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AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon scanning technology prioritising summary**

## **Stapled transanal rectal resection (STARR)**



**November 2010**

Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical

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ISBN

Publications Approval Number:

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The production of these Horizon scanning prioritising summaries was overseen by the Health Policy Advisory Committee on Technology (HealthPACT). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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# PRIORITISING SUMMARY

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**REGISTER ID** **S000124**

**NAME OF TECHNOLOGY** **STAPLED TRANSANAL RECTAL RESECTION (STARR) FOR OBSTRUCTED DEFECATION SYNDROME (ODS)**

**PURPOSE AND TARGET GROUP** **TO RESTORE NORMAL RECTAL ANATOMY AND ALLEVIATE ODS SYMPTOMS IN PATIENTS WITH CONFIRMED INTERNAL RECTAL PROLAPSE AND/OR RECTOCELE**

**STAGE OF DEVELOPMENT (IN AUSTRALIA)**

- |  |   |
|--|---|
| <input type="checkbox"/> Yet to emerge<br><input type="checkbox"/> Experimental<br><input type="checkbox"/> Investigational<br><input type="checkbox"/> Nearly established | <input type="checkbox"/> Established<br><input checked="" type="checkbox"/> Established <i>but</i> changed indication or modification of technique<br><input type="checkbox"/> Should be taken out of use |
|--|---|

**AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

- Yes  
 No  
 Not applicable

**INTERNATIONAL UTILISATION**

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
China		✓	
Egypt		✓	
France	✓	✓	
Germany	✓	✓	
Greece		✓	
Israel		✓	
Italy	✓		✓
Spain		✓	
Switzerland	✓	✓	
United Kingdom	✓	✓	
United States	✓	✓	

## **IMPACT SUMMARY**

Stapled transanal rectal resection (STARR) is a surgical procedure which aims to restore normal rectal anatomy and thereby alleviate symptoms of obstructed defecation syndrome (ODS). Eligible patients are those with confirmed internal rectal prolapse (intussusception) and/or rectocele, either of which may create an anatomical impediment to the normal expulsion of stool. The STARR procedure was first performed in about 2001 and is typically performed by colorectal surgeons. STARR is an adaptation of stapled haemorrhoidectomy and most typically relies on the same widely available circular stapling devices to resect redundant rectal tissue.

## **BACKGROUND**

Constipation can be broadly classified into three categories: normal transit constipation, slow transit constipation and obstructed defecation syndrome. ODS is more complex than normal and slow transit constipation and can have functional, metabolic and/or anatomic origins. Several anatomic abnormalities may give rise to ODS, including rectal prolapse, rectocele, pelvic organ prolapse, sigmoidocele, enterocele, solitary rectal ulcer syndrome (Khaikin and Wexner 2006). The most common organic causes of ODS are rectal prolapse and rectocele. Rectal prolapse occurs where the ligaments and muscle that normally securely attach the rectum (the lowest 12-15 cm of the large intestine) to the pelvis weaken and allow it to slip or fall out of place. Rectocele results from bulging of the anterior wall of the rectum into the vagina, and is due to weakening of the pelvic support structures and thinning of the rectovaginal septum (the tissues separating the rectum from the vagina).

Initial treatment of ODS is medical and/or behavioural but in the rare circumstance where conservative treatment fails surgery may be indicated. A range of surgical options exist; however, none is recognised as a gold standard. The success rate for traditional surgical options ranges from 80% to 95% but these procedures reportedly have high recurrence and complication rates. Additionally, they may not be suitable for patients with simultaneous rectal prolapse and rectocele (Rosen 2010; Titu et al 2009).

STARR is intended for the treatment of clinically and morphologically confirmed internal rectal prolapse and/or rectocele in symptomatic ODS patients (Schwander et al 2008). The procedure typically involves the sequential use of two conventional PPH circular staplers, such as those used during prolapse and haemorrhoidectomy procedures. An anterior and posterior full-thickness rectal wall resection is created, and the intended result is a circumferential transanal resection of the rectum. The magnitude of the resection is limited by the size of the circular stapler housing, with newer staplers capable of resecting larger volumes of tissue (Farouk et al 2009).

