random permuted blocks. Assignment of the treatment was made by a nurse in the ward before the operation.
- Qualitative data were analysed by means of chi-squared test for comparing the two groups and McNemar test for comparing preoperative and postoperative data.

Study population issues:
- The two groups were similar with regard to parity, previous episiotomy, hysterectomy, haemorrhoidectomy and cystopexy. Preoperative symptoms were also similar between the two groups.

Other issues:
- This study was included in the original overview

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
	Defaecography: Descent of the anorectal junction was reduced by both operations without statistical differences between the two groups. 7 patients in the STAPL group had a small residual rectocele. Both rectocele and intussusception were corrected in all patients in the STARR group. Anorectal manometry: Neither operation modified anal pressures Overall satisfaction (measured at 20 months) STARR: Excellent 11 (44%); Good 11 (44%); Fairly good 2 (8%); Poor 1 (4%) STAPL: Excellent 9 (36%); Good 10 (40%); Fairly good 4 (16%); Poor 2 (8%) Definitions of clinical outcomes: • Excellent: symptom-free • Good: 1–2 episodes per month of use of laxatives without digital assistance, use of enema or bleeding. • Fairly good: more than 2 episodes per month • Poor: symptoms unchanged.		

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Harris MA (2009)[3] **Non-randomised controlled trial** USA Recruitment period: 2005–7 (for STARR) Study population: women with ODS caused by rectocele and/or rectal intussusception n = **73 (36 STARR, 37 transvaginal rectocele repair)** Mean age: STARR = 53.2 years, transvaginal repair = 57.9 years Sex: 100% (73/73) female Patient selection criteria: For STARR patients, an ODS score > 10 (out of 24) had to be noted. The presence of rectocele and/or rectal intussusception was confirmed by defaecography. Patients with the following conditions were excluded: incontinence to solid stool, full-thickness rectal prolapse, perineal infection, rectovaginal fistula, resting enterocele or sigmoidocele, complex pelvic floor prolapsed, pregnancy, inflammatory bowel disease or carcinoma, severe paradoxical pelvic floor dysfunction, and psychiatric impairment. Technique: STARR procedure performed using two circular staplers. Neither procedure was described in detail. Follow-up: STARR = 7.9 months, transvaginal repair = 13.6 months (p = 0.048) Conflict of interest/source of funding: two of the authors are paid consultants and proctors for Ethicon Endo-Surgery Inc.	Number of patients analysed: **73 (36 STARR vs 37 transvaginal repair)** ***Mean ODS score*** |	STARR	Transvaginal repair
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Preoperative	16.5	8.7
Postoperative (timepoint not stated)	1.97	1.86 | ***Failure rate (patients still with difficulty emptying after the procedure)*** • STARR = 16.7% (6/36) • Transvaginal repair = 21.6% (8/37), p = 0.80 ***Recurrence rate*** • STARR = 2.7% (1/36) • Transvaginal repair = 10.8% (4/37), p = 0.17 The recurrence in the STARR group occurred at 4 months; the patient subsequently had another STARR procedure. The four recurrences in the control group were at 9, 20, 30 and 48 months respectively; 1 patient had a STARR procedure, 1 had a transanal repair, 1 opted for no treatment and the remaining patient left the practice. ***Operative time (min)*** • STARR = 52.7 • Transvaginal repair = 85.5, p < 0.0001 ***Length of hospital stay (days)*** • STARR = 2.6 • Transvaginal repair = 3.0, p = 0.22	**Complications** • STARR = 61.1% (22/36) • Transvaginal repair = 18.9% (7/37), p = 0.0001 **Complications in STARR group** • Rectal bleeding = 19% (7/36) (one patient required reoperation to control bleeding from the staple line) • Rectal pressure and tenesmus = 16.7% (6/36) • Faecal incontinence = 8.3% (3/36) • Diarrhoea = 5.6% (2/36) • Perineal herpes = 2.8% (1/36) • Pruritis ani = 2.8% (1/36) • *Clostridium difficile* infection = 2.8% (1/36) • Rectal pain = 2.8% (1/36) **Complications in trans vaginal repair group** • Wound infection = 5.4% (2/37) • Anal fissure = 2.7% (1/37) • Faecal incontinence = 2.7% (1/37) • Yeast infection (not otherwise defined) = 5.4% (2/37) • Vaginal bleeding = 2.7% (1/37) ***Dyspareunia*** • STARR = 10.5% (2/19) • Transvaginal repair = 12% (3/25), p = 0.84 (It was not clear how many patients had dyspareunia before treatment). ***Estimated blood loss (ml)*** • STARR = 42.9 • Transvaginal repair = 107.9, p = 0.0015	**Follow-up issues**: • No losses to follow-up were described. • The follow-up period is shorter for the STARR group than the controls. **Study design issues**: • Multicentre trial. • Patients who underwent transvaginal rectocele repair between 1997 and 2002 were used as historical controls. Adverse events may have been under-reported for these patients, in contrast to the STARR patients who were asked to report adverse events at every visit. • ODS score included 8 symptoms, scored 0 to 3 according to frequency of symptom. **Study population issues**: • The mean preoperative ODS score was statistically significantly lower in the control group than the STARR group (8.7 vs. 16.5, p < 0.0001). The ODS score assigned to the control group was not as accurate as for the STARR group, both pre- and postoperatively. • Overall, there was no difference in defaecography findings between the groups. • Additional procedures in the control group included 6 haemorrhoidectomies, 10 sphincteroplasties, 2 perineorrhaphies, 2 colporrhaphies and 1 enterocele repair. In the STARR group, there were 3 anal dilatations and 1 transanal repair.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Jayne DG (2009)[4] **Case series (register data)** UK, Germany, Italy Recruitment period: 2006–8 Study population: patients with ODS and evidence of anatomic defects (rectocele and/or internal rectal prolapse) **n = 2838** Mean age: 54.7 years (range 17–92) Sex: 83% (2364/2838) female Patient selection criteria: inclusion recommendations were that patients should have recognised symptoms of ODS with evidence of anatomic defects on defaecography and adequate anal sphincter function, as assessed by at least digital rectal examination. Exclusion recommendations included contraindication to general anaesthesia, immunocompromised status, coexisting inflammatory or septic conditions of the anorectum. Technique: STARR procedure performed using two circular staplers (PPH-01® Ethicon Endo-Surgery). Follow-up: 12 months Conflict of interest/source of funding: supported by Ethicon Endo-Surgery Europe and MedAlliance. The paper states that Ethicon Endo-Surgery had no influence on data analysis or interpretation.	Number of patients analysed: **2224 (patients with 12-month follow-up data)** ***ODS scores (41% completion, scale 0–40, higher score indicates more severe symptoms)*** • Baseline = 17.8 (95% CI 15.5 to 16.0) • 12 months = 5.8 (95% CI 5.3 to 6.4) p < 0.001 ***Symptom severity scores (57% completion, scale 0–36, higher score indicates more severe symptoms)*** • Baseline = 15.1 (95% CI 14.9 to 15.3) • 12 months = 3.6 (95% CI 3.4 to 4.8) p < 0.001 PAC–QOL scores (60% completion) showed a significant improvement in all four components (actual figures not quoted). ***Cleveland Clinic Foundation incontinence scores (62% completion, a lower score indicates an improvement in incontinence)*** • Baseline = 2.7 (95% CI 2.6 to 2.9) • 12 months = 1.6 (95% CI 1.4 to 1.8) p < 0.001 ***Percentage of patients reporting defecatory urgency 'most of the time' or 'all of the time'*** • Baseline = 39.9% • 6 months = 37.1% • 12 months = 26.8% The main difference between the registries in terms of outcome data was in the incontinence scores, which showed a worsening incontinence in the UK registry but an improvement in the Italian and German registries. The authors state that efficacy is between 85% and 93%, depending on the outcome measure.	