# Horizon Scanning in Surgery: Application to Surgical Education and Practice

# Stapled transanal rectal resection for obstructed defecation syndrome

## September 2013

**American College of Surgeons**
**Division of Education**

Prepared by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical for the American College of Surgeons

# Disclaimer

This report is not a comprehensive systematic review. Rather, it is an assessment of an emerging surgical procedure or technology in which the methodology has been limited in one or more areas to shorten the timeline for its completion.

Therefore, this report is a limited evidence-based assessment that is based on a search of studies published in the peer-reviewed literature. This report is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements in health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

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# Objective

This horizon scanning assessment provides short, rapidly completed 'state of play' documents. These provide current information on technologies to alert clinicians, planners and policy makers of the advent and potential impact of a new or emerging procedure or device. This information can then assist clinicians, planners and policy makers to control and monitor the introduction of new health technologies as well as assist in the prioritization and allocation of resources to promote efficient utilization of available resources.

This report is a preliminary summary of the safety, effectiveness and cost-effectiveness of stapled transanal rectal resection for obstructed defecation.

# Introduction

## Indication

Obstructed defecation syndrome (ODS), one of the causes of constipation, is characterized by the inability to evacuate contents from the rectum. Patients with ODS require mechanical aids or manual assistance (insertion of finger into the vagina or anal canal) to achieve fecal evacuation. Other symptoms include excessive straining, incomplete evacuation, and excessive time needed to evacuate (Alame and Bahna 2012). There are many functional and anatomical causes of ODS. Functional abnormalities that contribute to ODS include pelvic floor dyssynergia, decreased rectal compliance and decreased rectal sensation (Alame and Bahna 2012). Anatomical abnormalities that have been linked to ODS include rectoceles, rectoanal intussusception, paradoxical puborectalis contraction, pelvic organ prolapse, descending perineum syndrome, solitary rectal ulcer syndrome, sigmoidoceles and enteroceles (Khaikin and Wexner 2006). However, anatomical abnormalities may also be found in asymptomatic patients.

Once secondary causes for constipation, such as malignancy and slow-transit constipation, have been excluded, anorectal physiologic studies, including electromyography, anorectal manometry, measurement of the rectal anal inhibitory reflex, and the balloon expulsion test, are used to evaluate patients with ODS. Anatomic and functional causes of ODS are determined using radiologic studies including triple contrast defecography under fluoroscopy and dynamic magnetic resonance imaging (MRI) defecography (Alame and Bahna 2012).

## Burden of disease

Constipation is one of the most common gastrointestinal complaints in the United States. More than four million Americans have frequent constipation, accounting for 2.5 million physician visits a year (National Institute of Diabetes and Digestive and Kidney Diseases 2007). Constipation has also been reported to have resulted in 92,000 hospitalizations and several hundred million dollars in laxative sales per year (Lembo and Camilleri 2003). One study summarizing the frequency of physician visits for constipation in the US between 1958 and 1986 found there was an age-related increase in the rate of physician visits, with the steepest rise occurring in the age groups 60 to 64 and over 65. The study also reported that 85 percent of these patients received a prescription for medications, most frequently laxatives (Sonnenberg and Koch 1989). Approximately half of constipated patients suffer from ODS (Khaikin and Wexner 2006). ODS usually affects middle-aged females, particularly multiparous women. Within this group, significant independent risk factors include irritable bowel syndrome, vaginal or laparoscopic hysterectomy, unemployment, using three or more medications, symptomatic pelvic organ prolapse, urinary incontinence surgery and other pelvic surgery (Varma et al 2008). Quality of life in patients with ODS is negatively affected by the need to spend long periods of time on the toilet, feelings of incomplete evacuation and the need for the use of enemas or suppositories to defecate.

## Technology

Stapled transanal rectal resection (STARR) is a surgical procedure that aims to restore normal rectal anatomy and thereby alleviate the symptoms of ODS. Eligible patients are those with confirmed anatomical abnormalities, including mucosal prolapse, intussusception, or rectocele, which create an anatomical impediment to the normal expulsion of stool. The STARR procedure is an extension of stapled hemorrhoidopexy, but instead of resecting the hemorrhoid prolapse, it achieves a full-thickness resection of the lower rectum that incorporates any rectocele, intussusception, or prolapse (Jayne and Stuto 2009). STARR is typically performed by colorectal surgeons (Murtagh and Forel 2010).

Two different STARR procedures have been described in the literature (Endo-Surgery 2013; Wadhawan et al 2010). The original STARR procedure involves the use of two circular hemorrhoidal staplers (Proximate HCS Hemorrhoidal Circular Stapler PPH01, Ethicon Endo-surgery, Inc., Somerville, New Jersey, and Cincinnati, Ohio, USA) with a disposable circular anal dilator and a purse-string suture anoscope. The newer STARR procedure, referred to as TRANSTAR, utilizes a circular stapler specifically designed for STARR procedures (TRANSTAR™, Ethicon Endo-Surgery, Inc.), a circular anal dilator with an obturator, and a purse-string suture anoscope. The newer TRANSTAR technique is purportedly more technically challenging than the conventional STARR procedure and has a higher complication rate. However, its advantage is that the resection area is not limited by the size of the stapler, meaning that the entire rectal intussusception can be resected as a single specimen (Isbert et al 2010; Wadhawan et al 2010). In addition, the STARR procedure requires retraction of the opposite

rectal wall with a retractor and resection is performed 'blind' after insertion of the stapler (Lenisa et al 2009).

### Surgical procedure

Prior to STARR, patients undergo an enema and receive prophylactic antibiotics. Anesthesia may be either general or spinal. A circular anal dilator is introduced into the anal canal and secured with skin sutures. If the original two-stapler STARR procedure is used, the prolapsing rectum is retracted into the stapler housing using one of two methods. One method involves placing two or three traction sutures in a semi-circumferential manner at intervals above the anorectal junction. The other method involves placing three traction sutures at the apex of the prolapse in the 10, 12 and 2 o'clock positions. The posterior rectal wall is protected with a spatula. The stapler is introduced into the rectum and positioned above the proximal suture. Pressure is applied so that the redundant rectal wall is captured in the anvil of the stapler. The stapler is then fired to perform the resection (NICE 2009). The same procedure is repeated for the posterior rectal resection. Again, two methods can be used to retract the prolapsing rectum: two or three semi-circumferential sutures are placed anteriorly above the anorectal junction or three sutures are placed at the four, six and eight o'clock positions (NICE 2009).

With the newer STARR procedure that utilizes the specifically designed TRANSTAR stapler, the selected prolapsing tissue is secured using a number of short running circumferential sutures. The entire length of the prolapsing rectal wall is then secured using a single suture, knotted tightly. This suture is held in traction and the stapler device is positioned and fired to open the prolapsed wall laterally. The circumferential resection is completed by several firings of the stapler (NICE 2009).

## Stage of development

STARR was initially used in Italy. It then spread across Europe where most of the published literature emanates from. Following guidance on the STARR procedure issued by the National Institute of Clinical Excellence (NICE) in 2006, national registries were set up in Italy, Germany, and the United Kingdom by the national coloproctology societies to collect data on all patients undergoing STARR (Jayne and Stuto 2009). STARR is not widely performed in the United States (Levitt et al 2011). The complexity of ODS, in terms of its diagnosis and definition and the unclear effectiveness of the STARR procedure, may have limited its diffusion. The lack of a gold standard technique for correcting ODS may also have hampered the initial evaluation of STARR in randomized controlled trials because of the absence of an obvious comparator (Jayne and Stuto 2009).