## **CLINICAL NEED AND BURDEN OF DISEASE**

Constipation affects 2% to 27% of the population in western countries. In the United States, constipation is responsible for 2.5 million physician visits and 92,000 hospitalisations annually (Lembo and Camilleri 2003). ODS occurs in 25% to 50% of constipated patients with defecatory dysfunction, and is most commonly due to dysfunction of the pelvic floor or anal sphincter rather than to anatomical abnormalities

(Lembo and Camilleri 2003; Khaikin and Wexner 2006). Isolated defecation dysfunction is present in only 25% of people with chronic constipation, with other forms of constipation comprising the majority of these cases (Steele and Mellgren 2007).

An Australian survey of young (n=14,761), middle aged (n=14,070) and elderly (n=12,893) women produced a prevalence estimate of constipation for each of the cohorts. The prevalence was 14.1% (confidence interval [CI] 13.5-14.7) in young women, 26.6% (CI 25.9-27.4) in middle aged women and 27.0% (CI 26.9-28.5) in elderly women. One-third of the young women and 50% of the middle aged and elderly women sought help for constipation (Chiarelli et al 2000).

### **DIFFUSION**

The diffusion status of STARR is unclear. As originally developed, STARR does not appear to require any unique instrumentation. Therefore the threshold for diffusion is low in most jurisdictions. The overwhelming majority of the published literature regarding STARR emanates from Europe, and it appears the procedure is geographically widely diffused there. However, with the exception of Italy, the volume of cases appears fairly modest, reflecting either limited uptake or limited application. The unclear effectiveness of the procedure or the complexity of ODS may limit diffusion to some degree. Another factor may be the availability of second or third generation staplers, which are able to resect larger volumes of tissue. An example is the Contour® Transtar™ (Eticon EndoSurgery, Cincinnati, Ohio, USA) which was introduced in 2006, yet may not be licensed in all jurisdictions.

The STARR procedure appears to be similar to that used for some time to undertake haemorrhoidectomy; therefore, the stage of development of STARR in an Australian clinical setting is established but with a changed indication (ODS).

### **COMPARATORS**

In severely symptomatic patients for whom conservative therapy fails, a range of abdominal, transvaginal, transperineal and transanal surgical alternatives have been proposed. As no particular surgical approach has achieved overall superiority, no gold standard exists (Jayne et al 2009). The surgical approach used to treat patient with ODS is generally dependent on surgeon preference (Titu et al 2009). There have been few studies comparing STARR to other surgical alternatives (Goede et al 2010).

Given the infrequency of surgical treatment for ODS, behavioural and/or medical interventions may also be considered comparators of STARR.

### **SAFETY AND EFFECTIVENESS ISSUES**

A literature search revealed at least 19 case series studies reporting the use of STARR in patients with ODS, three of which were included in this summary based on patient numbers and duration of follow-up (Table 1). It appears likely that the study by Jayne et al (2009) incorporates some of the patients included in Titu et al (2009) and Goede et al (2010). Additionally, the study by Goede et al (2010) most likely captures all of the patients reported by Titu et al (2009), as these studies share corresponding authors.

**Table 1: Included STARR studies**

Authors / Year	Country	Study years	n	Study type	Follow-up
Jayne et al 2009	UK Germany Italy	2006-2008	2,838	Nonrandomised prospective multicentre audit	12 months
Titu et al 2009	UK	2001-2007	230	Case series	12-68 (median 24) months
Goede et al 2010	UK	2001-2010	344	Case series	5-386 (median 98) weeks

*Study Profiles*

Jayne et al (2009) reported short-term (12 months) post-STARR patient outcomes based on data contained in the European STARR registry. Outcomes of interest included effectiveness (ODS and symptom scores), quality of life (QOL), incontinence, and safety profile at baseline, 6 weeks, 6 months and 12 months. The registry is a voluntary effort involving surgeons in the UK, Germany and Italy and is acknowledged as being susceptible to biases surrounding patient selection, symptom and complication reporting, among others. At the time of analysis the registry included 2,838 patients of whom 2,224 had reached 12 months follow-up. Mean age was 54.7 years and 83.3% of patients were female.