**Complications (n = 2838)** • Persistent pain = 7.1% (202/2838) • Urinary retention = 6.9% (195/2838) • Bleeding = 5.0% (143/2838) • Septic event = 4.4% (124/2838) • Staple line complication = 3.5% (100/2838) • Faecal incontinence = 1.8% (52/2838) • Anastomotic stricture = 0.6% (17/2838) • Dyspareunia = 0.1% (3/2838) • Rectal necrosis (requiring a diverting stoma) = 0.04% (1/2838) • Rectovaginal fistula = 0.04% (1/2838) • Miscellaneous = 5.5% (155/2838) Two complications were described as serious (rectal necrosis and rectovaginal fistula). The authors note that defaecatory urgency was probably not a *de novo* symptom in many patients as 40% reported it at baseline.	**Follow-up issues**: • 12-month data were available for 78% (2224/2838) of patients. **Study design issues**: • The European STARR registry was launched in 2006 with the objective to collect data on as many patients as possible undergoing STARR. • Primary endpoint defined as the change in ODS score at 12 months after surgery. • Although recommendations were made with regard to preoperative investigation, patient preparation, operative technique and postoperative care, the ultimate care decisions were made by individual investigators in line with local policy. • Experience of the surgeons submitting data to the registry varied from only a few cases to more than 100 cases. • The ODS and symptom severity scores are unvalidated tools for assessing symptoms of outlet obstruction. Both systems use scores for 9 symptoms, including frequency of defaecation, incomplete evacuation, and use of laxatives. • Data completion for the ODS score was particularly poor (41%). **Study population issues**: • Most patients were entered from the Italian registry (n = 2193). There appeared to be differing criteria for patient selection between the three countries, with Germany including less symptomatic patients.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Arroyo A (2008)[5] **Case series** Spain Recruitment period: 2001–6 Study population: patients with ODS **n = 104** Mean age: 58.3 years Sex: not reported Patient selection criteria: Persistence ≥ 3 symptoms of ODS (feeling of incomplete evacuation, pain on effort, unsuccessful attempts at defaecation over a long period, defaecation with use of perineal support and/or odd posture, digital assistance and evacuation achieved with the use of enemas). Radiological criteria (dynamic magnetic resonance imaging or defaecography) were rectoanal intussusception extending > 10 mm into the anal canal, rectocele larger than 3 cm on straining, and entrapment of barium contrast after defaecation. Medical therapy and biofeedback had failed in all patients. Exclusion criteria were any type of urogenital prolapse or pelvic floor descent or functional disorders (anismus, dyssynergic defaecation), tenesmus, anal incontinence and failure of anal sphincter pressure, severe anal fibrosis, history of gynaecological surgery, perineal infection, pregnancy, inflammatory intestinal disease. Technique: STARR procedure performed using two circular staplers (details not reported) **Median follow-up: 26 months (range 12–72)** Conflict of interest/source of funding: none reported	Number of patients analysed: **104** ***Mean preoperative and postoperative constipation scores*** 		Pre-operative	3 months	6 months	1 year
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Frequency	1.5	0.6	0.5	0.8
Difficulty	1.7	0.7	0.5	0.6
Completeness	3.2	0.8	0.6	0.8
Abdominal pain	1.0	0.5	0.6	0.6
Time	1.3	0.4	0.3	0.4
Assistance	1.8	0.2	0.1	0.2
Failure	1.8	0.7	0.4	0.6
History	1.2	1.2	1.2	1.2
Total score	13.5	5.0	4.2	5.1 | ***Correction of rectocele and intususception = 95.2% (99/104)*** (assessed radiologically) ***Radiological or clinical failure at 1 year = 10.6% (11/104)*** (Radiological failure was defined as the persistence of pathological images after surgery. Clinical failure was defined as the persistence of symptoms after surgery.) Mean hospital stay = 2.2 days Associated haemorrhoidal prolapse was corrected in 90.4% (94/104) of patients.	***Pain score during first week after surgery*** (linear analogue scale from 0 to 10) • < 3 = 75.0% (78/104) • 4–6 = 18.3% (19/104) • > 6 = 6.7% (6/104) (one patient had to have staples close to the dentate line removed because of persistent pain) ***Tenesmus at 1 week =*** 14.4% (15/104) ***Faecal incontinence*** • 1 month = 22.1% (23/104) • 6 months = 8.7% (9/104) • 12 months = 8.7% (9/104) (spontaneously resolved without treatment in all but 9 patients) ***Urge to defaecate*** • 1 month = 26.9% (28/104) • 3 months = 14.4% (15/104) • 6 months = 6.7% (7/104) • 12 months = 5.8% (6/104) ***Persistent bleeding = 2.9% (3/104)*** (required surgical revision in the first 48 hours) ***Anastomotic stenosis = 1.0% (1/104)*** (improved with digital dilatation and resolved at 1-year follow-up)	**Follow-up issues**: • There were no losses to follow-up. **Study design issues**: • Prospective data collection • Consecutive patients • Preoperative and postoperative constipation was assessed using the validated Agachan–Wexner constipation scoring system. Scores range from 0 to 30 with higher scores indicating more severe symptoms.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Boccasanta P et al (2004) [6] **Case series** Recruitment period: 2001 Study population: patients with ODS associated with intussusception and rectocele **n = 90** Mean age: 57.6 years Sex: 97% (87/90) female Patient selection criteria: patients with at least 3 symptoms of ODS, failure of medical therapy and biofeedback performed for 2 months, at least 2 of the following findings at defaecography: rectoanal intussusceptions ≥ 10 mm extending into the anal canal; rectocele deeper than 3 cm on straining; entrapping barium contrast after defecation. Exclusion criteria included non relaxing puborectalis muscle, genital prolapse or cystocoele, recurrent rectocele and/or enterocele, and faecal incontinence. Technique: STARR procedure performed using two circular staplers (PPH-01®, Ethicon Endo-Surgery) Mean follow-up: 16.3 months (outcomes reported at 12 months) Conflict of interest/source of funding: none	Number of patients analysed: **90** ***Postoperative symptoms measured at 12 months.*** | | Preoperative | Postoperative | |---|---|---| | Feeling of incomplete evacuation | 89 (98.9%) | 17 (18.9%) | | Assistance required to evacuate | 79 (87.8%) | 4 (4.4%) | | Painful evacuation effort | 57 (63.3%) | 18 (20%) | | Laxatives | 47 (52.2%) | 9 (10%) | | Enema | 40 (44.4%) | 2 (2.2%) | | Abdominal pain | 26 (28.8%) | 11 (12.2) | | Bleeding | 16 (17.8%) | 2 (2.2%) | | Mean score: Constipation Scoring System | 13.02 | 4.52 | | Mean score: Continence Grading Scale | 0.24 | 0.39 | ***Defaecography*** Both rectocele and intussusception were corrected in all patients in the STARR group. ***Anorectal manometry*** Anal pressure did not significantly change after procedure. ***Patient satisfaction*** | | 1 month | 12 months | |---|---|---| | Excellent | 32 (35.5%) | 48 (53.3%) | | Good | 42 (46.7%) | 33 (36.7%) | | Fairly good | 11 (12.2%) | 5 (5.6%) | | Poor | 5 (5.6%) | 4 (4.4%) | Definitions of clinical outcomes: • Excellent: symptom-free. • Good: 1–2 episodes per month of use of laxatives without digital assistance, use of enema or bleeding. • Fairly good: more than 2 episodes per month. • Poor: symptoms unchanged.	**Complications:** Early complications (< 7 days) • urinary retention = 5.6% (5/90) • bleeding requiring readmission = 4.4% (4/90) • pneumonia = 1.1% (1/90) Late complications: (1 month) • urge to defaecate = 17.8% (16/90) • incontinence to flatus = 8.9% (8/90) • stenosis = 2.2% (2/90) Late complications: (12 months) • urge to defaecate = 1.1% (1/90) • incontinence to flatus = 1.1% (1/90) • stenosis = 3.3% (3/90)	**Follow-up issues:** • No losses to follow-up were described **Study design issues:** • Prospective data collection • All surgical teams had previous experience in conventional operations for rectocele, rectal prolapse and stapled anopexy for haemorrhoids (at least 30 operations) • Preoperative and postoperative constipation was assessed using the validated Agachan–Wexner constipation scoring system. Scores range from 0 to 30 with higher scores indicating more severe symptoms. **Other issues:** • This study was included in the original overview