### Regulatory approval

Both the PPH01 circular stapler and TRANSTAR stapler have United States Food and Drug Administration (FDA) 510(k) listings (K030925 and K053631 respectively) for use in STARR treatment of ODS (Food and Drug Administration (FDA) 2013a; Food and Drug Administration (FDA) 2013b). On 3 August 2012, the FDA initiated a Class I recall of both of these devices.

- PPH01 Ethicon PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories 33 mm
- STR10 Ethicon TRANSTAR® Circular Stapler Procedure Set

The recall applied to lots manufactured by Ethicon Endo-Surgery, Inc. between 16 April 2011 and 24 July 2012. The recall was due to difficulties in firing the device, which resulted in incomplete staple formation and firing stroke.

### Current clinical trials

No active clinical trials (either recruiting or ongoing) were identified on the use of STARR for ODS. One study on the surgical treatment of ODS (PRO-REST) was identified, but it is not yet recruiting. The PRO-REST randomized controlled trial will compare STARR with laparoscopic ventral rectopexy (Table 1).

Table 1 STARR trials identified on ClinicalTrials.gov

| Study | Location | Study population, design | Status and primary outcome | Estimated end date |
|---|---|---|---|---|
| Surgical treatment of obstructed defecation syndrome (PRO-REST) | Not provided | RCT comparing STARR to laparoscopic ventral rectopexy in patients with ODS (ODS score > 11)<br>Estimated enrollment: 40 | Study not yet open for recruitment.<br>Start date: August 2013.<br>Primary outcome: ODS score before and 12 months after surgery | August 2015 |

RCT: randomized controlled trial, STARR: stapled transanal rectal resection

Source: ClinicalTrials.gov (accessed 30 July 2013)

## Current treatment and alternatives

Conservative therapy (dietary modification, biofeedback) is considered the first line of treatment in patients with suspected ODS once proximal cancer, slow-transit constipation, irritable bowel syndrome, and anismus have been ruled out (Farouk et al 2009). Indications for surgery include failure of conservative treatment; presence of symptoms for longer than 12 months; finger-assisted defecation; large anterior rectocele (> 4 cm) entrapping feces at defecation; incomplete emptying of or failure to empty the rectum at defecography; excessive perineal descent; and sigmoidocele or enterocele, usually after hysterectomy (Xynos 2012). There are numerous surgical procedures, using different approaches (abdominal, vaginal, transanal or perineal), that are available for the treatment of anatomical deformities associated with ODS (Table 2) but none have been identified as the gold standard (Xynos 2012).

Table 2 Procedures for the surgical treatment of anatomical deformities associated with ODS (Xynos 2012)

| Treatment | Anatomical deformity |
|---|---|
| Resection of prolapsing rectal mucosa | Anterior mucosa prolapse |
| Posterior colporrhaphy | Anterior rectocele |
| Resection plication of anterior rectal mucosa | Anterior rectocele |
| Posterior rectopexy (with or without prosthesis) | Intussusception (internal rectal prolapse) |
| Resection rectopexy | Rectocele<br>Intussusception (internal rectal prolapse)<br>Sigmoidocele<br>Enterocele |
| Ventral prosthesis colporectopexy | Rectocele<br>Intussusception (internal rectal prolapse)<br>Sigmoidocele<br>Enterocele |

Details of success rates and complications for procedures on rectoceles and prolapses (intussusception, mucosal, complete) are outlined overleaf.

**Rectoceles**

Rectoceles can be repaired through the vagina (transvaginal approach), through the anus (transrectal approach) and through the area between the vagina and anus (transperineal approach). With respect to transvaginal repair, there are two techniques that are used. The traditional technique is known as a nonanatomic longitudinal repair. The more recent 'anatomic' technique is referred to as 'defect specific' repair (Ellis 2005). The traditional technique is successful in preventing vaginal bulging in 80 percent of patients and corrects the need for digital assistance in 67 percent of patients. However, less favorable clinical results have been reported with 33 percent of patients reporting failure to relieve evacuatory difficulty. In addition, postoperative dyspareunia is present in 25 percent of patients and 10 percent of patients develop a recurrent rectocele requiring reoperation (Ellis 2005). Results from studies on the newer defect-specific rectocele repair technique are promising, with over 80 percent of patients reporting improvement in symptoms of constipation; however, postoperative dyspareunia has been found to range from 18 to 37 percent in some studies and 36 percent report a problem with fecal incontinence (Ellis 2005).

As with transvaginal repair of rectoceles, there are different approaches that can be used in transrectal repair including anatomic defect-specific rectocele repair, which is the most widely

used technique, and a nonanatomic repair technique. Results with either of the techniques have been variable, with improvement in constipation ranging from 48 to 71 percent (Ellis 2005).

There are only limited data on the transperineal repair approach.

**Prolapses**

Prolapse repairs can be done through abdominal or perineal approaches. Abdominal repairs can be performed with an open or laparoscopic technique. The operations can be further categorized as resection alone, rectopexy with resection, and rectopexy alone. Perineal repairs include rectosigmoidectomy and Delorme repairs (Kim 2013).

*Abdominal approaches*

Rectal fixation, using foreign material, of the prolapsed rectum to the sacrum has reported recurrence rates ranging from 2 to 10 percent. Continence generally improves postoperatively with preoperative rates of 60 to 80 percent decreasing to 20 percent. Complications of this technique include pelvic sepsis (1% with mesh, 2% with Ivalon sponge), stricture (2%) and fecal impaction (7%). The recurrence rates for suture rectopexy with sigmoid resection average 3 to 4 percent ranging from 0 to 10 percent. Continence improves in 35 to 60 percent of patients and constipation improves in 60 to 80 percent. In comparison to suture rectopexy with resection, suture rectopexy alone has almost no risk of sepsis, as well as a similar recurrence and restoration of continence rate, but constipation is not improved (Kim 2013). Abdominal approaches, with either a suture rectopexy or an Ivalon wrap procedure, are the most commonly reported techniques for repair of rectal intussusception associated with incontinence or a solitary rectal ulcer (Ellis 2005). Disappointing results have been obtained with respect to improvement of ODS symptoms following surgical repair of rectal intussusception, with complete resolution of symptoms only occurring in approximately 20 percent of patients and worsening of the symptoms occurring in 33 to 48 percent (Ellis 2005).

*Perineal approaches*

Perineal repair include perineal rectosigmoidectomy and the Delorme procedure. The recurrence rates for perineal rectosigmoidectomy are higher than for abdominal repair, ranging from 0 to 50 percent. Complications include pelvic bleeding and anastomotic dehiscence. Recurrence rates for the Delorme procedure average 12 percent. Fecal incontinence is alleviated in 50 to 75 percent of patients and constipation has been reported to improve in 50 percent. Postoperative bleeding occurs in 1.5 percent (Kim 2013).

# Literature review

## Search criteria

**Keyword/MeSH terms utilized:**

Text words: fecal impaction, faecal impaction, obstructed defecation, obstructed defaecation, ODS, constipation, STARR, TRANSTAR, transanal rectal resection, trans-STARR, PPH01, PPH03

MeSH words: fecal impaction, constipation, colorectal surgery

**Databases searched:**

PubMed, the Cochrane Database of Systematic Reviews, and Trip

## Inclusion criteria

Inclusion criteria for identification of relevant studies

| Characteristic | Criteria |
|---|---|
| Publication type | Randomized controlled trials |
| Patient | Patients with ODS |
| Intervention | Stapled transanal rectal resection (STARR), including TRANSTAR |
| Comparator | Any surgical or conservative intervention |
| Outcome | Treatment success, patient satisfaction, quality of life, change in symptoms, adverse events, complications |
| Language | English only |

## Included studies

A total of 76 studies were retrieved using the search strategy; upon review of the search results, four Level II randomized controlled trials (RCTs) were selected for inclusion in this report (Appendix A and Appendix B). Characteristics of the included studies are summarized in Appendix A and Table 3.