Titu et al (2009) reported immediate (operative incidents, post-operative complications and patient recovery) and intermediate outcomes (intermediate complications, symptom resolution and patient satisfaction) in a consecutive series of patients followed up at 2, 6 and 12 months. All surgeries were performed or supervised by the same surgeon. Mean patient age was 58 years and 81% of patients were female.

Goede et al (2010) reported early complications, ODS scores, incontinence, faecal urgency, recurrent symptoms and patient satisfaction in a consecutive series of patients followed up at 6 weeks, 2 months and annually thereafter. The decision to treat, scoring and data collection rested with the same surgeon for all patients. Mean patient age was 54 years and 68% of patients were female.

*Safety*

Jayne et al (2009) reported an overall morbidity rate of 36.0% and noted that the majority of reported complications were minor in nature. Of the 2,838 cases, a total of 1,588 complications were observed in 1,011 patients. The most common complications were defecatory urgency (20.0%), persistent pain (7.1%), urinary retention (6.9%), bleeding (5.0%), anorectal sepsis (4.4%), staple line complications (3.5%) and faecal incontinence (1.8%). The significance of defecatory urgency is unclear as 39.9% of patients reported this symptom preoperatively so this may not be a new symptom. Two serious complications occurred, including one case of rectal necrosis requiring a diverting stoma and one case of rectovaginal fistula.

The complications documented by Titu et al (2009) were very similar to those documented by Jayne et al (2009). Defecatory urgency was the most common

complication and occurred in 47% of patients, which is much higher than the rate reported in Jayne et al (2009). Titu et al (2009) reported moderate to severe pain in a higher proportion of patients than Jayne et al (2009) (56% versus 7.1%). Urgency and pain both resolved with time and by 12 months were an issue for  $\leq 1\%$  of patients. Overall the authors reported that 7% of patients experienced major complications; however, the nature of these complications was not entirely clear. Staple line dehiscence occurred in 1% of patients, and 5% experienced bleeding with eight patients requiring a return to surgery. One case of rectovaginal fistula was reported, although this is likely to be the same case referenced by Jayne et al (2009).

Goede et al (2010) reported that 69 intraoperative and early postoperative complications occurred in 56 patients (16.3%). The details of these complications are similar to those already discussed in Jayne et al (2009) and Titu et al (2009). Goede et al (2010) did not appear to classify urgency as a complication, but the authors noted its occurrence in 72% of patients at 8 weeks. This fell to 11.5% at 52 weeks and to 0% in a small group of patients followed beyond 4 years.

### *Efficacy*

Although 2,224 patients reached 12 months follow-up in the study by Jayne et al (2009), data completeness varied considerably across the scoring tools used in the registry. Baseline and 12 month ODS scores were available for 41.0% of patients, symptom severity (SS) scores for 57.0%, incontinence scores for 61.5%; and QOL scores for 60.0% to 64.0%. Both the ODS and SS tools used are unvalidated but the authors stated that no validated tool was available. Notwithstanding the above, all measures showed significant positive change from baseline to 12 months. ODS improved from 5.81 (95% CI, 5.27-6.36) to 17.79 (95% CI, 15.49-16.01) ( $P<0.001$ ), SS improved from 3.6 (95% CI, 3.35-4.85) to 15.10 (95% CI, 14.86-15.34) ( $P<0.001$ ), and incontinence improved from 1.59 (95% CI, 1.40-1.77) to 2.70 (95% CI, 2.60-2.93) ( $P<0.001$ ).

Titu et al (2009) reported a statistically significant improvement in continence ( $P<0.0001$ ). Constipation improved in 77% of patients and remained unchanged in the remainder. The majority of patients (77%) were happy with the outcome of surgery, 10% were partially satisfied, 7% were unsure, 2% were dissatisfied and 3% were extremely dissatisfied. When asked whether they would recommend STARR to a friend, 66% of patients said they would be very happy to, 20% said probably, 10% were not sure and 4% said probably or definitely not.