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Gagliardi G (2008)[7] **Case series** Italy Recruitment period: before 2005 Study population: patients with ODS caused by rectal intussusception and/or rectocele **n = 85 patients operated on by the study authors (an additional 38 patients were referred after being treated elsewhere)** Mean age: 53 years (range 30–77) Sex: 100% (85/85) female Patient selection criteria: symptoms of ODS not responding to conservative treatment (dietary modifications and laxatives in all patients, biofeedback in 28% of patients). All patients had rectocele and/or intussusception. Patients with anxiety and/or depression were included (n = 30). Technique: two circular staplers were used (Ethicon Endo-Surgery). Mean follow-up: 20 months (range 3–44) Conflict of interest/source of funding: not reported	Number of patients analysed: **85 patients treated by the authors** ***Mean bowel movement frequency per week*** • Preoperative = 3.6 ± 3.9 • Postoperative = 4.3 ± 3.9, p = 0.34 ***Patients with ≥ 3 symptoms of ODS*** • Preoperative = 89% (76/85) • Postoperative = 52% (44/85), p < 0.001 Subjective improvement was noted in 65% (55/85) of patients. Recurrent rectocele = 29% (20/68) (recurrence was more likely in patients with larger rectoceles). Recurrent intussusception = 28% (22/79) (recurrence was more likely in patients with lower bowel action frequency and in patients with a preoperative sense of incomplete evacuation). Lack of improvement was more frequent in patients with preoperative self-digitation (OR 4.14; 95% CI 1.46 to 11.7), puborectalis dyssynergia (OR 16.4; 95% CI 1.91 to 141.3), and enterocele (OR 6.18; 95% CI 1.13 to 33.8). Incontinence resolved in 53% (8/15) of patients reporting it preoperatively. Nine patients had additional procedures because of persistent ODS symptoms.	**Perioperative complications** • Bleeding = 11.8% (10/85) (two required intervention) • Perianastomotic abscess = 2.4% (2/85) (surgically drained through transanal approach) • Stenosis = 2.4% (2/85) (one resolved with anal dilatation, the other required removal of anastomotic pocket at the staple line) • Haemorrhoidal thrombosis = 3.5% (3/85) • Anal fissure = 1.2% (1/85) • Sepsis with retropneumoperitoneum (resolved with intravenous antibiotics) = 1.2% (1/85) **Postoperative complications** • New onset anal incontinence = 5.9% (5/85) of patients (1 case spontaneously resolved after 6 months, the others persisted at a mean follow-up of 17 months). • Urgency = 10.6% (9/85) (2 resolved after 12 months) • Tenesmus = 5.9% (5/85) • Pain = 10.6% (9/85) (described as not debilitating) • Dyspareunia = 1.2% (1/85)	**Follow-up issues**: • No losses to follow-up were described. **Study design issues**: • Retrospective analysis. • Multicentre study (7 units). • An additional 9 patients underwent STARR during the study period but had incomplete records and so were excluded from entry to the study. • All surgeons who performed STARR were experienced in colorectal surgery and stapled haemorrhoidopexy. **Study population issues**: • Intussusception was diagnosed by defaecography in 94% (74/79) of patients. Of the 68 patients with rectocele, 64 (94%) underwent preoperative defaecography. Only 60 patients received vaginal contrast at defaecography, which may have underestimated the incidence of enterocele. • 9% (8/85) of patients had puborectalis dyssynergia.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Gagliardi G (2008) cont.	Number of patients analysed: **38 patients referred after STARR was performed elsewhere** Reasons for referral included constipation, recurrence, rectovaginal fistula, necrotising pelvic fasciitis, prostatitis and abscess. Recurrent rectocele = 29% (11/38) Recurrent intussusception = 37% (14/38) Postoperative constipation = 61% (23/38) 29% (11/38) patients were found to have puborectalis dyssynergia; in 9 of them symptoms improved with pelvic rehabilitation and biofeedback. 37% (14/38) patients underwent 19 operative interventions.	**Complications in 38 patients referred after STARR was performed elsewhere** One patient had septic shock the night of the operation. A hysterectomy and Hartmann's procedure were performed after necrosis of rectum and uterus were found. The patient died the day after reintervention. Postmortem revealed necrotising pelvic fasciitis. • Tenesmus = 13% (5/38) • Urgency = 13% (5/38) • Dyspareunia = 3% (1/38) • Rectovaginal fistula = 7.9% (3/38) (managed by fistula repair with diverting colostomy) • Incontinence = 29% (11/38) (4 cases improved with pelvic rehabilitation and biofeedback, 2 patients underwent levatorplasty) • New onset perineal pain = 53% (20/38) (described as debilitating and requiring constant analgesics in 7 patients)	**Other issues** • The 38 patients referred from other surgeons were referred for complex problems requiring specialist care. These patients represent a selected population.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Renzi A (2008)[8] **Case series** Italy Recruitment period: 2006 Study population: patients with ODS caused by rectal intussusceptions and/or rectocele **n = 30** Mean age: 56.6 years Sex: 93% (28/30) female Patient selection criteria: ODS score ≥ 12 (out of 20) and intussusceptions ≥ 10 mm and/or rectocele extending 2 cm or more from the rectal wall contour shown by cinedefaecography, and with a failure of 6 months medical therapy (1.5 l/day of water, high-fibre diet and lactulose 10 g/day). Patients with previous anal and rectal surgery, intestinal inertia, anismus, associated II/III degree genital prolapse, symptomatic cystocele and any form of anxiety and depression were excluded. Technique: dedicated device used (Contour Transtar® stapler kit, Ethicon-Endosurgery). Follow-up: 6 months Conflict of interest/source of funding: none	Number of patients analysed: **29** Preoperative distribution according to ODS score ODS score – Number of patients (%) 12 – 14: 8 (27.5) 15 – 17: 16 (55.1) 18 – 20: 5 (17.2) ***Postoperative ODS scores at 6 months*** ODS score – Number of patients (%) 0 – 3 'Excellent': 9 (31.0) 4 – 6 'Good': 14 (48.2) 7 – 9 'Adequate': 2 (6.8) 10 – 20 'Poor': 4 (13.7) 'Excellent', 'good' and 'adequate' scores were considered to be successful outcomes (86%) ***Mean ODS score*** • Preoperative = 15.8 ± 2.4 • Postoperative (6 months) = 5.0 ± 2.3, p < 0.0001 ***Mean constipation scoring system (Agachan-Wexner)*** Signs and symptoms – preoperative – 6-month follow-up Frequency: 0.5 – 0.5 Difficulty: 3.2 – 1.2 completeness: 3.4 – 1.6 Pain: 2.1 – 1.0 Time: 2.8 – 0.7 Assistance: 1.6 – 0.7 Failure: 1.7 – 0.5 History: 1.7 – 1.7 Mean total score: 17.0 – 7.9 All comparisons were statistically significant (p<0.001) except for frequency and history.	**Early complications** • Perineal haematoma (no treatment required) = 55.2% (16/29) • Acute urinary retention = 10.3% (3/29) • Bleeding (no transfusion necessary) = 6.8% (2/29) • Perianal sepsis = 0% (0/29) **Late complications (6 month follow-up)** • Urge to defaecate = 17.2% (5/29) • Incontinence to flatus = 6.8% (2/29) • Dyspareunia = 0% (0/29) • Rectal stenosis = 0% (0/29)	**Follow-up issues**: • One patient (3%) was lost to follow-up and was excluded from analysis. **Study design issues**: • Prospective data collection • Obstructed defaecation score used 5 symptoms scored 0 – 4, according to frequency (higher scores indicate more frequent symptoms). • The Agachan–Wexner constipation scoring system is validated for assessing constipation. **Other issues:** • The percentages reported in the paper for early complications do not match the number of events. The percentages have been recalculated, assuming that the numerator and denominator are as reported. • The mean preoperative constipation scores and the scores at 6 months are exactly the same as those reported for an earlier case series by the same author[9].