Table 3 Characteristics of the included studies

| Study/Location | Study type | Intervention | No. of patients | Duration of follow-up |
|---|---|---|---|---|
| Renzi et al (2011)<br>*Italy* | RCT | TRANSTAR<br>STARR | 32<br>31 | 24 months |
| Boccasanta et al (2011)<br>*Italy* | RCT | TRANSTAR<br>STARR | 50<br>50 | Mean 36.2 months (SD 4.2)<br>Mean 36.3 months (SD 4.4) |
| Lehur et al (2008)<br>*France and Italy* | RCT | STARR<br>Biofeedback | 59<br>60 | 12 months |
| Boccasanta et al (2004)<br>*Italy* | RCT | STARR<br>STAPL | 25<br>25 | Mean 22.3 months (SD 4.8)<br>Mean 23.4 months (SD 5.1) |

RCT: randomized controlled study; STARR: stapled transanal resection; STAPL: stapled anopexy

**Renzi et al (2011)**

Renzi et al (2011) conducted a single center RCT comparing 31 patients treated with STARR to 32 patients treated with TRANSTAR. The study was conducted between November 2005 and September 2007and had a 24-month follow-up period. Patients in the STARR group were treated using two PPH01 staplers while patients in the TRANSTAR group were treated with the CCS-30 Contour TRANSTAR stapler. Inclusion criteria were an ODS score of at least 12, rectal intussusception (≥ 10 mm) or a rectocele extending 2 cm or more from the rectal wall, and failure to respond to six months of conservative therapy. Patients were excluded if they had previous anal and rectal surgery, intestinal inertia, anismus, associated II or III degree genital prolapse, a symptomatic cystocele, or any form of anxiety or depression. Patients in the two groups did not differ with regards to preoperative ODS scores ($p$ = 0.64) and the gender distribution across both groups was similar. The TRANSTAR group and the STARR group included a similar distribution of women who had undergone a prior hysterectomy, were nulliparous and who had given birth. The mean age of included patients was 53 years (standard deviation [SD] 5.2; range 41–75) in the TRANSTAR group and 55 years (SD 4.3; range 38–69) in the STARR group. The procedure was performed with subarachnoid anesthesia. The primary endpoint of the study was the rate of success at 24 months, as defined by ODS scores: excellent (0 to 3), good (4 to 6), or adequate (7 to 9). The sample size calculation for this study was based on it having the ability to detect a difference of 25 percent points in the success rate with 80 percent power at a significance level of 5 percent. The secondary endpoint of the study was the success rate at 12 months, mean change in ODS score at 12 and 24 months, mean change in Agachan-Wexner constipation score (Agachan et al 1996) at 12 and 24 months, duration of hospital stay, and complication rates (early and late postoperative period).

**Boccasanta et al (2011)**

In this single center RCT, 100 patients were randomly assigned to either the STARR or the TRANSTAR group (50 patients in each group). The STARR group was treated with two PPH01 staplers and the TRANSTAR group was treated with one CCS-30 Contour TRANSTAR stapler. Inclusion criteria were patients with an ODS score of more than 15, internal rectal prolapse or rectal intussusception, rectocele (> 3 cm), a continence score of less than 3, a resting pressure of greater than 40 mmHg, and a squeeze pressure of greater than 100 mmHg. Previous surgery for rectal prolapse or rectocele, internal rectal prolapse, concomitant enterocele or genital prolapse, psychiatric disorders, and absolute contraindications to surgery were exclusion criteria. Both patient groups had similar mean ODS and continence scores at baseline. Patients in the STARR group had a mean age of 54.8 years (range 27–77) and patients in the TRANSTAR group had a mean age of 57.1 years (range 31–74). The procedure was performed under caudal anesthesia. The study was conducted between January and December 2006 and the mean follow-up was 36.3 months in the STARR group and 36.2 months in the TRANSTAR group. The primary outcome of the study was the rate of failure at three years of follow-up, defined as residual mucosal rectal prolapse with an ODS score of greater than 5 at clinical examination. The sample size calculation for this study was based on the ability to detect a 10 percent difference in recurrence rate between treatments with 80 percent power at a significance level of 5 percent. The secondary endpoints included operative time, blood loss, complications, hospital stay, postoperative pain assessment, time to return to normal activity, post-surgery ODS score, quality of life, costs, and patient satisfaction score.

**Lehur et al (2008)**

This multicenter RCT compared patients treated with STARR (n=59) to patients treated with electromyographic biofeedback (n=60). The STARR group was treated with a PPH01 stapler. The patients were at least 18 years of age, eligible for surgery, and had ODS associated with rectal intussusception or rectocele (on dynamic defecography). Exclusion criteria were clinically evident external sphincter injury, fecal incontinence, enterocele requiring surgery, and anterior defect, colpocele or cystocele requiring a combined surgical approach. The study was conducted between February 2004 and November 2005, with patients followed up at the end of treatment and at three, six and 12 months. Patients in the STARR group had a mean age of 56 years (SD 9.2; range 34–80) and all patients had general anesthesia. Patients in the biofeedback group had a mean age of 56 years (SD 14.3; range 24–78). The primary effectiveness variable was ODS score. Success was defined as a change in ODS score from baseline to 12 months resulting in a 50 percent or more reduction in symptoms. The sample size calculation for this study was based on the ability to detect a 20 percent difference in success rates with 80 percent power at a significance level of 5 percent. Secondary endpoints included safety and adverse events, quality of life measures, continence grading scores and patient-reported success.

**Boccasanta et al (2004)**

This single center RCT conducted between October 1999 and 2001, consecutively enrolled women who 1) persistently had at least three or more of the following symptoms after conservative therapy: feelings of incomplete evacuation, painful effort, unsuccessful attempts with long time spent in the bathroom, defecation with use of perineal support and/or posture, digital assistance, evacuation only by the use of enemas and 2) who had the following finding on defecography: rectoanal intussusception of 10 mm or more extending into the anal canal; rectocele of 3 cm or more on straining; and, entrapping barium contrast after defecation. Patients were randomized by permuted blocks to either the STARR (n=25) or the STAPL (n=25) procedure. The STARR procedure, which was performed with two circular PPH01 staplers, was compared with the STAPL procedure (stapled anopexy with a PPH01 stapler followed by perineal levatorplasty). Both procedures were performed by the same surgical team. The mean age of participants was similar between the two groups (53.2 years [SD 15.3] STAPL versus 54.6 years [SD 14.2] STARR) and patients underwent follow-up at seven days and 1, 3, 6, 12, and 20 months. In both groups, anesthesia was general in 15 patients and spinal in 10 patients. The primary endpoints were postoperative pain (visual analog scale), anorectal manometry changes and rate of symptom reduction. Secondary endpoints included operative time, intraoperative and postoperative complications, hospital stay, and time to return to work. The sample size calculation for this study was based on the ability to detect a 20 percent clinically important difference in postoperative pain and rectal sensitivity threshold volume between treatments with 80 percent power at a significance level of 5 percent.

# Critical appraisal

There were a total of four studies included in this report and all were prospective randomized controlled trials, three of which were conducted in Italy. Only one study reported adequate blinding of both patients and data assessors. Renzi et al (2011) blinded patients and researchers involved in data collection and analysis. Both articles by Boccasanti et al (2004 and 2011) report that intraoperative details were recorded by a nurse blinded to the procedure although blinding of patients to treatment was not reported. Allocation concealment in the study by Lehur et al (2008) was not possible due to the nature of the interventions. The maximum follow-up time point

reported was 36 months (Boccasanta et al 2011) and all studies had a follow-up assessment at 12 months. In the study by Lehur et al (2008), only 42 percent of patients were followed up at the 12 month time point (52% of patients in the STARR group and 32% of controls). No patients were lost to follow-up in the studies by Boccasanta et al, (2004 and 2011) whilst two patients were lost to follow-up (one in each treatment) in the study by Renzi et al. (2011).