Goede et al (2010) reported that ODS and incontinence scores showed significant improvements from baseline to follow-up. ODS improved from mean  $1.6 \pm 3.1$  (range: 0 – 18) to mean  $14.6 \pm 5.4$  (range: 0 – 30) ( $P<0.0001$ ) and incontinence improved from mean  $0.4 \pm 1.3$  to mean  $3.5 \pm 3.3$  ( $P<0.0001$ ). Of the 235 patients for whom pre and post ODS scores were available, 61% were asymptomatic at follow-up, 39% had improved and one patient showed no change. Despite the improvement in incontinence scores, four patients experienced deterioration. The majority of patients (81%) reported being highly satisfied with the procedure and would have it again or recommend it to someone else, and a further 9% indicated they would probably undergo the procedure again or

recommend it to someone else. Amongst dissatisfied patients the principal complaint was faecal urgency.

### **COST IMPACT**

One study addressing the relative cost of STARR was identified in the literature (Schiano di Visconte et al 2006). The study is a non-English language study and the limited information presented here is based on the available English language abstract.

Schiano di Visconte et al (2006) systematically calculated hospital costs associated with STARR and some conventional surgical alternatives used to treat the same anatomical defects. The total expenditure to repair an internal rectal prolapse using STARR was €3,579.09 (AU\$5,062.02 current dollars<sup>1</sup>) compared to €5,877.41 (AU\$8,312.61 current dollars) using Delorme's procedure. In the case of rectocele repair the total expenditure for STARR was again €3,579.09 (AU\$5,062.02 current dollars) versus €5,401.15 (AU\$7,640.90 current dollars) for an abdominal approach or €3,469.32 (AU\$4,916.69 current dollars) for a perineal approach. The study also indicates STARR produces the largest revenue stream except when compared to rectocele repair accomplished by an abdominal approach.

The relevance of the Italian cost and revenue data to the Australian context is unknown.

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified in the included literature.

### **OTHER ISSUES**

A multi-reloadable transverse stapler (Contour Transtar) developed specifically for the STARR procedure was introduced in 2006. The new stapler is capable of resecting a larger volume of tissue and potentially allows the resection to be tailored to the clinical circumstances (Jayne et al, 2009). However, the new stapler increases the technical demands of the procedure, without offering additional clinical benefit (Wadhawan et al 2010). When performed using the transverse stapler the procedure is often referred to as Trans-STARR or Transtar. None of the studies cited in this report used the transverse stapler and, in general, it appears that most of the published literature reports experience with circular PPH stapler devices.

NICE recently issued guidance indicating that the current evidence on the safety and efficacy of STARR is adequate to justify its use. The guidance indicates that STARR should only be performed in hospitals with units specialising in the treatment of pelvic floor disorders. Patient selection and management should involve a multidisciplinary team including an urogynaecologist or urologist and a colorectal surgeon experienced with the STARR procedure (NICE 2010).

### **SUMMARY OF FINDINGS**

STARR is likely to have a low diffusion threshold given the procedure, as typically described, entails little or no STARR-specific technology. The available evidence

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<sup>1</sup> 1 EURO = 1.41433 AUD (Source: XE Universal Currency Converter, 11 October 2010).

consists only of case series reports. These suggest that STARR generally improves symptoms and is safe. However, a significant minority of patients will experience complications and many more may experience new or aggravated symptoms (i.e. faecal urgency) in the short to medium term. In those studies which reported patient satisfaction, approximately 20% of patients reflected some degree of reticence about the procedure. Randomised clinical trials are needed to evaluate STARR against other treatment options.

#### **HEALTHPACT ASSESSMENT**

Based on the frequency of complications following the STARR procedure, including the advent of new or aggravated symptoms it is unlikely this technology has great potential for uptake in Australia; therefore, it is recommended that the following be conducted:

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                 | <input checked="" type="checkbox"/> Archive                |

#### **HEALTHPACT ACTION**

#### **NUMBER OF STUDIES INCLUDED**

Total number of studies	3
Level IV evidence	3

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**SEARCH CRITERIA TO BE USED**

Stapled transanal rectal resection  
STARR  
Obstructed defecation syndrome  
ODS

**HEALTH PACT DECISION**

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                 | <input type="checkbox"/> Archive                           |
| <input type="checkbox"/> Refer                   | <input type="checkbox"/> Decision pending                  |

**PRIORITY RATING**

- High**                       **Medium**                       **Low**