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Renzi A (2006)[9] **Case series** Italy Recruitment period: 2002–4 Study population: patients with ODS caused by rectal intussusceptions and/or rectocele. **n = 71** Mean age: 48.8 years (range 23–77) Sex: 96% (68/71) female Patient selection criteria: ODS score ≥ 12 (out of 20) and intussusceptions ≥ 10 mm and/or rectocele extending 2 cm or more from the rectal wall contour shown by cinedefaecography, and with a failure of 6 months medical therapy (1.5 l/day of water, high-fibre diet and lactulose 10 g/day) and biofeedback performed for 8 weeks. Patients with previous anal and rectal surgery, intestinal inertia, anismus, associated II/III degree genital prolapse, symptomatic cystocele were excluded. Technique: STARR procedure performed using two circular staplers (PPH-01® Ethicon Endo-Surgery). Follow-up: 6 months Conflict of interest/source of funding: none	Number of patients analysed: **68** Preoperative distribution according to ODS score ODS score: Number of patients (%) 12 – 14: 21 (30.8) 15 – 17: 37 (54.4) 18 – 20: 10 (14.7) ***Postoperative ODS scores at 3 and 6 months*** ODS score: 3-month follow-up n (%); 6-month follow-up n (%) 0 – 3 'Excellent': 22 (32.3); 22 (32.3) 4 – 6 'Good': 32 (47.0); 32 (47.0) 7 – 9 'Adequate': 8 (11.7); 7 (10.2) 10 – 20 'Poor': 6 (8.8); 7 (10.2) 'Excellent', 'good' and 'adequate' scores were considered to be successful outcomes (89.7%) ***Mean ODS score*** • Preoperative = 15.1 ± 2.8 • Postoperative (6 months) = 5.1 ± 2.9, p < 0.0001 ***Mean constipation scoring system (Agachan–Wexner)*** Signs and symptoms: Pre-operative; 3-month follow-up; 6-month follow-up Frequency: 0.5; 0.4; 0.5 Difficulty: 3.2; 1.3; 1.2 completeness: 3.4; 1.7; 1.6 Pain: 2.1; 1.0; 1.0 Time: 2.8; 0.5; 0.7 Assistance: 1.6; 0.5; 0.7 Failure: 1.7; 0.4; 0.5 History: 1.7; 1.7; 1.7 Mean total score: 17.0; 7.5; 7.9 All comparisons were statistically significant (p < 0.001) except for frequency and history.	**Early complications** • Perineal haematoma (no treatment required) = 23.5% (16/68) • Acute urinary retention = 4.4% (3/68) • Bleeding (no transfusion necessary) = 2.9% (2/68) • Perianal sepsis = 0% (0/68) **Late complications (3-month follow-up)** • Urge to defaecate = 4.4% (3/68) • Incontinence to flatus = 2.9% (2/68) • Dyspareunia = 1.4% (1/68) • Rectal stenosis = 1.4% (1/68) The first three of these complications spontaneously resolved within 6 months. The rectal stenosis was successfully treated by a new circular stapler resection.	**Follow-up issues**: • Three patients (4%) were lost to follow-up and were excluded from analysis. **Study design issues**: • Prospective data collection • Obstructed defaecation score used 5 symptoms scored 0 to 4, according to frequency (higher scores indicate more frequent symptoms). • The Agachan–Wexner constipation scoring system is validated for assessing constipation.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, odds ratio; PAC-QOL, Patient Assessment of Constipation–Quality of Life; STAPL, single stapled transanal prolapsectomy with perineal levatorplasty; STARR, stapled transanal rectal resection.