In general, sample sizes were small; this may, in part, be due to the difficulty in recruiting patients who meet the inclusion criteria. The study with the largest enrolment was Lehur et al (2008) which enrolled 119 patients (59 in the STARR arm and 60 in the biofeedback arm). However, Lehur et al (2008) estimated that a sample size of 206 patients was required for the study to detect a 20 percent clinically important difference in success rates with 80 percent power at a significance level of 5 percent. The trial was terminated at 119 patients due to slow recruitment and half of the patients randomized to the biofeedback arm withdrew from the study before six months. Hence, the results for this study should be interpreted with caution. Furthermore, this study compared STARR to biofeedback and, hence, is of limited utility as biofeedback is not an appropriate comparator to the STARR procedure.

The internal validity of the studies was unclear as outcomes reported were varied and the methods used to evaluate success have not been validated in other well-controlled trials.

A conflict of interest was noted in the study by Lehur et al (2008) which was supported by grants from Ethicon Endo-Surgery. None of the other three studies reported receiving financial support from any company with interests in the procedure or product.

# Safety and efficacy

## Safety

Four studies were included in the analysis of safety. No deaths were reported in any of the included studies. The STARR procedure was utilized in all studies and in one study, two severe adverse events were reported following the procedure including 12-hour postoperative bleeding and one case of pain in the right upper abdominal quadrant requiring hospitalization (Lehur et al 2008). Complications reported following the STARR procedure are available in Table 4. The TRANSTAR device was compared with the STARR procedure in two studies and the incidence of adverse events in both groups was similar. In the study by Boccasanta et al (2011), the procedure caused a vaginal lesion in one patient due to entrapment of the vaginal wall in the stapler device. The lesion was identified during the procedure and repaired intraoperatively. The STAPL procedure was associated with complications in 20 of the 25 patients; frequent complications included delayed perineal wound healing in 10 patients and dyspareunia in five (Table 4).

Table 4 Adverse events and complications following STARR

| | STARR | TRANSTAR | biofeedback | STAPL | P value |
|---|---|---|---|---|---|
| **Renzi et al (2011)** n (%) | n=30 | n=31 | NA | NA | NA |
| *Early complications (within 1 month)* | | | | | |
| Mild perineal hematoma | 6 (20) | 7 (23) | NA | V | >0.99 |
| Acute urinary retention | 3 (10) | 4 (13) | NA | NA | >0.99 |
| Bleeding | 2 (7) | 1 (3) | NA | NA | 0.61 |
| Perianal sepsis | 0 (0) | 0 (0) | NA | NA | - |
| Mortality | 0 (0) | 0 (0) | NA | NA | - |
| *Late complications* | | | | | |
| Urge to defecate[a] | 3 (10) | 3 (10) | NA | NA | >0.99 |
| Incontinence to flatus[a] | 3 (10) | 3 (10) | NA | NA | >0.99 |
| Dyspareunia[b] | 1 (3) | 0 (0) | NA | NA | 0.49 |
| **Boccasanta et al (2011)** Mean (SD) | n=50 | n=50 | NA | NA | NA |
| *Operative and early outcomes* | | | | | |
| Blood loss, mL | 72 (15.6) | 67 (12.2) | NA | NA | 0.06 |
| Pain[c] | 4 (0.6) | 3 (0.6) | NA | NA | 0.07 |
| Dose of paracetamol/codeine, mg/d[d] | 1000 (335.0) | 890 (253.3) | NA | NA | 0.07 |
| Bleeds, patients | 2[e] | 0 | NA | NA | NR |
| Lesion of the vagina wall, patients | 0 | 1 | NA | NA | NR |
| **Lehur et al (2008)[f]** n (%) | n=54 | NA | n=39 | NA | NA |
| Anal pain, n (%) | 1 (2%) | NA | 1 (3%) | NA | NR |
| Local infection, n | 1 | NA | 0 | NA | NR |
| Incontinence, n | 1 | NA | 0 | NA | NR |
| Bleeding, n | 1 | NA | 0 | NA | NR |
| Urinary infection, n | 1 | NA | 0 | NA | NR |
| Depression, n | 1 | NA | 0 | NA | NR |
| Severe adverse event, n[g] | 2 | NA | 0 | NA | NR |
| **Boccasanta et al (2004)** n(%) | n=25 | NA | NA | n=25 | NA |
| *Early complications (within 7 days of operation)* | | | | | |
| Urinary retention | 2 (8) | NA | NA | 2 (8) | NR |
| Bleeding | 1 (4) | NA | NA | 0 | NR |
| Delayed healing of the perineal wound | - | NA | NA | 10 (40) | NR |
| Mortality | 0 | NA | NA | 0 | NR |
| *Late outcomes[h]* | | | | | |
| Urge to defecate | 4 (16) | NA | NA | 1 (4) | NR |
| Incontinence to flatus | 2 (8) | NA | NA | 1 (4) | NR |
| Stenosis | 1 (4) | NA | NA | 1 (4) | NR |
| Rectovaginal fistula | 0 | NA | NA | 0 | NR |
| Dyspareunia | 0 | NA | NA | 5 (20) | NR |

[a]spontaneously resolved within 6 months; [b]spontaneously resolved within 12 months; [c]mean (SD) value of visual analogue scale during hospital stay; [d]mean daily dose during hospital stay; [e]one treated with reoperation and one with transfusion; [f]timeframe over which adverse events were monitored was not explicitly stated; [g]included 12-hour postoperative bleeding which was managed under general anesthesia with additional sutures and one instance of pain in the right upper abdominal quadrant several weeks after surgery which required hospital care; [h]timeframe not explicitly stated.
NR: not reported; STARR: stapled transanal rectal resection; STAPL: stapled transanal prolapsectomy associated with perineal levatorplasty.

# Efficacy

### Mean operative time and mean hospital stay

Three of the studies, one comparing STARR to STAPL (Boccasanta et al. 2004) and the other two comparing STARR to TRANSTAR (Boccasanta et al 2004; Renzi et al 2011), reported mean operative times (Table 5) and mean hospital stay (Table 6). Mean length of hospital stay did not differ significantly between treatments for any of the three studies. One of the STARR versus TRANSTAR studies (Boccasanta et al 2011) reported a significantly longer operating time for the TRANSTAR procedure (p = 0.008) (Table 5). No differences were reported in operating times between treatments in the other two studies.

Table 5 Mean operative time reported by Boccasanta et al (2004, 2011) and Renzi et al (2011).

| **Boccasanta et al (2011)** | **STARR (n=50)** | **TRANSTAR (n=50)** | **P value** |
|---|---|---|---|
| | 42 minutes (SD 6.9) | 52 minutes (SD 8.7) | 0.008 |
| **Renzi et al (2011)** | **STARR (n=31)** | **TRANSTAR (n=32)** | **P value** |
| | 28 minutes (SD 11.5) | 33 minutes (SD 15.7) | ns |
| **Boccasanta et al (2004)** | **STARR (n=25)** | **STAPL (n=25)** | **P value** |
| | 41 minutes (SD 6.0) | 43 minutes (SD 8.7) | ns |

ns: not significant (p>0.05); SD: standard deviation; STAPL: stapled transanal prolapsectomy; STARR: stapled transanal rectal resection; TRANSTAR: stapled transanal rectal resection with curved, multifire stapler.