Study details	Key efficacy findings	Key safety findings	Comments
Renzi A (2006) cont.	***Cinedefaecographic data***		

	Pre-operative	Post-operative	p value
Dynamic perineal descent	23 (33.8)	23 (33.8)	NS
Rectorectal intussusception	27 (44.2)	13 (19.1)	<0.0001
Rectoanal intussusception	34 (55.7)	0 (0)	<0.0001
Rectocele	62 (95.3)	11 (17.7)	<0.0001
Sigmoidocele (first degree)	5 (7.3)	5 (7.3)	NS

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, Odds ratio; PAC-QOL, patient assessment of constipation – Quality of life; STARR, stapled transanal rectal resection

Study details	Key efficacy findings	Key safety findings	Comments
Stolfi VM (2009)[10] **Case report** Italy Recruitment period: not reported Study population: patient with retroperitoneal sepsis and subcutaneous emphysema after STARR **n = 1** Age: 46 years Sex: female Patient selection criteria: not reported Technique: STARR procedure performed using two circular staplers (PPH-01) **Follow-up: not reported** Conflict of interest/source of funding: none reported	The patient developed severe diarrhoea and fever, associated with deep perineal and low abdominal pain, on the second postoperative day. Intravenous antibiotic treatment was started immediately. Subcutaneous abdominal emphysema occurred 12 hours after onset of symptoms. A CT scan showed generalised peritoneal and mediastinal emphysema, a perirectal fluid collection with subcutaneous emphysema, partial dehiscence of the posterior rectorectal suture line, and a right ischiorectal phlegmon with gas collection in that area. Emergency laparotomy and loop sigmoid colostomy was performed after 24 hours of antibiotic therapy. The abscesses were drained via catheters transperineally and through the levator ani. The patient was discharged after a total hospital stay of 13 days. The rectal wound healed completely in 3 months. At that time, a stricture of the anastomosis was diagnosed and successfully treated with balloon dilatation. The colostomy was closed 1 month later.		

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, Odds ratio; PAC-QOL, patient assessment of constipation – Quality of life; STARR, stapled transanal rectal resection

Study details	Key efficacy findings	Key safety findings	Comments
Alabiso ME (2008)[11] **Case series** Italy Recruitment period: 2005– 6 Study population: patients who had undergone STARR for ODS related to rectal intussusception and anterior rectocele **n = 32** Mean age: not reported Sex: not reported Patient selection criteria: not reported – 634 defaecographic examinations were carried out, of which 32 were postoperative follow-up studies of patients who had undergone STARR for ODS. Technique: STARR procedure performed using two circular staplers **Follow-up: 24 months** Conflict of interest/source of funding: none reported	Routine defaecography performed at least 12 months after surgery showed isolated rectal diverticulum in 6.2% (2/32) of patients. The findings emerged at follow-up visits 24 months after surgery. The diverticula identified were located at the level of the surgical suture. The authors note that rectal diverticula are generally asymptomatic and usually clinically insignificant unless complications arise. Complications associated with rectal diverticula include diverticulitis with perforation and abscess formation, rectal prolapse due to inverted rectal diverticulum, post-inflammatory rectal stenosis, rectovesical fistula and faecal impaction in the diverticulum.		**Follow-up issues**: • There were no losses to follow-up. **Study design issues**: • Patient selection not described • The paper also describes 4 patients with rectal diverticula after surgery for mucosal-haemorrhoidal prolapse (Longo technique). • The main body of the text states that both patients with diverticula were female but the abstract states that they were both male.

Abbreviations used: CI, confidence interval; ODS, obstructed defaecation syndrome; OR, Odds ratio; PAC-QOL, patient assessment of constipation – Quality of life; STARR, stapled transanal rectal resection

Study details	Key efficacy findings	Key safety findings	Comments
Titu LV (2009)[12] **Case series** UK Recruitment period: 2001–7 Study population: patients with obstructed defaecation **n = 230** Median age: 58 years (range 19–90) Sex: 81% (187/230) female Patient selection criteria: patients with failed medical treatment for ODS and symptomatic intussusception. Exclusion criteria included pelvic floor dyssynergia, slow transit constipation, enterocele or sigmoidocele at rest, vaginal vault prolapsed, symptomatic cystocele, large external rectal prolapsed, small rectocele or rectoanal intussusceptions, active perineal infection, inflammatory bowel disease, radiation proctitis, neoplasia, pregnancy Technique: procedure performed using 2 circular staplers. **Median follow-up: 24 months (range 12–68)** Conflict of interest/source of funding: none	Number of patients analysed: 230 Median operative time = 35 min (range 20–95) Day cases = 69% (159/230) Of the 142 patients with faecal incontinence preoperatively, 98% reported an improvement. Incontinence worsened in 1.3% (3/230) of patients. Median reduction in Wexner incontinence scores after surgery = 5 (95% CI 4.5 to 5.5) Constipation improved in 75% (58/77) of patients. There were 2 recurrent rectoanal instussusception at 12 months postoperatively. ***Patient satisfaction*** • Very happy = 77% (178/230) • Partially satisfied = 10% (24/230) • Unsure = 7% (17/230) • Dissatisfied = 2% (4/230) • Extremely dissatisfied = 3% (7/230) 66% (152/230) of patients would be ‘very happy’ to recommend STARR to a friend, 20% (45/230) would probably recommend it, 10% (23/230) were not sure, 1% (3/230) would probably not recommend it and 3% (7/230) would definitely not recommend it.	Intraoperative complications: • Dehiscence of staple line requiring manual suturing = 0.9% (2/230) Early postoperative complications: • Reactive haemorrhage requiring reoperation = 2.6% (6/230) • Secondary bleeding = 1.7% (4/230) (2 required emergency transanal surgery) • Urinary retention requiring catheterisation = 1.7% (4/230) • Rectovaginal fistula = 0.4% (1/230) (developed on the 5th postoperative day and repaired surgically) • Faecal impaction = 0.9% (2/230) (responded to medical treatment) • Faecal urgency = 46.5% (107/230) (during the 1st postoperative week) • Severe pain = 3.5% (8/230) Complications at 8 weeks postoperatively • Chronic pain = 4.4% (10/230) • Faecal urgency = 10.4% (24/230) • Incontinence to flatus = 0.9% (2/230) • Incontinence to faeces = 0.9% (2/230) • Constipation = 7.4% (17/230) • Rectal stenosis = 0.9% (2/230)	

Efficacy

One RCT reported that treatment was successful in 82% (44/54) of patients in the STARR group, compared with 33% (13/39) of patients treated with biofeedback ($p < 0.0001$) at 12 months[1]. Another RCT reported that 88% (22/25) of patients treated with STARR had a good or excellent clinical outcome (1–2 episodes per month or symptom free) at 20 months, compared with 76% (19/25) of patients treated with single-stapled transanal prolapsectomy with perineal levatorplasty (STAPL) [2]. A non-randomised comparative study reported a failure rate of 17% (6/36) for women in the STARR group with a mean follow-up of 8 months compared with 22% (8/37) of women treated with transvaginal repair with a mean follow-up of 14 months ($p = 0.80$)[3].

Registry data on 2224 patients showed that STARR had a success rate of between 85% and 93% at 12 months, depending on the outcome measures used[4]. In 1 case series, a successful outcome was reported in 89% (93/104) of patients at 12 months, and in another a good or excellent clinical outcome was reported in 90% (81/90) of patients[5,6].