Table 6 Mean length of hospital stay reported by Boccasanta et al (2004, 2011) and Renzi et al (2011).

| **Boccasanta et al (2011)** | **STARR (n=50)** | **TRANSTAR (n=50)** | **P value** |
|---|---|---|---|
| | 3 days (SD 0.6) | 4 days (SD 1.0) | ns |
| **Renzi et al (2011)** | **STARR (n=31)** | **TRANSTAR (n=32)** | **P value** |
| | 28 hours (SD 12.5) | 30 hours (SD 12.6) | ns |
| **Boccasanta et al (2004)** | **STARR (n=25)** | **STAPL (n=25)** | **P value** |
| | 2 days (SD 0.8) | 3 days (SD 0.8) | ns |

ns: not significant (p > 0.05); STAPL: stapled transanal rectal resection; STARR: stapled transanal rectal resection; TRANSTAR: stapled transanal rectal resection with curved, multifire stapler.

### Time to return to work/normal activity

Two studies reported on time to return to work or normal activity after the procedure, one comparing STARR to STAPL (Boccasanta et al 2004) and the other comparing STARR to TRANSTAR (Boccasanta et al 2011). Across the two studies, STARR patients returned to work or normal activity in around 10 to 16 days after treatment. Neither of the two studies found significant differences between the procedures in the time taken to return to work or normal activity (Table 7).

Table 7 Time to return to work/normal activity reported by Boccasanta et al (2004, 2011).

| **Boccasanta et al (2011)** | **STARR (n=50)** | **TRANSTAR (n=50)** | **P value** |
|---|---|---|---|
| | 16 days (SD 5.3) | 15.5 days (SD 3.9) | ns |
| **Boccasanta et al (2004)** | **STARR (n=25)** | **STAPL (n=25)** | **P value** |
| | 10 days (SD 4.5) | 11 days (SD 0.7) | ns |

ns: not significant; STAPL: stapled transanal rectal resection; STARR: stapled transanal rectal resection TRANSTAR: stapled transanal rectal resection with curved, multifire stapler.

### Patient-reported satisfaction/success

Three studies reported on patient satisfaction, one comparing STARR to STAPL (Boccasanta et al 2004), another comparing STARR to TRANSTAR (Boccasanta et al 2011), and the third comparing STARR to biofeedback (Lehur et al 2008). Good to excellent results were reported by 88 percent (22/25) and 76 percent (19/25) of patients in the STARR and STAPL groups at 20 months and by 66 percent (33/50) and 78 percent (39/50) of the STARR and TRANSTAR patients at three years. Patient satisfaction did not differ significantly between treatments in either study ($p > 0.05$). The study by Lehur et al. (2008) assessed patient satisfaction 12 months postoperatively. Significantly better scores were reported for STARR compared with biofeedback training, with median (interquartile range) scores of 8 (6 to 10; n=51) and 4 (3 to 6; n=34), respectively ($p < 0.0001$).

### Quality of life

Quality of life was assessed in two studies (Lehur et al 2008; Boccasanta et al 2011). Lehur et al (2008) used the Patient Assessment of Constipation-Quality of Life (PAC-QOL) score, comprised of 28 self-administered questions, to assess quality of life in STARR and biofeedback patients at 12 months. The subscales of the PAC-QOL assessed physical discomfort, worries and concerns, and dissatisfaction. Significant improvements in total PAC-QOL scores from baseline were observed for both the STARR and biofeedback treatments ($p < 0.0001$ and $p < 0.002$ respectively). No comparison was made between treatments. Boccasanta et al (2011) compared quality of life in STARR and TRANSTAR patients using the Short Form (36) Health Survey. A significant improvement in the scores was seen in both treatments compared with baseline ($p < 0.01$), but no difference was observed between treatments and the length of follow-up associated with these results is unclear.

### Treatment success

Treatment success was reported in three of the included studies (Boccasanta et al 2011; Lehur et al 2008; Renzi et al 2011) but was defined a different way in each. Lehur et al (2008) defined treatment success as a decrease in ODS score (Amin et al 2003) of at least 50 percent from baseline at 12 months. A substantial number of patients were not included in the 12-month analyses. Renzi et al (2011) defined a successful treatment as one that had an ODS score (Renzi et al 2006) classed as excellent, good or adequate (scores ranging from 0 to 9) at 24 months, whilst Boccasanta et al (2011) considered a successful treatment as one in which patients had no residual mucosal rectal prolapse and an ODS score (Altomare et al 2008) of 5 or lower at the three-year follow-up.

Treatment success for the STARR procedure ranged from 70 percent to 82 percent across the three studies (Table 8). One of the studies that compared STARR to TRANSTAR reported significantly greater treatment success with the TRANSTAR procedure ($p = 0.035$). Renzi et al

(2011) reported that the difference observed in treatment success at 24 months follow-up was not present at the 12 months follow-up ($p$ = 0.21). The study by Lehur et al (2008) comparing STARR to biofeedback reported significantly higher treatment success for the STARR procedure ($p$ < 0.001).

Table 8 Success rates reported for ODS treatments

| **Renzi et al (2011)[a] (24-month follow up)** n (%) | **STARR (n=30)** | **TRANSTAR (n=31)** | **P value** |
|---|---|---|---|
| | 21 (70) | 27 (87) | ns |
| **Boccasanta et al (2011)[b] (36-month follow-up)** n (%) | **STARR (n=50)** | **TRANSTAR (n=50)** | **P value** |
| | 44 (88) | 50 (100) | 0.035 |
| **Lehur et al (2008)[c] (12-month follow-up)** n (%) | **STARR (n=54)[d]** | **Biofeedback (n=39)** | **P value** |
| | 44 (82) | 13 (33) | < 0.0001 |

[a] Successful treatment defined as ODS scores ranging from 0 to 9; [b] Successful treatment defined as ODS score ≤ 5 and no residual rectal prolapse at 36 months; [c] Successful treatment defined as a decrease in ODS score of ≥ 50 percent from baseline at 12 months; [d] n = number of patients at visit 3, the end of the 3-month treatment/adaptation phase; ns: not significant; STARR: stapled transanal rectal resection; TRANSTAR: stapled transanal rectal resection with curved, multifire stapler

### Change in symptoms of ODS

Boccasanta et al (2004, 2011) and Lehur et al (2008) all reported on changes in symptoms following surgery. Boccasanta et al (2004) reported that all preoperative symptoms significantly improved 20 months postoperatively for both STARR and STAPL treatments ($p$ < 0.001) (Table 9). No statistically significant differences were found between the two treatments, except for dyspareunia which was only observed following the STAPL procedure ($p$ = 0.018). Boccasanta et al (2004) also reported on the resolution of continence and constipation using the Constipation and Continence Grading Systems. All signs and symptoms from the Constipation Scoring System (frequency, difficulty, completeness, pain, time, assistance, failure and history) were significantly lower after the STARR and STAPL treatments ($p$ < 0.001), with no statistically significant difference observed between the two treatments at 20-month follow-up. In comparison, the mean Continence Grading Scale score did not change statistically in either treatment. Similarly, Boccasanta et al. (2011) reported a significant reduction in ODS scores three years postoperatively for STARR and TRANSTAR treatments for all preoperative symptoms ($p$< 0.001), compared with baseline (Table 10), but inter-treatment comparison was not statistically significant. Patients experienced fewer anal and rectal symptoms three years after treatment with STARR and TRANSTAR treatments, with the exception of continence and fecal urgency (Table 11) (Boccasanta et al 2011). Continence did not change following surgery for patients treated with either STARR or TRANSTAR whereas fecal urgency, which was absent in both treatment groups before the operation, became more frequent in the STARR group ($p$ = 0.035). Lehur et al (2008) reported on change in incontinence symptoms (principally flatus and lifestyle alteration) following STARR and biofeedback. Significant improvements from baseline were observed for the STARR treatment at 12 months but not for the biofeedback treatment ($p$ = 0.0001 and $p$ = 0.0356 respectively). The difference in improvement between STARR and biofeedback was not significant ($p$ = 0.086). Reductions in other symptoms following STARR and biofeedback were

also reported by Lehur et al (2008), but no within- or between-treatment statistical comparisons were reported (Table 12).

Table 9 Preoperative and 20 months postoperative symptoms in STAPL and STARR treatments reported by Boccasanta et al (2004).

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

Values are number of patients (%).

[a] > 2 episodes per week/month; [b] >1 episode/week; STAPL: stapled transanal rectal resection; STARR: stapled transanal rectal resection

Note: all symptoms significantly improved postoperatively for both treatments and there were no between-treatment symptom differences ($p<0.001$), except dyspareunia which was only observed after STAPL ($p = 0.018$).

Table 10 Preoperative and postoperative symptoms in STARR and TRANSTAR treatments reported by Boccasanta et al (2011).

| **Symptoms** | **Preoperative** | | **Postoperative (3 years)** | |
|---|---|---|---|---|
| | STARR (n=50) | TRANSTAR (n=50) | STARR (n=50) | TRANSTAR (n=50) |
| Mean time spent at the toilet | 2.9 (0.57) | 2.9 (0.62) | 0.5 (0.58) | 0.4 (0.64) |
| Attempts to defecate per day | 2.5 (0.50) | 2.6 (0.53) | 0.4 (0.50) | 0.3 (0.48) |
| Anal/vaginal digitation | 2.8 (0.42) | 2.9 (0.57) | 0.4 (0.54) | 0.4 (0.49) |
| Use of laxatives | 2.6 (0.52) | 2.7 (0.48) | 0.6 (0.53) | 0.6 (0.50) |
| Use of enemas | 3.0 (0.55) | 2.9 (0.58) | 0.5 (0.50) | 0.4 (0.50) |
| Incomplete/fragmented defecation | 2.6 (0.49) | 2.7 (0.49) | 0.5 (0.5) | 0.4 (0.49) |
| Straining at defecation | 2.4 (0.49) | 2.3 (0.44) | 0.3 (0.46) | 0.3 (0.46) |
| Stool consistency | 1.8 (0.51) | 1.9 (0.52) | 0.3 (0.45) | 0.2 (0.43) |
| Total | 20.6 (1.84) | 20.9 (1.35) | 3.5 (1.72) | 3.1 (1.63) |

Values are mean ODS score (standard deviation)

STARR: stapled transanal rectal resection; TRANSTAR: stapled transanal rectal resection with curved, multifire stapler

Note: Significant reductions in all ODS scores were observed postoperatively for both treatments ($p < 0.001$), compared with baseline. No significant between-treatment differences were found.

Table 11 Preoperative and postoperative anal/rectal symptoms in STARR and TRANSTAR patients reported by Boccasanta et al (2011).

| **Symptoms** | **Preoperative** | | **Postoperative (3 years)** | |
|---|---|---|---|---|
| | STARR (n=50) | TRANSTAR (n=50) | STARR (n=50) | TRANSTAR (n=50) |
| Pain | 27 (54) | 26 (52) | 4 (8) | 3 (6) |
| Rectal bleeding | 21 (42) | 20 (40) | 3 (6) | 1 (2) |
| Tenesmus | 17 (34) | 18 (36) | 1 (2) | 0 |
| Mucorrhea | 9 (18) | 8 (16) | 0 | 0 |
| Fecal urgency | 0 | 0 | 17 (34) | 7 (14) |
| Continence score | 0.5 (0.17) | 0.5 (0.16) | 0.5 (0.18) | 0.5 (0.20) |

Values are numbers of patients (%) for symptoms and mean (standard deviation) for continence score.

STARR: stapled transanal rectal resection; TRANSTAR: stapled transanal rectal resection with curved, multifire stapler

Note: Significant reductions in all symptoms, excluding fecal urgency and continence, were found in both treatment groups. Continence did not change postoperatively for either treatment, whilst fecal urgency became more frequent in the STARR group (p = 0.04).

Table 12 Preoperative and postoperative symptoms reported by Lehur et al (2008).

| **Symptoms** | **Preoperative** | | **Postoperative (12 months)** | |
|---|---|---|---|---|
| | STARR (n=54) | Biofeedback (n=39) | STARR (n=46) | Biofeedback (n =25) |
| Descending perinea | 15 (28) | 14 (36) | 4 (9) | 6 (24) |
| Permanently descended perinea | 13 (24) | 4 (10) | 0 | 3 (12) |
| External mucosal prolapse | 7 (13) | 1 (3) | 0 | 0 |
| Urinary incontinence | 9 (17) | 7 (18) | 3 (7) | 0 |

Values are number of patients (%).

STARR: stapled transanal rectal resection

Note: No statistical intra- or inter-treatment comparisons were reported

### Postoperative defecography

Defecography was conducted by both Boccasanta et al (2004) and (2011). Boccasanta et al (2004) reported that the posterior rectal inclination angle was significantly smaller three months after both the STARR and STAPL procedures ($p < 0.0001$). No significant differences were reported between STARR and STAPL. Boccasanta et al (2011) found a significant reduction of all parameters (anterior and posterior intussusception thickness and descent and rectocele depth) for the STARR and TRANSTAR treatments six months postoperatively ($p < 0.001$). Significantly better results were achieved with TRANSTAR for intussusception in the posterior rectal wall ($p < 0.01$ for thickness and $p = 0.03$ for descent).

**Other outcomes**

*Anorectal manometry*

Boccasanta et al (2004) reported that both resting and squeeze pressures did not significantly change following STARR or STAPL; however, STARR was significantly more effective than STAPL in reducing the rectal sensitivity threshold volume ($p < 0.01$).

*Radiologic findings*

Radiologic findings conducted by Lehur et al. (2008) found that at baseline 14 percent (6/42) of STARR patients and 11 percent (4/37) of biofeedback patients had a paradoxic contraction (anismus). This occurred in 15 percent (6/39) of STARR patients and 5 percent (1/20) of biofeedback patients 12 months after treatment.

*Prolapse recurrence*

In Boccasanta et al (2011), 12 percent (6/50) of patients in the STARR treatment and none in the TRANSTAR had a prolapse recurrence at clinical examination. However, the timing of this clinical examination (days or months after the operation) was not reported.

## Cost impact

Two Italian studies were identified that discussed the relative costs of STARR for ODS.

Schiano di Visconte et al (2006) compared the cost of STARR to other conventional surgical techniques in the repair of rectoceles and rectal intussusception. A systematic calculation of the costs incurred and an estimate of the revenue associated with each hospitalization was conducted. The results presented below are from the English abstract of the study; the remainder of the study was published in Italian.

The total cost of the STARR technique for rectocele repair amounted to US$4,674.95[1] compared with US$7,055.07 for the abdominal approach and US$4,531.62 for the perineal approach. With respect to intussusception repair, the cost of the STARR procedure was US$4,674.95 compared with US$7,677.17 for the Delorme procedure.

In their RCT comparing the efficacy of STARR to TRANSTAR for ODS in patients with an internal rectal prolapse or rectal intussusception and a rectocele (> 3 cm), Boccasanta et al (2011) also compared the operation costs of the two procedures. TRANSTAR was significantly more expensive than STARR owing to significantly higher material, operating room, and hospital stay costs (Table 13).