In a case series of 230 patients with a median follow-up of 24 months, 77% (178/230) of patients were very happy with the result and 10% (24/230) were partially satisfied. 3% (7/230) were extremely dissatisfied with the procedure[12].

Safety

Defaecatory urgency/urge incontinence

In 1 RCT, defaecatory urgency was reported in 16% (4/25) of patients after STARR and 4% (1/25) of patients after single stapled transanal prolapsectomy[2]. In three case series, the rates of urgency were 4% (3/68), 11% (9/85) and 17% (5/29)[9,7,8]. In a further 2 case series, rates of urgency decreased during the follow-up period from 27% (28/104) and 18% (16/90) at 1 month to 6% (6/104) and 1% (1/90), respectively, at 12 months follow-up[5,6].

In a non-randomised comparative study, 8% (3/36) of patients in the STARR group reported faecal incontinence after the procedure, compared with 3% (1/37) of patients in the transvaginal repair group[3]. One case series reported that 22% (23/104) of patients had faecal incontinence at 1-month follow-up, which reduced to 9% (9/104) at 12-month follow-up[5]. Another case series reported that 47% (107/230) of patients had faecal urgency during the first postoperative week but < 1% (2/230) had faecal incontinence after 8 weeks[12].The register data reported that 2% (52/2838) of patients had postoperative faecal incontinence[4].

Bleeding

Bleeding was reported as a complication in all 10 studies, with rates of 2% (1/54), 3% (3/104), 3% (2/68), 4% (1/25), 4% (4/90), 4% (10/230), 5% (143/2838), 7%

(2/29), 12% (10/85) and 19% (7/36)[1,5,9,2,6,12,4,8,7,3]. In 6 of these studies, it was stated that at least 1 patient required readmission or reoperation for bleeding.

Urinary retention

Urinary retention was reported as a complication in 6 studies, with rates of 2% (4/230), 4% (3/68), 6% (5/90), 7% (195/2838), 8% (2/25) and 10% (3/29)[12,9,6,4,2,8].

Sepsis/necrosis

In the STARR registry, 4% (124/2838) of patients had a septic event[4]. There was also 1 case of rectal necrosis, requiring a diverting stoma, which the authors described as a serious complication.

In a case series of 38 patients referred to a specialist centre after STARR was performed elsewhere, 1 patient had septic shock the night of the STARR procedure. At reoperation, necrosis of the rectum and uterus were diagnosed. The patient died a day later and the postmortem revealed necrotising pelvic fasciitis[7].

One case report describes a patient with severe retroperitoneal sepsis with mediastinal and subcutaneous emphysema after STARR. This was treated by transperineal pelvic drainage and a loop sigmoid colostomy[10].

Rectovaginal fistula

In the registry data of 2838 patients, there was 1 case of rectovaginal fistula reported[4]. A case series of 230 patients reported 1 case of rectovaginal fistula[12]. Another study of 38 patients referred for complications after STARR reported 3 cases of rectovaginal fistula[7].

Stenosis/stricture

Stenosis was reported as a complication in 7 studies, with rates ranging from 0.6% (17/2838) to 4% (1/25)[2,4,5,6,7,9,12].

Rectal diverticulum

One study describes 2 patients with rectal diverticula in a series of 32 patients who had undergone routine defaecography at least 12 months after the STARR procedure[11].

Validity and generalisability of the studies

- One RCT used biofeedback as the comparator, although it states that STARR should not be considered as first-line therapy[1]. Half of the patients randomised to biofeedback withdrew early from the study. Patients who had previously been treated with biofeedback were excluded from entry to the study.

- The other RCT is a randomised comparison of two novel techniques, rather than one novel technique in comparison with an established procedure[2]. This limits the conclusions that can be drawn with regards to the STARR procedure.
- Different studies used different scoring systems to assess the severity of symptoms associated with ODS.
- Five studies listed failure to respond to medical treatment and/or biofeedback in the inclusion criteria[2,5,6,7,9].
- Five studies specified that patients with faecal incontinence were excluded from entry to the study[1,2,3,5,6].
- Most studies listed quite specific and select inclusion and exclusion criteria.
- Although some studies have followed patients up for longer than 12 months, few report outcomes assessed beyond 12 months.
- Only one study used a dedicated stapling device[8].

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

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

- Circular stapled haemorrhoidectomy. NICE interventional procedures guidance 34 (2003). Available from www.nice.org.uk/IPG34
- Stapled transanal rectal resection for obstructed defaecation syndrome. NICE interventional procedures guidance 169 (2006). Available from www.nice.org.uk/IPG169

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 D Jayne, Miss K Telford (Association of Coloproctology of Great Britain and Ireland).

- One Specialist Adviser considered this procedure to be established practice and the other described it as definitely novel and of uncertain safety and efficacy.
- Adverse events reported in the literature include pain, urinary retention, bleeding, sepsis, staple line complications, strictures, new faecal incontinence, rectovaginal fistula, rectal necrosis, rectal wall haematoma, rectal wall perforation and dyspareunia.
- One adviser commented that there are no data on long-term outcomes of efficacy.
- Key efficacy outcomes include reduction in obstructed defaecation symptoms as assessed by one of the available obstructed defaecation scores and improved quality of life.
- Careful patient selection is important.
- Both advisers state that the procedure should be performed by surgeons who have undergone the necessary training and have a specialist interest in pelvic floor dysfunction.
- One Specialist Adviser considered the potential impact of the procedure on the NHS to be moderate and the other thought it would be minor.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent 23 questionnaires to 1 trust for distribution to patients who had the procedure (or their carers). NICE received 9 completed questionnaires.

The Patient Commentators raised the following issues about the safety/efficacy of the procedure which did not feature in the published evidence or the opinions of Specialist Advisers, and which the Committee considered to be particularly relevant:

- Five patients reported an improvement in quality of life, including being able to visit the cinema and theatre.

Issues for consideration by IPAC

- There are a large number of European studies on STARR which have been published in languages other than English.

References

1. Lehur PA, Stuto A, Fantoli M et al. (2008) Outcomes of stapled transanal rectal resection vs. biofeedback for the treatment of outlet obstruction associated with rectal intussusception and rectocele: a multicenter, randomized, controlled trial. Diseases of the Colon & Rectum 51: 1611–8.

2. Boccasanta P, Venturi M, Salamina G et al. (2004) New trends in the surgical treatment of outlet obstruction: clinical and functional results of two novel transanal stapled techniques from a randomised controlled trial. International Journal of Colorectal Disease 19: 359–69.

3. Harris MA, Ferrara A, Gallagher J et al. (2009) Stapled transanal rectal resection vs. transvaginal rectocele repair for treatment of obstructive defecation syndrome. Diseases of the Colon & Rectum 52: 592–7.

4. Jayne DG, Schwandner O, Stuto A. (2009) Stapled transanal rectal resection for obstructed defecation syndrome: one-year results of the European STARR Registry. Diseases of the Colon & Rectum 52: 1205–12.

5. Arroyo A, Gonzalez-Argente FX, Garcia-Domingo M et al. (2008) Prospective multicentre clinical trial of stapled transanal rectal resection for obstructive defaecation syndrome. British Journal of Surgery 95: 1521–7.