Table 13 Operation costs for STARR and TRANSTAR (Boccasanta et al 2011).

| | **STARR n=50** | **TRANSTAR n=50** | **p[a]** |
|---|---|---|---|
| Materials | 1405 (53.4) | 2097 (52.2) | < 0.001 |
| Operating room and hospital stay | 1790 (137.8) | 1913 (228.6) | 0.02 |
| Total | 3202 (147.8) | 3984 (237.5) | < 0.001 |

Values are mean US dollars (standard deviation)[2]

[a]By 2-sample t test; STARR: stapled transanal rectal resection, TRANSTAR: stapled transanal rectal resection with curved, multifire stapler

[1] Values converted from Euro where 1 EURO = $1.31 US (Source: OZFOREX Currency Converter, 15th July 2013)

[2] Values converted from Euro where 1 EURO = $1.33 US (Source: OSFOREX Currency Converter, 29th July 2013)

## Clinical practice guidelines and consensus statements

Two consensus documents were identified (Bove et al 2012; Corman et al 2006).

A consensus statement produced by an international working party convened in Rome was identified (Corman et al 2006). The statement provided recommendations on the indications for STARR, its usage, and appropriate operators. No evidence for the recommendations was directly cited. The panel recommended that the patient evaluation include:

- Clinical assessment, including evaluation of sphincter function;
- Proctosigmoidoscopy;
- Colonoscopy or barium enema;
- Defecography (required) with optional vaginography (dynamic MRI is an alternative);
- Small bowel series (optional);
- Transit study (optional);
- Anal manometry, including rectal compliance (rectal capacity is optional);
- Electromyography (optional);
- Voiding cystourethrogram (optional);
- Pelvic assessment by a gynecologist or a urologist (optional).

The panel emphasized the necessity of documenting the presence of anatomical or functional abnormality and ruling out other colorectal causes of impaired bowel function.

The recommendations also stated that patients who are considered eligible for STARR should have failed conservative treatments and have a documented anatomical abnormality. The indications and exclusions listed for the STARR procedure are summarized below (Table 14).

Table 14 Summary of patient indications for STARR (Corman et al 2006)

| Symptomatic indications for STARR | Clinical indications for STARR | Exclusion criteria for STARR procedure |
|---|---|---|
| Evacuation by prolonged or repeated straining<br>Frequent calls to defecate prior to or following evacuation<br>Use of digital means to effect evacuation<br>Laxative or enema use required to defecate<br>Sense of incomplete evacuation<br>Excessive time spent in the toilet<br>Pelvic pressure, rectal discomfort, and perineal pain | Rectocele<br>Perineal descent<br>Rectal intussusception (internal prolapse)<br>Mucosal prolapse<br>Genitourinary prolapse<br>Enterocele | External full-thickness rectal prolapse<br>Perineal infection<br>Recto-vaginal fistula<br>Inflammatory bowel disease (including proctitis)<br>Radiation proctitis<br>Anal incontinence (Cleveland Clinic Florida; Wexner Score > 7)<br>Anal stenosis precluding insertion of the stapling device<br>Enterocele at rest<br>Significant gynecological or urinary pelvic floor abnormality requiring combined treatment<br>Presence of foreign material adjacent to the rectum (e.g. mesh)<br>Absence of anatomical or physiological abnormality associated with ODS<br>Intraoperative technical factors that preclude the safe execution of the operation<br>Significant rectal or perirectal fibrosis<br>Prior rectal anastomosis |

ODS: obstructed defecation syndrome

The panel also recommended that the technique described by Longo (Longo 1998) should be followed, using the Ethicon Endo-Surgery PPH01 or TRANSTAR stapling devices. The panel indicated that the surgeon should have experience in the use of the instrument, and that various aspects of the surgery and technique require further study.

A second consensus statement was produced by the Italian Association of Hospital Gastroenterologists and Italian Society of Colorectal surgery (Bove et al 2012). The statement discussed the treatment of chronic constipation and obstructed defecation in a question and answer format; the supporting evidence was assigned a level and a grade. With regard to whether STARR can be effective for treating patients with ODS who do not respond to medical and rehabilitative treatment, it stated that one study demonstrated the efficacy and safety of STARR in patients who failed to respond to rehabilitative treatment (biofeedback; Lehur et al 2008). Similarly, in response to the question as to whether STARR can significantly improve the quality of life in patients suffering from ODS as a result of rectal intussusception or a rectocele when compared with biofeedback (non-surgical intervention) the same study was cited as the only evidence. No guidance on patient selection, setting, or appropriate usage of STARR was provided.

## Training and education impact

The consensus statement from the international working group (Corman et al 2006) describes the appropriate surgeon as one who has knowledge and experience in the use of the stapling instrument. Additionally, the surgeon should have training and experience in performing anorectal colonic surgery, experience with evaluation, interpretation and management of defecatory disorders, familiarity with other pelvic disorders and a willingness to participate in an outcome analysis.

The National Institute for Health and Clinical Excellence (NICE) has produced guidance on the treatment of obstructed defecation with stapled transanal rectal resection (STARR). The guideline concludes that the evidence on the safety and efficacy of the STARR procedure for ODS is adequate and consequently the procedure may be used. The guidance states that STARR should be carried out in units which specialize in the investigation and management of pelvic floor disorders. The guidance also specifies that multidisciplinary teams that include a urogynecologist or urologist and a colorectal surgeon with experience in STARR should be involved in patient selection and management (NICE 2010).

# Summary

ODS is a condition characterized by the inability to evacuate contents from the rectum. Patients who have failed conservative treatment and who have a characteristic history combined with an anatomical abnormality may be considered for STARR. Currently there is no gold standard recognized for the surgical treatment of ODS.

A systematic search of the literature on the use of STARR for obstructed defecation identified four randomized controlled trials: two compared STARR to TRANSTAR, one compared STARR to STAPL and one compared STARR to biofeedback. Across the four studies, STARR was evaluated in a total of 165 patients whilst TRANSTAR was evaluated in 72 patients.

**Safety**

With respect to surgical procedures, STARR had a similar safety profile in terms of number and types of incidences to TRANSTAR and STAPL. An exception was dyspareunia which was reported by more STAPL patients. Incidences reported in two or more studies for STARR included pain, bleeding and urinary retention.

**Efficacy**

Compared with the non-surgical treatment of biofeedback, STARR was similar with respect to length of hospital stay and time to return to work but was significantly better in terms of treatment success. This was reflected in higher success rates reported by patients.

With respect to the other surgical treatments, STARR was comparable to TRANSTAR in terms of length of hospital stay but TRANSTAR resulted in significantly greater treatment success. Furthermore, fecal urgency became more frequent and prolapse recurrence was reported following STARR but not TRANSTAR. Interestingly, the greater treatment success was not reflected in patient-reported success rates, quality of life or change in ODS symptoms, which did not differ between the two procedures.

Compared with STAPL, STARR was similar with respect to length of operating time, length of hospital stay, time to return to work, patient reported success and change in ODS symptoms. However, STARR was more effective at reducing the rectal sensitivity threshold volume. In addition, dyspareunia occurred following STAPL but not STARR.

**Cost impact**

STARR was found to be less expensive than TRANSTAR for ODS. Specifically, with respect to rectocele repair, STARR was found to be similar in cost to the perineal approach and less expensive than the abdominal approach. With intussusception repair, STARR was cheaper than the Delorme procedure.

**Clinical practice guidelines and consensus statements**

Two consensus statements were identified on the use of STARR for ODS. One of them defined the inclusion and exclusion criteria for STARR in terms of symptoms and clinical findings as well as outlining who should perform the procedure (Corman et al, 2006). The other, which only briefly discussed STARR, gave it a Grade B recommendation for its effectiveness in treating patients with ODS who failed rehabilitative therapy and at improving the quality of life in patients with

rectal intussusception or a rectocele (Bove et al. 2012). This was based on one randomized controlled trial.