6. Boccasanta P, Venturi M, Stuto A et al. (2004) Stapled transanal rectal resection for outlet obstruction: a prospective, multicenter trial. Diseases of the Colon & Rectum 47: 1285–96.

7. Gagliardi G, Pescatori M, Altomare DF et al. (2008) Results, outcome predictors, and complications after stapled transanal rectal resection for obstructed defecation. Diseases of the Colon and Rectum 51: 186–95.

8. Renzi A, Talento P, Giardiello C et al. (2008) Stapled trans-anal rectal resection (STARR) by a new dedicated device for the surgical treatment of obstructed defaecation syndrome caused by rectal intussusception and rectocele: early results of a multicenter prospective study. International Journal of Colorectal Disease 23: 999–1005.

9. Renzi A, Izzo D, Di Sarno G et al. (2006) Stapled transanal rectal resection to treat obstructed defecation caused by rectal intussusception and rectocele. International Journal of Colorectal Disease 21: 661–7.

10. Stolfi VM, Micossi C, Sileri P et al. (2009) Retroperitoneal sepsis with mediastinal and subcutaneous emphysema complicating stapled transanal rectal resection (STARR). Techniques in Coloproctology 13: 69–71.

11. Alabiso ME, Grassi R, Fioroni C et al. (2008) Iatrogenic rectal diverticulum in patients treated with transanal stapled techniques. Radiologia Medica 113: 887–94.

12. Titu LV, Riyad K, Carter H, et al. (2009) Stapled transanal rectal resection for obstructed defecation: a cautionary tale. Disease of the Colon & Rectum 52: 1716–22.

Appendix A: Additional papers on stapled transanal rectal resection for obstructed defaecation syndrome

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
Arroyo A, Perez-Vicente F, Serrano P. (2007) Evaluation of the stapled transanal rectal resection technique with two staplers in the treatment of obstructive defecation syndrome. Journal of the American College of Surgeons 204: 56–63.	Non-randomised comparative study (17 vs. 20) n = 37 Follow-up = 6 months	Comparison of two different staplers. The rate of intraoperative haemorrhage and formation of granulomas on the staple line were significantly different between the two groups.	Small numbers in each patient group.
Bassi R, Rademacher J, Savoia A. (2006) Rectovaginal fistula after STARR procedure complicated by haematoma of the posterior vaginal wall: report of a case. Techniques in Coloproctology 10: 361–3.	Case report n = 1	Rectovaginal fistula after 30 days, which required surgical correction.	Complication is already listed in table 2.
Carriero A, Picchio M, Martellucci J et al. (2010) Laparoscopic correction of enterocele associated to stapled transanal rectal resection for obstructed defecation syndrome. International Journal of Colorectal Disease 25: 381–7.	Case series n = 20 Follow-up = 24 months	Median (range) obstructed defecation score: Preoperative = 10 (6–14) Postoperative = 2 (0–14), ($p < 0.001$) There were no ODS related symptoms at follow-up.	Small case series
De Nardi P, Bottini C, Faticanti Scucchi L et al. (2007) Proctalgia in a patient with staples retained in the puborectalis muscle after STARR operation. Techniques in Coloproctology 11: 353–6.	Case report n = 1	Persistent pain, tenesmus and faecal urgency. Several staples were found to be stuck to the puborectalis muscle. The patient recovered fully after the staples were removed.	Complications are already listed in table 2.
Dindo D, Weishaupt D, Lehmann K. (2008) Clinical and morphologic correlation after stapled transanal rectal resection for obstructed defecation syndrome. Diseases of the Colon & Rectum 51: 1768–74.	Case series n = 24 Median follow-up = 18 months	Significant decrease in constipation scores after STARR. Pre-existing intussusceptions were no longer visible in 75% (15/20) of patients. Two severe complications (bleeding and persistent pain requiring reintervention)	Larger case series are included.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Dodi G, Pietroletti R, Milito G et al. (2003) Bleeding, incontinence, pain and constipation after STARR transanal double stapling rectotomy for obstructed defecation. Techniques in Coloproctology 7: 148-153.	n = 14 (patients who presented with severe complication or recurrence of ODS after STARR) Follow-up = 12 months	Complications: severe intraoperative bleeding which required multiple layer manual sutures (n = 1), severe rectal bleeding (n = 2), pelvic sepsis (n = 1), persistent anal pain (n = 7), faecal incontinence (n = 3), recurrent ODS (n = 7). Authors conclude that parity, spastic floor syndrome and psychoneurosis seem to be the risk factors predisposing to failure of the STARR procedure.	Larger case series are included. The complications listed have all been noted by studies included in table 2. (included in table 2 of original overview)
Frascio M, Stabilini C, Ricci B et al. (2008) Stapled transanal rectal resection for outlet obstruction syndrome: results and follow-up. World Journal of Surgery 32: 1110–5.	Case series n = 25 Mean follow-up = 25 months	88% (22/25) of patients had fairly good, good, or excellent functional outcome. Late complications included 3 cases of urge to defecate and 8 cases of incontinence to flatus. One patient had haemorrhage requiring reintervention.	Larger case series are included.
Frascio M, Lazzara F, Stabilini C et al. (2009) Pseudodiverticular defecographic image after STARR procedure for outlet obstruction syndrome. International Journal of Colorectal Disease 24: 1115–6.	Case report n = 1	Patient presented with recurrence of symptoms 1 month after STARR. Defecography showed a diverticular cavity, caused by a bridge of rectal mucosa.	Appendix (diverticula are already mentioned as a complication)
Gelos M, Frommhold K, Mann B. (2010) Severe mesorectal bleeding after stapled transanal rectal resection (STARR-operation) using the `Contour Transtar curved cutter stapler'. Colorectal Disease 12; 265–6.	Case report n = 1	Severe mesorectal bleeding required laparotomy.	Appendix (bleeding requiring reintervention is already mentioned in table 2).
Grassi R, Romano S, Micera O et al. (2005) Radiographic findings of post-operative double stapled transanal rectal resection (STARR) in patient with obstructed defecation syndrome (ODS). European Journal of Radiology 53: 410-416.	Case series n = 54 Follow-up = 6 months	Significant reduction of the rectocele and intussusception in all patients. Significant reduction in excessive straining, assistance and painful evacuation effort.	Larger case series are included. (this study was included in table 2 of original overview)