## Recommendation

Whilst this report contained four randomized control trials, two of them essentially compared the same procedure using different stapling devices (STARR versus TRANSTAR). Another study compared STARR to biofeedback which is considered a form of conservative therapy and guidelines state that the eligibility criteria for any surgical treatment of ODS is that the patient must first fail conservative therapy. Whilst three of the studies used ODS scores in their measure of treatment success, they were defined a different way in each. In general, the study sample sizes were small and the study that included biofeedback as a comparator had significant losses to follow-up. As such, the evidence is too poor in terms of quantity and quality to make sound conclusions regarding the safety and efficacy of STARR in comparison to other surgical procedures for the treatment of ODS. More randomized controlled studies with greater sample sizes are required that compare STARR to other surgical procedures before recommendations can be made about this procedure. This may be hampered by the lack of an accepted gold standard for ODS combined with the complexity surrounding the symptoms and diagnosis of ODS. Another barrier that may limit the use of the STARR procedure by surgeons is the potential of a rectovaginal fistula, although none were reported in the studies included in this report.

Taking into account the poor quality of evidence in this report, STARR does not appear to have any serious safety issues compared with the other procedures assessed. In addition, it is not a technically difficult procedure, is easier to perform than perianal delormes, and is preferable to abdominal rectopexy. Thus, STARR may offer a potential alternative surgical procedure to people suffering ODS. It is difficult to assess from the two studies included in this report as to whether the TRANSTAR procedure, using the specifically designed stapler, is more effective than the STARR procedure, which uses the hemorrhoidal stapler, as although treatment success rates were higher for TRANSTAR, this did not translate into improved patient reported success rates. In addition, the TRANSTAR procedure was reported as being more expensive.

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# Appendix A

**NHMRC Evidence Hierarchy: designations of 'levels of evidence' according to type of research question**

| Level | Intervention [1] | Diagnostic accuracy [2] | Prognosis | Aetiology [3] | Screening Intervention |
|---|---|---|---|---|---|
| I [4] | A systematic review of level II studies | A systematic review of level II studies | A systematic review of level II studies | A systematic review of level II studies | A systematic review of level II studies |
| II | A randomized controlled trial | A study of test accuracy with: an independent, blinded comparison with a valid reference standard,5 among consecutive persons with a defined clinical presentation[6] | A prospective cohort study[7] | A prospective cohort study | A randomized controlled trial |
| III-1 | A pseudorandomized controlled trial (i.e. alternate allocation or some other method) | A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among non-consecutive persons with a defined clinical presentation[6] | All or none[8] | All or none[8] | A pseudorandomized controlled trial (i.e. alternate allocation or some other method) |
| III-2 | A comparative study with concurrent controls:<br>▪ Non-randomized, experimental trial[9]<br>▪ Cohort study<br>▪ Case-control study<br>▪ Interrupted time series with a control group | A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence | Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial | A retrospective cohort study | A comparative study with concurrent controls:<br>▪ Non-randomized, experimental trial<br>▪ Cohort study<br>▪ Case-control study |
| III-3 | A comparative study without concurrent controls:<br>▪ Historical control study<br>▪ Two or more single arm study[10]<br>▪ Interrupted time series without a parallel control group | Diagnostic case-control study[6] | A retrospective cohort study | A case-control study | A comparative study without concurrent controls:<br>▪ Historical control study<br>▪ Two or more single arm study |
| IV | Case series with either post-test or pre-test/post-test outcomes | Study of diagnostic yield (no reference standard)[11] | Case series, or cohort study of persons at different stages of disease | A cross-sectional study or case series | Case series |

Explanatory notes

1 Definitions of these study designs are provided on pages 7-8 *How to use the evidence: assessment and application of scientific evidence* (NHMRC 2000b*)*.

2 The dimensions of evidence apply only to studies of diagnostic accuracy. To assess the effectiveness of a diagnostic test, there also needs to be a consideration of the impact of the test on patient management and health outcomes (Medical Services Advisory Committee 2005, Sackett & Haynes 2002).

3 If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the 'Intervention' hierarchy of evidence should be utilized. If it is only possible and/or ethical to determine a causal relationship using observational evidence (i.e. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilized.

4 A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review *quality* should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome or result as different studies (and study designs) might contribute to each different outcome.

5 The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study (Whiting et al. 2003).

6 Well-designed population-based case-control studies (e.g., population-based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfill the requirements for a valid assembly of patients. However, in some cases, the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies, a selected sample of patients already known to have the disease is compared with a separate group of normal, healthy people known to be free of the disease. In this situation, patients with borderline or mild expressions of the disease and conditions mimicking the disease are excluded which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect because the spectrum of study participants will not be representative of patients seen in practice (Mulherin and Miller 2002).

7 At study inception, the cohort is either non-diseased or all at the same stage of the disease. A randomized controlled trial with persons either non-diseased or at the same stage of the disease in *both* arms of the trial would also meet the criterion for this level of evidence.

8 All or none of the people with the risk factor(s) experience the outcome and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus and clear proof of the causal link has come from the disappearance of small pox after large-scale vaccination.

9 This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (i.e., utilize A vs. B and B vs. C, to determine A vs. C with statistical adjustment for B).

10 Comparing single arm studies (i.e. case series from two studies). This would also include unadjusted indirect comparisons (i.e. utilize A vs. B and B vs. C, to determine A vs. C but where there is no statistical adjustment for B).

11 Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

Note A: Assessment of comparative harms or safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms are rare and cannot feasibly be captured within randomized controlled trials; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note B: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question, for example, level II intervention evidence, level IV diagnostic evidence, or level III-2 prognostic evidence.

Source: Hierarchies adapted and modified from: NHMRC 1999; Bandolier 1999; Lijmer et al. 1999; Phillips et al. 2001.

# Appendix B

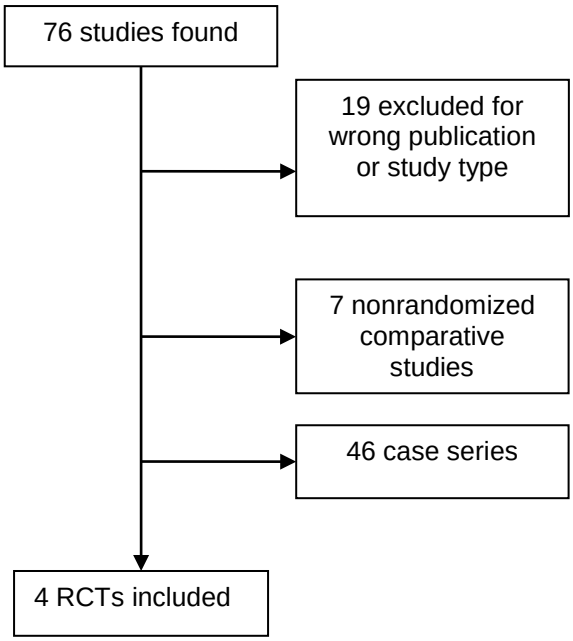


Figure 1 Study selection process

**Additional papers not included in this assessment**

*Case series*

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**Studies excluded from this assessment**

*Wrong study type (wrong indication or treatment)*

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*Wrong publication type (letter, editorial, case report, review, guideline)*

Asteria CR, Bellarosa S, Chiarioni G, Mazzola F, Bruni O, Villanacci V & Bassotti G. Long-term follow-up of after STARR for obstructed defecation. *Tech Coloproctol*, 2012 Nov 29 Epub ahead of print.

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National Institute for Health and Clinical Excellence (NICE) 2010 *Treating obstructed defaecation syndrome by removing excess tissue from the anus with a stapler device* http://guidance.nice.org.uk/IPG351 [Accessed].

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*Economic study*

Schiano di Visconte M, Piccin A, Di Bella R, Giomo P, Pederiva V, Cina LD & Munegato G. Cost-revenue analysis in the surgical treatment of the obstructed defecation syndrome. *Chir Ital* 2006; 58(6): 743-752.