Lenisa L, Schwandner O, Stuto A et al. (2009) STARR with Contour Transtar: prospective multicentre European study. Colorectal Disease 11: 821–7.	Case series n = 75 Follow-up = 12 months	9% intraoperative difficulties, 7% postoperative complications and no mortality. The mean reduction of the ODS score was -15.6 (95% CI: -17.3 to -13.8, $p < 0.0001$). 4 patients (5%) had deterioration.	Larger case series are included.
Ommer A, Albrecht K, Wenger F et al. (2006) Stapled transanal rectal resection (STARR): a new option in the treatment of obstructive defecation syndrome. Langenbecks Archives of Surgery 391: 32–7.	Case series n = 14 Mean follow-up = 19 months	All patients showed improvement in rectal evacuation. One patient had recurrence of ODS 6 months after surgery.	Larger case series are included.
Pechlivanides G, Tsiaoussis J, Athanasakis E et al. (2007) Stapled transanal rectal resection (STARR) to reverse the anatomic disorders of pelvic floor dyssynergia. World Journal of Surgery 31: 1329–35.	Case series n = 16	ODS remained unaffected in 44% (7/16) of patients, disappeared in 19% (3/16) and improved significantly in 38% (6/16). Two patients with failed STARR had coexisting enterocele, which had been missed preoperatively. The remaining 5 patients with failed STARR improved with subsequent biofeedback treatment.	Larger case series are included.
Pescatori M, Zbar AP (2009) Reinterventions after complicated or failed STARR procedure. International Journal of Colorectal Disease 24: 87–95.	Case series n = 20 Median follow-up = 18 months (from reintervention)	Post-STARR surgery was performed for 3 complications and 10 failures including recurrent ODS, severe proctalgia and faecal incontinence. Surgery included enterocele repair, staple removal, fistulectomy, rectosigmoid resection, and levatorplasty. 50% (6/12) of patients evaluated at 12 months remained unchanged (all with psychoneurosis). The authors conclude that the STARR procedure, when complicated or failed, has a poor outcome following surgical reintervention. It requires careful patient selection to determine the associated pelvic floor pathology and pre-existing psychopathology.	The focus of the study is to assess efficacy of reintervention after STARR had failed or there were complications.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Petersen S, Hellmich G, Schuster A et al. (2006) Stapled transanal rectal resection under laparoscopic surveillance for rectocele and concomitant enterocele. Diseases of the Colon & Rectum 49: 695–9.	Case series n = 41	STARR procedure combined with laparoscopy for patients with enterocele. Three major complications (2 bleeding and 1 late abscess in the staple line).	Larger case series are included.
Reboa G, Gipponi M, Logorio M et al. (2009) The impact of stapled transanal rectal resection on anorectal function in patients with obstructed defecation syndrome. Diseases of the Colon & Rectum 52: 1598–1604.	Case series n = 33 Median follow-up = 18 months	Significant improvement in constipation scoring system, quality of life, and visual analog scale ($p < 0.0001$) was observed. Postoperative defecography confirmed the correction of internal rectal prolapse ($p < 0.01$) and rectocele ($p < 0.0001$) with an increase in rectal sensitivity ($p < 0.0001$).	Small case series.
Romano G, Bianco F, Caggiano L (2009) Modified perineal stapled rectal resection with Contour Transtar for full-thickness rectal prolapse. Colorectal Disease 11: 878–81.	Case series n = 3 Follow-up = 2–4 months	All patients reported an improvement of constipation and continence.	Small case series
Sciaudone G, Di Stazio C, Guadagni I et al. (2008). Rectal diverticulum: a new complication of STARR procedure for obstructed defecation. Techniques in Coloproctology 12: 61–3.	Case report n = 1	Rectal wall diverticulum diagnosed 6 months after STARR (patient presented with severe constipation requiring enemas and a worse condition that preoperatively). The patient underwent transanal diverticulectomy and direct rectal wall repair.	Case report of a complication already described in table 2.

Appendix B: Related NICE guidance for stapled transanal rectal resection for obstructed defaecation syndrome

Guidance	Recommendations
Interventional procedures	**Stapled transanal rectal resection for obstructed defaecation syndrome. NICE interventional procedures guidance 169 (2006). (current guidance under review)** 1.1 Current evidence on the safety and efficacy of stapled transanal rectal resection (STARR) for obstructed defaecation syndrome (ODS) 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 STARR for ODS 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 the public* is recommended (available from www.nice.org.uk/IPG169publicinfo). • Audit and review clinical outcomes of all patients having STARR for ODS. 1.3 The studies are based on heterogenous groups of patients. Patient selection is important in clinical practice and should be clearly defined in future studies. 1.4 Publication of safety and efficacy outcomes will be useful, and the Institute may review the procedure upon publication of further evidence. A registry is in development by the Association of Coloproctology of Great Britain and Ireland, and clinicians are encouraged to enter patients into this registry (www.acpgbi.org.uk).

	Circular stapled haemorrhoidectomy. NICE interventional procedures guidance 34 (2003). 1.1 Current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. 1.2 Clinicians wishing to learn circular stapled haemorrhoidectomy should be trained, mentored and monitored, as described in the Association of Coloproctology's consensus document on the procedure (see the Association's website: www.acpgbi.org.uk).

Appendix C: Literature search for stapled transanal rectal resection for obstructed defaecation syndrome

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	13/07/09	Issue 3, 2009
Database of Abstracts of Reviews of Effects – DARE (CRD website)	13/07/09	N/A
HTA database (CRD website)	13/07/09	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	13/07/09	Issue 3, 2009
MEDLINE (Ovid)	13/07/09	1950 to July Week 1 2009
MEDLINE In-Process (Ovid)	13/07/09	July 10, 2009
EMBASE (Ovid)	13/07/09	1980 to 2009 Week 27
CINAHL (NHS Evidence)	13/07/09	1981 to Present
BLIC (Dialog DataStar)	09/07/09	1995 to date

Trial sources searched on 09/07/09

- 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 09/07/09

- 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

MEDLINE search strategy

The MEDLINE search strategy was adapted for use in the other sources.

1 Surgical Stapling/
2 Sutures/
3 ((Stapl* or Sutur*) adj3 (transanal* or trans-anal* or trans* anal*)).tw.
4 STARR.tw.
5 (Doub* adj3 (stapl* or sutur*) adj3 procedure*).tw.
6 DSP.tw.
7 ((Transanal* or trans-anal* or trans* anal*) adj3 anteroposter* adj3 (proctotom* or rectotom*)).tw.

8	(Stapl* adj3 Mucosectom*).tw.
9	or/1-8
10	(Obstruct* adj3 (defaecat* or defecat*) adj3 (syndrome* or disorder*)).tw.
11	ODS.tw.
12	Rectocele/
13	(Rectocele* or Proctocele*).tw.
14	(R-IMP or P-IMP).tw.
15	exp Intestinal Obstruction/
16	((Intestin* or Pelvic*) adj3 (Obstruct* or Occlus*)).tw.
17	Rectal Prolapse/
18	((Rectal* or mucosal* or anus* or anal* or recti* or anorectal*) adj3 (prolapse* or intussuscep* or hernia*)).tw.
19	(Colon* adj3 Inertia*).tw.
20	Fecal Incontinence/
21	((Fec* or Faec* or Anal* or Anus* or Bowel*) adj3 Incontinen*).tw.
22	or/10-21
23	9 and 22
24	((Transtar or contour) adj3 staple*).tw.
25	23 or 24
26	2005*.ed.
27	2006*.ed.
28	2007*.ed.
29	2008*.ed.
30	2009*.ed.
31	or/26-30
32	25 and 31
33	Animals/ not Humans/
34	32 not 33